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Office of Chief Scientist (OCS)

Office of Counterterrorism and Emerging Threats (OCET)

Landscape Analysis of Adoption of Advanced Manufacturing in Non-Medical Industries

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1 EXECUTIVE SUMMARY

The United States (U.S.) Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety and effectiveness of human and veterinary drugs, biological products, medical devices, radiation-emitting products, and tobacco products, as well as the security of the nation's food and cosmetics supply. Manufacturing, one of the largest sectors in the U.S. economy, accounts for 11% of gross domestic product.[1,2] To support activities associated with regulated products and promote supply chain resilience and reliability in manufacturing, the Agency must continually understand new and evolving advanced manufacturing technologies and processes. The National Strategy for Advanced Manufacturing Report from October 2022 defines advanced manufacturing as "the innovation of improved methods for manufacturing existing products, and the production of new products enabled by advanced technologies."[3] Advanced manufacturing describes a complex concept that includes novel technologies, evolving and innovative operational processes, and new methods for evaluating processes that can improve product quality, address shortages, reduce costs, and speed time-to-market.

The Office of Counterterrorism and Emerging Threats (OCET) within the FDA Office of the Commissioner (OC)/Office of the Chief Scientist (OCS) contracted Booz Allen Hamilton (Booz Allen) to conduct a landscape analysis of non-medical industries to evaluate the conditions, approaches, best practices, and lessons learned from U.S. Government (USG) and non-governmental entities related to the implementation, adoption, and regulation of novel or disruptive advanced manufacturing technologies. Objectives focused on gaining a better understanding of:

- Advanced manufacturing technologies and processes adopted over the last ten years and those that are expected to be adopted within the next five to ten years;
- Challenges and best practices related to the implementation, adoption, and regulation of advanced manufacturing;
- Factors influencing the implementation, adoption, and regulation of advanced manufacturing; and
- Indicators of potential advanced manufacturing technology usage and future growth. [1]

Performing this landscape scan and analysis enables FDA to take a proactive approach to better understand how emerging or disruptive advanced manufacturing technologies and processes relate to and impact the industries FDA regulates. This includes how to: 1) regulate products manufactured using advanced technologies; 2) provide effective and timely guidance on regulatory requirements; 3) best invest in advanced manufacturing resources, research, and training; 4) help accelerate the adoption of these technologies; and 5) further supply chain resilience and timely patient access to medical products.

Approach

The evaluative approach consisted of two parts: 1) developing a catalog of adopted and emerging advanced manufacturing technologies, processes, and platforms across non-medical industries; and 2) conducting an assessment of best practices and challenges and their potential applicability to FDA.

The North American Industry Classification System (NAICS) was leveraged to first help identify 18 non-medical industries to include in the scope of the landscape scan. A multi-method data collection approach included review of approximately 2,500 documents (literature and non-literature) and 17 interviews (with 36 total individuals) across 15 stakeholder organizations (USG and non-governmental organizations). The advanced manufacturing ecosystem consists of diverse groups of stakeholders who work to advance common goals of improving product quality, preventing shortages, and making production more efficient. They include, but are not limited to, USG (regulatory and non-regulatory agencies),

[1] The objectives of this evaluation did not include the development of recommendations or conclusions but rather focused on presenting an overview of the current landscape of adopted and emerging advanced manufacturing technologies and processes in non-medical industries. To this end, Booz Allen produced the information in this report to inform FDA leadership and support future planning and decision making.

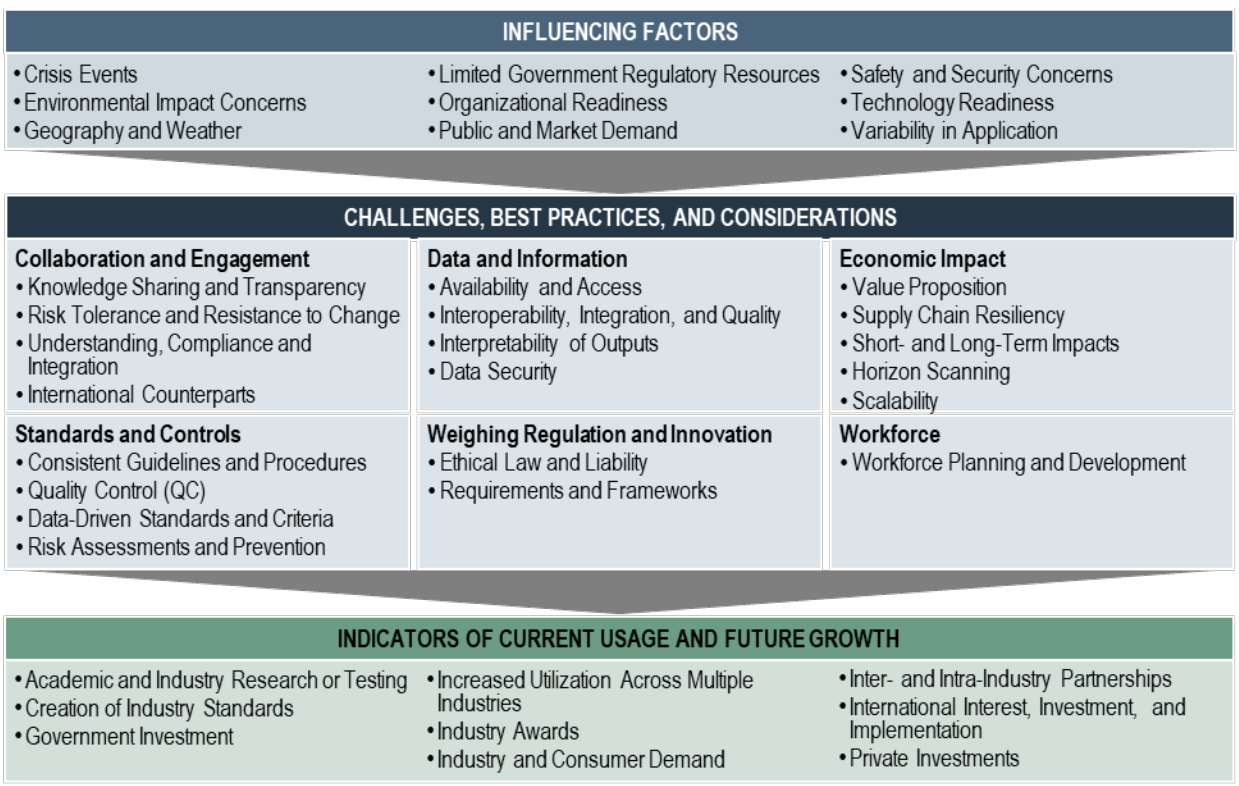
public-private partnerships, private manufacturers, academic institutions, trade associations, standards organizations, and professional organizations.

Findings

The technology cataloging phase consisted of identifying potential benefits, limitations and risks, and stages of adoption or emergence. Findings indicated that most advanced manufacturing methodologies, technologies, processes, and platforms identified across non-medical industries are adopted in some capacity in one or more industries. While there are many novel applications of technologies emerging in non-medical industries, only five technologies themselves classify in a stage of emergence. They are bioreactors, cloud-based computing, smart sensors, quantum computing, and four-dimensional (4D) printing.

During the assessment phase, best practices and challenges for implementation, adoption, and regulation emerged as findings. Findings were organized into high-level themes and subthemes, and also elucidated potential indicators of current usage and future growth, as well as factors that have potential to advance or hinder implementation and market adoption. Figure 1-1 provides a visual summary of the report findings. These findings may be used to inform FDA's approach for supporting advanced manufacturing moving forward. The connection between influencing factors, implementation and adoption, regulation, and indicators shape how advanced manufacturing technologies and processes continue to evolve in the non-medical space.

Figure 1-1: Assessment Findings



2 OVERVIEW

2.1 Background

The United States (U.S.) Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety and effectiveness of human and veterinary drugs, biological products, medical devices, radiation-emitting products, and tobacco products, as well as the security of the nation's food and cosmetics supply. Manufacturing, one of the largest sectors in the U.S. economy, accounts for 11% of gross domestic product.[1,2] To support activities associated with regulated products and promote supply chain resilience and reliability in manufacturing, the Agency must continually understand new and evolving advanced manufacturing technologies and processes. The National Strategy for Advanced Manufacturing Report from October 2022 defines advanced manufacturing as "the innovation of improved methods for manufacturing existing products, and the production of new products enabled by advanced technologies."[3] Advanced manufacturing describes a complex concept that includes novel technologies, evolving and innovative operational processes, and new methods for evaluating processes that can improve product quality, address shortages, reduce costs, and speed time-to-market.

2.2 Scope and Objectives

The Office of Counterterrorism and Emerging Threats (OCET) within the FDA Office of the Commissioner (OC)/Office of the Chief Scientist (OCS) contracted Booz Allen Hamilton (Booz Allen) to conduct a landscape analysis of non-medical industries to evaluate the conditions, approaches, best practices, and lessons learned from U.S. Government (USG) and non-governmental entities related to the implementation, adoption, and regulation of novel or disruptive advanced manufacturing technologies. Objectives focused on gaining a better understanding of:

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3 APPROACH AND METHODOLOGY

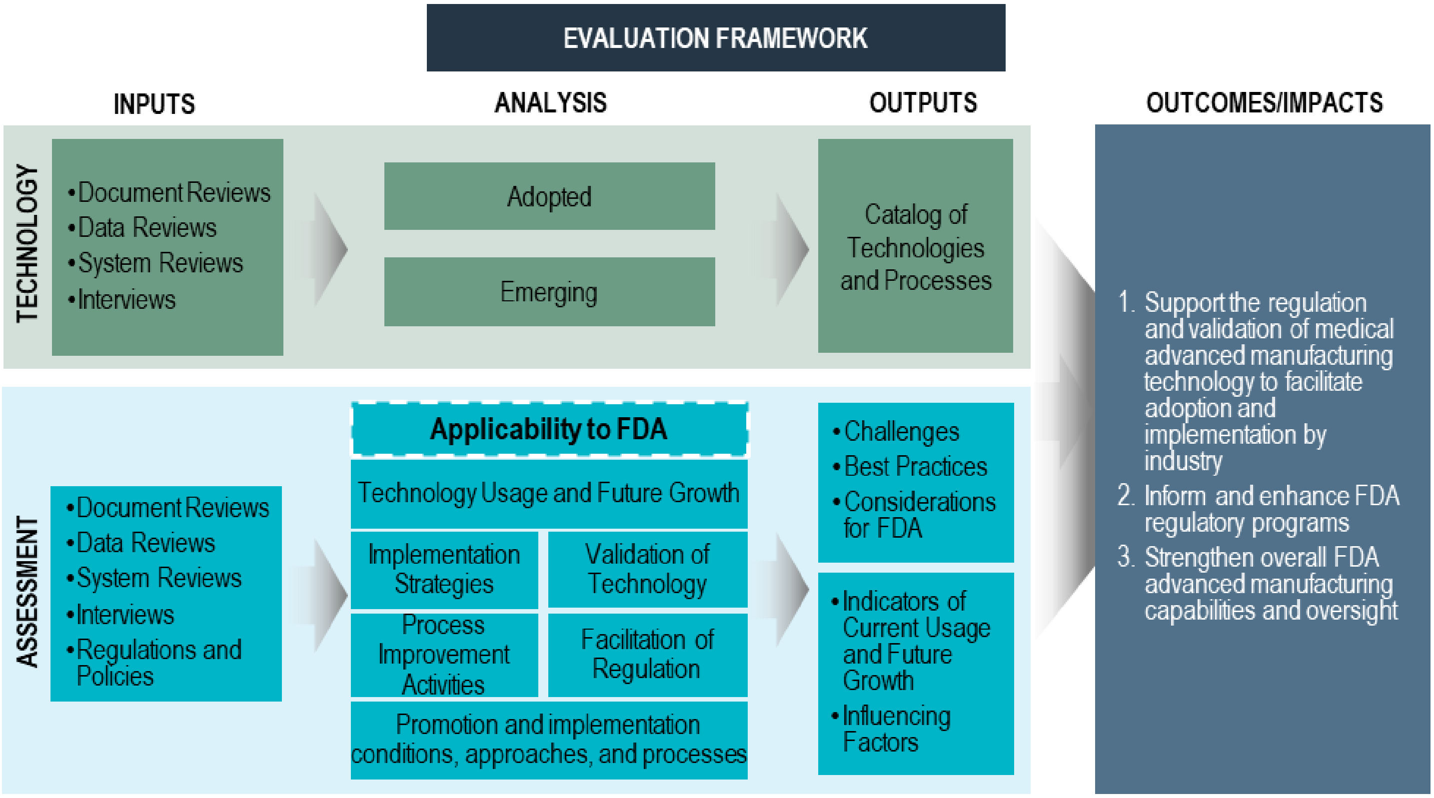
3.1 Evaluation Framework

The evaluative approach consisted of two parts: 1) developing a catalog of adopted and emerging advanced manufacturing technologies, processes, and platforms across non-medical industries; and 2) conducting an assessment of best practices and challenges, and their potential applicability to FDA.

[2] The objectives of this evaluation did not include the development of recommendations or conclusions but rather focused on presenting an overview of the current landscape of adopted and emerging advanced manufacturing technologies and processes in non-medical industries. To this end, Booz Allen produced the information in this report to inform FDA leadership and support future planning and decision making.

Figure 3-1 presents the evaluation framework developed to facilitate a structured and informed approach. The multi-method data collection included a literature review, analysis of non-literature documentation (e.g., guidance, standards, policy, regulations, law), and stakeholder interviews across USG and non-governmental organizations. These data sources supported identification of advanced manufacturing best practices, challenges, key indicators of usage and future growth, and influencing factors across industries.

Figure 3-1: Evaluation Framework



Key Definitions

The following definitions provide meaning and context to terms used in this report.

Table 3-1: Key Terms and Definitions

Term	Definition
Adoption	The acceptance of — in this case, technology — used to modernize an organization and/or industry.[4]
Advanced Manufacturing	The innovation of improved methods for manufacturing existing products, and the production of new products enabled by advanced technologies.[3]
Advanced Manufacturing Methodologies	Conceptual approaches for how advanced products are manufactured (e.g., additive manufacturing, distributed manufacturing, lean manufacturing, smart manufacturing).
Advanced Manufacturing Technologies	A form of advanced manufacturing that innovates or automates existing techniques, or combines with other technologies to improve manufacturing speed, efficiency, and quality. This may encompass analytical techniques, tools, or software, among others.
Advanced Manufacturing Technology Applications	The specific instances in which advanced manufacturing technologies are executed in operation.
Advanced Manufacturing Processes	A series of actions, operations, or step taken to produce an advanced manufactured product.
Advanced Manufacturing Platforms	A mechanism (e.g., system, infrastructure, network, interface) to connect, communicate, share, organize, or obtain ideas, data, information, and knowledge.
Implementation	A process of planned and guided activities to launch, introduce, and/or maintain technologies to innovate or improve an organization and/or industry.[5]
Emergence	The characterized stage of novel, relatively fast-growing — in this case, innovative technology — that is being developed or has recently been introduced into the market but is not yet fully established. These technologies have the potential to significantly impact society and the economy.[6]
End Product	Physical products created via advanced manufacturing processes.
Output	Process data or manufacturing data generated by advanced manufacturing technologies that can provide human operators or other technologies with insights or alerts to inform decision making.
Regulation	A set of requirements issued by a federal government agency used to implement laws passed by U.S. Congress.[7]

3.2 Key Stakeholders of Non-Medical Industries

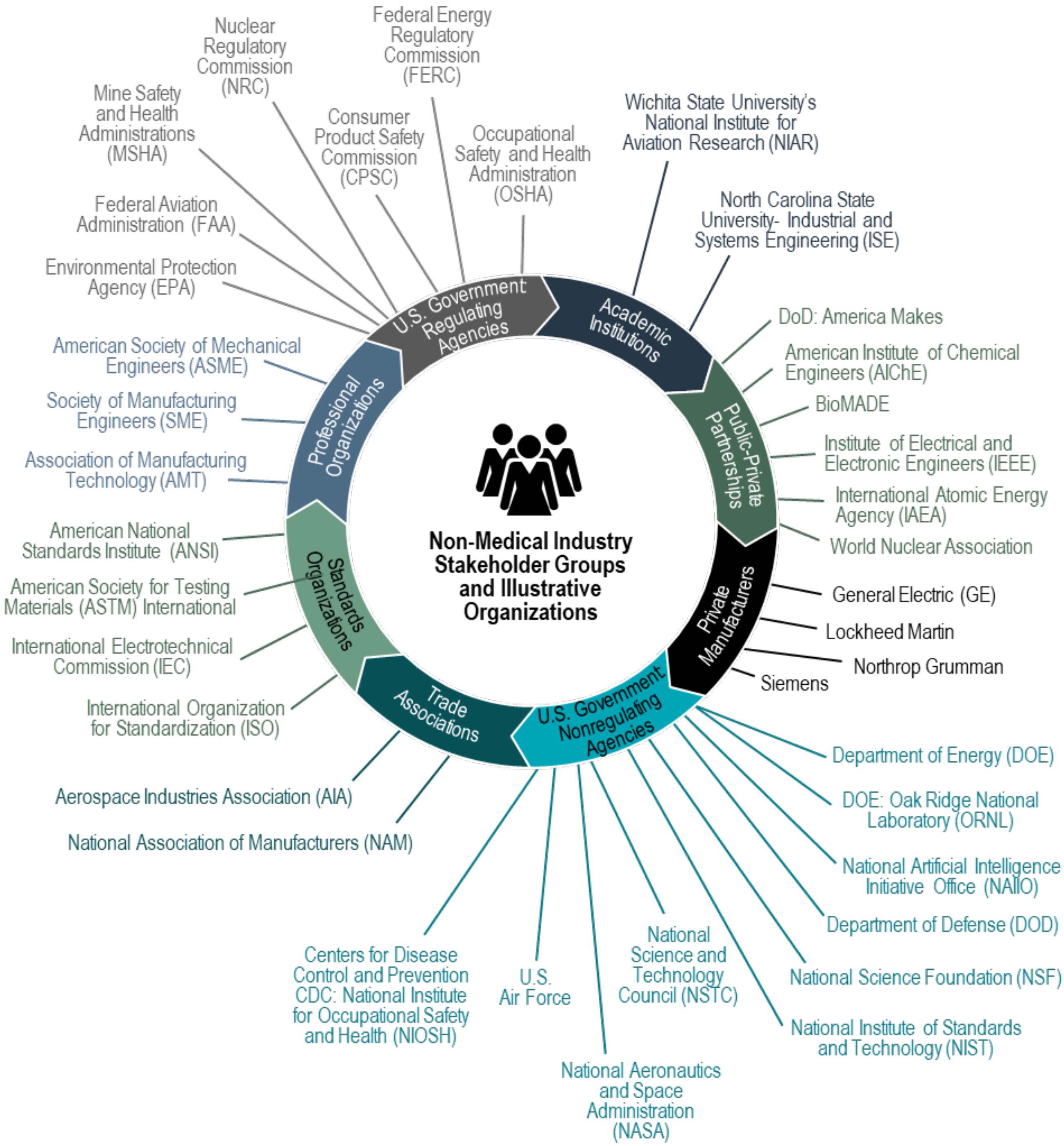
The advanced manufacturing ecosystem consists of diverse industries and products that play a critical role in the emergence and adoption of advanced manufacturing technologies and processes. Table 3-2 identifies and describes key USG and non-governmental stakeholder groups of advanced manufacturing in non-medical industries (see Section 3.3 for a list of the 18 industries evaluated and Section 8.3 for an illustrative list of non-medical stakeholders). These stakeholder groups work towards common goals of improving product quality, preventing shortages, and making production more efficient. FDA actively engages with these groups to understand lessons learned and best practices in adopting and implementing relevant technologies and apply them to FDA-regulated products.

Table 3-2: Key Stakeholder Groups of Advanced Manufacturing in Non-Medical Industries

Key Stakeholder Groups	Description
Academic Institutions	Play a unique role in the advanced manufacturing sector. In addition to contributing to the advanced manufacturing professional workforce, universities foster an environment of innovation.[8] Their industrial engineers and highly skilled students and faculty tackle the nation's most pressing manufacturing challenges using state-of-the-art processes and disruptive technologies in areas such as big data, automation, robotics, nanomanufacturing, and three-dimensional (3D) printing.[9]
Private Manufacturers	Provide the public with a variety of regulated and non-regulated products through global commercialization. They propel their respective industries forward by implementing and integrating advanced manufacturing technologies into their processes at varying levels of maturity.
Professional Organizations	Focus on technical innovation, improved domestic infrastructure availability, and maintaining robust connectivity among sectors. They move the manufacturing industry forward through activities such as providing advocacy and education, funding innovative research, and reducing barriers to scale up and commercialization.
Public-Private Partnerships	Refer to public USG agencies partnering with academia, research institutes, or private industry organizations. They help address challenges presented by novel advanced manufacturing technologies, as well as collaboratively drive the field forward. Manufacturing United States of America, a network of such public-private partner institutes, collaborate with industry, academia, and government to solve America's manufacturing challenges.[10]
Standards Organizations	Are member-supported organizations, often accredited by the American National Standards Institute (ANSI), who develop and maintain standards to meet industry needs.[11] Standards facilitate efficient production, as well as innovation opportunities, by removing technical barriers. They provide users with suitable frameworks for achieving optimal design, improved product quality, increased interoperability of products, and improved production and delivery systems. For example, the America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC), a cross-sector coordinating body, accelerates the development of industry-wide additive manufacturing standards and specifications consistent with stakeholder needs and facilitate the growth of the additive manufacturing industry. The AMSC does not develop standards or specifications, and focuses on coordinating standards development activity.[12]
Trade Associations	Serve as an advocate for the manufacturing industry and represent stakeholders across the industry value and supply chain. They play a key role in knowledge sharing, thought leadership, and networking for the promotion of advanced manufacturing. Examples of trade associations relevant to this report include the National Association of Manufacturers (NAM) and the Additive Manufacturing Trade Association (AMTA).
United States Government	Plays a multifaceted role in advanced manufacturing. Regulatory agencies must develop new regulations and develop or amend guidance documents and regulatory review processes to account for major advancements in technology that can affect the outputs of these technologies. Non-regulatory agencies participate in research and development of these advanced manufacturing technologies and/or aid industry to strengthen global understanding of the technologies.

Figure 3-2 illustrates non-exhaustive examples of organizations within each stakeholder group. This report includes findings from research publications, interviews, and other public documents sourced from various organizations.

Figure 3-2: Illustrative Organizations per Stakeholder Group



3.3 Landscape Scan

The North American Industry Classification System (NAICS) guided the selection of the non-medical industries for this systematic landscape assessment. The NAICS identifies industry groups based on the similarity of production processes and covers all economics activities across 20 sectors and 1,012 industries.[13] After reviewing relevance and value with OCET, 18 non-medical industries were selected, to include:

- *Aerospace Research, Technology, and Development*
- *Agriculture*
- *Air Transportation*
- *Artificial Intelligence (AI): Manufacturing and Technology*
- *Chemical Manufacturing*
- *Construction*
- *Data Processing*
- *Defense*
- *Energy: Electric and Nuclear*
- *Life Sciences*
- *Metal Manufacturing*
- *Mining (Except Oil and Gas)*
- *Motor Vehicle Manufacturing*
- *Petroleum and Coal Products*
- *Safety: Consumer and Worker*
- *Telecommunication*
- *Uranium Mining, Processing, and Atomic Energy*
- *Waste Management and Remediation Services*

A comprehensive research framework aligned data collection to the evaluation objectives, including metrics and data sources. A Data Collection Instrument (DCI) tool was developed to organize, manage, and track the data collected, which included almost 6,000 literature and other documents (e.g., guidance, standards, policy, regulations, law), as well as stakeholder interviews across USG and non-governmental organizations. Key findings from interviews and document reviews were mapped to the objectives and coded for thematic and trend analysis.

- ***Literature Review:*** For the review, 2,000 literature documents were down selected for relevance from 6,000 originally sourced. The selected documents included non-peer-reviewed sources to capture emerging, novel, and disruptive technologies and processes.
- ***Other Documentation:*** The review also included 400 non-literature documents, such as standards, policies, directives, roadmaps, guidances, regulations, laws, congressional reports, government websites, and private industry publications.
- ***Stakeholder Interviews:*** Interviewees were selected from a list of USG and non-governmental non-medical industry stakeholders (see Appendix D: Non-Medical Industry Stakeholders) with academic, trade, professional, regulatory, and private industry expertise. The 17 interviews conducted, with 36 individuals across 15 stakeholder organizations, contributed a diverse range of perspectives for this analysis.

During the technology cataloging phase, potential benefits, limitations and risks, and stages of emergence or adoption were identified per advanced manufacturing methodology, technology, process, and platform. Manufacturing Readiness Levels (MRLs) are industry-recognized criteria used to assess the maturity or readiness of a manufacturing product or system, including technology development, for full-scale production.[14] Table 3-3 outlines the MRL levels (on a scale from 1 to 10, with 10 being the most mature manufacturing process), definitions, and alignment upon which a high-level bucket of “adopted” or “emerging” was applied.

Table 3-3: Alignment of MRLs to Emerging or Adopted Stage

MRL Level	MRL Definition	Emerging or Adopted Alignment Stage
1	Basic manufacturing implications identified	Emerging
2	Manufacturing concepts identified	
3	Manufacturing proof of concept developed	
4	Capability to produce the technology in a laboratory environment	
5	Capability to produce prototype components in a production relevant environment	
6	Capability to produce a prototype system or subsystem in a production relevant environment	
7	Capability to produce systems, subsystems, or components in a production representative environment	
8	Pilot line capability demonstrated; Ready to begin low-rate initial production	
9	Low-rate production demonstrated; Capability in place to begin full rate production	Adopted
10	Full rate production demonstrated and lean production practices in place	

During the assessment phase, data were analyzed and organized into themes and subthemes—encapsulating best practices and challenges for implementation, adoption, and regulation. Findings also identified key indicators of current usage or potential growth, as well as factors that advance or hinder implementation and adoption.

3.4 Limitations

The following limitations potentially impacted the data collection, analysis, or findings.

- The scope of this landscape scan crossed a diverse array of non-medical industries, with varying degrees of applications per advanced manufacturing technology or process. A technology or process adopted in several industries may be emerging in others and limits the ability to label the degree and rate of adoption and emergence with a level of certainty.
- Peer-reviewed literature or studies often lag technological advancements, which impact the availability of documentation for novel or emerging applications. Therefore, other documentation (e.g., news articles, trade press, interview notes, organization websites) supplemented these types of sources. Obtaining corroborating evidence for impacts and outcomes was challenging due to the inherent nature of novel and emerging technologies.
- Non-governmental entities proved difficult to engage, despite direct and frequent outreach, and impacted the ability to garner direct input from those organizations.

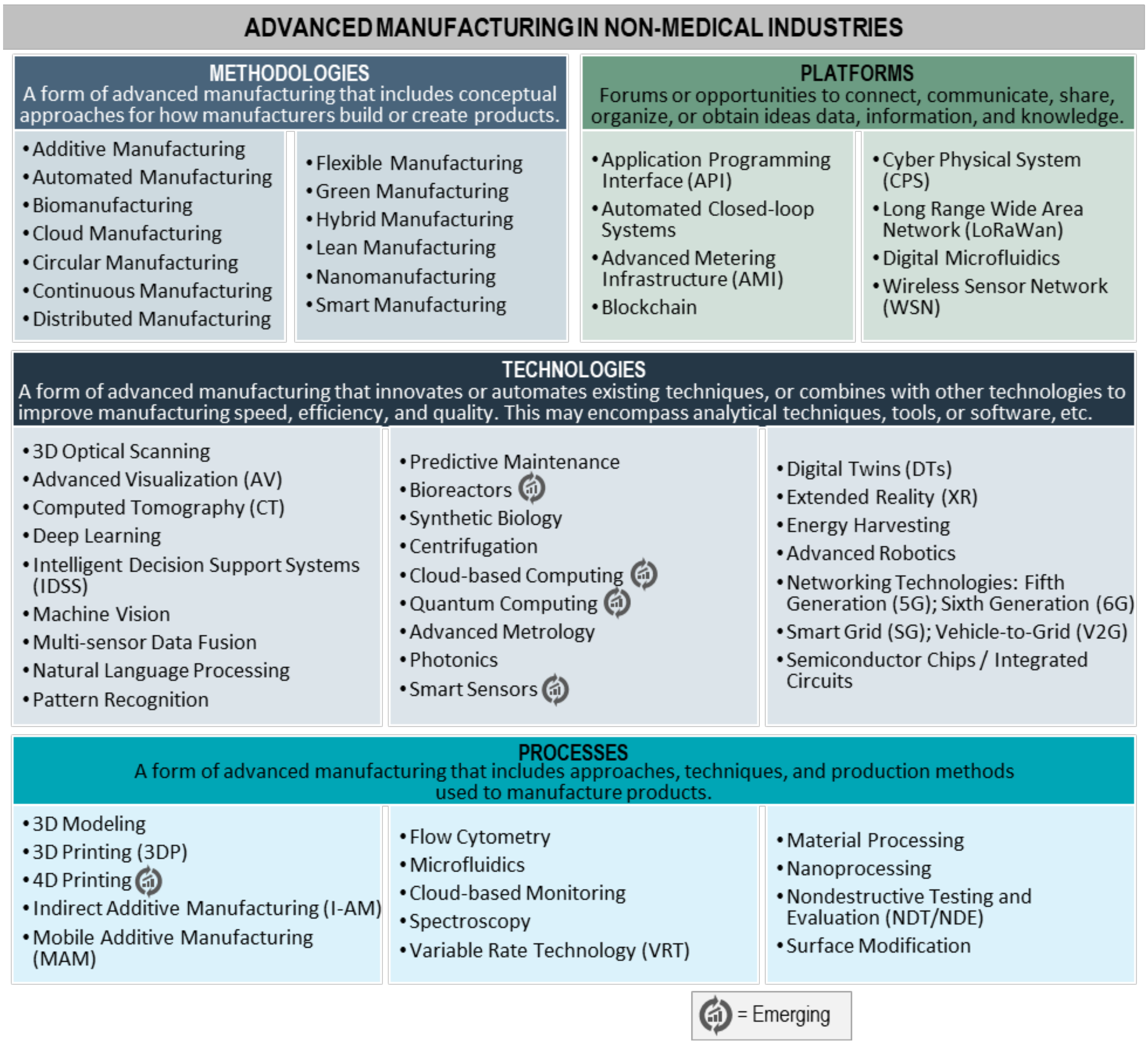
4 CATALOG OF ADVANCED MANUFACTURING TECHNOLOGIES IN NON-MEDICAL INDUSTRIES

4.1 Summary of Advanced Manufacturing Emergence and Adoption

This catalog of advanced manufacturing technologies in non-medical industries was developed as the initial phase of this landscape analysis, and is categorized into methodologies, technologies, processes, and platforms. Figure 4-1 provides a summary view of the results of the catalog. Technologies and processes identified as “emerging” are denoted by an icon and all others are considered as “adopted”.

Based on data collected, five examples were identified as in a stage of *emergence* (i.e., MRL 1-8) across non-medical fields. They are: 1) four-dimensional (4D) printing, 2) bioreactors, 3) cloud-based computing, 4) quantum computing, and 5) smart sensors. In most cases, advanced manufacturing methodologies, technologies, processes, and platforms are in a stage of adoption (i.e., MRL 9 and 10) in some capacity or application in one or more non-medical industries. While there are additional instances in which advanced manufacturing technologies are emerging through specific applications, or use of the technology, there is no evidence to show the technologies themselves are novel or emerging in non-medical industries. Full catalog details are available to reference in the following sections of the report, including the description, application, key benefits, limitations and/or risks, and stage of emergence or adoption.

Figure 4-1: Catalog of Advanced Manufacturing Technologies in Non-Medical Industries



4.2 Advanced Manufacturing High-Level Methodologies

Advanced manufacturing methodologies provide high-level conceptual approaches to manufacture products. Technologies and processes utilize multiple methodologies depending on their application. For example, energy harvesting uses green manufacturing to reduce negative environmental impacts as well as smart manufacturing methodologies because piezoelectric sensors and electric vehicles (EV) communicate without human interference. This section highlights methodologies currently in use across non-medical industries. While the use of specific methodologies in advanced manufacturing technologies and processes may classify as emerging, the methodologies themselves did not fall under this classification.

4.2.1 ADDITIVE MANUFACTURING

Description: Additive manufacturing, commonly known as 3D printing, consists of joining materials to make parts from 3D model data, usually layer upon layer.[15] Developing 3D objects through repeated layering of materials, using one of eight methods (i.e., binder jetting, biofabrication or bioprinting, directed energy deposition, material extrusion, material jetting, powder bed fusion, sheet lamination, or vat photopolymerization), as opposed to subtractive manufacturing.[16] 3D printing is not the only additive manufacturing process industry is monitoring. 4D printing, indirect additive manufacturing, and mobile additive manufacturing are also emerging and disruptive.

Applications: Various industries apply additive manufacturing. For instance, the aerospace industry leverages additive manufacturing for the development of commercial aerospace components. Additionally, industries like automobile manufacturing or construction, may use additive manufacturing to build large, moderately complex components.[17,18]

Key Benefits: Additive manufacturing serves as a more versatile, flexible, and cost-effective means for fabricating, in comparison to traditional manufacturing, which usually requires resource-intensive scale up (e.g., molds, formative techniques, machining/subtractive techniques).[19]

Limitations and/or Risks: Limitations include insufficient software availability and quality standards, expensive equipment, pre- and post-processing, and demanding calibrations.[20] In regard to powder bed fusion—in particular, selective laser melting (SLM)—shrinkage due to temperature differences, deformation, and residual stress may occur.[21,22]

Stage of Emergence or Adoption: Since its first uses in the 1980s, additive manufacturing has gained traction in various applications. While its technologies and applications continue to advance, as an overall methodology additive manufacturing aligns within the adoption stage.[23]

4.2.2 AUTOMATED MANUFACTURING

Description: Automation of manufacturing processes is the combination of technologies and capabilities, including sensing, process control, robotics, data analytics, and system modeling, intended to reduce the need for human input throughout the manufacturing process (i.e., decreasing human-machine interaction time). These advancing technologies allow manufacturers to capture large amounts of data to support development of advanced process control (APC) strategies, real-time automation of operations, and continual verification of processes.[3]

Applications: Aircraft manufacturers use automated manufacturing robots for drilling, fastening, and aircraft painting. The aerospace industry combined laser removal and ablation with robotics to provide operational and environmental benefits, as well as leveraged movies for complex installations related to harness routing.[24,25] Additionally, life science industries leveraged automated manufacturing to create microfluidic devices, including chemical reactors and bioanalytical devices.[26]

Key Benefits: Manufacturers are better able to control and design complex processes by using sensors to measure process variables and attributes. Additionally, manufacturers benefit from enhanced product quality, reduced costs (e.g., equipment maintenance costs) and touch labor, improved production efficiency, and reduced waste from automated manufacturing.[24,25,27]

Limitations and/or Risks: Automated manufacturing can become costly when attempting to modify designs quickly (i.e., composite automation).[28] Manufacturers may also experience security risks and vulnerabilities due to heavy reliance on network communications to operate various systems.[26]

Stage of Emergence or Adoption: Levels of automated manufacturing have increased since the 1980s, thus aligning within the adoption stage, due to its continual advancement within the fourth industrial revolution.[29]

4.2.3 BIOMANUFACTURING

Description: Biomanufacturing is the use of biological systems outside of their natural context for the commercial development of products, tools, and processes.[30,31]

Applications: Industries may leverage biomanufacturing to create new pathways for developing biological materials (e.g., cellular components, biomaterials), bioreactors, and biological systems (e.g., tissues, organs), to help improve supply chain management, manufacturing environments, and environmental compatibility.[32] Life science industries could combine biomanufacturing with 3D Printing to generate functional 3D tissues and biodegradable thermoplastics.[33] Novel applications of biomanufacturing include engineering microbes to decompose plastic in landfills, utilizing biomass to engineer materials and chemicals, and cultivating food without harming the environment.[30]

Key Benefits: Biomanufacturing has great potential in the development of products like fuels, chemicals, and construction materials with less environmental impact from their manufacture and use than traditional engineering practices.[34,35] As the field matures, biomanufacturing has the potential to lead to a new generation of tissues, devices, and systems that have applications across medical and non-medical industries.[32]

Limitations and/or Risks: Despite advancements in biomanufacturing, in non-medical industries there is still incomplete understanding of the types of interactions that occur between the cells themselves, and humans' ability to control or manipulate their interactions.[36] Further, biomanufacturing processes could result in the generation of chemical or biological byproducts that may be toxic or hazardous to workers and require targeted training for workers and biosafety risk control measures.[37]

Stage of Emergence or Adoption: Use of biomanufacturing continues to increase for product development, and the U.S. recognizes its future applications and potential for growth, as illustrated by the President's Council of Advisors on Science and Technology commissioning of a report on its impact to the bioeconomy.[35] Given current usage, biomanufacturing, as a methodology, aligns within the adoption stage.

4.2.4 CLOUD MANUFACTURING

Description: Cloud Manufacturing (CMfg) incorporates current manufacturing technologies and innovative cloud computing technologies, allowing the sharing of capabilities between divisions and manufacturing units, and the connection of various components such as Internet of Things (IoT), cloud computing, and virtualization.[38,39]

Applications: Various industries like construction or automobile manufacturing can utilize CMfg within computer-aided process design, to include monitoring, control, production planning, design, and management.[40] Such process planning applications may leverage a service-oriented cloud-based approach or a web-based, service-oriented system.[41]

Key Benefits: CMfg benefits may include reduced manufacturing time and production costs; improved production capability; and increased production flexibility, efficient online scheduling, and simplistic data correction.[40] Manufacturers may also integrate market and manufacturing resources or data to help address issues and maximize efficiency in enterprise logistics.[40]

Limitations and/or Risks: Uncertainties in the implementation of CMfg include reservations surrounding cybersecurity, connectivity availability, transformation of resources into the cloud environment, interoperability, privacy, vendor-lock in, service quality, consumption-based billing, and questions about how transparent to be with users and consumers regarding infrastructure.[38] There are also research gaps regarding the growth of the cloud-based platforms, their interfaces, and the service-oriented delivery of automated services.[41]

Stage of Emergence or Adoption: Although in use, industry remains uncertain of the technology due to its potential limitations and unknowns. Therefore, CMfg aligns within the adoption stage.

4.2.5 CIRCULAR MANUFACTURING

Description: Circular manufacturing centers on implementing various strategies (e.g., recycling, reuse, reverse logistics, closed-loop supply chain) to close resource loops, decrease resource use, and prolong resource lifecycles.[42] Circular strategies within this methodology are supported by additive manufacturing via sustainable design (i.e., circular additive manufacturing).[43]

Applications: Diverse industries apply circular manufacturing. For example, some feedstock manufacturers utilize circular manufacturing to reprocess various materials, repair parts, and recycle feedstock.[43] Some of the other materials/products produced by circular manufacturing are paper products, rubber and plastics, electrical equipment, and computer products.[44]

Key Benefits: Post-implementation and adoption, industries may observe reduced production of wastes, improved material use, reduced costs and consumption of energy, extended product lifetime, and enhanced product quality.[43]

Limitations and/or Risks: Challenges to circular manufacturing processes include high initial start-up costs, supply chain complexities, inadequate cooperation between businesses, deficient information on product design or production, scarce workforce technical skills, quality concerns, and if disassembly of products is required, it may be time-consuming**.**[43]

Stage of Emergence or Adoption: Several industries and technologies are adopting and aiding in circular manufacturing (e.g., repairing tools with laser technology). However, this manufacturing field has potential applications related to energy consumption methodologies. Circular manufacturing aligns within the adoption stage.

4.2.6 CONTINUOUS MANUFACTURING

Description: Continuous manufacturing (also known as continuous processing, continuous production, or continuous flow process) supports a steady flow of material across unit operations. In this manufacturing approach, input materials are continuously added to and transformed within the process while outputs are continuously removed from the system.[45] This innovative methodology incorporates continuous monitoring (e.g., real-time or near-real-time detection via probe and sensors, or online via Process Analytical Technology [PAT] tools) and advanced strategies for process and feedback control.

Applications: Chemical producers apply continuous manufacturing (CM) for aseptic spray drying, crystallization, and synthesis, as well as twin-screw wet granulation.[46] Recently, a new continuous pressure infiltration process was developed to produce continuous-fiber-reinforced metal matrix composite wires. The process uses pressure infiltration to melt fiber bundles, making it possible to control the production as the production speed and wire diameter.[47] Additionally, continuous manufacturing is used in electricity production and water treatment. This approach ensures sufficient product supplies and makes efficient use of the machinery available.[48]

Key Benefits: CM may yield improved product uniformity, quality, and sustainability; increased efficiency; enhanced tracking and tracing; reduced production runs; optimized process parameters; and improved safety. Manufacturers applying continuous manufacturing are also able to integrate all processes across product development, diversify the types of products, reduce scale-up costs, and speed transitions to market.[49,50]

Limitations and/or Risks: Barriers to greater methodology adoption include high start-up and transition costs (e.g., new technology purchases, staff education, updating infrastructure) and the need for manufacturers to have a thorough understanding of the process (i.e., upskilling requirements).[49,50,51]

Stage of Emergence or Adoption: While use of continuous manufacturing across non-medical industries remains limited, it has been exercised in production. CM aligns within the adoption stage.[49]

4.2.7 DISTRIBUTED MANUFACTURING

Description: In distributed manufacturing, a single remote quality management system (QMS) oversees one or more mobile units deployed to multiple locations and may integrate with other methodologies, such as cloud-based manufacturing or automated systems.[52] The approach leverages digital technology-enabled small-scale manufacturing (e.g., produced in limited batch size, volume, instances of production, market) to allow localized on-demand production and consumption models that are in closer proximity to the end user through mini factories or production units. [53,54,55,56]

Applications: Distributed manufacturing applications include on-demand spare automotive parts, with one example from literature referencing a shortage of semiconductor chips causing automotive factory closures.[57] Early usage of distributed manufacturing can also be seen in the production of parts manufactured for remotely located oil and gas rigs.[57] Literature indicates there could be growth for distributed forms of manufacturing in the dental industry. The production of dental crowns, implants, and dentures are produced at a significantly localized level, because they are typically only built in a dental office.[57]

Key Benefits: This manufacturing strategy can effectively shorten supply chains and increase supply reliability, provide flexible and timely material production (dependent on manufacturing scale), allow for cycles within material life, and support sustainability initiatives (e.g., reduced consumption of fossil fuel energy).[58,59]

Limitations and/or Risks: Challenges include managing distributed manufacturing networks that are in different geographic locations, as well as increased complexities for future virtual and cloud-based collaboration models and smart technologies.[59]

Stage of Emergence or Adoption: Despite its current challenges, as well as further opportunities for enhancement, distributed manufacturing has progressed for the past 20 years and aligns within the adoption stage.[59]

4.2.8 FLEXIBLE MANUFACTURING

Description: Flexible manufacturing involves the integration of operation intelligence to help to make processes agile and adaptable to changes in demand. This methodology also provides product customization and generally two types of flexibilities: 1) machine flexibility, in which the machine can be modified to produce new product types and/or change the order of operations; and 2) routing flexibility, in which machine(s) may be used to perform the same operation on single or different products.[3]

Applications: Industries may leverage flexible manufacturing for single-use systems, assembly and fabrication, manufacture of sanitary ceramics, manufacture of custom kitchen furnishings, and textile manufacture. Example components include self-driving forklifts and automated robotized arms and conveyors. Within the flexible manufacturing system, manufacturers can integrate machinery through IoT and/or a traceability system to achieve a digital audit trail of operations.[60]

Key Benefits: Benefits include process and operational optimizations, occupational safety, resource management, customer satisfaction, and sustainability. In terms of process and operational factors, manufacturers may improve process efficiencies, automation, productivity, flexibility, and operational tasks through flexible manufacturing. Additionally, personnel working with a flexible manufacturing system can work in a safer and healthier environment due to fewer accidents and improved working conditions. Manufacturers leverage flexible manufacturing to enhance overall resource management and reorganize labor for production system efficiencies. Additional customized production capabilities may also enhance customer satisfaction. Through flexible manufacturing, manufacturers support sustainability by helping to minimize waste and extend product lifetime.[60]

Limitations and/or Risks: Although flexible manufacturing can support certain sustainability activities, a potential limitation with flexible manufacturing is energy consumption, which impacts factors like environmental protection and process life cycle analysis.[61]

Stage of Emergence or Adoption: Flexible manufacturing concepts initially emerged in the 1960s, and there are currently dozens of flexible manufacturing systems used globally. Although widely used, there will continue to be opportunities for novel uses as advanced technologies and processes become more automated. Given its current state, flexible manufacturing aligns within the adoption stage.[62]

4.2.9 GREEN MANUFACTURING

Description: Green manufacturing centers on innovative production methods that emphasize waste reduction and recycling to reduce consequential environmental impacts.[63]

Applications: Green manufacturing has been applied within in-situ bioremediation, sustainable building design, and invisible mine development. Additionally, manufacturers are practicing natural resource conservation (e.g., organic farming, renewable energy) to increase manufacturing energy efficiencies.[63]

Key Benefits: Implementation of green manufacturing lowers environmental impact; supports resource, energy, cost, and time savings; and advances productivity and efficiency. Effective adoption also reduces waste and pollution; helps to lower carbon footprint; optimizes resiliency and sustainability across the manufacturing life cycle, including the supply chain; and helps to build the foundation for a global circular economy.[63]

Limitations and/or Risks: Although the feasibility of green manufacturing has been demonstrated in laboratory studies, many of the underlying processes and influential factors in the environment are unclear, and its practical application is challenging. Additionally, implementation requires manufacturers to take a proactive approach in reviewing and improving their existing procedures for waste reduction and recovery and determining their readiness level for adoption.[63] Integrating a newer process in an existing system can present more challenges than benefits.

Stage of Emergence or Adoption: Green manufacturing aligns within the adoption stage, as efforts to encourage more manufacturers to implement sustainable practices into their existing systems are progressing.[63]

4.2.10 HYBRID MANUFACTURING

Description: Hybrid manufacturing is a methodology that integrates additive (i.e., 3D printing) and subtractive manufacturing (e.g., computer numerical control [CNC] machining) within a machine.[64] These methods (i.e., 3D printing, direct energy deposition) utilize one-step hybrid machines because they can perform subtractive and additive manufacturing in a single process. Hybrid systems and one-step hybrid machines offer many advantages compared to traditional manufacturing processes. Over time, hybrid manufacturing has evolved to encompass other traditional manufacturing technologies, such as welding and forming.[65]

Applications: Automotive and aerospace industries leverage hybrid manufacturing for various applications. Automobiles have a massive number of parts, many with complex geometries. Having the ability to create these parts with many fewer machines has the potential to help car manufacturers save money. The aerospace industry uses hybrid manufacturing to design intricate parts that are complex and lightweight.[64]

Key Benefits: Industries may benefit from improved efficiency of product fabrication, reduced volume of machinery needed and errors observed, and increased opportunities for new applications of traditional manufacturing routes and processes through hybrid manufacturing.[64,65] Additionally, industries have more flexibility in the production of unique parts not available through additive or subtractive processes separately.[64]

Limitations and/or Risks: Limitations can include ineffective dimensional precision, coarse surface quality, and small productivity for certain applications.[65]

Stage of Emergence or Adoption: Hybrid manufacturing aligns within the adoption stage, with widespread use beginning in the early 1990s.[65]

4.2.11 LEAN MANUFACTURING

Description: Lean manufacturing is a smart manufacturing methodology (see Section 4.2.13) in which an automated system addresses changes in customer demand in real time, requiring demanding levels of coordination, robust logistics systems, and effective focus on quality.[66,67] Digital thread is a framework used within lean and smart manufacturing that enables continuity within data through the design and manufacturing life cycles.[68]

Applications: Lean manufacturing is used to service machines remotely so that a manufacturing plant can focus on producing parts and utilizing sensor technology to ensure product quality and production efficiency (e.g., cable manufacturing, printing industry, automotive parts). In addition to operational and production efficiency applications, manufacturers can apply lean manufacturing in 3D printing to produce tools (e.g., using material extrusion of polymers).[24] The automotive industry is interested in a range of autonomous mobile robots, which can greatly improve the speed of delivery of critical parts to the assembly line.[69]

Key Benefits: Implementation can improve operational performance, as well as shop floor management and efficiencies. For instance, lean manufacturing may help to enhance production plans, minimize idle activities, improve resource management, enhance task automation, and reduce costs (e.g., when used in material extrusion).[24,66] Manufacturers can also improve shop floor management and validate and incorporate digital threads on factory floors.[24,66] Through the use of digital thread, models can be created and reused, decreasing engineering costs and increasing automation. For example, through the integration of a digital thread framework, one private manufacturer was able to manage resources efficiently by developing preliminary 3D models and simulations for tools examining how the designed tools interacted with other existing parts of F-35 aircrafts. Using this process, the company found that this approach reduced the need for major design changes at a later point.[24]

Limitations and/or Risks: Although manufacturers can use lean manufacturing to support incorporation of digital thread technology, the integration may be expensive and require significant time.[24] Further, manufacturers must consider change management activities and how the organization's culture may impact the effectiveness of adopting lean manufacturing approaches.[70]

Stage of Emergence or Adoption: Lean manufacturing aligns within the adoption stage for certain industries, while new applications (e.g., production management) may still consider the methodology as emerging.[66]

4.2.12 NANOMANUFACTURING

Description: Nanomanufacturing consists of processes that aid in the design, fabrication, modification, manipulation, or assembly of products on a near-atomic scale (i.e., between 1 and 100 nanometers [nm]) to produce new structures, materials, and devices.[71,72] Nanomanufacturing can be categorized into a top down (e.g., bulk materials broken down to nanoscale structures) or complex bottom-up (e.g., atoms fabricated into nanoscale structures) methods utilizing additive, subtractive, and replication/mass conservation processes.[73,74,75]

Applications: The agricultural industry utilizes nanofertilizers, nanopesticides, and nanobiosensors, and the food industry utilizes nanomaterials for food additives and packaging.[76] Additionally, due to nanomanufacturing's top down and bottom-up approach, there are a growing number of processes to support nanomanufacturing methods, such as chemical vapor deposition, epitaxy (e.g., molecular beam and atomic), lithography (e.g., dip pen and nanoimprint), roll-to-roll, and self-assembly.[75] Nanomanufacturing techniques can include nanomachining, nanofabrication, nanometrology, nanorobotics, nanoelectronics, and nanobiotechnology to assist with fabricating nanoscale components.[77] Nanotechnologies have also been utilized for therapeutic agents, pollutant removal, antimicrobial activities, nano-based sensors, nanocomputing, nanofiltration, nano-enhanced oil recovery, and nanoreinforcement.[77,78,79,80]

Key Benefits: Nanomanufacturing methods enable scaled-up, reliable and cost-effective manufacturing for novel and unique phenomena, at the nanoscale, for enhanced functionality of structures and materials.[74] Nanotechnologies support multiple industries (e.g., food and agriculture) and can address water remediation, food improvements, and biodiversity problems and challenges.[77] Nanomanufacturing can increase production efficiency (e.g., lesser processing steps, lower energy consumption, improve quality of the final product, enhance separation efficiency), resource use efficiency, and waste reduction.[76] Nanotechnology can also enhance the physical properties of nanomaterials (e.g., thermal stability, barrier, mechanical properties) when used for nanoreinforcement.[76]

Limitations and/or Risks: Nanomanufacturing methods have some human health impacts related to concerns of nanoparticle toxicity and packaged materials leaching and migrating into food.[76,81] Research pertaining to nanomaterial manufacturing and application are ongoing and concerns regarding occupational health risks (e.g., potential exposure levels, exposure routes, and material toxicity of nanomaterials) are being explored.[71] Further research was also identified as a need to improve nanomaterials and to gain a better understanding of environmental impacts.[76,77]

Stage of Emergence or Adoption: End products from nanomanufacturing are widely used across agriculture and environmental fields and align within the adoption stage. However, it has emerging applications in other industries, including but not limited to, integrated sensors, semiconductors, medical imaging equipment, drug delivery systems, structural materials, sunscreens, cosmetics, and coatings.[81]

4.2.13 SMART MANUFACTURING

Description: Smart manufacturing incorporates all aspects of product development, helping to produce high quality parts and enhance performance at the unit, plant, and supply chain levels. This is achieved by incorporating sensors, software platforms, and controls, providing opportunities to quickly address changes in the market, flexible manufacturing, data analytics, and real-time monitoring and control.[82]

Applications: Manufacturers utilize smart manufacturing for remote machine servicing to improve focus on part production and sensor technology to confirm product quality and production efficiency.[83] Further, manufacturing intelligence can be advanced by integrating industrial, manufacturing, management, and information technology; other advanced technologies such as Industrial Internet of Things (IIoT), AI, cloud computing, and big data; and human/organization components.[84,85]

Key Benefits: Smart manufacturing provides improved visibility, traceability, efficiencies, and flexibility during manufacturing, and the ability to detect and correct deviations in manufactured end products (e.g., via closed-loop quality execution and intelligent risk management).[3] Additionally, smart manufacturing streamlines procedures, reduces silos, and improves communication in the system.[83] There are great implications for improving resilience in response to emergencies, including supply chain resilience and speed to market through improvements in product yield, flexible digital infrastructure, and process risk mitigation.[3]

Limitations and/or Risks: Barriers to broader industry adoption of smart manufacturing, particularly for small to medium-sized manufacturing enterprises, include cost and limited workforce training. If small to medium-sized manufacturing enterprises do not implement smart manufacturing, they could be at a disadvantage in comparison to larger companies with advanced capabilities.[83] Other challenges with standing up smart manufacturing systems include security (e.g., confirming data security and overall system security) and financial issues (e.g., complex return on investment analyses), as well as system integration.[82]

Stage of Emergence or Adoption: Given its current utilization in production, smart manufacturing aligns within the adoption stage.

4.3 Technologies

Advanced manufacturing technologies are those that innovate or automate existing techniques, or combine with other technologies to improve manufacturing speed, efficiency, and quality. The term "technologies" may encompass analytical techniques, tools, or software, among others. This section describes the advanced manufacturing technologies adopted across non-medical industries over the past ten years or expected to emerge within the next five to ten years.

4.3.1 ARTIFICIAL INTELLIGENCE (AI) AND MACHINE LEARNING (ML)

3D Optical Scanning

Description: 3D optical scanning is a technology used to acquire and visualize complex topographical 3D surface, volume, and stability of objects data.[86,87,88] Its integration with AI can improve processes such as detection, monitoring, and diagnoses of material flaws or faults.[89]

Applications: 3D optical scanning can reverse engineer processes, digitize physical objects, design complex curved surfaces, verify the accuracy of products, calculate tool wear, conduct architectural surveys, develop industrial tools, aid design prototyping, conduct quality management, and support metrology of complex parts.[90]

Key Benefits: When using 3D modeling, objects can be measured more precisely, analyzed, and printed quickly. 3D optical scanners are safer and easier to operate as they are supported with better software and field of view lenses. Comparing version data is quick and straightforward when scanning a new prototype version.[90] Given the layer-by-layer printing nature of additive manufacturing, 3D surface topography data of printed surfaces are of crucial importance to aid both in-process corrective actions and post-process quality inspection, and thus can result in significant time and cost saving.[91] AI use can further improve its abilities related to product fault identification.[89]

Limitations and/or Risks: The initial cost of implementing 3D optical scanners is high. It requires software to complete scans and can have compatibility issues. Appropriate calibration and parameters (e.g., temperature, humidity) need appropriate adjustment or it can negatively impact the scanning accuracy.[90]

Stage of Emergence or Adoption: 3D optical scanning is currently used in production, but in limited applications. Therefore, 3D optical scanning aligns within the adoption stage.

Advanced Visualization (AV)

Description: AV is a category of technologies that utilize AI and ML capabilities on existing visualization tools to develop better visual images and enable users to better understand data.[92]

Applications: Existing tools that leverage advanced AV technologies include digital photogrammetry (a method that can obtain dense 3D geometric information such as data on spatial position and size from objects), in-situ near infrared (IR) imaging (a method that can scan IR wavelength range 0.6 to 5 microns), and thermographic imaging (a non-contact method to optically monitor the temperature of an object using an IR camera technology).[93,94,95,96] For example, metal additive manufacturing uses AV technology to detect imperfections and repeatability via thermographic imaging.[92] The automotive industry uses AV to automate inspections based on deep learning (DL) (e.g., to find cracks for civil infrastructures).[97] Industries can also use AV technology for image processing (e.g., to correct image perspective and contrast).[98]

Key Benefits: Digital photogrammetry, which is considered one of the best surveying methods to acquire visual data without direct contact with the material, can be a time and cost-efficient method of AV.[99,100] Additionally, in-situ near-IR cameras are considered efficient for remote inspection of materials and identifying defects in advanced manufacturing.[92,93,101]

Limitations and/or Risks: Despite its benefits, AV methods can be dependent on the performance of other components. For example, there may be a reliance on calibration that could impact the accuracy of the visualization.[92]

Stage of Emergence or Adoption: Though findings indicate AV has been adopted in some industries (e.g., metal additive manufacturing, automotive) additional research efforts and testing focused on in-situ monitoring to alter process parameters in real time are still being conducted.[92]

Computed Tomography (CT)

Description: CT produces cross-sectional images (i.e., tomographic images or slices) via computerized X-ray imaging, illustrating internal details of objects.[102,103] Once the machine's computer accumulates several slices, the computer digitally arranges them to form a 3D image of the object.[102] Evaluation of results derived from non-destructive evaluation (NDE) methods, through technologies like CT, can be automated and made more efficient by utilizing AI methods.[104,105]

Applications: Industries use CT to study the porosity and dimensional accuracy of components created by additive manufacturing, as well as the metrology of printed parts.[106] It has also been utilized to examine the internal structures of industrial materials (e.g., batteries, metals) and biological samples (e.g., animals, cells), among others.[107] Coupling CT with DL methods has also been shown to improve the quality of images and enable efficient and accurate classification of pores.[105]

Key Benefits: CT supports the quality control (QC) of components.[108] Users may also leverage CT to obtain more detailed information than traditional x-rays, as well as support product quality inspections by measuring micrometer-scale features or internal geometries (e.g., surface textures).[106,108]

Limitations and/or Risks: Obtaining higher resolution images of smaller subjects using CT may require significant time (e.g., minutes compared to hours), which may limit its usability for certain industries that require more efficient assessments.[103] CT has limitations with robust thresholding, as well as distinguishing between pores and intentional segments in a component.[109] The CT process also utilizes doses of radiation that can lead to structural damage unless the material is significantly cooled.[103]

Stage of Emergence or Adoption: Several industries have adopted CT for a variety of applications over the years (e.g., materials science, biomedical and life sciences).[103] However, CT has not been as widely adopted for metrological applications in the additive manufacturing space due to the need for enhanced calibration and performance verification to measure the increasingly complex geometries of 3D-printed products.[110]

Deep Learning (DL)

Description: DL is a subfield of ML that leverages information from multiple successive layers of artificial neural networks to learn and make decisions.[111] DL has some unique characteristics, such as its ability to automatically identify and select the features that it will use in the classification stage, while ML adds those features manually. Additionally, its algorithms require more sophisticated technological infrastructure and large amounts of training data to return accurate outputs, whereas an ML algorithm may operate on less advanced infrastructure with less training data.[112] DL has increased in value to industry as organizations have been able to obtain more access to training data and develop larger and more complex models for dynamic applications by leveraging improvements in computer hardware and software.[113] Types of DL methods include Bayesian neural networks, recurrent neural networks, deep belief networks, Restricted Boltzmann Machines, and convolutional neural networks.[114]

Applications: There are applications for DL in almost every industry. The aerospace industry uses various DL to monitor the fabrication of components, detect porosity in-situ, and analyze thermal images of 3D-printed components for quality monitoring.[115] The agricultural industry combines DL with computer vision to process and analyze data captured by drones to help monitor crop and soil health.[111] DL is also used to monitor the health of livestock (e.g., eating habits, livestock identification, behavior, count of livestock), analyze agricultural land to inventory plants, and develop plant health maps.[116,117] The energy industry has used DL for cybersecurity strategy, energy saving, smart grid management, fault diagnosis, electricity load forecasting, and renewable energy.[118] The energy industry has also used the technology to generate predictive analytics on biomass waste-derived porous carbons, as well as for smart city security and safety systems, smart energy management, wind and solar energy efficiency, and energy price forecasting.[80,119] The manufacturing industry applied DL to monitor tool wear in machining processes; customize product design and manufacturing; manage manufacturing, maintenance, and customers; logistics; after-sales service; and market analysis.[120,121] Users have also leveraged DL in conjunction with smart manufacturing processes to improve supply chain management.[122] Another application is the integration of DL with digital twin models to detect anomalies in industrial system functions.[123] The nuclear industry leverages DL to support assessments of reactor plant status, evaluate the validity of sensor readings, forecast operational limit safety and violations, find minute equipment changes and equipment failures, address non-vital alarms, and support energy management.[124,125,126]

Key Benefits: DL has several advantages dependent on application, including its ability to automatically learn data features; handle large amounts of intricate data; enhance performance; address missing, structured, and unstructured data; and support predictive modeling, scalability, and generalization. DL can also eliminate manual human intervention while allowing the use of robust datasets. DL may also help to shorten the product development lifecycle, optimize the performance of manufactured components, increase accuracy and efficiency of spectral analyses, and improve analyses of cybersecurity threats.[115,127,128,129,130]

Limitations and/or Risks: DL algorithms often require a large amount of training data, significantly more than other ML algorithms, and this often necessitates more computing power and resources.[121] These algorithms also require that the data is trustworthy and reliable, as unreliable data can lead to unintentional bias and skew the algorithm's decisions and outputs.[131] This complexity can cause the process to be time-consuming,[132] expensive,[133] and lead to the development of outputs that are difficult to interpret.[121] Because there are also potential privacy and security concerns for DL algorithms and associated data, there is a need for more research and innovation on processes for identifying and resolving these potential vulnerabilities.[80,123]

Stage of Emergence or Adoption: There have been multiple applications of DL algorithms across different industries, but there is continuing research to understand how industries can utilize it further. Some industries (e.g., manufacturing, energy) have seen DL more widely applied and adopted, whereas other industries (e.g., aerospace) have seen fewer applications of DL, likely aligning within the adoption stage.

Intelligent Decision Support System (IDSS)

Description: A decision support system (DSS) is technology that analyzes large datasets to support decision making and problem solving. IDSS applies artificial neural networks, intelligent systems, AI and ML, and algorithms to analyze the datasets (e.g., find patterns).[134]

Applications: Industries can use IDSS to learn, correlate, interpret databases, make operational decisions, and provide recommendations.[135] The agriculture industry utilizes IDSS to collect data on soil and weather, monitor health, and determine fertilizer application via ML recommendations and decisions.[136] IDSS can also process signals and large data to make partially autonomous manufacturing support systems.[137,138]

Key Benefits: IDSS can benefit decision making, automation, and operational efficiencies. For instance, because IDSS provides automation, it can reduce review and decision making time, and increase productivity.[137,139] Additionally, IDSS provides fast computation, remote maintenance support, and intelligent software.[137,139] Further, manufacturing industries utilize IDSS to decrease expenses, reduce downtime, and enhance the effectiveness of planning operations.[134,137]

Limitations and/or Risks: The benefits of IDSS may be more subtle than other methods in certain applications.[139] Additionally, certain industries (e.g., agriculture) may not find IDSS to be a standalone technology and it might not provide a significant return on investment.[79,139]

Stage of Emergence or Adoption: IDSS is considered adopted in the agriculture industry and in predictive maintenance applications; however, it may be emerging in other applications, such as weather forecasting.[138]

Machine Vision

Description: Machine vision, also known as computer vision, is technology that uses AI, one or more vision sensors, and application-specific software to interpret visual information and analyze tasks in smart manufacturing, QC, and worker safety.[140,141,142,143] The integration of AI can enhance machine vision with image-based analysis capable of comparing real-time images with reference images to assess potential defects, as well as natural language processing (NLP) capabilities to view and interpret labels. These additional functionalities make machine vision more useful and simpler to utilize compared to previous machine vision approaches that rely on rule-based methods and required significant programming and technical expertise.[144]

Applications: Machine vision includes several technologies (i.e., software and hardware products, integrated systems, actions, and methods) used to conduct automatic, image-based inspection and analysis. Machine vision may apply those technologies to monitor one or more steps in the manufacturing process, including process control and robot guidance systems.[3] Industries using machine vision include aerospace, agriculture, waste, and automotive. The aerospace industry uses machine vision for tasks such as measuring components, identifying problems and defects, and inspections.[145] The agriculture industry can combine computer vision with DL to monitor soil and crop health through the use of images taken from drones.[111] They also can combine computer vision with AI to help with product QC (e.g., checks for defects, size, color).[111] The waste industry can use computer vision to monitor waste containers, while the automotive industry utilizes machine vision for autonomous vehicles, advanced inspection technologies, and bin picking (warehousing).[143,146] Industries may also use machine vision in computer-based vision, defect identification, anomaly and problem detection, QC and inspections, efficiency and safety management, and measurement of components.[111,140,145,147]

Key Benefits: Machine vision improves product measurement consistency, accuracy, and efficiency.[123] It can automate processes, minimize human interaction in a potentially hazardous environment, and reduce material waste. When used in manufacturing, machine vision can support more rapid production processes (e.g., more consistent work, longer running production lines), increasing productivity. In relation to QC, machine vision helps address challenges associated with inspection of small-size products by leveraging sensors and cameras to capture and review images to assess product quality.[142]

Limitations and/or Risks: Machine vision relies on large, annotated datasets to train the models, which are typically expensive and challenging to obtain in industrial environments.[148] Users may also find that commercial software for visualization has limited capabilities, lacks QC, and/or does not effectively detect defects at small levels.[148] Further, users may observe limitations in machine vision performance, which factors within the image itself may impact (e.g., too many similar colors and features).[149]

Stage of Emergence or Adoption: Although several industries have adopted machine vision (e.g., waste, automotive, agriculture), it can also align within the stage of emergence in other industries or applications (e.g., aeronautical structures).[145]

Multi-sensor Data Fusion

Description: Multi-sensor data fusion technology supports the processing, attainment, and integration of information from several sensors and knowledge sources to provide a robust and complete description of an environment or process of interest.[150,151,152] While the technology has existed for many years, newer innovations have involved the use of intelligent computing methods and AI to enhance the technology's accuracy and usability. This coupling has enabled the efficient collection of data from multiple sensors and the sorting, analysis, and processing of the information to generate more accurate, consistent, and comprehensive inferences.[153]

Applications: Manufacturers can utilize multi-sensor data fusion in supervisory control and data acquisition (SCADA) systems, production and assembly manufacturing lines, CNC machines, machine monitoring, and smart wireless sensor networks and smart buildings.[154,155,156,157,158] Manufacturers can aggregate information collected from sensors, obtain a higher level of situational awareness of the manufacturing processes, and decide on subsequent activities based on the multiple levels of sensor analysis.[154] Manufacturers may also apply the technology to robotics for object recognition, environment mapping, perception, and localization.[152] Literature indicates multi-sensor data fusion has been leveraged within navigation or self-tracking applications for an autonomous vehicle.[152,158]

Key Benefits: Implementers may benefit from improved measurement accuracy and precision, enhanced conclusion validity, and increased data quality (e.g., improved land use or land cover quality and results).[158,159] Fusing data can also help to improve its reliability and lower energy consumption by forwarding only the resulting data to its end destination.[150]

Limitations and/or Risks: There may be high start-up and modification costs to implement multi-sensor data fusion systems due to the topological complexity and vast number of signals gathered.[154] There may also be complications when computing data from multiple sensors since the performance of each data fusion method is dependent on numerous factors (e.g., large datasets).[158,159,160]

Stage of Emergence or Adoption: Military and non-military industries have adopted multi-sensor data fusion technology fairly widely; however, it has novel applications that are in testing and prototyping that can be considered within a late stage of emergence (e.g., autonomous vehicles, decision fusion).[151,152,158] For example, autonomous vehicles take in large amounts of image data from cameras and sensors and use DL models (e.g., convolutional neural networks) to detect surrounding objects. However, fusing this information together and calibrating and synchronizing the needed components (e.g., camera, sensors, radar) appropriately to provide an accurate representation of the vehicle surroundings at a given point in time is an ongoing area of research.[161,162]

Natural Language Processing (NLP)

Description: NLP is a type of AI in which computers read, interpret, comprehend, and manipulate language.[163,164] NLP takes computational linguistics (a modeling of human language) and combines them with a variety of models (e.g., statistical, ML, DL) to allow computers to process human language as text or voice data to aid in understanding its meaning, intent, and speaker sentiment.[165]

Applications: NLP is used in manufacturing for machine maintenance, e.g., understanding maintenance logs of previous events, making maintenance decisions, and finding solutions to new problems by searching for a similar past issue.[166] Users can also utilize NLP to automatically translate speech or text, summarize documents, improve searches, and gather analytics from markets and social media.[164]

Key Benefits: NLP can help determine maintenance decisions, troubleshooting, root cause analysis, and downtime prediction.[166] Users may also use NLP to simplify or automate different business processes, as well as more efficiently compile and analyze data to aid organizational strategy.[164]

Limitations and/or Risks: NLP training can be difficult to apply for different use cases, as entities across industries may use varying terminology for the same concepts. It can also be difficult to use NLP for text data in the manufacturing space, as text data is not frequently leveraged for computational analysis in those spaces.[166]

Stage of Emergence or Adoption: NLP aligns within the adoption stage, as it is being scaled in industry and commercialized. Emerging applications include using NLP with ML and DL.[164]

Pattern Recognition

Description: Pattern recognition is a classification and data analysis technology that identifies data patterns (e.g., patterns in text, sounds, images), distinguishes varying angles of objects and shapes, and categorizes unfamiliar objects.[167,168] Historically, pattern recognition technologies utilized statistical methods like parametric and nonparametric Bayes decision rules or support vector machines to accomplish their goals.[169] However, modern pattern recognition technologies utilize AI and ML methods to improve their accuracies beyond what humans or traditional methods are capable of.[169] Today, pattern recognition is seen as a vital component of modern AI systems and is characterized by its ability to learn from data, detect familiar patterns even when obscured, and interpret different shapes and angles. Example algorithms that may be used in pattern recognition include local outlier factor, deep neural networks, and fast minimum covariance determinant, among many others.[170]

Applications: Pattern recognition users may leverage the technology for various applications such as scheduling maintenance activities and detecting anomalies (e.g., component or machine failures). ML may also be used to support predictive maintenance and quality management by identifying component relationships.[123,171]

Key Benefits: Pattern recognition can help to identify unexpected or abnormal occurrences accurately and predict issues prior to their occurrence.[172,173] Using pattern recognition for such anomaly detection aids in addressing root cause analysis, bottlenecks, and inefficient areas.[170,173]

Limitations and/or Risks: There may be limitations with pattern recognition due to limited datasets used to train the machine to identify desired outcomes.[172] If training data is too specific, niche, or tailored to a specific industry, there may be applicability issues when expanding beyond initial implementation.[171] Additionally, pattern recognition systems may require human intervention to assess or interpret results.[171,172] Further, anomaly detection quality can vary and may not be sustainable for use.[170]

Stage of Emergence or Adoption: Pattern recognition aligns within the adoption stage due to its widespread use.

Predictive Maintenance

Description: Predictive maintenance is a technology that monitors the degradation of equipment to identify the optimal time to replace the equipment prior to major deterioration or a system breakdown.[174,175] Industry traditionally has estimated the lifespan of equipment based on historical data, but has since implemented ML models into predictive maintenance technologies to better forecast when a failure may occur and the maximum lifetime of a machine.[175 176]

Applications: Industries may use predictive maintenance in diverse applications such as smart maintenance, forecasting needs (e.g., disruptions) and product quality, providing insights on the status of process operations, and leveraging ML algorithms (e.g., stepwise regression functions) to improve the efficiency and accuracy of response surface models.[172,175,176,177,178] Examples of industry applications of predictive maintenance include the automotive industry for process manufacturing of vehicles, and the nuclear and energy industry for various machinery types such as wind turbines (e.g., motor, fan, pumps) and nuclear reactor systems.[158,175,179,180,181]

Key Benefits: In regard to equipment, predictive maintenance applications can enhance equipment life cycle and quality, increase overall equipment effectiveness, and reduce the costs for equipment maintenance.[172,182] Additionally, predictive maintenance helps to detect error anomalies, reduce system faults, minimize production downtime, and increase efficiency in the use of financial and human resources (HR).[158,172,182]

Limitations and/or Risks: Limitations may include time and expensive installation processes.[172,183] This technology also requires broad and large datasets to train the model, which users must continuously update with recent failure and production-related data.[172,184] Moreover, predictive maintenance requires specialized skillsets to understand and analyze the condition monitoring data.[183] Since the integration of ML into predictive maintenance technologies is a newer development, susceptibility to new threats and possible performance variations can occur, causing challenges with implementation.[185]

Stage of Emergence or Adoption: Predictive maintenance aligns within the adopted stage in the non-medical space, including the automotive, computer, oil, and gas industries.[186] However, examples of emerging applications include train/railway data, roadside mechanical condition detectors, and applying AI and ML to guide predictive maintenance.[158]

4.3.2 BIOTECHNOLOGY

Bioreactors

Description: Bioreactors are devices used in manufacturing and bioengineering to produce an environment (e.g., similar to a native cell microenvironment) that supports the growth of biological mass (e.g., tissue or cell fabrication) through the conversion or degradation of material fed to the reactor.[187,188] Bioreactors use sensors to monitor and control environmental conditions for microbe growth, including environmental temperature, mixing, aeration, sterility, and acidity.[3] They are of interest to manufacturers due to their applications (e.g., food production, tissue engineering industries).[188]

Applications: Bioreactors in non-medical industries have the potential to meet many needs, including facilitating bioprocesses to develop substances such as foods, chemicals, and feeds.[188,189] Industries can leverage bioreactors to change raw materials into valuable byproducts (e.g., bioconversion of corn into ethanol and production of plant species).[188,190,191] In addition, bioreactors are a promising strategy for stem cell culturing.[187,192]

Key Benefits: Bioreactors provide structures that allow researchers to control and monitor the environmental conditions in bioprocesses.[188,192] By using advanced manufacturing capabilities to improve bioreactors, manufacturers optimize their capability to control those environmental conditions for growing cells.[3] Bioreactors are time- and cost-efficient and allow users to produce specific cell types and large quantities of stem cells.[188,191,192] Additionally, many bioreactors have a simple design and easy scale-up processes.[188,192]

Limitations and/or Risks: In some cases, bioreactors can have a more expensive and complex system compared to traditional research (e.g., use of cell culture vessels).[193]

Stage of Emergence or Adoption: Although bioreactors are regularly used to manufacture biologics in certain industries (e.g., medical), advances continue regarding efficiency, transportability, and CM capabilities. Consequently, bioreactors align within the emergence stage in most non-medical industries (e.g., stem cell culturing, bioconversion of plant species to express proteins).

Synthetic Biology

Description: Synthetic biology is a technology that combines biology, genetics, chemistry, engineering, and computer science to redesign living organisms for new abilities (e.g., building deoxyribonucleic acid [DNA] sequences, solving problems in medicine, manufacturing, and agriculture).[194,195,196]

Applications: Synthetic biology is used to develop biofuels and capture energy from the sun via manufacturing biological catalysts.[197] It is also used to produce chemicals (e.g., small carbon-based monomers that replace petroleum products) and biological fertilizers, further understand biological systems, develop lab-grown food such as meat and milk, conduct bioremediation, and support pollutant detection.[194,198,199]

Key Benefits: Synthetic biology produces chemicals efficiently and in a more ecologically-friendly manner, requires less energy, and can be less expensive than other manufacturing, computer, and robotic technologies.[194] It shortens the time required for evolution to occur due to the engineering of materials and microorganisms.[194,197] Synthetic biology allows for tailoring of materials for specific purposes.[194]

Limitations and/or Risks: Organisms or materials created via synthetic biology may not have optimal survival, reproductive capabilities, and mutations as compared to unaltered organisms.[194] There are environmental concerns about synthetic organisms and materials being accidentally or intentionally released into the environment, the downstream effects to human and animal health, and control efforts if used for bioterrorism.[194,197] Additionally, there is limited knowledge of long-term safety when working with synthetic biological products.[197]

Stage of Emergence or Adoption: Synthetic biology aligns with the adoption stage but may have novel applications that are emerging (e.g., synthetic metabolisms that include artificial food chains and foods, bioengineering of raw materials).[197]

Centrifugation

Description: Centrifugation is a molecular biology method of separating molecules of different densities by spinning them in solution around an axis, in a centrifuge rotor, at high speed.[200]

Applications: Centrifugation is used for spinning mesh disc reactions (SMDR). The spinning disc reactor (SDR) is an intensified reactor that uses centrifugal force to drive the reaction fluid to a thin film of high shear on the surface of the spinning disc.[201,202] Centrifugation is used to collect cells, precipitate DNA, purify virus particles, and distinguish subtle differences in the conformation of molecules.[200]

Key Benefits: The modularity of the centrifugation design combined with the flexibility to perform a range of chemical reactions in a single piece of equipment is an opportunity towards sustainable manufacturing.[201] Centrifugation can be used to separate liquids from solids much more cleanly than previous methods. This efficiency also allows the equipment to have extended life.

Limitations and/or Risks: Challenges associated with the spinning disc reaction include the cost of change (regulatory and capital costs), limited technical awareness, safety concerns, and lack of motivation for change.[201]

Stage of Emergence or Adoption: Centrifugation aligns within the adoption stage when applied to laboratory space for bioprocessing activities. However, there may be novel applications that align more with the emergence stage (e.g., spinning disc reaction).

4.3.3 COMPUTING

Cloud-based Computing

Description: Cloud-based computing uses the memory, storage, and computing capabilities of shared and interconnected computers and servers via the internet or an enterprise network, following the principle of grid computing.[79, 203] Cloud-based computing is a model for aiding on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction.[204]

Applications: Cloud computing can be applied for edge computing, fog computing, and integration with a wireless sensor network. Additionally, cloud computing can be used for on-demand self-service, broad network access, resource pooling (location independence), rapid elasticity, measured service, massive scale, homogeneity virtualization, resilient computing, low-cost software, geographic distribution, service orientation, and advanced security.[205]

Key Benefits: Cloud computing is cost-effective, scalable, flexible, and allows for location independence.[206] Integrating cloud computing with ML can increase throughput, minimize production delays, improve Quality-of-Service, and minimize response time for cloud applications.[204] The data storage is executed in services that can be accessed from anywhere in the world, through the internet, with no need to locally install programs or store data.[203]

Limitations and/or Risks: Cloud-based IoT systems can suffer from latency and bottlenecks due to the centralization of the system.[207] Cloud-based computing may also have service stability issues, memory allocation errors, network connectivity problems, server management issues, authentication query overflows, or denial of service attacks.[206] There may be confidentiality threats in cloud-based systems due to data breaches or data disclosed when resource sharing allocations change.[206] Other limitations may include the lack of computational resources, low data storage, loss of data packets, and optimization of multi-objective functions.[208]

Stage of Emergence or Adoption: Cloud-based computing aligns with the emergence stage. Cloud-based computing's applications—especially when related to integration of AI—are still in the research, testing, and piloting phases of development.[209]

Quantum Computing

Description: Quantum computing is a technology that harnesses quantum mechanics, computer science, physics, and mathematics to solve problems too complex and/or too time-intensive for classical computers.[210] Quantum computers compute in quantum bits, or qubits, that function similarly to traditional digital computers. Quantum mechanics allows the qubits to encode exponentially more information than bits. Scientists can quickly produce high quality solutions to difficult problems via information stored in the qubits.[211]

Applications: Quantum computing is used in Quantum-Dot Cellular Automata (QDCA), quantum annealing machines, and Gate-based quantum computers.[212] It can be utilized in quantum simulation, quantum ML, and unstructured data searches.[213] Quantum computing is used for optimizing complex systems, simulating quantum systems, cryptography, and drug discovery.[214]

Key Benefits: Quantum computers provide high-performance computing, efficiency, and mathematical solutions that are intractable for a traditional computer.[215] Quantum computers are smaller in size and require less energy than supercomputers.[210] They can process data more rapidly than other technologies and can augment AI and ML. Quantum technology can process and spot patterns in data more rapidly than classical machines, making quantum AI and ML tools more accurate and scalable.[216]

Limitations and/or Risks: Quantum computers require specific storage conditions that may not be readily available, are highly unstable, and are highly sensitive to environmental disturbances, dust, and temperature (e.g., they must be held in expensive refrigerators cooled to near-absolute zero temperatures). Currently, quantum computers are not commercially viable. Quantum computers could be at risk if advances in quantum decryption outpace advances in quantum encryption. In the event of a cyberattack, quantum computing could be utilized to bypass decryption in networks and could be used to obtain encrypted or other sensitive information.[216]

Stage of Emergence or Adoption: Quantum computing is aligned within the late stages of emergence. It is beginning to be adopted in some applications, such as military systems (e.g., devices that use quantum phenomena to measure precise timing and navigation, sensing, computing, and networking) and high-performance computing.[215,217]

4.3.4 IN-LINE SENSING AND PROCESS CONTROL

Advanced Metrology

Description: Metrology is the science of measurement, which is applied across science and engineering to measure dimensional and geometrical component features and improve quality and reliability.[218,219] The science has matured in recent years to keep up with industry advancements that have led to the development of products on a microscale and nanoscale, with new advanced metrological technologies evolving to meet these increasingly small measurement standards and provide additional part information and data.[219,220]

Applications: Examples of advanced metrology applications include infrastructure monitoring, compaction quality monitoring, non-contact coordinate measuring machine (CMM), automated inspection, damage detection, large volume metrology, and SCADA systems.[221] Advanced metrology can also be leveraged for intrusion detection systems, misuse detection, anomaly detection, fault detection and diagnosis, tool life monitoring methods, CT, IR monitoring, pyrometry, and imaging.[106,220,221,222,223,224] Advanced metrology may also be applied within synchrotron X-ray imaging and diffraction, mechanical testing, laser-induced breakdown spectroscopy, material characterization, microscopic characterization, scanning electron microscopy, and transmission electron microscopy.[225,226]

Additionally, advanced metrology can be used for electron energy loss spectroscopy (EELS), spectroscopy, in-situ monitoring and sensing, non-contact inspection, thermal imaging, laser ultrasonic testing, ex-situ characterization and inspection, and convolutional neural network.[98,177,202,225,227] Other applications include laser radar system, non-contact metrology, laser scanning, structured light, detail part validation, virtual opening verification, coating thickness inspection, seam validation, fastener flushness inspection, real-time monitoring, biometric methods, condition monitoring, and structural health monitoring.[24,116,228,229]

Key Benefits: Advanced metrology collects detailed characteristics and enhances decision making capabilities, such as fault diagnoses and health management.[224,226] In conjunction with DL, advanced metrology reduces dependencies on advanced signal processing technology and improves the accuracy of fault diagnosis.[228]

Limitations and/or Risks: Advanced metrology methods can exhibit varying challenges and limitations. For thermal imaging systems, the proximity of the manufactured object to the thermal camera is important because the camera only captures the object's upper surface. This becomes a challenge for larger objects that require scanning. External factors can cause additional challenges for metrology. For IR scanning and analyses, external factors like noise or ejected particles may impact the reliability of signal processing.[229,230]

Stage of Emergence or Adoption: Advanced metrology is applied across numerous industries and aligns with the adoption stage.

Photonics

Description: Photonics is a technology that generates a photon and captures its detection, as well as manipulation via transmission, emission, signal processing, modulation, switching, amplification, and sensing of light.[231]

Applications: Photonics is used to store, transfer, or manipulate information, but can also be used to include methods of harvesting energy from light and/or converting it to electricity.[232] Photonic technology is increasingly used in the oil and gas industries for instrumentation and measurement, electric power systems, space missions, transportation, civil structure, military and defense, ocean exploration, biomedical detection, environmental monitoring, and other areas.[233] Photonics plays a role in organic synthesis, communications, and fusion energy.[231] Lasers, optical fibers, cameras, phone screens, optical tweezers, lighting in cars and homes, computer screens, televisions (TVs), and high-performance computing are examples that integrate some form of photonic technology.[232] Photonics transmit data between high-performance computers while using less power and reduced signal loss compared to conventional electronics.[232] Photonic components in lasers have shaped the expansion of new manufacturing techniques such as laser welding, drilling, cutting, etching, and other surface modifications. It is also applied to quality assurance, production line monitoring, and management.[232]

Key Benefits: Integrated photonic components (e.g., lasers, detectors, waveguides, modulators, electronic controls, and optical interconnects) provide significant reduction in size, weight, and power, while dramatically improving performance and reliability compared to traditional electronics.[234] They improve efficiency because they do not have to overcome electrical resistance for the current to flow.[232] Devices that use photonics are more time and energy-efficient because light travels roughly 10 times faster than the speed of electricity, and data is transmitted faster and over longer distances.[232] Photonic technologies are less likely to be impacted by environmental factors such as their relative immunity from electromagnetic interference (EMI) and vibrations.[232] Photonic signals are more secure and safer when compared to electronic telecommunication.[232]

Limitations and/or Risks: There are limited industry applications for photonics because it cannot be used for electrical power transmission. Photonics can be expensive to implement and it may be challenging to combine various photonic components (e.g., silicon, silica, silicon nitride, lithium niobate) in a photonic platform or computer.[232]

Stage of Emergence or Adoption: Photonics align with the adoption stage but have novel emerging applications (e.g., plasmon lasers, data storage, bio-sensing, optical communications, photolithography), and increasing demand over recent years.[231,233]

Smart Sensors

Description: Smart sensors have onboard technologies (e.g., storage, microprocessors) that provide foundational data needed to transform feedback signals into digital insights.[235] There are different types of smart sensors (e.g., biosensors, level sensors, temperature sensors, pressure sensors, infrared sensors, proximity sensors) that measure biological or chemical reactions by generating signals to detect chemical compounds, usually by electrical, thermal, or optical signal reactions.[236,237,238]

Applications: Industries use smart sensors technology within several types of advanced sensors including Fiber Bragg Gratings (FBG) sensors, wearable sensors, in-situ microcontrollers, in-line sensing, optical sensors, sensor-based sorting (SBS), sensors for predictive modeling, smart meters, smart multi-sensors, spectroscopic sensors, free floating wireless sensors, biosensors, and soft sensors.[239,240] Manufacturers may also leverage smart sensors to complete quality testing, work safety, and environmental monitoring (e.g., monitor factory air quality and temperature, monitor worker safety through wearable technology while on construction sites).[241,242,243] Biosensors are being integrated into smart accessories (e.g., smart watches) and smart clothing (e.g., smart shoes) to allow for wearable monitoring abilities. The recycling industry can utilize smart SBS to improve waste sorting.[244] Additionally, the agriculture industry can combine smart sensors with unmanned aerial vehicle (UAV) technology to monitor crops, farmland, and health of livestock.[196,245] Further, users may utilize smart sensors to detect levels of specific gases.[239]

Key Benefits: Benefits include the ability to maintain product quality, improve supply forecasting and production planning, and provide real-time traceability.[241,246] Smart sensors are time efficient, cost-effective, and produce reliable analytical results.[235,240] Further, smart sensors can track data from various geographic locations, e.g., allowing farmers to view crops from anywhere via sensors combined with image recognition.[246] Biosensors can be beneficial for environments with limited resources due to their portability and ability to present in smaller sizes.[247,248]

Limitations and/or Risks: Smart sensors may not be the most accurate data collection method due to environmental factors, inaccurate installation or wearing, or potential observer bias (e.g., a worker may change their behavior if they know they are under surveillance).[249] When biosensors are used as monitoring systems, they can be considered invasive and may not be applicable or like a real life setting.[227] For certain applications, smart sensors can be costly and labor-intensive to install and remove.[136] Currently, there are no standards available for smart personal protective equipment (PPE), which could limit biosensors' efficiency across industries.[243] For wearable technologies, there are several concerns related to localization accuracy, location data privacy, connectivity, power consumption, social resistance, and high cost of wearables.[242] Using biosensors connected through AI systems can raise concerns with privacy and discrimination with how data can be accessed and by whom.[249] If industries deploy smart sensors systems in the workplace, there may be privacy concerns or risk of security hacking.[249,250]

Stage of Emergence or Adoption: Smart sensors align with the emergence stage.[251] Though biosensors have been under development for over 50 years, widespread adoption on the commercial and retail level is limited in non-medical industries.[236] Examples of emerging smart sensor technologies include SBS in the recycling and waste industries.[244]

4.3.5 SMART MANUFACTURING

In Section 4.2.13, we refer to smart manufacturing as an overarching advanced manufacturing methodology; however, in this section, we also use it to categorize several advanced manufacturing technologies that apply such an approach.

Digital Twins (DTs)

Description: A DT is a computer-generated virtual representation to model the state of a physical asset (e.g., machine, people, functional area, physical surroundings) using sensors. It is used to simulate, track, design, monitor, or diagnose the physical asset.[157,173,186,252,253] There are three types of DTs: 1) the product DT, which supports integrated associative design, simulations, assembly, integration, and regulatory verification and certification; 2) the production DT, which is used in production planning, engineering, and execution; and 3) the performance DT, which enables performance monitoring, predictive maintenance, and predictive end-of-life.[3] The use of DTs demonstrates the impact and potential of computational models and simulations in manufacturing.[3]

Applications: DTs simulate discrete and hybrid processes, modeling operating systems, conducting testing, and building complex design.[173, 254, 255] They can be used for inventory management, predictive maintenance, self-diagnosing, self-repairing, process optimization, process development, and error mitigation.[173,256,257] Their use varies across industry. The construction industry uses DTs for project management, whereas the agriculture industry uses DTs for crop management, machine tracking, tractor route planning, and farmer training.[253,258] In aerospace and aviation industries, DTs are utilized in monitoring spacecraft behavior and parts; while the manufacturing industry uses them for predictive maintenance, machine health monitoring, product design, and as a safety system to shut off machinery in functional failures.[123,173,254,258,259] In the mining industry, DTs are used to improve control and augment procedures remotely.[186]

Key Benefits: DTs use automation to predict issues before they occur and improve the lifecycle management of equipment across several industries.[125,186,253,260] They utilize IoT and AI to optimize several processes and evaluate their assets without compromising current operations. DTs allow for long distance and remote system monitoring or diagnosis.[229] DT simulations collect information to support problem solving experiments and product planning, as well as reduce the number of tests and time required per process.[254,258,261,262]

Limitations and/or Risks: DTs may be challenging for industry to integrate into their operations due to internet and technical infrastructure requirements.[255,258] DTs may be designed for a specific process or problem, which may lead to incompatibility for other industries, problems, or lack of standardization.[263] They also have scalability constraints that limit how simulations can be performed.[263] DTs utilized in cloud may have network, bandwidth, and data loss issues.[264] DTs are susceptible to cyberattacks due to the data and information stored about environment or equipment assets.[255]

Stage of Emergence or Adoption: DTs align with the adoption stage. They are used in limited manufacturing applications, but are emerging in other industries (e.g., nuclear power plant management).[255]

Extended Reality (XR)

Description: XR includes tools that integrate physical and virtual environments. Subdivisions of XR include augmented, virtual, and mixed reality (MR).[265] Augmented reality (AR) is the interaction between users and a digital superimposition of graphics, audio, or other sensory elements onto video streams of the real world.[266] Virtual reality (VR) is a visual experience that involves the generation of an interactive, virtual environment using computer software and hardware.[266] VR technology immerses "the user in the virtual environment in a way that mimics reality by collecting input from users such as head tracking, controllers, hand tracking, voice, joysticks, trackpads, or buttons."[266] MR is a virtual and digital environment integrated in a way that allows the user to interact with the physical environment.[265]

Applications: XR is leveraged for Multiple Remote Tower Operations (MRTO) in air traffic management, computer-simulated environments providing a 360-degree panorama, holographic communications, Microsoft HoloLens, and waveguide optical display systems.[267,268,269,270] XR is used for risk management in coal mines, as well as horticultural farming.[268,270,271] XR has also been used for training; within glasses; in maintenance manuals (augmented), remote maintenance software tools, illustrated parts catalogs, and maintenance in manufacturing and construction; for spatial AR systems; and as immersive and wearable technology.[268,272,273,274,275,276,277,278,279] Additionally, XR has been utilized within the aerospace industry (e.g., tower operations simulations), the U.S. Navy (e.g., AR pre-deployment training, information, and sensor displaying Navy diving helmet), and the food industry (e.g., visualization of food nutrition, food traceability, dietary assessment, education, food sensory science).[267,272,272,280] Within the aerospace industry, there are novel uses for XR including using VR to train astronauts on human-space interactions and using AR to facilitate in-space tasks and communication with Earth.[281] XR is undergoing development for integration within spacesuits to assist astronauts in space by providing a method of monitoring vitals and suit status, as well as advancing in-space navigational support.[282]

Key Benefits: AR provides new ways to assess food sensory perceptions, reduces time for maintenance activities, improves real-time communication, and provides simulation opportunities for complex scenarios.[272,276, 283] XR improves learning through cost-effective, dynamic training (e.g., simultaneous interaction of both digital and real components, unique scenarios in a safe environment).[277,279,284]

Limitations and/or Risks: Limitations of XR include the inability of trainings to completely replicate the real work environment, restrictions on developing motor skills within trainings, and vast resources (e.g., manpower, computer power, cost to author scenarios, setup, maintenance efforts) needed to develop realistic and specialized scenario simulations.[275,284,285] Further, XR may cause user skin irritation or injuries.[286] AR and MR have limits on the ability to recreate photorealistic experiences and lack timely object tracking.[272,275] AR requires time to develop animations and conduct calibrations and needs additional tools to address varying lighting environments.[272,276,287] VR has limitations regarding collaborative applications and users experiencing motion sickness.[279,286]

Stage of Emergence or Adoption: XR aligns with the adopted stage in various applications across multiple industries (e.g., agriculture, mining, food, military). However, it is also an example of an advanced manufacturing technology in which its varying applications can be seen in different stages of emergence and adoption—even within a particular industry. For example, the aerospace industry has adopted XR for tower operations simulations, but its application in astronaut spacesuit technology is still emerging.[284,288,289]

4.3.6 GREEN MANUFACTURING

In Section 4.2.9, we refer to green manufacturing as an overarching advanced manufacturing methodology; however, in this section, we also use it to categorize advanced manufacturing technologies that apply such an approach. Green manufacturing technologies can be utilized by organizations to transform current systems that are associated with wasteful manufacturing practices to more efficient techniques geared towards reducing harmful impacts to the environment.

Energy Harvesting

Description: Energy harvesting is a process wherein the sources (e.g., mechanical load, vibrations, temperature gradients, and light) are scavenged and converted to obtain relatively small levels of power (nanowatt [nW] to milliwatt [mW] range).[290] There are four types of energy harvesting processes: 1) harvesting small amounts of energy from the environment; 2) transforming that energy into electric energy; 3) using power conversion circuits to process the energy; and 4) leveraging the power for information processing, communication, and sensing.[291]

Applications: Applications for green manufacturing include vibrational (piezoelectric) energy harvesting, thermoelectric (heat) energy harvesting, radio frequency (RF) energy harvesting, photovoltaic technology, low temperature district heating, solar cells, environmental monitoring, phase change materials (PCMs), and future projections.[291,292] Industries may use common technologies for road energy harvesting (e.g., asphalt solar collectors, PCMs, piezoelectric generators, photovoltaic sensors, electromagnetic generators).[292] Energy harvesting can be used in wireless communications where sources, such as solar and wind, can be used as sustainable energy supplies. Solar power allows for devices to become self-sustainable (i.e., devices can renew their energy by absorbing sunlight). Devices and sensors can use thermoelectric energy sources whereby differences in temperature gradients generate electricity. It is possible for renewable energy to be used within IoT technologies whereby energy harvesting techniques may be an effective alternative to traditional battery systems.[293]

Key Benefits: Energy harvesting within the green manufacturing realm allows for increased sustainability by removing battery change issues, as systems designed with energy harvesting can operate for years. Energy harvesting also encourages environmentally friendly technologies and is a core component of future developments in smart cities and efforts towards a sustainable society.[294] For example, industries can utilize road energy harvesting for roadway lighting and to help promote the adoption of electric and hybrid vehicles for increased mainstream use in the future.[292]

Limitations and/or Risks: Energy harvesting requires high environmental durability and operational reliability. Energy conversion materials and the mechanisms behind their material deterioration remain a challenge due to limited research on material combinations. Additionally, there are limited available international standards that provide strong evaluation techniques for material properties in addition to evaluation protocols that can ensure material reproducibility.[291]

Stage of Emergence or Adoption: Despite photovoltaic technology's discovery in 1839, energy harvesting can still align with the adoption stage.[294] While energy harvesting technologies are adopted within some factories to consolidate cables and to minimize battery dependencies, other industries are still determining how to incorporate such technology (e.g., companies such as Sony, Ericsson, and Motorola have considered using energy harvesting techniques within rural stations).[293,293,295]

4.3.7 ROBOTICS

Advanced Robotics

Description: Advanced robotics utilize a form of autonomous control and sensor technology to instruct functional, mechanical, and movable structures.[3,196] Advanced robotics exhibit superior perception, integrability, adaptability, and mobility in manufacturing processes.[3,269]

Applications: Industrial applications include manufacturing, construction, transportation, and QC.[296] Robots can also be used in hazardous locations to perform dangerous tasks.[296] Advanced robotics can be used for building automation, automated drilling, solution-based printing, industrial collaborative robots, service robots, medical robots, search and rescue robots, unmanned aerial vehicles, and wearable exoskeletons.[296,297,298,299] In the agriculture industry, they can remove weeds, fertilize, plant seeds, diagnose field health, and run Global Positioning System (GPS)-aided steering systems.[136] Advanced robots are used in the military for patrolling sites, handling explosives, and protecting and increasing carrying capacity as wearable exoskeletons. The automotive industry utilizes industrial collaborative robots to increase production efficiency and reduce the human operator's ergonomic load.[298,300]

Key Benefits: Advanced robots perform jobs faster, safer, in a cost-effective manner, with higher efficiency, and can work long hours in an optimized manner with uninterrupted and predictable performance.[3,136,296] They have safety features to prevent harm to humans working alongside them.[301] Collaborative robots integrate well into manufacturing plants as they require minimal changes to existing production layout and can be redeployed for different tasks, as necessary.[302] Advanced robots can perform dangerous tasks and access areas that are unsafe or difficult for human access (e.g., mines).[296] The following examples highlight some of the industries that have high occurrences of advanced robotic integration:

- Agricultural field robots contribute to reliability of operations, improved soil health, and improved yield.[303] Advanced robotics can relieve farmers and harvest workers, etc., from risk-exposed or strenuous work.[304] Agricultural robots can also reduce food waste by using image recognition to pick only ripe produce.[304] They can result in more reliable monitoring and management of natural resources.[305] They also allow for greater control over plant and animal production, processing, distribution, and storage, which results in greater efficiencies and lower prices, safer growing conditions and safer foods, and reduced environmental and ecological impact.[305]
- Military advanced robotics used as exoskeleton suits assist soldiers in difficult tasks requiring additional strength, consequently saving time and energy. Exoskeletons can improve the current physical capabilities of a warfighter, allowing them to run faster, lift heavier objects, and relieve strain on the body during physical operations.[306]
- Automotive advanced robotics also used as exoskeleton suits minimize employee injury and aid in general assembly lines that tend to rely on manual labor. For example, Hyundai and Ford both used exoskeletons to assist with tasks that require overhead lifting or bending over.[307]

Limitations and/or Risks: Depending on the needs of the manufacturer, implementation of industrial advanced robots can be complex.[298] Some advanced robots can encounter security risks due to network vulnerabilities used to connect the robots.[27] Maintaining advanced robots can also be challenging due to their size and complexity. While exoskeletons efficiently aid manual tasks, the charging required for use can limit their availability.[297] Advanced robots can be slower and have limited payloads.[303,308]

Stage of Emergence or Adoption: Advanced robotics technology emerged in the 1980s and align with the adoption stage for several industries (e.g., agriculture, automotive, military).[27] However, there are many applications still just emerging (e.g., military training).[79] Industry has continued to identify opportunities to leverage other emerging technologies (e.g., DL) to improve existing advanced robotics capabilities (e.g., sensing, object recognition) while also adding new capabilities (e.g., high-level task planning, interpreting and anticipating human actions). These have been active research areas by industry to improve usability of robots in industrial operations.[309]

4.3.8 INDUSTRIAL INTERNET OF THINGS (IIOT)

IIoT is the collective network of connected devices, the communication between devices and the cloud, and the devices themselves.[310] IIoT environments provide organizations with greater software and automation capabilities to augment smart applications and improve their ability to respond to supply chain fluctuations.[311] The technologies listed below can be categorized as IIoT and may be practical advanced manufacturing applications.

Networking Technologies: Fifth Generation (5G) and Sixth Generation (6G)

Description: 5G is a wireless connection network used for cellular service that does not restrict transmission to any frequency of the electromagnetic spectrum so that there are wider channels across existing telecommunication frequencies.[312] 6G is a wireless communication network that will be the next iteration after 5G that will incorporate enhanced scalability, greater use of the radio spectrum, and dynamic connections.[312]

Applications: 5G technology has been applied to autonomous systems (e.g., drones), first responder support and surveillance activities, and strengthening sensor communication systems needed to detect and track devices.[312] 6G technology can be used to support autonomous vehicles and intelligent transportation such as traffic pattern tracking.[312]

Key Benefits: 5G technology provides high-bandwidth, low-cost communications, minimal latency, enhanced broadband services for IoT, flexibility for network customization, and advanced security when compared to other wireless technologies.[206, 313, 314] As 6G is rolled out in the future, it may provide enhanced scalability, low power consumption, long connection rages, and broader range of the radio spectrum to support higher connectivity and reliability compared to 5G.[312]

Limitations and/or Risks: 5G and 6G technology may present cybersecurity challenges and vulnerabilities.[312] 5G networks may have limited obstruction sensitivity, restricted coverage radius, and high transmission power, which 6G aspires to correct.[315]

Stage of Emergence or Adoption: 5G align with the adoption stage, while 6G aligns more with the emergence stage, as it is in testing and may not be deployed until the 2030s.[251, 316]

Smart Grid (SG); Vehicle-to-Grid (V2G)

Description: SG is a technology that enables two-way communication of control systems and computer processing between utility companies and its consumers.[317, 318] SG technology encompasses advanced sensors to assess grid stability; advanced digital meters to convey consumer information; and battery storage to store excess energy to meet consumer demand.[318] SG also encompasses automated functionalities that conduct outage reports, fault sensing and recovery, and power re-routing to circumvent problems.[318] V2G is an emerging technology that conducts bidirectional power exchange to supply or absorb energy while an emergency management system controls energy flows from/to the battery, acting as a source that can store or release energy at appropriate times.[319]

Applications: SGs are used for intelligent agents, energy storage, demand-side management, distributed generation, and intelligent energy networks.[118, 320, 321]

Key Benefits: SG technology introduces full visibility and asset control to utility companies and increased transparency with their consumers.[320] SG is environmentally friendly and promotes usage of renewable energy resources due to the integration of solar arrays and wind generators, which provides a cleaner, more efficient, affordable, and sustainable energy supply.[320, 322] SG's energy conservation efforts also aid in reducing mobility carbon emission due to SG's infrastructure ability to support Plug-n-play Electric Vehicles (PEVs) and hybrid vehicles.[322]

Limitations and/or Risks: Latency and efficient bandwidth usage can cause challenges with SGs when using fog computing if smart meter data analysis occurs too far from the consumer and industry premises.[322] Additionally, modern energy storage device regulations are lagging, which can slow down adoption rates. Risks can also arise when attempting to manage the grid balance between customers and the energy source.[80, 323] V2G and SG infrastructures can experience security risks due to increased susceptibility to computer and malware attacks.[321, 324]

Stage of Emergence or Adoption: SG technology aligns with the adoption stage. Though stakeholders began implementation, the rate of adoption has been slower.

4.3.9 SEMICONDUCTORS

Semiconductor Chips / Integrated Circuits

Description: A semiconductor chip (also known as an integrated circuit [IC], a microelectronic chip, or a computer chip) is a tiny electronic device built to store, move, and process data. Semiconductor chips are commonly comprised of elements, such as silicon and germanium, or from compounds, which allow for the chips to precisely control the electric current flow.[325,326] Manufacturers engaged in the semiconductor industry may produce integrated circuits, memory chips, microprocessors, diodes, transistors, solar cells or other optoelectronic devices.[327]

Applications: Semiconductor chips are essential parts used in communications, computing, healthcare, military systems, transportation, clean energy, and countless other applications.[326] Many products with roots in mechanical systems—such as manufacturing equipment—heavily depend on chip-based electronics. Semiconductors provide data storage and communication functionality in many devices (e.g., mobile phones, gaming systems, aircraft avionics, industrial machinery, and military equipment and weapons).[143,325] They are integral in various emerging technologies, including but not limited to, AI, autonomous systems, 5G communications, large-scale data processing and analytics, and quantum computing.[271]

Key Benefits: Semiconductors provide improved computational performance and higher processing power.[143]

Limitations and/or Risks: Prototyping and testing semiconductor chips designs can be expensive. These chips may need to be created in small quantities to validate and debug, but packaging facilities may not be equipped to handle such small batches. Chips may also be difficult to manufacture as they are small-sized items and require an adequate facility that has "clean rooms" and chemical and gas delivery systems.[143] Semiconductor chip supply chain can be negatively impacted by workforce gaps, challenges with supplier networks, and difficulty in obtaining raw materials.[328]

Stage of Emergence or Adoption: Semiconductor chips align with the adoption stage; however, they may be emerging in some applications (e.g., AI, autonomous systems, 5G and 6G communication, quantum computing).[326]

4.4 Processes

Manufacturing processes include a series of actions, operations, or steps taken to produce an advanced manufactured product. While the specific applications may differ, the processes apply to the manufacture of different product types across multiple industries. This section describes the manufacturing processes adopted across non-medical industries over the last ten years or expected to emerge within the next five to ten years.

4.4.1 ADDITIVE MANUFACTURING

Additive manufacturing, commonly referred to as 3D printing, can be referenced as both a methodology (see Section 4.2.1) in its general concept of developing 3D objects through repeated layering of material, but also serves as a category of processes for a more granular level of mechanisms for application.

3D Modeling

Description: 3D modeling is the process of designing 3D representations of an object or a surface. Computer-based 3D modeling software allows a subject matter expert to build a 3D object and determine its size, shape, texture, and other characteristics. The modeling process uses coordinate data relative to a reference point to create the 3D shapes within the software.[329] Common applications of 3D modeling include: 1) Computer-aided Design (CAD), which uses algorithms and software to simulate data and then develop and model a future product; 2) Design for Additive Manufacturing (DfAM), which is the science, skill, and art of designing to easily leverage 3D manufacturing; and 3) Finite Element Modeling (FEM), which is used to mathematically model and solve structural, fluid, and Multiphysics issues. FEM is applied in finite element analysis (FEA) to find and solve potential or existing structural or performance issues.[330,331,332]

Applications: One common use for 3D modeling falls within the realm of 3D printing. Architects plan buildings, demonstrations, and structures with 3D modeling software. 3D modeling also provides a safety measure as 3D renderings of buildings can reveal potential structural issues that would not have been previously seen in two-dimensional (2D) plans. DfAM has been leveraged in the aerospace industry to design lightweight, high-performance structures and heavy-loaded aerospace brackets.[333] FEM and CAD are used in the automotive industry to determine the structural mechanics of car parts under different loading conditions, the heat flow through the engine, or the distribution of electromagnetic radiation from an antenna.[334]

Key Benefits: 3D modeling technology increases accuracy in terms of types, amounts, and methods of material used for an end product, allowing for waste reductions. These benefits suggest that 3D modeling is a more environmentally sustainable alternative to traditional methods by reducing waste from creating numerous mock-up products and samples.[329, 335] Further, using virtual 3D models allows for issues and errors to be identified and resolved before fabrication.[329] In the cases where 3D modeling (e.g., CAD Design) is used to create a component that will be integrated into a final end product, the 3D visual provides a demonstration of how the object will look and perform relative to other components and products, reducing burdens on the production process. This technology can also help product uptake and investment as it allows for stakeholders to have a realistic visual of what the end product will look like from every angle.

Limitations and/or Risks: FEM and CAD can be computationally expensive and require large datasets.[128] Insufficient understanding and application of DfAM is said to be limiting the awareness of advanced manufacturing in industry as disseminating knowledge consistently has been an issue.[336]

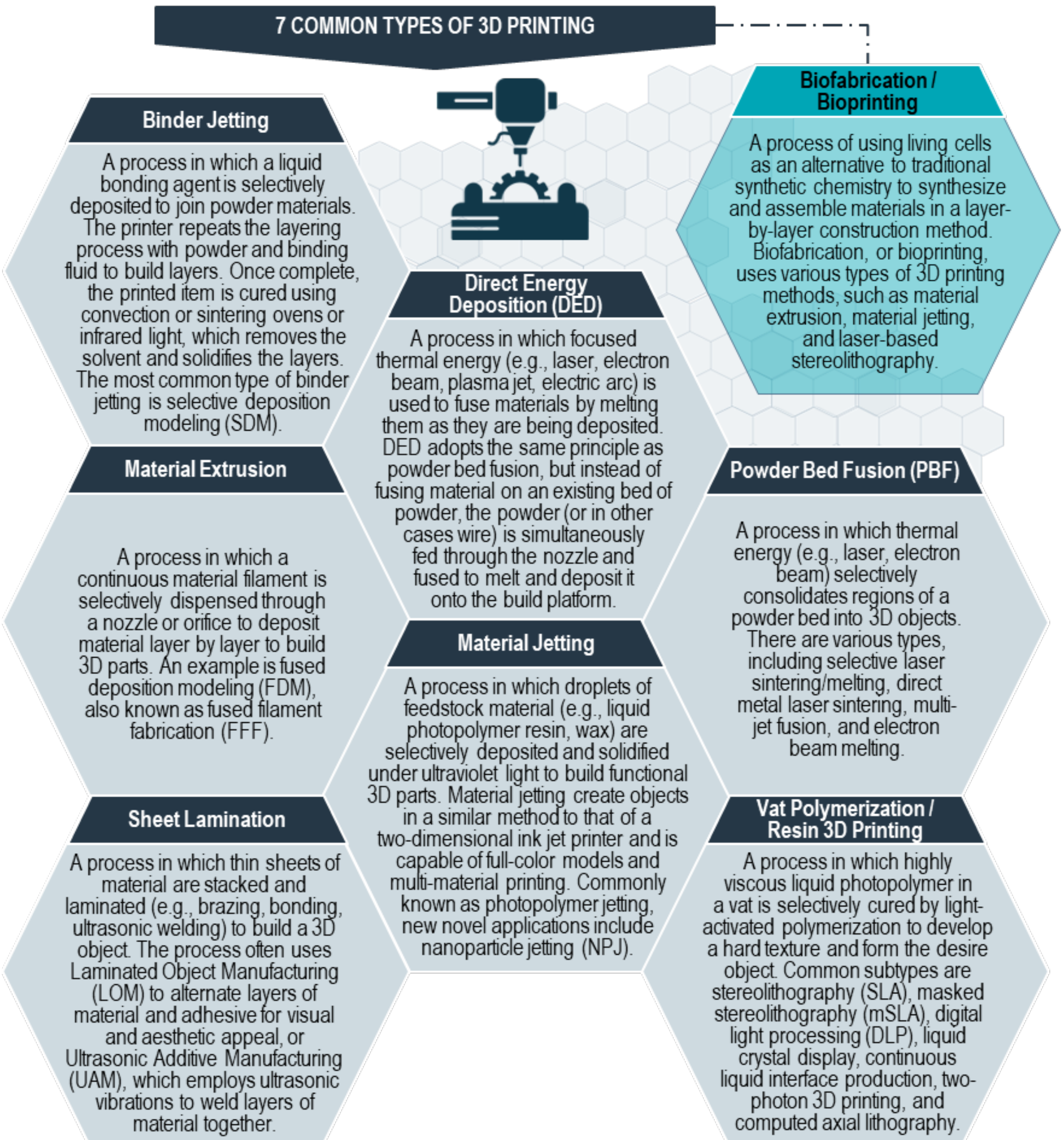
Stage of Emergence or Adoption: 3D modeling has been integrated deeply across many industries and aligns with the adoption stage.

3D Printing

Description: 3D printing is a method of creating an object layer-by-layer using modeling software (e.g., CAD) to create precise drawings. Once the virtual model is created, it is sliced into many thin, horizontal layers. This file is then uploaded to the 3D printer, which reads every layer of the model and subsequently prints them.[337] Thermoplastics are the most common material used for 3D printing, but novel technologies are enabling greater use of photopolymers, metals, composites, and powders.[338]

Figure 4-2 depicts the seven most common types of 3D printing (see Appendix E: 3D Printing Subtypes for details on each). Findings also indicated biofabrication/bioprinting as an additional emerging 3D printing process that may utilize the seven methods—or others—using living cells to fabricate end products.[338,339,340,341]

Figure 4-2: Common Types of 3D Printing



Applications: The advanced manufacturing applications of 3D printing are vast and cross many different industries. In the aerospace industry, 3D printing has been used to make lightweight, more durable parts.[342] It has also been used as a high-energy efficiency process for food production and is environmentally friendly, with good QC and low costs.[342] In the construction industry, it is used to print entire buildings or create construction components.[343]

Key Benefits: 3D printing can reduce costs and time due to rapid prototyping by printing on demand; thus, it allows engineers to quickly test new designs.[343] The flexibility of 3D printing also allows for more complex designs.

Limitations and/or Risks: Industries struggle with scalability. The restricted build size leads to concern that anything bigger than the print chamber needs to be made in parts. The effect of the increased usage of 3D printing technology will reduce the use of manufacturing labor, which will have economic impact.[344]

Stage of Emergence or Adoption: 3D printing aligns with the adoption stage. It is used within many industries but has novel applications, as new types of 3D printing are developed for novel emerging uses.

4D Printing

Description: 4D printing is an additive manufacturing technique whereby a 3D-printed object is transformed with the extra dimension of time.[345] Given the added dimension of time, 4D printed materials are sensitive to stimulation and reshape themselves when exposed to water, heat, air, or other substances.[266,345,346] Some 4D printed objects may also have multifunctional, self-assembling, and self-repair capabilities.[347] 4D printed materials, also known as smart materials, self-assemble based on their observed behavior after undergoing 4D printing. For example, if a material requires bending at a specific joint within a building, a 4D printed material can be used to assemble in the proper position if also observed to bend in the desired configuration.[345] Some 4D printed materials can be considered self-repairing as they can form new bonds, thus healing cracks in their composition or revert to their original shape after undergoing external stimulation, such as thermal stimulation. Overall, 4D printing allows for advances in materials, switching between multiple shapes or configurations, giving them a multifunctional purpose in reaction to a stimulus.[348]

Applications: 4D printing is currently being researched for use in creating robotics-like behavior without electronic, mechanical, or chemical devices and materials with shape changing capabilities (e.g., elongation, bending, corrugation, twisting, color change). 4D-printed materials are used to create self-healing pipes and self-healing hydrogels.[348] Other emerging applications include garments and mechanisms that respond to environmental stimuli. Since much of the current research is focused on how materials change shape after undergoing 4D printing, there is potential for 4D printing to be used to create toys, robots, lifters, and microtubes.[345]

Key Benefits: 4D printed materials are adaptable and dynamic with the potential to replace or update electronic-based materials.[345] The evolution of materials over time allows for increased potentials of saving printing time, material consumption, and cost. Predicting changes that can occur with time in materials may allow for storage space and transportation costs to be reduced. Using 4D printing to create self-healing materials enhances reliability and longevity of material systems.[349] Additionally, 4D printing offers a more energy-efficient process through a reduction of waste and product loss.[350]

Limitations and/or Risks: 4D technology is not widely available and may only exist in limited research institutes across the world. 4D printers require specific smart materials that are not widely applicable to all 4D printing and there are few 3D printers with the capability to use these materials, causing incompatibilities with pre-existing machinery. 4D printing material may be sensitive to environmental conditions and require precautions to print without defects.[345]

Stage of Emergence or Adoption: 4D printing aligns with the emergence stage. Research has been conducted for a decade and this technology is developing off of 3D printing applications. However, more knowledge and observation on smart materials and their interactions are needed.[345] Findings indicated future research efforts will focus on 4D printed materials for use within extreme conditions, such as in-space manufacturing, as they can provide methods of assembling parts without external power sources or human interaction.[348] Additional research initiatives of emerging 4D printing technologies include soft robotics, textiles, sensors, flexible electronics, and self-evolving structures that can be useful in diving suits or in the repair of objects in deep waters.[351]

Indirect Additive Manufacturing (I-AM)

Description: I-AM is an additive manufacturing technique that involves building a mold and then injecting material (e.g., wax, resin, plastic, ceramic, metal) into the mold.[352,353]

Applications: I-AM can be used to build parts, components, and products through lost wax processing, injection of resin, ceramic injection molding (CIM), metal injection molding (MIM), and powder injection molding (PIM).[354]

Key Benefits: I-AM can be more cost-effective and provide manufacturers with excellent product surface finishing. Additionally, I-AM has the potential to scale up cellular metals in structural applications and is cost-efficient.[354]

Limitations and/or Risks: There are limited qualitative studies conducted, which can limit available research.[354] However, because this process utilizes molds, limitations from injection molding become applicable (i.e., high costs for start-up and design changes, and length of turnaround time).

Stage of Emergence or Adoption: Indirect additive manufacturing aligns with the adoption stage. I-AM is used across industries and has continued potential for novel AM applications.

Mobile Additive Manufacturing (MAM)

Description: MAM is a technique used to closely integrate architectural, mechanical, and materials design; manufacturing process; sensing; and control.[355] This process allows users to build parts or components, as needed, on site and build large objects with size that exceeds a robot's static workplace.[356]

Applications: MAM can be used in a multi-robot system or for building scalable solutions through interaction (i.e., collaboration, cooperation, coordination) with human operators. The construction industry utilizes MAM for remodeling, repairs, modeling large building components, and renovations. For example, MAM allows for construction companies to manufacture pipelines on a mobile site and then build and repair pipelines on the main construction site.[355] MAM can be utilized within the field of in-space manufacturing where composite 3D printers, for example, are utilized within the International Space Station to fabricate needed parts.[357]

Key Benefits: MAM can be a time-saving technology that is convenient for industries to repair materials on site. MAM can be used for first aid where a mobile unit can print or repair missing or damaged components and respond quickly to an event. Further, manufacturing companies can utilize the time-saving process of building materials on site to quickly respond to increased demand of a product.[355]

Limitations and/or Risks: MAM encounters challenges when the mobile robot printer experiences different terrain conditions. For example, construction sites can include dusty and bumpy terrains which can impact the overall mobility scheme of the robot printer.[358] Instability of the mobile robot printer can impact the resolution of the manufactured product and ultimately the fabrication.[359]

Stage of Emergence or Adoption: MAM aligns with the adoption stage. It is currently being used within the construction industry, but novel applications can also be identified in other industries.[316] Although MAM has been adopted within in-space manufacturing, applications have only been seen in a controlled environment. The applications of MAM within the extreme conditions of space itself are still emerging as well.[357]

4.4.2 BIOTECHNOLOGY

Flow Cytometry

Description: Flow cytometry is a technique that analyzes cells or particles as they move past laser(s) while suspended in a solution. Each particle is analyzed for visible light scatter and fluorescence parameters.[360]

Applications: Flow cytometry has been leveraged in various applications such as milk analysis, detection of small particles, and microbial analysis.[361] For example, flow cytometry can be used to assess milk quality and count milk somatic cells.[362] Additionally, the ability of flow cytometry to quickly count microorganisms supports various food microbiology applications.[363] Some of these applications include determining the number of viable bacteria found in food and water. Further, flow cytometry is used within the brewing and vinification industries to analyze yeast populations.[364]

Key Benefits: Flow cytometry has the capability to measure a large number of parameters on a single sample, as well as obtain information on millions of cells quickly.[364, 365] Adopting flow cytometry within manufacturing processes increases safety, especially within food and beverage industries, as a preventive measure against contamination and sickness.

Limitations and/or Risks: Limitations include issues with debris interference, which may require additional dilutions to provide a clean sample.[366]

Stage of Emergence or Adoption: Given its current use in the food and water industries, flow cytometry aligns with the adoption stage.

Microfluidics

Description: Microfluidics is a process by which small volumes of fluid are used to create a controlled microchannel environment. Droplet-based microfluidics systems are a microfluidic technology where droplets act as compartments for chemical analysis.[367]

Applications: Microfluidic devices can continuously produce chemicals, transfer a fluid across the device, read the change in volume from a chemical reaction, and transfer chemical analysis information.[368,369] Microfluidics is used to manufacture liposomes, encapsulate proteins, and monitor particle size for process control and product validation.[26] Applications for droplet-based microfluidics include digital polymerase chain reactions (PCR), which is a method of conducting ultrahigh-throughput screening to rapidly screen a massive amount of samples in a shorter amount of time than conventional methods.[367]

Key Benefits: Microfluidics is heavily used within the biotechnology field (e.g., genomics, biochemical assays, live cell studies) and can be more efficient than traditional analysis techniques, as it allows for rapid end product development and high throughput within the manufacturing process compared to existing processes and technologies.[370] Since only small volumes of fluid are needed, the number of samples and reagents used are decreased, which also saves costs and decreases waste.[371] These combined efficiencies can potentially allow for more tests to be completed per volume, which can—in turn—help create resiliencies within the supply chain. In addition, the potential for developing lab-on-chips also enables analysis to occur with limited amounts of samples.[372] Lastly, droplet-based microfluidics allows for standardization of resource dimensions (e.g., sizes of wells), eliminating the need for custom procedures that differ across laboratories. Such standardization can allow samples across laboratories to be directly compared and validated against each other.[367]

Limitations and/or Risks: There is an abundance of biomaterials that can be used within microfluidics. However, there is a lack of standardization for compatibility in use. This challenge has limited the advancement and industrialization of microfluidics as a process, but also limited the use of other technologies—such as 3D printing—to support further development of microfluidics.[370,373]

Stage of Emergence or Adoption: Microfluidics has multiple uses identified within non-medical industries and aligns with the adoption stage. Additional research is needed into the droplet size needed to perform droplet-based microfluidics to maintain sensitivity in results.[367]

4.4.3 CLOUD

Cloud-based Monitoring

Description: Cloud-based monitoring is a technology used to aggregate simple events of low-tech devices and derives a complex decision. Cloud-based monitoring uses intelligence to review lower-level data and derive high-level systems or events.[271]

Applications: Cloud-based monitoring is used in sensors to collect data, transfer information, and conduct real-time analytics and cloud storage.[374] It can be used for remote monitoring and control in electric induction motors, power plants, and waste-to-energy plants.[375] Additionally, CNC monitoring may apply cloud-based monitoring.[376] In the agriculture industry, farmers implement cloud-based monitoring to monitor environmental data (e.g., soil, temperature, air humidity) through the internet and a monitoring system, in digital records, for harvest and inventory management, pest and disease monitoring, and yield and quality data collection.[271] In the mining industry, real-time mine visualization and risk management are executed with cloud-based monitoring. This technology has also been applied for maintenance in the manufacturing, construction, avionics, and military industries.[319]

Key Benefits: Cloud-based monitoring is an efficient decision making tool in emergency situations.[319] In agriculture, it enables the detection of diseases, quality assessment, and grading of horticulture crops.[271]

Limitations and/or Risks: Cloud-based monitoring can be complex in a multiple cloud structure. It may lack visibility or integration with other industry systems. Cloud-based monitoring requires staff that are familiar with cloud-based application and, currently, there may be a lack of workforce across industries with the necessary familiarity.[377]

Stage of Emergence or Adoption: Cloud-based computing aligns with the adoption stage, but novel applications may be emerging (e.g., manufacturing insights that identify upcoming issues or disruptions, improved computing with Application Programming Interfaces [APIs]).

4.4.4 PROCESS CONTROL

Spectroscopy

Description: Spectroscopy is a process that utilizes electromagnetic radiation beams (e.g., x-rays, ultra-violet [UV] and IR) to observe a sample's response to stimuli (i.e., beam), and can consist of the following techniques: X-ray photoelectron (XPS), energy-dispersive X-ray spectroscopy (EDXS), Fourier transform infrared (FTIR), UV, and Raman.[378] Two spectroscopic techniques that are currently used in advanced manufacturing are FTIR and near-IR spectroscopy. FTIR has been used to determine material and chemical composition, as well as structure, while Raman spectroscopy is used for its ability to conduct non-destructive analyzation of a material's chemical composition.[379]

Applications: Industries have applied differing spectroscopic techniques to aid identification and analyzation. The aerospace industry uses EDXS and FTIR to confirm the presence and distribution of aluminum oxide on 3D printed structural materials. The agriculture industry uses spectroscopy to help identify different conditions in the hydration in plants[380], reduce food waste, identify high quality food products, improve food supply forecasting, and enhance production planning.[241] Electronic manufacturers have also used Raman spectroscopy to verify graphene sheet existence in 3D fabricated aluminum nanocomposites.[381]

Key Benefits: The advantages of spectroscopy include structure identification, qualitative and quantitative analysis of the composition of a sample, reduced testing time and costs, and energy efficiency.[225,374]Spectroscopic techniques such as XPS and EDXS can provide elemental analysis, chemical characteristics analysis, and raw material characterization of manufactured parts. Additionally, Raman spectroscopy can provide an opportunity to conduct non-destructive analysis of a material's chemical composition and can be applied to different sample types (e.g., solids, powders, liquid, gels, slurries).[382]

Limitations and/or Risks: Some spectroscopy techniques (e.g., XPS) can require sophisticated instrumentation to provide detailed information on chemical bonding. FTIR also exhibits sensitivities to water and carbon dioxide, making some compounds difficult to analyze.[225,382] Lastly, UV spectroscopy's strong, heat-induced radiation light may limit its applicability to metal and alloy additive manufactured parts.

Stage of Emergence or Adoption: Spectroscopy technologies are broadly used across the manufacturing industry, thus aligning with the adoption stage. However, novel applications are emerging, such as for the identification and characterization of microplastics in the environment.[225,381,382]

Variable Rate Technology (VRT)

Description: VRT is an agricultural technology that enables variable rate application of materials (e.g., seeds, fertilizer) in precision agriculture based on conditions such as plant growth or soil nutrients and type.[383] A subset of VRT is variable rate nitrogen application technology (VRNT). This subset allows for changes in application rate of materials to match the identified need for fertilizer within a precise location. A control system uses maps and/or sensors to calculate soil needs against location, and in turn, a controller triggers a delivery of needs to that specified location.[384]

Applications: VRT is used in agricultural robots to identify soil factors, weather conditions, crop health, and other recommendations. VRT is used to optimize agricultural techniques without impacting plant health (e.g., by soil compaction, erosion).[136] VRT can be used for decision support for agrochemical inputs and used to address sustainable farming practices.[385]

Key Benefits: VRT helps detect crop issues, reduce human errors in farming, and improve weeding efficiency. VRT in robots improves farming efficiency by being able to work long hours, have predictable performance, and protect the environment.[385,386]

Limitations and/or Risks: VRT can be complex to implement and may not perform better for profit or saving water. For example, the agricultural industry has displayed hesitation towards adopting VRT. However, providing additional information on the technology's use and potential benefits may help increase adoption rates.[386]

Stage of Emergence or Adoption: Due to challenges with economic costs balanced against profit, larger farms may adopt VRTs as opposed to smaller farms; however, this technology aligns with the adoption stage.[386]

4.4.5 PROCESSING TECHNIQUES

Material Processing

Description: Material processing is a method of converting raw materials into useful objects through modification of various properties of the metal by creating a shape from a starting material, and refining its structure and shape through chemical, thermal, and physical processes. Material processing encompasses ceramic processing, metal fabrication, metal forming, and polymer processing.[387] Microwave processing is a novel example of ceramic processing that addresses limitations of conventional thermal processes, such as undesired changes in structure or properties due to interactions with heat.[388] Ultrafast lasers are another example of a novel technology within the field of material processing and provide opportunities for microfabrication of materials without negative effects from heat. [389] Material processing is utilized within individual manufacturing processes for components of devices used in day-to-day life, scaling up to use within processes to treat larger parts of manufactured end products.[388]

Applications: Microwave processing involves directly radiating materials, which provides heat energy, allowing materials to be manipulated. This technique is used to join bulk metals, as well as ceramic and polymer composites together. Applications of microwave processing extend to sintering advanced materials, such as metallic powders. Within the construction industry, microwave processing has been studied to determine if there is increased effective asphalt production through the use of microwave heating to internally dry materials.[390] Ultrafast lasers can be used to conduct material processing whereby structural modifications occur after a material interacts with light. As ultrafast lasers are much faster than traditional laser techniques, heat diffusion to the outside of the processed area is reduced, making this an effective technique for microfabrication of both soft and hard materials. Soft materials can include biotissues, while hard materials can include metals, ceramics, and polymers. Currently, this technique is used during the development of photonic devices and biochips. Ultrafast lasers can also be utilized to meet requirements during automotive manufacturing.[389] Ultrafast lasers are used to repair components in the semiconductor manufacturing process at International Business Machines Corporation (IBM).[389] Ceramics that have undergone processing can be applied to various applications, including, but not limited to, solar cells, semiconductors, magnets, lamps, radiators, electrodes, armor for military vehicles, nuclear fuel, and engines.[391]

Key Benefits: Microwave processing is a sustainable, cost-effective method of manufacturing that provides higher rates of production as compared to conventional processes. Materials are directly heated and at a quicker rate, enabling improvements in physical and mechanical properties, as well as reduced defects.[390] The use of ultrafast lasers enables improvements in precision and time cost. Picosecond lasers, a type of ultrafast laser, have been used to manufacture diesel engine injectors, resulting in increased reliability, power, and environmental sustainability of the system. Using ultrafast lasers over traditional lasers provides precision and control benefits, leading to more reliable end products.[389]

Limitations and/or Risks: Some material processing steps may require additional steps (i.e., post-processing) to refine the product's shape and structure.[387] A limitation of microwave processing is that the heated materials may develop thermal instabilities that can affect adjoining materials due to differences in temperature gradients. However, this is mitigated by using a hybrid heating technique in which both microwave and conventional methods are used.[390] Output power of ultrafast lasers may fluctuate, causing an extremely unstable process once the laser is near the threshold point.[389] Within ceramic processing, flaws at the microstructural level create an intensified stress field, increasing the potential of end product failure.[391]

Stage of Emergence or Adoption: Material processing as a broad field aligns with the adoption stage. Ultrafast lasers were first seen applied in mass production to the drilling of inkjet nozzles.[389] Picosecond lasers have also been used within automobile manufacturing since 2009.[389] However, other techniques, such as microwave processing, are still considered emerging, as additional research is needed to understand exactly how the properties of various materials interact after undergoing microwave processing in order to be applicable to manufacturing sectors broadly.[390]

Nanoprocessing

Description: Nanoprocessing is the modification and creation of materials that are in the size range of 1 to 100 nm.[76]

Applications: Nanoprocessing techniques have been used for nanosensors and nanopackaging. Within the food industry, nanoprocessing has been used during packaging and QC to boost shelf stability, flow characteristics, flavor, and color during processing.[392] Additionally, nanoprocessing is used within the agricultural industry for nanofertilizers and nanopesticides. Existing nanoscale manufacturing is comprised of deposition, etching, polishing, assembly, packaging, and wire bonding. Water purification is also enhanced through nanoporous membranes.[76]

Key Benefits: Agriculture can benefit from increased yields, higher production rates, more nutritional crops, effective resource usage, reduced waste, lower energy consumption, and lower environmental impact when using nanotechnology such as nanofertilizers, nanopesticides, and nanofiltration.[76]

Limitations and/or Risks: There is limited research and thorough evaluation of nanoparticle behaviors resulting from nanoprocessing (e.g., toxicity, exposure, health risks).[76]

Stage of Emergence or Adoption: Nanoprocessing aligns with the adoption stage due to identified applications across some non-medical industries (e.g., food, agriculture).

Non-Destructive Testing (NDT) and Evaluation (NDE)

Description: NDT and NDE cover a wide range of analytical techniques to inspect, test, or evaluate chemical/physical properties of a material, component, or system without causing damage. Early established NDT techniques include ultrasonic, X-ray radiography, liquid penetrant testing (LPT), magnetic particle testing, and eddy-current testing, which were initially developed for the steel industry.[107] NDE techniques can include CT and neutron tomography. Among these, ultrasonic and radiographic detection are also effective inspection techniques for composite structures.[393]

Applications: The automotive industry is developing NDT robotics to identify car damage in hard-to-reach areas (e.g., combustion chamber). A probe with a camera is inserted in an engine, provides a video feed to the operator, and is remotely controlled to remove damaged areas.[25] Steam generator tubes are inspected using NDT techniques that consist of the detection, characterization, and measurement of loss of tube wall thickness, erosion, cracking, etc. This check is performed using multi-frequency, digital, robot-operated, and remote-controlled equipment. In order to reduce the plant idle time, the inspection is carried out in turns by acquisition operators/analyst teams during the 24 hours of the day until the inspection is finished.[394] Data-constrained modeling (DCM) is used within NDT to determine the composition of a sample, provide more detailed information, and calculate material distributions below CT resolution.[108]

Key Benefits: NDT techniques have demonstrated effectiveness in quality assurance throughout the lifecycle of composite products (e.g., process design and optimization, process control, manufacture inspection, in-service detection, structural health monitoring).[108] Some NDT techniques, such as synchrotron-based micro-computed tomography (µSXCT), are used to provide the best speed, spatial resolution, and signal-to-noise ratio as a result of the high intensity, monochromatic, practically parallel, and tunable beams.[108] Additionally, CT's versatility and cone-beam allows for great scanning efficiencies.[108]

Limitations and/or Risks: Defect detection in CT, when applied to metal advanced manufacturing, can experience limited scan resolution, lack of robust thresholds, and limited ability to differentiate between specific defects.[109] There tends to be limited budgets and instrument calibrations to gain a better understanding of NDT's systematic errors associated with dimensional measurements. Additionally, there is limited research on how to penetrate large, dense, metallic parts, which can hinder adoption.[108]

Stage of Emergence or Adoption: NDT and NDE align with the adoption stage, with widespread utilization of NDT growing across industries.

Surface Modification

Description: Surface modification is a process whereby material surfaces of products can be modified physically (e.g., shape, surface change) and/or chemically (e.g., oxidizing, nitriding, carbiding, coating, ion infusion). Physical modification is completed through processes such as etching, grit-blasting, and machining. Chemical modification is conducted through processes such as plasma and chemical vapor deposition, atomic layer deposition, and electro-chemical deposition. Surface modification is typically required for many additive manufacturing methods after fabrication (e.g., material extrusion, binder jetting, powder bed fusion, directed energy deposition, vat polymerization, and material jetting).[395]

Applications: Surface modification is utilized in metal and alloy modification, polymers, biomaterials, ceramics, textiles, and plastics.[395,396,397,398,399,400]

Key Benefits: Surface modification encourages adhesions of coatings, prevents oxidation, decreases staining, improves bond strength, and advances resistance to corrosion and wear.[396,401,402]

Limitations and/or Risks: The major drawbacks of surface modification are the environmental and process hazards associated with the use of large quantities of chemicals. Any savings in equipment cost is usually offset by the increased cost of environmental controls.[398]

Stage of Emergence or Adoption: Surface modification aligns with the adoption stage, with some emerging applications including nanostructures and food packaging.[396]

4.5 Platforms

Advanced manufacturing platforms offer a mechanism (e.g., system, infrastructure, network, interface) to connect, communicate, share, organize, or obtain ideas, data, information, and knowledge.

4.5.1 APPLICATION PROGRAMMING INTERFACE (API)

Description: An API is a set of rules that enables two or more applications to communicate with each other. An API acts as an intermediate layer to process data between the applications or systems.[403]

Applications: APIs are used in industry to make data more available for third-party companies, developers, and others to leverage information and functionality.[404] APIs are integrated in many web-based services that pull information from third-party websites, universal logins that integrate with email, mapping applications, software-as-a-service (SaaS) products, IoT and smart devices.[403] The travel and transportation industries use APIs to pull hotel and flight information to provide deals to customers. APIs in streaming services such as Netflix help users discover new content they may like. The manufacturing industry may integrate APIs to connect to customers and industry partners, innovate, and conduct real-time monitoring.[405]

Key Benefits: APIs connect different applications across industry, provide opportunities for workflow automation, save time compared to manual data curation, and break down collaboration silos. APIs allow businesses to connect and accelerate innovation through digital transformation. APIs also provide system and user security and privacy through authentication requirements, cookie or query strings, and permissions.[403] APIs are cost-efficient, provide a better customer service experience, allow for business intelligence data collection, and improve industry-level collaboration.[314]

Limitations and/or Risks: APIs may have security or privacy concerns such as private or proprietary data exposure, cyberattack susceptibility, and bypassing of security measures (e.g., firewalls).[314]

Stage of Emergence or Adoption: APIs are used in several industries and align with the adoption stage.

4.5.2 AUTOMATED CLOSED-LOOP SYSTEMS

Description: Closed-loop automation is a platform that oversees the automation and management of a network. This system uses data and analytics to monitor and identify network issues, adjust, and optimize the performance of the network.[406]

Applications: Automated closed-loop systems are used for data analytics, ML, and AI capabilities to provide actionable insights into network events. They can be used for incident management to automate and streamline the escalation and approval processes.[407] Automated closed-loop systems are utilized so that 5G networks can provide uninterrupted communication service and consistent device configuration across the network. In hybrid and cloud environments, automated closed-loop systems can also support provider connection to different networks, predictive planning, and root cause analysis.[407,408]

Key Benefits: Automated closed-loop systems increase network data collection and automation, prevent administrators' manual mediation of issues, and increase organizational efficiency.[407] They allow networks to automatically address issues, enhance security, and optimize network traffic flow.[408]

Limitations and/or Risks: There may be security risk susceptibility, such as cyberattacks, if a hacker can bypass the detection and investigation built into the platform.[408]

Stage of Emergence or Adoption: Automated closed-loop systems align with the adoption stage but have novel applications emerging.[407]

4.5.3 ADVANCED METERING INFRASTRUCTURE (AMI)

Description: AMI is a communication system of smart meters, networks, and data management systems that enable communication between utilities and customers.[409]

Applications: AMIs allow for automation of processes (e.g., measuring electricity use), connection, enable and disable functionality, and identification and isolation of outages. They are used in the power industry to monitor home electricity usage, provide services that monitor voltage, and modernize the power grid.[409]

Key Benefits: AMI provides lower costs for metering, billing, and outage costs; empowers customers to utilize their data; and lowers company expenditures through smart devices.[409] This communication process allows for companies and users to understand their electrical consumption.

Limitations and/or Risks: AMIs may be susceptible to cyberattacks wherein hackers attempt to breach the system and collect customer information (e.g., personal data). There may also be damage or software issues with the AMI components that impact monitoring or measurement of network use. Some sections of the network are used by low-bandwidth technologies such as ZigBee or WiFi, and other sections of the AMI are used on high-bandwidth technology, which could create issues with sending certificates to the various networks.[410]

Stage of Emergence or Adoption: AMI aligns with the adoption stage, but has novel applications still emerging (e.g., utility companies integrating smart meters, grid modernization, AMI-enabled pre-pay programs, time-based rates).[409]

4.5.4 BLOCKCHAIN

Description: Blockchain is a platform of tamper-resistant digital ledgers that allows for a community of users to record transactions.[411] Blockchain records cryptographically signed transactions, groups them into blocks, and cryptographically links them to the previous block after validation. All users within the network store data on their own and synchronize it to the rest of the data chain based on a consensus model demonstrating decentralization of the network. As new blocks are added, older blocks become more difficult to modify and make the blocks tamper evident.[412]

Applications: Blockchain is used in cryptocurrency (e.g., Bitcoin), smart contracts, and distributed ledgers between businesses due to the use of cryptographic functionality.[411] The music industry uses blockchain for managing music rights and copyright payments. The education industry uses blockchain for exchanging ideas, regulating student tuition payments, decentralizing, and storing different types of education information permanently. Governments and public institutions may utilize blockchain on data records for storing digital signatures, tracking identification for voting, and registering businesses.[413]

Key Benefits: Blockchain is a platform that helps users or businesses create tamper-resistant records since each block is permanently saved and cannot be changed. It utilizes decentralized and distributed ledgers to process transactions, which reduces latency and eliminates a single point of failure. Blockchain provides transparency by sharing transaction details between all users in the network. Blockchain is cost-efficient, quicker, and better for risk management than other traditional transaction platforms.[413]

Limitations and/or Risks: Because blockchain stores transactions in a ledger, as the number of transactions grows, there may be issues with scalability. There are privacy concerns with blockchain as the transactions cannot guarantee transaction privacy or could be linked to users' personal information. Blockchain can also be energy inefficient because the mining process requires a huge volume of computing power to verify the transactions securely. Blockchain may be susceptible to cyberattacks wherein a hacker may capture, alter, and rebroadcast a transaction, which could impact data integrity.[413]

Stage of Emergence or Adoption: Blockchain is a platform currently in use across multiple industries and therefore align with the adoption stage.

4.5.5 CYBER-PHYSICAL SYSTEM (CPS)

Description: CPSs are engineered and physical systems that integrate computation, control, sensing, and networking in physical infrastructure and objects, helping to link them to each other and the internet.[414,415] CPSs are centered on the interaction of networking, physical, and computation processes.[416]

Applications: CPSs have been leveraged within smart learning environments, aerospace industry, civil infrastructure monitoring, green buildings, water management systems, SGs, and transportation systems.[417,418]

Key Benefits: CPSs help to improve production quality and efficiency while reducing production costs by incorporating advanced technologies such as cloud computing, AI, and IIoT. Within transportation systems, CPSs enhance performance.[417] CPSs can also improve smart manufacturing, energy supply and use, and defense and homeland security.[419]

Limitations and/or Risks: Limitations include platform, network, and/or management vulnerabilities. Additionally, CPSs may be vulnerable to physical or cyber threats, as well as privacy issues, which may impact their overall safety, reliability, and deployment.[416]

Stage of Emergence or Adoption: CPSs align with the adoption stage because they are currently connecting physical and cyber environments and serving as critical components of Industry 4.0. The National Strategy for Advanced Manufacturing defines Industry 4.0 as "a paradigm relating to the transformation of technology, industry, and societal patterns, and processes that are derived from augmented interconnectivity and smart automation."[416] Novel applications of CPS include the Internet of Cyber-Physical Things (IoCPT).[416]

4.5.6 LONG RANGE WIDE AREA NETWORK (LORAWAN)

Description: LoRaWAN is a low-power, broadband network that connects to gateway, IoT devices, smart meters, sensors, and application and network servers via a star-topology or hub and spoke configuration.[420] Within LoRaWAN, the gateway obtains IoT device data and sends it to the application server. LoRaWAN can provide a coverage area spanning over tens of kilometers.[421]

Applications: LoRaWAN has been leveraged for smart cities and buildings, as well as logistics and transportation management for traceability of high value assets in transit.[422]

Key Benefits: LoRaWAN delivers low power, long coverage and range, high capacity, and low-cost hardware.[422]

Limitations and/or Risks: Limitations include its reliance on gateways (due to its inability to transmit data directly to the server) and limited data transmission speeds.[423] Further, to meet IoT networking requirements, LoRaWAN must be densified.[422]

Stage of Emergence or Adoption: While LoRaWANs align with the adoption stage, additional research is being conducted to address challenges in mobility management. Novel applications of LoRaWAN include integration into 4G, 5G, and Long-Term Evolution (LTE) networks.[421]

4.5.7 DIGITAL MICROFLUIDICS (DMF)

Description: DMF is a subset of microfluidics, as well as an alternative to droplet microfluidic systems. It is considered an automation platform used to assist digital and physical tool integration so tools can be used together across platforms.[424] Within DMF, all processes are completed on chips, and uses electrowetting-on-dielectric (EWOD) technology, dielectrophoresis (DEP), or acoustic wave forces to control the flow of individual droplets in processes, such as assays, in which liquid droplets can be manipulated separately.[425]

Applications: Research is currently examining the possibilities of developing lab-on-chips using DMF where entire biological or chemical laboratories can be integrated into a chip allowing the manipulation of small amounts of chemicals and fluids.[426] Applications for DMF are within the field of optics, including "liquid" screens that become brighter in sunlight and adjustable lenses.[427] EWOD based systems are used within food safety to monitor levels of contaminants as they provide increased sensitivity that can detect low volumes of harmful bacteria.[428] DMF is able to cultivate cell cultures by providing methods of continuously replenishing necessary resources needed for propagation enabling culture and analysis to complete on a chip.[429]

Key Benefits: Through having all processes completed on a chip, there is increased control, decreased cross-mixing, decreased diffusion, and simplified manipulation.[430] EWOD allows for increased control and flexibility when using DMF systems. Using EWOD in DMF systems has several other advantages, including faster reaction times, increasing efficiencies in mixing, decreased contamination, and lower costs.[428]

Limitations and/or Risks: As DMF is an emerging technology within the field of microfluidics, there are challenges to integrate the technology with electrowetting performance to match samples for analysis, which can affect DMF implementation within the field and within specific applications.[424] Using EWOD for organic solvents based reactions is challenging because of chemical properties within the organic based solvents that hinder their movement on chips.[428] To create lab-on-chip technologies, a high-level of integration is required among all parts meaning that additional technologies are required to condense components to fit within the overall device.[372]

Stage of Emergence or Adoption: Digital microfluidics align with the emergence stage. Currently, integration of EWOD into chips still needs more research to be integrated into existing biological and chemical technologies.[428] Although there have been some applications for DMF already noted, such as within food safety, there is still a need for further research and development before DMF can be commercialized.

4.5.8 WIRELESS SENSOR NETWORK (WSN)

Description: A WSN is a collection of spatially distributed sensors and base station(s). Each sensor connects with the base station. The sensors (which produce sensory data) provide real-time monitoring of components such as physical conditions, vibration, temperature, and motion.[431,432]

Applications: WSNs have applications within civilian, industrial, and military sectors, as well as entertainment, disaster management, environmental monitoring, and monitoring and communication of data.[431,433] For example, the military uses WSNs to improve situational awareness and enhance tactical planning for deployments.[434] Additionally, industries can leverage WSNs to support disaster management via its ability to provide image and audio information (e.g., following earthquake rescue efforts).[435] Further, environmental industries have used WSNs for river health monitoring and watershed monitoring.[436]

Key Benefits: WSNs can provide real-time information (e.g., within the enhancement of a data center's performance).[437]

Limitations and/or Risks: Limitations include privacy and security concerns, restricted computational capacity, and limited node energy and shortage memory capacities.[431,433]

Stage of Emergence or Adoption: WSNs align with the adoption stage, as the WSN concept is not new.[438]

5 CHALLENGES AND BEST PRACTICES

Identifying and understanding the challenges and success strategies impacting the implementation, adoption, and regulation of novel, emerging, and disruptive technologies across other industries can help FDA consider how they might apply—or avoid—similar approaches to their regulation of products. For the purposes of this report, we refer to implementation as an advanced manufacturing technology or process (or application, product, material, etc.) officially entering commercialization in the marketplace. While regulatory agencies may, to some degree, impact or influence aspects of how and when such implementation occurs, they do not directly control implementation. Implementation of new technology is largely driven by industry and manufacturers. Adoption, on the other hand, is largely reflective of the markets' acceptance, use, and demand. Industry and government stakeholders can help to increase confidence and reduce risk in adopting new technologies and processes, but again, it is ultimately up to manufacturers.

Regulatory agencies assist with the implementation of new technologies through issuing guidances and working with industry to clarify regulatory and data requirements, review and approve products made through the use of novel technologies, and advance regulatory science to support the adoption and resolve challenges associated with the use of advanced manufacturing technologies.[439] However, facilitation of this regulation and oversight can vary across government agencies and industries. Non-regulatory agencies, Standards Developing Organizations (SDOs), academic institutions, and other organizations (e.g., trade, professional) also play a role in how advanced manufacturing is regulated. Their work provides critical research and baseline data to drive development of frameworks and standards that inform future regulation. In addition, these other organizations provide information and educational materials to lawmakers, regulators, and technology adopters to facilitate the development and adoption of technologies.

Booz Allen conducted an analysis for FDA of the best practices and challenges related to advanced manufacturing implementation, adoption, and regulations in non-medical industries. The following section presents findings within six high-level themes: collaboration and engagement; data and information; economic impact; standards and controls; weighing regulation and innovation; and workforce. Findings are further organized by subthemes, under which relevant challenges and best practices—and associated use cases—are summarized. Stakeholder-suggested solutions are listed if specifically identified in relation to a specific challenge. Areas of relevance within each subtheme to FDA are noted, as appropriate.

5.1 Collaboration and Engagement

The advanced manufacturing ecosystem includes a variety of stakeholders (see Table 3-2) that possess varying technological expertise and skillsets. While some organizations have exhibited reluctance to collaborate because of proprietary information or competitive advantage, others are resistant due to their lower tolerance levels for risk and change. However, findings indicate that information sharing throughout the product's lifecycle (e.g., development, approval, production, sale, maintenance) can encourage industry to contribute effective advanced manufacturing technology applications necessary for adoption. The sections below highlight how formal and informal collaboration and engagement can help different stakeholder groups strengthen information sharing practices, improve the industry's overall knowledge base of advanced manufacturing technologies, foster more robust understanding of the market needs and technological capabilities, and accurately and appropriately define regulatory principles for advanced manufacturing technologies that are comprehensive and realistic.

5.1.1 KNOWLEDGE SHARING AND TRANSPARENCY

Challenges

Limited Information Sharing: Manufacturers have historically operated within a closed environment to protect proprietary information.[440] Research indicated manufacturers who operate within these closed environments can experience technology "lock-ins", which can increase their dependency on specific vendor offerings.[441] During an interview with one trade association, interviewees specifically emphasized how hesitancy to share information on successful implementation of emerging technology remains an issue (e.g., secrecy of applying AI and ML technology into production line machinery) and will continue to negatively impact advanced manufacturing implementation rates.[440]

Limited information sharing not only impacts implementation rates, it can also hinder regulatory efforts. For example, nuclear industry stakeholders are exploring increased utilization of small modular reactors (SMRs) to decrease the overall carbon footprint and produce large amounts of low-carbon electricity, in comparison to traditional reactors. The International Atomic Energy Agency (IAEA) identified a need to establish collaborative solutions that facilitate information sharing on the safety and security of some SMR designs, which may require some level of harmonization across varying international policies and regulations to avoid repetitive regulatory efforts.[442] However, with over 70 SMR designs being developed internationally, regulators are experiencing challenges with assessing first-of-a-kind designs, ensuring regulatory bodies have the necessary technical expertise, and revising pertinent regulations.[442] The nuclear regulators noted the importance of industry feedback to facilitate international collaboration, but also acknowledged that industry's comfort level in information sharing ultimately dictates what feedback is voluntarily shared with regulators.[442] To overcome these challenges, IAEA hosted the first Nuclear Harmonization and Standardization Initiative (NHSI) meeting to engage nuclear regulators and industry leaders in discussions on roadmaps that highlight safe deployment of SMRs. Meeting attendees engaged in working groups to build frameworks for regulatory information sharing to increase efficiencies and share lessons learned for different countries' regulatory review processes. Through the working groups, IAEA found that some nuclear regulators agreed industry feedback and increased information sharing is needed to address regulatory challenges. However, they also believed successful information sharing will require greater transparency and collaboration between government and industry stakeholders.[443]

Stakeholder-Suggested Solutions: To increase information sharing and collaboration, stakeholders identified the following solutions for both industry and governmental partners:

- Increase attendance at public meetings and workshops to strengthen connections within associated industries to gain better understanding of existing challenges, mitigation strategies, and lessons learned from failed and successful cases.[444]
- Engage in government-led collaborative activities (i.e., workshops, webinars, trainings, conferences), where governmental partners can provide insight and address industry questions on regulatory frameworks, and industry allies can share lessons learned in success cases to alleviate hurdles and prevent duplicative adoption missteps.[445]
- Strengthen stakeholder relationships by establishing partnerships with smaller manufacturers to provide insights on viable strategies previously used by larger manufacturers to meet regulatory requirements.[446]
- Leverage technology-specific lessons learned from organizations on their early engagement with regulatory bodies for a smoother regulatory experience.[445]

Best Practices

Promote Continuous Learning: Active knowledge sharing between stakeholders can promote continuous learning regarding new technologies and issues related to implementation, adoption, and regulation. For example, notable active collaboration efforts have benefited the field of nanotechnology. The development of National Institute for Occupational Safety and Health's (NIOSH's) workplace guidance "Approaches to Safe Nanotechnology" and the National Science Foundation's (NSF's) "GoodNanoGuide" stem from ongoing communication between material developers, occupational and environmental health and safety researchers, and government officials.[447, 448] These partnerships helped to produce valuable science-based data, inform future guidance and policymaking, and identify policy challenges related to this technology.

Leverage Public-Private Partnerships: Increasing government and private organization collaboration can aid in addressing challenges experienced on both sides within the advanced manufacturing ecosystem. Public-private partnerships can be used to share data and models, leverage lessons learned on use of new materials, and provide insight into production and qualification processes to accelerate the development of advanced technologies and materials.[449] For example, the agricultural industry leveraged collaboration for precision pest management. Broad collaborations were found to be critical in supporting communication among users (e.g., scientist, industry professionals, commercial growers) to translate scientific research, determine the best performing technology, and identify which technologies best aligned with pest management needs.[450] The following are examples of positive, collaborative, knowledge sharing efforts between government and organizational partnerships aimed at furthering successful adoption of advanced manufacturing technologies:

- During interviews, one government agency referenced a program in which Oak Ridge National Laboratory's Manufacturing Demonstration Facility supports small- and medium-sized companies by providing education on advanced technologies and implementation feasibility paired with use of scientific laboratories and equipment.[451, 452] The program illustrates how government-facilitated partnerships can help smaller businesses better understand novel technologies and their potential implementation risks.
- The NSF collaborated with the White House Office of Science and Technology Policy (OSTP) to form a National AI Research Resource (NAIRR) Task Force through the National AI Initiative Act of 2020.[453] The task force designed a road map to promote collaboration, innovation, and economic prosperity with AI. NSF—in partnership with other government agencies and private organizations—then led a $200 million multi-sector investment in the establishment of 11 National Artificial Intelligence Research Institutes to collaboratively support the development and use of AI to advance a multitude of industries.[454,455]
- The Department of Defense (DoD) engaged in various partnerships (e.g., Joint Additive Manufacturing Working Group [JAMWG], Department of the Navy [DON] Naval Additive Manufacturing Technology Interchange [NAMTI], Air Force Technical Interchange Meeting [AFTIM], Army Community of Practice) with defense industry stakeholder groups and academia to increase the uptake and integration of into the supply chain and to assist with aligning additive manufacturing activities.[456] During an annual NAMTI meeting, senior

Navy leaders and additive manufacturing stakeholders discussed current state, opportunities, gaps, and challenges regarding implementing additive manufacturing. Following the interchange, DON had over 70 additive manufacturing projects in progress, thus indicating an overall rapid increase in the research and adoption of additive manufacturing.[457]

- In 2019, the U.S. Consumer Product Safety Commission (CPSC) organized and led the Interagency Working Group on Consumer Product Safety of Internet-Connected Products working group that included the National Institute of Standards and Technology (NIST) National Cybersecurity Center of Excellence (NCCoE) and their academic partners, FDA, Federal Trade Commission (FTC), Federal Communications Commission (FCC), U.S. Department of Energy (DOE), and Department of Homeland Security (DHS). The purpose of the working group exemplifies public-private partnership collaboration: "to articulate and understand each agency's roles and responsibilities on Internet-connected products, identify potential gaps that agencies are experiencing, find opportunities to learn from each other in a collaborative manner, create an opportunity for interagency cooperation, promote the development of voluntary, consensus-based standards, and develop high-level best practices guidance to ensure that connected consumer products are designed and produced to be safe and secure."[458]

Create Bilateral Government-Industry Communication: Building two-way relationships between regulatory agencies and industry enables a more robust and informed evaluation of the technology, and provides transparency and awareness of issues related to the emerging technologies. In one interview, experts from a federal agency noted they try to initiate individual conversations with industry companies and as a result, those companies are more forthcoming with technological information than when speaking in a larger setting with other invested stakeholders. There are various ways for industry to engage in these types of conversations with regulators. The Association of Equipment Manufacturers (AEM) is an example of an organization that has created a forum for industry to communicate with regulators in smaller, less public venues. AEM has created targeted topic-specific committees that serve as an open forum for like-minded members to discuss the direction of industry, identify issues, and propose solutions. These committees intend to build individual relationships with industry organizations as a way to better understand advanced technologies. The committee supports industry organizations by initiating contact with lobbyists to support the development of advanced technologies.[459] In one instance, AEM provided feedback to regulators that overly broad "right to repair" laws can be damaging, as they would allow unauthorized access to source codes resulting in safety and sustainability risks and inhibiting innovation. Subsequently, AEM partnered with other industry organizations to develop diagnostic and repair tools that equipment owners can use to repair their own machinery, providing an individual "right to repair."[460,461]

When regulators expand dialogue with industry, it not only builds relationships, but enables both parties to create programs to help solve specific challenges identified with a technology and assist with development of guidances and/or regulations targeting the specific issue.[446] For instance, regulatory agencies can interact with industry to solicit ideas or gather feedback through several communication methods and channels (e.g., Federal Register docket, formal meetings during product development, public workshops). In turn, industry can then develop a solution or answers that they present back to the regulatory agency. During an interview, experts from one non-regulatory federal agency stated that they successfully utilized this process to propose ideas to industry organizations who, in return, conducted research and developed a series of relevant materials. While this was an agency-initiated project, there were many stakeholders involved, including industry and academic organizations, that provided valuable feedback on the material and, ultimately, produced a stronger, more uniform outcome.[473,462]

Some technical knowledge sharing within the additive manufacturing field has occurred via focused meetings, working groups, and workshops sponsored by organizations that are focused on standardization. Such events are attended by representatives in industry, government, and academia.[464] Whether formal (e.g., working groups, public-private partnerships) or informal (e.g., public meetings, ad hoc), this collaborative dialogue allows regulators to better understand industry and stakeholder perspectives, and gain a more thorough understanding of advanced manufacturing technologies. One professional organization noted during their interview that it would be beneficial for regulatory agencies to have an increased presence at conferences to support collaboration between stakeholders and to increase awareness of the regulatory process and expectations.[445] Some non-regulatory agencies have already partnered with trade associations to disseminate knowledge of new findings and proposed recommendations benefitting worker populations.[461]

Improving public information and stakeholder consultation efforts were also found to better position government and industry to address concerns expressed by the public. Findings suggested creating a knowledgeable and supportive public can enable the timely review of facilities (e.g., new mines).[463] With a public consultation option, organizations were able to facilitate dialogue, as well as actively encourage and document questions and answers with the public and other stakeholders. These principles were also found to be applicable when sharing information during meetings or workshops for industry, academia, and government representatives.[464] Federal Energy Regulatory Commission (FERC) foster public engagement through a program called WorkshOPP, which is a specialized office that offers virtual workshops and guidance on how to submit public comments effectively, which can improve outcomes not only for commenters, but also for the agency.[465]

***Increase Targeted Collaborations**:* Organizations also collaborate across targeted specialty areas to promote knowledge sharing and understanding throughout a range of technologies and applications. For instance, one non-regulatory government agency noted how they have teams who work across specialties, throughout the development stage of technologies, to broaden their knowledge base and limit the potential for unknowns or uncertainties.[446] Another non-regulatory government agency described a similar practice in which staff are embedded across various specialty centers within their organization, thus allowing them to facilitate smoother transitions when multiple groups collaborate internally.[462]

Organizations also engage in targeted interactions with stakeholders across the ecosystem to develop a more sustainable manufacturing network and improve product quality, innovation, and cost-effectiveness.[466] As these manufacturing networks expand, findings suggest Original Equipment Manufacturers (OEMs) may be wary of rogue suppliers changing their production processes without notifying the OEM. Such changes could impact production quantity, quality, and safety, and this concern has incentivized OEMs to publicly share knowledge and divulge non-critical data (i.e., data that are not core to their competitive advantage) on their production processes to improve the safety of the technology and its outputs.[467] Other manufacturers may desire to follow suit to stay informed of any process changes from suppliers and prevent potential quality issues.

Industries can also establish formal consortia or associations targeted in building infrastructure to support technological governance, including commonalities in accessing and sharing knowledge and data. As regulations shift around certain technologies, consortia promote adaptability in procedures for knowledge sharing.[470] Consortia also provide collaborative opportunities to pool resources together to facilitate research that would otherwise be too expensive or require a variety of expertise that one entity is unable to provide on their own. Additionally, consortia encourage relationship building between partner organizations, allowing individuals to build on their expertise, which can contribute to increases in workforce development.[468]

The Industry IoT Consortium is an example of a consortia focused on promoting the adoption of IoT technology across organizations. The Consortium aims to develop best practice frameworks for deploying IIoT technologies across different industries, including energy, manufacturing, and healthcare, as well as providing connections with SDOs.[469] Such consortia promote knowledge sharing and best practices, in addition to serving as standard-bearers to align regulatory, ethical, and technical approaches and improve data governance.[470]

***Share Knowledge Across the Supply Chain**:* Organizations can combat uncertainty and promote technology adoption by creating a more expansive knowledge base among those in their supply chain using the technology or outputs of the technology. A culture of knowledge sharing can also create a more resilient supply chain. Many organizations utilize unique manufacturing or production processes for similar technologies, which can lead to differences in knowledge, resources, and regulatory oversight.[461] Key elements of understanding include material behavior, testing/inspection techniques, and product performance.[313] Findings indicate that organizations are advocating for such knowledge sharing across the supply chain to become a best practice. For example, the International Organization for Standardization (ISO) standard 26683-3:2019 "Intelligent transport systems — Freight Land Conveyance Content Identification and Communication — Part 3: Monitoring Cargo Condition Information During Transport" established requirements for the transport and condition monitoring of food and perishable goods that could fulfill some key elements and apply to other areas.[471] The requirements noted how information sharing (e.g., certificate of origin, inventory and status, potential hazards) will improve the visibility and reliability of the goods, and organizations can use this information for quality management and supply chain monitoring purposes.

Considerations for FDA

This research highlights several key points that FDA can add to its armamentarium as it continues to address how to enhance sharing and transparency between and among stakeholders. The most frequently reported need and influential practice was presence at collaborative activities (e.g., research, workshops, webinars, trainings, conferences) and increased individual or small group interactions that built a partnership between government and industry, which can be a mechanism to share information (e.g., challenges, mitigation strategies, lessons learned, market intelligence) and build trusted partnerships. There is also benefit from programs like the FERC WorkshOPP to help optimize utility and impact of public comment exercises. . Consortia and public-private partnerships were cited in interviews and literature as providing value to both regulators and regulated industry.

5.1.2 RISK TOLERANCE AND RESISTANCE TO CHANGE

Challenges

Implementation Risks and End User Risk Tolerance: Adoption of advanced manufacturing technology can be challenging due to the varying levels of risk tolerance. For industries that tend to be more conservative when it comes to innovation and operations, evidence of proper technology functionality may be required before adoption, to avoid risks of downed production times.[472] Research suggests varying risk tolerances can stem from the inability to monitor results of technologies that have little to no previous field experience.[473] For safety-critical industries, like construction, manufacturers expressed hesitancy towards widespread adoption of 3D printing technologies due to the uncertainty of the long-term safety of 3D-printed buildings.[474] The World Nuclear Association reported that within the nuclear industry the qualification of the laser beam powder bed fusion (PBF-LB) manufacturing process is required to demonstrate that the process can deliver the required components in a reproducible way, so that the properties and quality comply with relevant nuclear safety classification. It was indicated that further research and development (R&D) was needed to identify specific tests to determine when specimen and final product quality was achieved.[475] In addition to advanced manufacturing processes, additional part qualifications may be required prior to implementing to strengthen confidence in part productivity and investments.[451] Within the nuclear industry, regulators asserted that part efficiency must be confirmed prior to implementation, as nuclear power plants (NPPs) can't risk potential downtime attributed to offline parts or part failure, which can, overtime, incur high costs.[443] Industry expressed a reluctance to adopt new technologies without sufficient insight into product risks.[484]

Stakeholder-Suggested Solutions: To address challenges with risk tolerance or resistance to change, the following solution were suggested by stakeholders:

- Conduct technology assessments within Industry to increase awareness of potential failure modes, and consider integrating an initial qualification process (e.g., build process qualification, printing and post-processing, evaluation and testing) before continuing onto production.[476]
- Identify product champions to allow staff opportunities to assist with producing and managing a strategic roadmap for a particular technology or set of technologies.[445] Product champions can collaborate with internal

stakeholders (e.g., decision makers) to identify organizational needs for implementation (e.g., cost, schedule, user capabilities) and opportunities to leverage the technology across the organization.[445,570] In addition, product champions can collaborate with external stakeholders to share feedback and best practices. [445]

Cost of Change: The cost of change due to potential organizational shifts can increase resistance towards advanced manufacturing adoption. Technologies that require changes to existing business models and high initial investments for learning and skills were identified as being less likely to be adopted.[136] AI and cloud computing technology are examples of emerging technologies projected to require an increased capital investment for equipment and workforce training costs.[477] Despite increasing interest for emerging technologies like AI, organizational management can lack motivation to adopt emerging technologies due to high initial investments for equipment and personnel (e.g. new hire acquisition and training, upskilling/reskilling existing workforce).[201,477] Industry leaders' decision to invest in workforce training can be difficult to attain, especially if incorporating personnel's concerns about job security. Since the first industrial revolution, automation has raised employee fears of being replaced by machines.[478] The current human workforce continues to express similar concerns with losing their jobs to digital technologies.[479] During interviews, one government agency indicated further challenges with understanding how to keep their workforce flexible and educated with the adoption of advanced manufacturing technologies. They emphasized how the inability to encourage flexibility and knowledge transfer among the existing workforce may dissuade industry leaders from implementation and will likely be a continuing challenge for industries. [461]

Stakeholder-Suggested Solutions: To address challenges identified with the cost of organizational change, the following solution was provided:

- Prior to allocating large investments towards acquiring advanced manufacturing technologies, manufacturers may benefit from gauging their level of organizational readiness (e.g., requiring Production Readiness Reviews (PRR) to assess manufacturing maturity and risk using the MRL criteria prior to the production decision; requiring analyses that demonstrates conformance of policies, processes, procedures, systems to standards requirements).
- Assessing the benefits of advanced manufacturing technologies against current processes can identify concerns and determine how much an organization is willing to invest and change (e.g., financially, existing workforce skillsets).[480]

Considerations for FDA

Understanding industry's challenges with resistance may help provide insights for organizational needs when engaging with emerging technologies. Some industries' workforce exhibited skepticism or concerns when interacting with advanced manufacturing technology due to limited knowledge. Organizational readiness plays a large part in the adoption and implementation of technology, and there may be benefit from working with consortia or government to help organizations to a point where they can make the switch. In addition, reducing the risk and cost of adopting new technologies by proving them outside of a production setting may increase the likelihood of adoption. There may be benefits to exploring how to apply lessons learned from industry to enhance workforce comfort, confidence, acceptance, knowledge, and understanding of advanced manufacturing technologies, especially if there are cost-effective mechanisms or economies of scale for training.

5.1.3 UNDERSTANDING, COMPLIANCE, AND INTEGRATION

Best Practices

Collaborate to Develop Standards and Industry Resources: Collaborative efforts between regulators and other industry stakeholder groups (e.g., industry, SDOs, non-regulatory agencies) can promote consistent understanding of what is needed and expected for novel advanced manufacturing technologies or processes. Such collaboration can also help inform the development of standards, policies, and guidances that are clear, concise, and accurate. Within the nuclear industry, collaboration and alignment of regulatory oversight with other organizations involved in the inspection and quality management of the construction of nuclear components has provided clarity in the regulatory review process. For example, collaboration occurs between additive manufacturing developers, SDOs, and industry organizations to develop criteria for quality assurance that can be broadly applied. This includes establishing Code Cases for advanced manufacturing technologies, identifying any research gaps, and conducting tests to illustrate how advanced manufacturing technologies are applicable to various nuclear components.[481] Code Cases are developed and published by American Society of Mechanical Engineers (ASME) and provide alternative methods of complying with existing Code requirements previously approved. The Nuclear Regulatory Commission (NRC) uses Code Cases as acceptable substitutes for parts of established codes, and additive manufacturing developers are able to use Code Cases without needing prior approval from the NRC, as long as the developers identify any modifications used, helping promote overall compliance for advanced technologies.[482]

There are also organizations that dedicate efforts specifically towards expediting the adoption of advanced manufacturing and respective standards. For example, the America Makes and ANSI AMSC was established in 2016 and accelerates development of industry-wide standards for additive manufacturing based on stakeholder specifications in the pursuit of advancing additive manufacturing. AMSC created a collaborative platform for representatives across industry areas to identify gaps in advanced manufacturing standardization to inform development of a roadmap prioritizing standards development for additive manufacturing. This roadmap also proposes SDOs or other organizations who can take the lead on further standards development.[12] AMSC's roadmap identified and prioritized gaps where standardization previously existed, or areas where further research was needed to inform revisions to standards. After the roadmap's development, AMSC took the critical follow-on step to track progress on the gaps being closed through meetings with SDOs and noted which gaps were addressed. The roadmap has been revised and republished multiple times to stay up-to-date on changes in progress and to document new gaps to address.[12] The creation of such roadmaps increases predictability and preparation for emerging technologies by providing a managing framework for a combination of "competition, innovation, and collaboration" by which regulatory agencies can refer. The creation of roadmaps that span industry, policy, and institutional domains allows innovation to continue with consistent communication on product improvements without disruptions during the manufacturing process.[483]

As another example, National Aeronautics and Space Administration (NASA) and NSF formed internal programs and projects to support research in advanced manufacturing processes and technologies. As such, research investments can strengthen regulator's understanding of technologies, thus allowing for more effective oversight and realistic methods to ensure industry compliance. Additionally, if an issue regarding a specific aspect of an advanced manufacturing technology or process is identified, an agency can brainstorm to resolve the issue through standards, regulatory infrastructure, or capability building programs. This can also encourage testing of current standards against the new technology with the intent of determining if further regulatory improvements are needed to improve performance across industries. Information about advanced technologies reach regulators through various methods including, but not limited to (refer to Knowledge Sharing and Transparency for further information):

- Dissemination of findings at conferences,
- Creation of roadmaps and action plans (e.g., NRC Action Plan), that source specific technological information through further reports, and
- Regulatory funding of programs researching advanced technologies.

Findings suggest creating reference materials from this process to provide an overall evaluation of the technology, data supporting its state of emergence, and information on the technology's feasibility for use that would otherwise be unavailable.[484] NIST has various classes of reference materials available including ones that certify values for processes, creating consistency and uniformity across products, and ones that characterize information on the use of processes or measurement challenges that need resolution. Together, these varying types of reference materials provide a foundation of knowledge about a technology and its certified value parameters, as well as provide a traceability chain to ensure that measurement uncertainties are minimized.[485]

Considerations for FDA

As mentioned in the best practices above, ASME develops Code Cases to provide alternative compliance methods and NRC subsequently uses Code Cases as acceptable substitutes for parts of established codes. Roadmaps, such as those created by ANSI/AMSC, can help provide a strategic and informed vision of addressing the needs and challenges related to regulating innovative technologies. Additional roadmaps may be considered for advanced manufacturing capabilities of relevance to FDA-regulated industries. Other USG internal programs and projects (i.e., NSF and NASA) are producing valuable insights and information by supporting research in advanced manufacturing that may be applicable to FDA's intramural and extramural research efforts. In addition, collaborative research and knowledge sharing projects with other USG organizations investing in advanced manufacturing research has been a beneficial mechanism to share knowledge and information.

5.1.4 INTERNATIONAL COUNTERPARTS

Best Practice

Increase Collaborative Activities with International Partners: As advanced manufacturing technologies are implemented in the global market, collaborative activities (e.g., meetings, resource sharing) between domestic and international regulatory bodies, and non-regulatory organizations (e.g., SDOs), can promote compliance while not limiting innovation. For example, the U.S. has traditionally set its own standards for technologies; however, the nation has started to consider additive manufacturing as an international movement requiring collaboration with other countries. The U.S., Norway, and Poland collaborated on a U.S. Marine Corps UAV that was 3D-printed by Norway and tested by the U.S. in Poland. During the same year, the U.S. and Norway held joint training, as well as a personnel exchange. These activities demonstrated a successful sharing of data and lessons learned, as well as proliferated discussions and research on the capacities of additive manufacturing.[486] Research indicated collaborative efforts among SDOs internationally involve holding regular meetings to determine if additive manufacturing standards are realistic and result in compliance.[487] Aligning regulations and standards with international partners and collaborating with other national regulatory bodies also helps simplify supply chain production requirements and promotes uptake of regulation and technology by both manufacturers and governing bodies. For example, policymakers in the U.S. and Brussels are coordinating to mitigate methane. By aligning regulations, the international regulatory bodies can "simplify operator requirements, create uniform reporting standards, ensure effectiveness, and serve as a model for other regions."[488]

Considerations for FDA

International collaborations can not only help foster a broader understanding of advanced manufacturing technologies and help establish stronger, more cohesive regulatory standards, but they may also help with obtaining or sharing data that can increase supply chain visibility (e.g., where and how production of medical products is taking place). International collaborations of U.S. government agencies, like that between Poland and the U.S. Marine Corps, can provide unique experiences in advanced manufacturing (e.g., data standards, risks, regulation). This can also help identify strategic ways to increase presence through global partnerships and to proactively exchange information on technology to best address emerging public health concerns and inform strong regulatory policies.

5.2 Data and Information

Advanced manufacturing technologies often require access to quality datasets to establish strong foundations for implementation. This is often difficult due to inefficient data management practices and limited availability of long-term performance data. SDOs are also strongly dependent on data or databases that may not yet exist (due to the novelty of the technology), are disjointed, lack interoperability, or have data quality that is not strong enough for interpretation. Additional challenges can arise with their existing systems' ability to successfully integrate and interpret the incoming data. Cybersecurity threats compound these hurdles and can impact manufacturers' productivity and may influence rates of implementation and adoption.

5.2.1 AVAILABILITY AND ACCESS

Challenges

Insufficient Amounts of Data*:* Some advanced manufacturing technologies require large amounts of data to train effective algorithms to support emerging manufacturing processes. In some instances, the need for large quantities of data can be attributed to manufacturers' shift from a planned, time-triggered control system that utilizes deterministic algorithms, to event-triggered control systems that use sensors and require data for specific events to evoke manufacturing.[489] Deterministic algorithms are used in manufacturing for their ability to fabricate predictable end products and provide a stable control system based on time triggers. Using Radio Frequency Identification (RFID) tags to dictate each production line's equipment sequence of steps on the production floor, event-triggered control systems provide increased efficiency and minimized material waste, and thus have become a more popular manufacturing alternative.[489] This type of data collection requires extensive data collection and equipment communication to support each step to ensure system stability. Despite the advantages of an event-triggered production line, manufacturers can encounter sensing delays, equipment communication congestions, and slowed system responses due to the large amounts of data needed for each production step. Additionally, gathering and storing the needed industrial data to support product fabrication can be costly and impacts manufacturers seeking data to train their algorithms.[148] Security risks and restrictions become an issue when manufacturers are attempting to exchange data via public/private networks when they, for instance, decide to implement an event-triggered control system and do not have the specific data in house.[490]

Stakeholder-Suggested Solution: To overcome issues with data availability and access, the following solutions were identified by stakeholders:

- Consider conducting data synthesis to generate synthetic data if unable to obtain real-world data. Synthetic data has the ability to learn data characteristics and can resemble real-world data.[490]

Limited Data Storage and Sharing Infrastructure: Inadequate or decentralized data storage presents another challenge for standardization. For instance, regulatory bodies are imposing testing protocols and certifications for aerospace components, but the certification processes of additive manufactured components are challenged by the lack of material property databases specifically for additive manufacturing materials and limited data-related failure mechanisms.[491] An interviewee and industry expert noted that there are complexities when trying to create additive manufacturing material standards within industry SDOs. Often these organizations depend on volunteers and the compilation of certain types of data, which is often complex and constrained by company proprietary issues.[451] Often, SDOs need information and/or data that industry frequently finds is inefficient or difficult to submit, which hinders industry's willingness to participate.[461] In response, organizations like the Open Data Institute (ODI), a United Kingdom-based nonprofit, aims to work with companies and governments to foster open data ecosystems through activities like research and reports, toolkits, and training. Industry Data for Society Partnership (IDSP) have been created and aim to address societal challenges by creating a channel where private-sector data can be more open and accessible. Businesses are exploring the idea of sharing data assets through a concept called "data philanthropy" to share data with researchers, nonprofits, the government, and the public for the public good, to demonstrate good citizenship and stimulate innovation and mitigate business risk.[492]

Best Practice

Remove Data Silos: Data silos occur when organizations house information in dissimilar or out-of-date systems or when there are technological or business-related barriers that prevent data sharing.[493] Removing these silos and connecting data sources has been found to enable organizations to conduct cross-analyses, gain perspective on the state of their production line, and help optimize the agility, traceability, and transparency of data.[466, 494] Several strategies have helped industry be more proactive about preventing the development of data silos and removing them. These include using data discovery tools to review and connect data sources, implementing a data governance framework that guides the data management strategy of an organization and establishes best practices for data collection and data sharing, investing in data management solutions that connect different data sources and allow the data to be shared with different technologies and systems, promoting a culture of collaboration that emphasizes the importance of using data and sharing insights, and defining roles and responsibilities for those in data management positions.[493] Additionally, organizations can document and communicate their data collection methodologies to improve data usability and better understand how to apply data elsewhere.[461]

Considerations For FDA

With the onset of a new technology, challenges arise when data that could help to inform regulatory decisions does not exist or is difficult to share due to its complexity or accessibility. Regulators can stay abreast of these complexities and industry frustrations through collaboration and engagement opportunities. By doing so, they can remain more aware of these flaws (e.g., unavailable, partial data) and make more informed regulatory decisions. Limited data or small datasets can impact the validity and integrity of the models used in production, and therefore impact end product quality.

Challenges

System Data Integration: Successful integration of data with manufacturers' existing systems can present as a challenge even after data is obtained. Integration of advanced manufacturing becomes less appealing and advantageous if the data it requires is unable to integrate with existing systems.[451] Adjusting existing infrastructure to prepare for advanced manufacturing data can require fundamental changes and substantial funding. For example, legacy systems interfaces are often closed, or without documentation of their interfaces, and operating engineers may not be able to support the data needs of the emerging technologies.[489,495]

Existing systems with outdated technical environments can also impede seamless data integration. Technology may not have value in the market if its data is unable to integrate with a previously existing legacy system or the larger manufacturing scheme. [451] The nuclear energy industry is an example of a field that expressed interest in more rapid, widespread adoption of other advanced manufacturing technologies (e.g., 3D-fabricated replacement parts for reactors) and has begun using ML algorithms to increase reliability and reduce errors through task automation, including the analysis of event reports and the identification of errors and procedure issues.[496, 497] However, ML algorithms require adequate data storage to successfully analyze large amounts of data and many NPP can encompass outdated technical equipment with limited random access memory (RAM) space.[125] Industry experts explained how the qualification of new manufacturing processes can require significant amounts of testing data to demonstrate performance prior to implementing in the nuclear environment, which can be costly and lengthy.[444] Thus, this would require detailed planning, adequate data and storage, and lengthy testing to avoid challenges with data integration and possible NPP downtimes.

Process standardization was identified as an additional concern that is often associated with data and system integrations. When data transmission occurs over a diversified range of communication sources, challenges can arise and be attributed to the lack of standards that dictate common communication practices.[177] Advanced manufacturing technologies, like DTs, are having challenges with adoption because current implementation processes lack consistency and have limited interoperability across their applications.[263] DL and ML also experience challenges with data fusion scalability because the manufacturing systems and cyber resources (i.e., computation resource) may not operate harmoniously since data is collected from differing systems.[498] DL algorithms experience poor interoperability because they require high volumes of data and substantial computing resources to train their algorithms.[121] Challenges with effective data interoperability or communications can negatively impact manufacturers if they are unaware of how to approach initial integrations.

Stakeholder-Suggested Solutions: To address challenges experienced by industry regarding data interoperability and integration, the following solutions were suggested by industry stakeholders:

- Invest in upgraded manufacturing equipment/software to avoid end users from turning off applications when not in use and ensure manufacturing data is current and available for OEM compliance. [499]
- Use edge computing methods to move the data processing closer to the data collection point while limiting the cloud to tasks that do not require immediate action.[500,501] In addition, applications with stringent latency requirements can be enabled by utilizing edge computing.[502]
- Use distributed computing to spread processing power across multiple locations, servers, or pieces of equipment when systems experience high capacity.[503]
- Engage with external organizations (e.g., industry, academia, other regulators, international, technical laboratories) to collaborate and share recent advancements, research outcomes, technical data, operating experience, and lessons learned.[444] See Section 5.1.1 for additional collaboration and engagement suggested solutions.

Potential for Adaptive Model Drift: Even if adaptive models receive high quality training data, they can begin to drift upon integration into the manufacturing process and begin to receive production data. [504] Model drift is a decrease in the model's performance, leading to inaccurate predictions over time that may occur due to changes in data collection or changes in the relationships between variables in the model.[505] Over time, this decrease in performance can limit the trustworthiness of a model and require periodic retraining to limit the potential for inference degradation. When model drift occurs during production, several options are available for organizations: online learning (updating the model in real time), periodic retraining (training the model with recent data when performance decreases), retraining on a subsample (leveraging human experts to select a representative subsample of the population and training the model on the data), or feature dropping (testing the individual features of a model and removing the features that are the most inaccurate). However, organizations must be cautious when determining when to intervene and retrain a model as incorrect assessments can be the basis for important decisions and unnecessary retraining can take up valuable resources and increase the risk of downtime.[506]

Stakeholder-Suggested Solutions: To prevent model drift from occurring or to reduce the impact of it, the following solutions were suggested by industry stakeholders:

- Organizations can set the model back to its original baseline by retraining the models or retaining the model using production data.[132,146,507]
- Those utilizing production data generated from the manufacturing process can leverage other advanced manufacturing technology by integrating automatic data capturing systems in their connected ecosystem to allow for real-time and error-free collection.[508]
- To help organizations identify when model drift occurs, the ISO/International Electrotechnical Commission (IEC) 23053:2022 "Framework for AI Systems Using Machine Learning (ML)" requires that manufacturers monitor their model performance and retrain the model as needed so it generates consistent and accurate outputs.[132]
- Pretraining a neural network with domain knowledge of prototype systems and having the model utilize the system to generate new predictions can help industry avoid retraining a model.[509,510]

Best Practices

Validate and Test Quality: Effective performance of advanced manufacturing technologies requires large quantities of reliable and unbiased data, and manufacturers note the importance of data quality for ensuring that these technologies operate correctly. This is especially important when beginning to train an AI model. Utilizing high quality test and validation data is necessary for these models to achieve optimal performance and should be entirely unique from training data to maximize accuracy.[404] Conducting routine quality audits of these data and of production data can also promote consistent performance and provide organizations with valuable insights to inform their policymaking and to monitor equipment usage as processes and systems change.[177]

It is also important that organizations conduct process validation and evaluate their production data to confirm processes operate consistently and meet specifications and quality standards. Process validation involves monitoring performance indicators to validate that the process is continuously functioning correctly, determine if there are any deviations from the applicable performance specifications, and identify opportunities to optimize process parameters for reduced cost and improved efficiency.[511] With some advanced manufacturing technologies, process inputs (e.g., number of parts per build, size of parts) can be variable compared to traditional manufacturing techniques (e.g., injection molding). When conducting process validation for these types of technologies, organizations can run tests to determine a "worst case build file" to determine how changes to different variables (e.g., horizontal printing compared to vertical printing, smaller prints compared to larger prints) affect product quality. These tests can then help organizations identify what range of settings produce the desired product and enable them to monitor ongoing production and use generated data to continuously validate the process.[512]

Use Orthogonal Data: Using orthogonal data (e.g., process data, image data) can improve reliability and model accuracy.[226, 513] If these data cannot be obtained from different sources, the ISO and the IEC published ISO/IEC 23053:2022 "Framework for AI Systems Using Machine Learning (ML)," recommends training data or test sets have a statistical distribution consistent with that of the production data for the model to make accurate predictions.[132] Housing these data in a high quality database (e.g., one that minimizes redundancy to save resources, protects accuracy of information, safeguards access to data, fits its intended purpose) can also help industry and researchers to assess the validity and accuracy of data and models and compare different methodologies.[514, 515]

Integrating data from multiple different sources can provide organizations with a more accurate real-time assessment of their production line and improve their ability to forecast and respond to supply and demand changes.[516] It can also improve the robustness of ML models and decision making of digital systems.[504] Effective and robust data gathering is essential in configuring context-adaptive, decision support-connected systems that continuously supervise production processes.[137] Further, having access to large amounts of data from heterogenous sources can help organizations more effectively monitor, analyze, and improve processes. Industry can also use the data to apply optimization techniques that can enhance production (e.g., machine maintenance scheduling, product quality, use of resources).[184]

Organizations have also utilized various software sets (e.g., capacity requirements planning systems, manufacturing execution systems, computerized maintenance management information systems) to gather data from across their production line. Organizations have used this data in a variety of ways to improve their monitoring capabilities and production performance. As illustrative examples, this type of data collection enabled Kia Motors to reduce their production times and improve their ability to forecast maintenance costs and failure rates; National Engineering Industries Limited gained more visibility of their shop floor, production line, and enterprise performance; and Deutsche Bahn used their data to improve their ability to predict equipment failures, resulting in a 25% reduction in maintenance costs.[517]

Standardize Data: Industry developed methods for cleaning and structuring data to make it usable. Proactive measures to standardize data and system process parameters have helped organizations improve their ability to integrate systems. This includes standardizing the formatting, terminology, and syntax of common data captured from different technologies; defining and following data collection methodologies to improve consistency and reusability; and leveraging existing and validated concepts where possible.[518]

After the data is cleaned and structured, there is often necessity to merge data sets. One method involves uploading data to a computing platform and utilizing a software library to prepare and merge the data. Domain experts can then leverage their expertise and statistical inferences to review the prepared data and identify and remove outliers deemed anomalous.[519] Another method combines ML algorithms with asynchronous tasks (e.g., root cause analysis, prognosis estimation, recalibration of the applied ML model) to gather data from in-situ monitoring systems and identify meaningful correlations between designs, process parameters, and post-process analysis.[148,520]

Literature expands and confirms the needs for additive manufacturing material databases, especially for characteristics of steels, titanium alloys, ceramics, and nickel alloys, as these materials are gaining popularity in various industries (e.g., aerospace).[115, 521] NIST researchers recognize the need to standardize data to facilitate data interoperability through a common data dictionary (CDD) and common data model (CDM) to enable additive manufacturing scalability and sustainability. They highlight that specific needs include a data structure that is supportive of data sharing throughout the technology life cycle, and a system for accessible data interoperability. After appropriate integration, these data can modernize additive manufacturing process development.[522] NIST's Information Modeling and Testing Group is a specific working group focused on planning, testing, and maturing models for a variety of datasets and computer languages. Overall, these efforts assist in consensus standards of additive manufacturing data models in a shared public repository for an allied additive manufacturing community.[522] In response, NIST has created their own Additive Manufacturing Material Database (AMMD). This database includes material specifications for two types of nickel alloys, but currently does not provide material specifications for other types of materials (i.e., metals, ceramics, or polymers).[523]

Integrate Technologies and Their Data*:* Enabling technologies and their data to communicate with one another can generate additional value for industry by establishing an intelligent system capable of better anticipating and resolving issues and continuously learning and improving. According to a PwC Pulse Survey, investing in cloud-based enterprise is a top business priority for Chief Information Officers. Migrating data to an entirely new system can be a risky investment. Rather than permanently moving data to an entirely new system, business leaders are connecting their old legacy systems with modern systems to drive innovation.[524] Enterprise-resource-planning systems can manage data from various systems, allowing for a centralized data collection and transparent data that can be used for planning, scheduling, and performance.[525] Several companies have leveraged interoperable systems and data to help improve their production processes using novel advanced manufacturing technologies. For example, Siemens utilizes IEC 62541: "OPC Unified Architecture" to improve the communication between different automated industrial systems and thus increase productivity and reduce downtime.[526,527] General Electric also leverages IEC 62541 and an edge-to-cloud software platform connecting various machinery to streamline their supply chain and improve the effectiveness and maintenance of equipment.[526,527] Interoperability has been shown to encourage adoption of new technologies and can help organizations overcome the limitations of individual technologies.[528] Recently, a growing number of organizations have leveraged the greater networking power of 5G and moved from cloud computing to edge computing to reduce data latency and enable real-time analysis. This helps to promote safe operation of autonomous vehicles; improve security systems (e.g., video monitoring, biometric scanning); and support predictive maintenance, customizable production, and smart manufacturing initiatives.[529] See above in System Data Integration for reference to edge computing as a suggested solution.

Considerations for FDA

New technologies both require and generate increasing amounts of data (e.g., sensor data, image data). Data integration, security, and surety aspects of submissions will be relevant as they become more prominent manufacturing operations features. Working with industry group on guides for legacy systems integration and standards for validation and testing of models has been shown beneficial in other industries.

Receiving quality and accurate data and information is essential in the regulatory review process. Anticipating changes may be a consideration for data systems, data management, and data security—to read, interpret, and assess the incoming data from submissions. Especially as the data become increasingly complex and voluminous with novel technologies.

5.2.2 INTERPRETABILITY OF OUTPUTS

Best Practices

Understand and Validate Outputs**:** It is helpful for business leaders and data scientists to understand and be able to explain ever-growing complexities of advanced technologies and their capabilities and outputs.[530] Within the world of AI, "explainability" is the concept of ensuring the model and its outputs can be explained, understood, and trusted. This helps users determine if the model meets its expected impact and if there any potential algorithmic biases to consider. Explainability helps validate that the model is accurate, fair, and transparent and can be used to adhere to any requirements or regulatory standards applicable.[531] Other considerations for validating models can include ensuring the model has reproducibility (i.e., data outputs are consistent every time the same inputs are used), replicability (i.e., ensuring that the outputs are consistent across studies with different data inputs), and external validity (i.e., ensuring that the outputs are representative of the population and the model's context of use). Assessments and certifications establish validity, and also evaluating the validity of the assessments themselves to the intended context of use helps ensure that AI/ML is used in a trustworthy and ethical manner.[532]

NIST offers a series of principles that state how AI should provide explanations for its outputs or processes that are meaningful and understandable to the intended user and provide the correct justification for why the AI-generated an output or performed in a certain manner. The principles indicate AI should only operate as intended and when it has sufficient confidence in its outputs.[533] NIST's recommendations can apply to other aspects of advanced technology usage and governance to help make it easier for industry and their stakeholders to understand how new technologies operate and why they produce certain outputs.

Understandable, meaningful, and reliable outputs are important for improving rates of adoption and acceptance among industry, as well as making it easier to assess the performance of the technology and troubleshoot as necessary.[513,534,535] Manufacturers and their workforce can benefit from understanding how advanced manufacturing technologies operate and the value and meaning of their outputs. For instance, there are a variety of ML models, but choosing a suitable model for each application requires extensive knowledge of the process, application, and confines of the model. Therefore, organizations may utilize simpler models featuring easy interpretability which can be scaled up or made more elaborate over time. Interpretation is necessary for industrial process operations to function, and industrial personnel tend to trust first-principle models more than data-driven models, not because they are more accurate, but because they are more interpretable.[513] Additionally, operators and decision makers may find it crucial to establish a level of trust in the technology before they are willing to accept it, so a stepped approach may lead to greater willingness to adopt the technology and its outputs.[513]

Integrating computational design into production workflows, connecting computational design tools, and leveraging centralized information tools have also allowed organizations to design, collaborate, manufacture, and operate with greater efficiency and quality of outputs.[536] Connecting sensors to existing digital networks can augment the usability of available data on outputs and allow organizations to create more robust models that they can update automatically with minimal input from users.

***Monitor Processes*:** Many organizations across industry have integrated advanced manufacturing technologies in their production lines and installed methods to continuously monitor the quality and consistency of finished products. Should a technology malfunction, organizations may find value in having prepared strategies to mitigate any potential negative impacts and correct the issue. These methods can help organizations monitor if the technology is operating correctly and that outputs are meeting quality and performance specifications. Many manufacturers have found it necessary to conduct post-production tests, especially on products that are created using new technology, to evaluate the mechanical and structural characteristics of finished products and to develop simulations and models of their products, assessing the conditions leading to defects.[537,538] These conditions may include stress evolution, high cycle fatigue, and temperature, among others.[537,538,539]

It is also imperative to understand the critical factors of a technology that affect manufacturing quality and what the appropriate responses are if an error or nonconformance occurs. Manufacturers may use a structured method, like a Failure Mode and Effects Analysis (FMEA), to identify and address risks and possible failures in the product or process before malfunction occurs.[540] Manufacturers have developed response strategies based on the importance of the equipment to the continued functioning of the operation. For instance, for non-critical equipment, the strategy could be operating to failure and then repairing or replacing the equipment once a failure occurs.

Considerations for FDA

Since manufacturers have expressed problems with prioritizing the types of data that is used for products, additional regulatory science metrics or tools could facilitate reporting and evaluation. In addition, there may be opportunities enhance understanding, guidance, and standards around the most effective methods to identify and address risks and failures with these new technologies before they occur.

5.2.3 DATA SECURITY

Challenges

Cybersecurity Threats to Network Infrastructure: Organization's network infrastructures are becoming more susceptible to cybersecurity attacks, which inherently compromise data security and impede the implementation of internet-based advanced manufacturing technologies.[149] A manufacturer's facility can encounter different attacks (e.g., distributed denial of service (DDoS), physical, eavesdropping, malware, ransom, phishing) that can negatively impact the proper functioning of the facility's sensors, network servers, gateways, or technological devices.[541] Manufacturer facility network infrastructures may unknowingly be more susceptible to risk when they have outdated firmware, insecure network protocols, or hardware components. However, manufacturers may not regularly update their hardware and software due to a variety of factors, such as cost, time, or expertise. The following illustrative examples highlight different advanced manufacturing technologies that exhibit security risks for industry's network infrastructures:

- Smart manufacturing technologies connect production systems to larger networks or the internet in ways that they previously weren't, exposing them to cyberattacks from external parties;[80]
- V2G's underlying infrastructure can experience security challenges due to limited communication ranges, vehicle mobility and the amount of daily trading data over vehicular networks;[321]
- Smart sensors and robots rely on network connections to operate and can become susceptible to infiltration due to their dependency of network connections to operate;[27]
- AI models may obtain or depend upon datasets containing personal and/or private data, which can be impacted as a result of cyber hacks;[163] and
- Due to heavy reliance on network integrations between systems, automated, cloud, and smart manufacturing technologies can experience increased cybersecurity risks and vulnerabilities[28,38,82]

Stakeholder-Suggested Solutions: To address issues identified regarding data security, industry stakeholders have suggested the following solution:

- Investigate antivirus software thoroughly before installation to prevent potential non-malicious network filtering which may cause process failures.[490,542]
- Leverage advanced cybersecurity tools to improve data security solutions. Advanced software tools (e.g., AI-based solutions) can reduce cyber risks in connected systems, better control data sharing, detect threats, and defend systems against cyberattacks.[543] Organizations can also use AI techniques to improve smart detection and prevention mechanisms.[544] Connecting these technologies to one another and amalgamating their data can provide additional security capabilities and allow suppliers to maintain continuous custody over sensitive information, machines, and material, in addition to enhance their ability to verify end-use and end user of sensitive capabilities.[545]
- Utilize privacy-preserving architecture that balances data collection and processing capabilities with safeguards to protect data privacy if data is regularly shared externally (e.g., across other centers or with supply chain partners). Several different architecture types are available to fulfill these needs, including privacy by design (incorporating privacy measures into the system to promote privacy as a core principle and integrate it into its build), differential privacy (adding noise to the data to prevent specific individuals or components from being identifiable but maintaining the original dataset's statistical properties), and homomorphic encryption (allowing encrypted data to be used and processed securely without the need for decryption).[546] These approaches can allow an organization to secure the privacy of their information and their systems in the development of ML models or when sharing this data with others.

Best Practices

Establish Proactive Cybersecurity Approaches: Proactively implementing system security measures can help an organization secure their valuable and sensitive data. Organizations can conduct risk assessments on their systems and ask their supply chain partners and collaborators do the same.[296] Many government agencies have provided such guidance to manufacturers—requesting a focus on cybersecurity resiliency and data protections. For example, the Cybersecurity and Infrastructure Security Agency (CISA) provides guidance to the manufacturing sector and recommends manufacturers conduct comprehensive risk analysis, allocate personnel and resources for security, establish and maintain partnerships with federal, state, and local officials, and seek out relationships with information sharing organizations and platforms. CISA's recommended practices suggest that manufacturers focus on physical security, cybersecurity, personnel, and supply chain security.[547] NIST's Cyber Security Best Practice Guide provides targeted information to assist manufacturers in the protection of their manufacturing control systems and the integrity of their systems, information, and data by providing guidance. The guide encourages organizations to safeguard their historical system data; block the execution of unapproved software; identify any unusual behavior in the network and any hardware, software, or firmware alterations; support secure remote access; and authenticate and authorize safe system users.[548]

Industry also recommends various strategies that manufactures can use to proactively protect their systems and networks. For instance, organizations have found best practice to institute authentication controls and consider a "zero-trust" model for data and network access.[549,550] Regularly assessing whether cybersecurity software and countermeasures (e.g., encryption protocols, firewall signatures) are up-to-date can help organizations maintain a proactive approach to cybersecurity and limit the potential for cyberattacks.[551] Frequently reviewing and adjusting user system permissions can further boost defense, and mitigation or incident response plans can reduce the response and reset time of a system that suffers a cyberattack.[543,552,553] Vulnerability analyses (i.e., identifying weaknesses in the network) or penetration testing (i.e., detecting of logic errors or weaknesses without damaging the system) is another best practice to identify data security weaknesses.[554,555]

Considerations for FDA

Data security and cybersecurity are topics FDA has been addressing for years and is continuously shaping guidance and knowledge to help address evolving issues. With each new technology employed in the manufacturing of products comes new challenges and issues. Other USG organizations, like CISA and NIST, provide specific data security guidance for manufacturers to help promote best practices and reduce risks. Staying ahead of threats and preventing malicious attacks is difficult given illicit entities are developing newer and more intricate ways to gain access to data and infrastructure. Continued and expanded exploration of data security risks, mitigation, and security measures across industries may be valuable to create consistent security requirements and expectations within and outside of medical products.

5.3 Economic Impact

The benefits of adopting advanced manufacturing technologies—such as greater efficiency, more consistent quality, and faster throughput—often come with significant upfront costs in the form of capital equipment purchases, changes to infrastructure, and additional workforce training. Understanding whether these new technologies can integrate into existing business plans and product lifecycle systems, and how their value may affect organizations in the short-term (e.g., supply network adjustments) and the long-term (e.g., material waste) can help industry develop their technological strategy and plan their implementation approach. The potential for continually increasing efficiency and scalability with advanced manufacturing technologies can lead to compounding long-term benefits for an organization that far outweigh the initial time and funding investments.

5.3.1 VALUE PROPOSITION

Challenges

***Adoption Costs Can Outweigh Perceived Benefits**:* While interest in advanced manufacturing technologies has grown across industries in recent years, findings suggest associated costs remain a challenge. One non-regulatory agency noted manufacturers may not view adoption of advanced manufacturing technologies as productive if they are unable to observe significant changes to their output or processes following implementation.[451] Transitioning from traditional manufacturing techniques can be challenging due to familiarity of the existing equipment and material costs, despite advanced manufacturing's technological benefits.

As an example, for decades the chemical industry used certain batch reactors for manufacturing, but they are now looking to replace them with new reactor technology to improve the product yield of high value chemicals. However, manufacturers would be required to invest significant capital into the procurement and installation and understand that the reactors are depreciating assets with no resale value.[201] As such, some U.S. and Indian chemical manufacturers expressed concerns regarding investing in technologies with low TRLs and high uncertainty of long-term performance when they are already profiting from their existing technology. The cost, benefits, or losses associated with adopting a technology, which can prove irreversible, can impact decisions about the timing and further adoption.[136]

Input and Material Costs: Manufacturers have identified ML algorithms as an example of an advanced manufacturing technology that is beneficial but requires potentially costly datasets to train the ML models. Findings indicated that some manufacturers, who were unable to use internally gathered data and required real-world data, encountered challenges with costly training datasets and gathering data in a real-world industrial setting.[148]

Implementing ML models can be an expensive venture for organizations, and the various costs of implementation can relate to physical hardware capable of running algorithms; software to collect, analyze, and process data; labor to create and implement models; and data to train and validate the model. While the actual cost per model will depend on the functionality, size, and complexity of model, the minimum cost for deploying and maintaining a model is estimated to be approximately $60,000 over the first five years. If an organization aims to develop an infrastructure capable of hosting additional models, the expected minimum cost can rise to $95,000.[556]

If not financially prepared, continuing data costs can possibly deter organizations from implementing ML into their existing systems. Manufacturers also identified additive manufacturing as an advanced manufacturing process that provides manufacturers with an increased variety of material inputs, 3D-fabricated part flexibility, and applications. However, they also noted that material costs are a challenge compared to the materials needed for traditional manufacturing.[557]

Regulatory Costs*:* The potential costs stemming from regulatory complexity may also deter small businesses from entering the advanced manufacturing market. Some regulatory agencies acknowledge smaller organizations may not have the resources to meet certifying standards, which can deter them from entering the market.[473] Babson College surveyed more than 1,800 small business owners (i.e., at least four employees and at least $150,000 in revenue) to gain feedback on the U.S. business landscape and regulatory environment. The survey results reported small business owners feel stifled by federal, state, and local regulations as they add costs and complexity to their operations. Business owners also expressed difficulty understanding government regulations and noted they typically have limited staffing resources to assist with understanding and complying with regulations. Survey respondents estimated dedicating over 200 hours per year toward addressing regulatory and tax compliance, which can be financially challenging since many respondents rely on financial institutions for funding and tend to receive less than half of their requested amount.[558, 559] Though larger organizations can also experience regulation compliance costs, a study conducted by the U.S. Chamber of Commerce on small businesses and regulatory impact indicated small businesses (i.e., less than 50 employees) may experience regulatory costs 20% higher than average for larger organizations.[560] The study cited an example highlighting how a greenhouse gas regulation issued by the Environmental Protection Agency (EPA) impacted smaller businesses 65 times more than their larger competitors.[560] If these smaller businesses are not financially prepared to bear these additional costs from regulatory complexity, the study noted monetary obligations derived from regulations (e.g., limited access to funding and staffing resources) can become a major challenge, which may impact their ability to adopt or scale up current advanced manufacturing technology efforts.

Stakeholder-Suggested Solutions: To address identified challenges with adoption and operating costs, stakeholders have suggested the following solutions:

- Conduct efficient planning and financial analyses to prepare for investments needed to implement advanced manufacturing technology (e.g., adoption, maintenance, upgrade costs).
- Conduct cost-benefit analyses prior to implementing to gain a better understanding of the return on investment, in addition to gaining buy-in and support for advanced manufacturing adoption from top management.
- Determine if advanced manufacturing technology adoption should occur in a phased, iterative approach or in a larger scale project to better understand the financial requirements needed upfront and throughout.[561]
- Foster opportunities between smaller manufacturers and regulatory bodies to provide guidance on regulatory frameworks and gain insight on the obstacles smaller- and medium-sized organizations may experience when implementing newer technologies.[446]

Cost of Maintaining Equipment*:* In addition to the costs of implementation, the installation and configuration of equipment and needed system upgrades to house and operate new technologies can present continuing challenges. For example, within the agricultural industry, if an organization implements an advanced technology (e.g., in-situ sensors for crop monitoring during growing season), a study found that installation and removal expenses were costly and labor-intensive both before and after growing season.[136] Despite observed benefits, some industry stakeholders may be less willing to spend additional money on the resources needed to implement and maintain new technologies or prefer existing technologies where costs and maintenance procedures are better understood. Within the agricultural industry, findings suggest some farmers may decide to continue utilizing traditional farming equipment (e.g., tractors, harvesters, plows) where costs, performance, and equipment maintenance are more familiar and better understood. Some farmers sought to avoid the potential burden of maintaining more elaborate, computerized equipment or having to integrate new equipment that may require frequent upgrades.[562] As findings suggest, scheduled equipment upgrades can increase financial obligations and lead to uncertainty within organizations when determining whether to adopt a technology.[117]

***Hiring, Upskilling, Reskilling Costs**:* In addition to the price of equipment acquisition and maintenance, securing a skilled workforce to operate advanced manufacturing technology can increase the cost of adoption. Organizations are making huge investments to hire, train, and retain qualified employees capable of operating advanced manufacturing technologies.[563] For example, organizations have identified several technical domain experts (e.g., data scientists, AI engineers, data engineers) as necessary to upgrade their systems to incorporate AI-enabled industrial processes into their current operation.[564] AI technology implementation can include the cost of upgrading existing machinery, digitization of manufacturing equipment, and hiring and training employees to effectively operate advanced manufacturing technology.[121] Despite the benefits that may come from implementing advanced manufacturing technologies, findings suggest manufacturers are having to decide if those benefits are worth the financial commitment. Costs associated with obtaining, upgrading, and maintaining equipment; hiring skilled personnel; and providing workforce training were shown, in some instances, to negatively influence the adoption rate of advanced manufacturing.

Best Practices

***Conduct Cost-Benefit Analyses to Assess Return on Investment*:** When looking to integrate a new advanced manufacturing technology into their production process, organizations have found it helpful to demonstrate how it works and its relative advantage over the existing technology or process to gain trust and generate support from their internal and external stakeholders. Understanding the potential benefit of a new technology and whether it can effectively address a business problem or integrate into existing systems can promote implementation and adoption.[131,136,565] For instance, the developers of a mobile platform that connects agribusiness stakeholders with their supply chain through big data applications found that developing meaningful and trusting relationships with users (i.e., purchasers) has been key to demonstrating value and increasing rates of adoption. The developers of this big data technology application partnered with agriculture cooperatives that had existing relationships with farmers to establish trusted pathways for collaborating with farmers and sharing information on the platform. This collaboration proved to be critical to attracting farmers to the platform and integrating them into the network.[566]

Cost-benefit analyses can also help executives determine the impact of implementation compared to the price of equipment, materials, and labor. While the initial costs of additive manufacturing can be high, depending on the industry, significant potential long-term cost savings have motivated organizations to adopt the technologies. For example, in the aerospace industry, the development of lighter parts can reduce fuel costs; and in the automotive industry, additive manufacturing enables the rapid development of complex replacement parts.[567] A NIST publication found that additive manufacturing is cost-effective for small-batch fabrication using continued centralized manufacturing and can become increasingly more cost-effective with more automated processes. NIST also found that organizations can leverage economies of scale if they adopt other new technologies with additive manufacturing equipment (e.g., smart systems) to compound the potential impact or if they adopt larger additive manufacturing setups to reduce the overall raw material cost.[568] Other new technologies and processes – such as those for advanced materials – can reduce the cost of production and the need for a large inventory, as well as downstream costs, due to their increased efficiency and reduced emissions.[20] Green manufacturing technologies (as discussed in 4.2.9) are another example in which cost-benefit analysis can be critical. One study indicated an association between corporate green investment (CGI) and profitability—that infusing greening activities into corporate sustainability goals and practices can improve corporate reputations, in turn, enhancing long-term profitability.[569] Understanding these potential long-term cost reductions, compared to the upfront costs of adopting new technologies, can help organizations determine the feasibility of technological integration.

Employ a Flexible Approach*:* When implementing novel advanced manufacturing technologies, taking an overall flexible and adaptable approach to evolving and variable needs can help create a smoother experience that is also economically efficient and can bolster its value proposition. The DoD uses an approach for their plan to modify and adopt policies for additive manufacturing across technical and business processes—to increase agility and incorporate new developments in machines, materials, and technologies.[456]During interviews, a different government agency noted how they encourage organizations to use an agile mindset to capitalize on opportunities to implement new technologies.[473] That agility, or willingness to adjust, can be taken a step further in applying a formal Agile methodology or framework, which employs a rapid, iterative, feedback-driven process to gain competitive advantage. According to an interview with one professional organization, applying Agile frameworks to implementation is a practice many organizations are driving towards, both on the business and manufacturing ends.[570] A study by IEEE supported that sentiment, indicating a majority (58%) of respondents' organizational units are using agile and/or lean methods. While the use of formal Agile frameworks may be a best *business* practice to bolster value proposition, research for this report did not result in use cases with clear application of for *production* or *implementation* of products using advanced manufacturing technologies.

Considerations for FDA

Understanding the potential value of new technologies and connecting multiple technologies can help with making informed regulatory decisions. Incorporating and connecting a selection of advanced manufacturing technologies into existing research programs, labs, and facilities could provide additional insights into the advantages these new technologies offer and help to evaluate the effects of connecting these technologies and their respective data. Leveraging internal and external partnerships can be used identify and conduct assessments on new technologies to evaluate potential advantages and challenges organizations face when transitioning their systems to utilize new technologies. Best practices developed by industry, the government, or collaborations may help reduce the economic risk of adoption while maintaining safety and performance.

Industry has adopted adaptive management practices to make the implementation and scaling of advanced manufacturing technologies more efficient. This strategy may enable organizations to change their production methods quickly, but this also may affect the products on the market. If an approved product's manufacturing is going through a change management process, awareness and insight of how this approach and these changes impact the safety, effectiveness, and quality of the end product may be beneficial.

In addition, many organizations also had to research the competencies needed to safely operate these new technologies and shift their hiring strategy or implement training to reskill and upskill their workforce. Government can partner with industry in developing competencies that will meet regulatory requirements as well as use those competencies to help expand their own workforce to regulate novel advanced manufacturing technologies. There may be additional ways to help small businesses more easily understand guidance documents and implement requirements to ensure medical product safety and efficacy. Small businesses may not have the resources needed to properly comply with regulation on new technologies, placing them at a competitive disadvantage.

5.3.2 SUPPLY CHAIN RESILIENCY

Challenges

Resource Limitations*:* An organization's supply chain resiliency– including its ability to navigate supply chain ecosystems and access to supply chain resources (e.g., data, raw materials)—can greatly influence its efforts to implement advanced manufacturing technologies. For example, automobile and electronic manufacturers have been challenged with meeting the demand for semiconductor chips. [571] Chip manufacturing can take several months and is costly due to the time and resource expenses needed to build the factories. An additional limitation with chip manufacturing is that it is primarily off-shored from the U.S. and reliant on a small number of companies that produce the chips. For example, over 70% of semiconductor manufacturing is completed by TSMC in Taiwan and Samsung in South Korea. [572] This indicates that any supply chain disruptions or an increased demand for chip manufacturing heavily affects the rest of the world as they are dependent on a few companies to produce chips. Findings also indicate that some smaller and/or newer manufacturers have experienced issues gaining access to supply chain ecosystems and struggle with long material lead times, making it difficult to plan for material availability.[445,571] These supply struggles can make it difficult for organizations to scale up production or maintain consistent supply.

Stakeholder-Suggested Solutions: To overcome initial challenges with supply chain readiness and resiliency, semiconductor manufacturers are discussing the following suggestions:

- Consider focusing on supply chain impacts for determining when, where, and products are manufactured, especially as it relates to national security or international dependency.[573]
- Foster transparency in industry partnerships (e.g., semiconductors) to address shortages and improve supply chain resilience, with the intention of facilitating information flow between producers, suppliers, and end users.[574]
- Optimize current manufacturing equipment through the use of other advanced technologies, such as AI, to ensure equipment is well-maintained and supply chain disruptions are minimized.[499]

Best Practices

***Focus on Supply Chain Resiliency*:** As consumers demand more customized services, organizations need to redesign their supply chain strategies across all key stages (i.e., manufacturing, packaging, and distribution) according to the needs of their consumers. Supply networks also need to evolve, and organizations need to bring in logistics and distribution managers to properly implement the necessary supply chain processes to make it consistent and sustainable.[575]

With the amount of data that advanced manufacturing technologies generate and utilize, industry can apply this data beyond their production processes and into their supply chain management practices. Organizations can use enterprise-resource-planning systems to collect and store data from across their production and distribution processes (e.g., planning, procurement, manufacturing, inventory management, warehouse management, order management). These systems enable organizations to better understand their supply chain operations and improve their ability to leverage data from across the supply chain.[576] One metal manufacturer implemented an enterprise-resource-planning system to connect data from their production line and supply chain with their accounting processes. The system enabled the manufacturer to leverage supply chain data for the creation of production, purchasing, and inventory schedules, which led to improved operations and reduced costs. In another example, a different manufacturer utilizes their enterprise-resource-planning system to monitor and control their supply chain, which enables them to track the quantity of materials used and the finished products produced as well as monitor the number of products that fail quality tests. This connected system has resulted in fewer errors and improved visibility of their supply chain.[577]

Integrating big data into supply chain management practices has the potential to help organizations achieve economic sustainability by improving the effectiveness of parameters like cost, time, and supply of materials.[578] While internal data can aid in this process, compiling data from across the industry may offer additional value. Access to data from national databases can help industry define and adjust performance requirements, as needed, to maximize the efficiency and effectiveness of their technology. Industry can consider collaborating with supply chain stakeholders to identify and overcome common challenges, helping to mitigate existing barriers to market.[475]

Despite the potential benefits of utilizing big data for supply chain management, developing a supply chain capable of hosting advanced manufacturing technologies may require suppliers with resources and infrastructure that can handle the demands this amount of data would put on systems.[451] As organizations incorporate new technologies into their production processes, understanding the potential needed adjustments internally and across their supply chain (e.g., need for other technologies, increased material demand, infrastructure improvements needed for interoperable and scalable systems) can help organizations be more prepared to meet consumer demand. Many modern manufacturing and logistics technologies may also require custom-designed supply network monitoring, resilient factories, advanced decision support systems, resilient production networks, adaptable workstations, and shared operational control to create sustainable supply chains.[136] One healthcare company upgraded its enterprise-resource-planning system to improve its supply chain service, but it only saw improvements after it made complementary improvements to its demand forecasting system. One consumer goods company saw their supply chain service improve upon adjusting its operational strategy, but the company and its suppliers did not have the technologies needed to support the changes and thus saw its service level decline to its original level. These examples show that integrating new technologies into the supply chain requires appropriate adjustments to both operational strategy and technological capabilities.[579] Proper technological and operational planning have enabled organizations to make data-driven decisions in their supply chain and provided a competitive advantage over their competitors that lag in adopting new technology.[580]

Understanding the impact of new technologies, regularly conducting internal supply chain resiliency assessments, and leveraging analytical tools to identify efficiencies in the supply chain (e.g., procuring or transporting goods closer to the end consumers) can better prepare organizations to respond to rapid changes in supply and demand. Such tactics enable organizations to be dynamic in their supply chain management strategies and utilize advanced manufacturing technologies to respond to fluctuations in supply and demand. Manufacturing processes that are agile (e.g., able to respond to supply and demand fluctuations), lean (e.g., optimize production cost and product quality), and predictive/controllable (e.g., able to forecast and manipulate the production processes as needed) can help promote supply chain resiliency. Organizations embracing agile manufacturing approaches have demonstrated improvements in their business performance, but those also utilizing big data and business analytics demonstrated even greater improvements.[581] Organizations can integrate data from their suppliers with cloud computing and big data technologies to spread this resiliency across their supply chain.[38] Cloud computing enables scalability so organizations can efficiently adjust their resources based on the current demand and offers organizations tailored solutions to meet their needed capabilities, such as the ability to leverage ML capabilities and improve the accuracy of demand forecasting.

Identify Opportunities to Shorten Supply Chains: Shorter supply chains with more agility and greater diversity in operations can help organizations maintain a consistent supply of products and keep up with demand. Organizations can shorten their supply chain by reducing the number of steps involved in the production and distribution of end products and by focusing on sustainable and local materials and production processes. Research indicates some organizations have found success in emphasizing greater supply chain digitization, as well as relocating and reshoring their production to bring the process closer to their consumer base. These successes been accomplished by creating greater internal alignment to stakeholder responsibilities and creating solid financial and operational plans that are aligned at all levels of the organization.[582] Other organizations have found success using a multi-pronged approach that involves evaluating the performance of suppliers, identifying potential opportunities for consolidating suppliers, leveraging data and cloud-based systems to improve the efficiency and reduce the complexity of communication and information flow, and assessing metrics (e.g., delivery time, inventory levels, production costs) to identify areas in need of improvement.[583] Shortening the product lifecycle can enable more rapid responses to market changes and allow manufacturers to develop more modularized, flexible, and responsive design, manufacturing, and service processes.[466] Additionally, when supply chains are shorter, organizations can perform response planning (i.e., assessing upstream product demand to inform production) to enable faster production and review cycles, as well as improve their ability to respond to changes in demand.[584]

Organizations can also “shift their production process to the left” (i.e., validate the manufacturing process sooner to accelerate production readiness and shorten the production cycle) to help ensure alternatives are available and that alternatives meet the needed specifications and performance requirements to replace the original if a shortage were to occur.[585] Organizations may invest in the supply of their needed components and alternatives to limit supply chain disruptions and invest in capabilities to react to disruptions as needed.[571]

***Localize Suppliers**:* Many supply chains have also become globe-spanning networks of suppliers and consumers, which led to significant shortages and supply chain disruptions during the coronavirus pandemic. As a result, many organizations have had to reconsider their previous supply chain management practices to better prepare themselves for future supply chain disturbances. Some organizations have broadened their network and incorporated additional suppliers to limit the risk of a complete supply chain slowdown should one supplier face a disruption. Others have continued the pre-pandemic trend of decentralizing production and moving it closer to their intended markets to improve service and reduce the risk of distribution disruptions.[586] Implementing new technologies can help these organizations become more resilient, such as cloud computing to more efficiently store data, AI to improve decision making and distribution of materials, and manufacturing robots to automate processes and reduce the potential for a supply shutdown should a disruption prevent workers from being on the production floor.[587] Experts have also advocated for organizations to emphasize flexibility in their production, which can be done by investing in materials and facilities that can be repurposed and by training workers in multiple skills to enable more efficient redeployment when changing production lines (see Section 5.6.1 for additional information on workforce cross-training and upskilling).[586]

***Emphasize Agility in the Supply Chain**:* Adaptive and sustainable production systems that allow organizations to monitor demand enable quicker responses to disruptions (e.g., product changes, alterations to operational parameters). Making manufacturing systems self-adaptive (i.e., able to adjust the production structure in real-time in response to its environment or product and operator features) with variable demand can improve the deployment of these technologies and lead to lower costs with greater outputs, even in disruptive production environments.[136,588] One approach to a self-adaptive supply chain aimed to digitize all data across the supply chain, shorten order lead times, and reduce inventory levels for a medium-sized organization. The researchers developed the architecture to meet these needs, built a system that utilized interconnected smart objects to perform automated data processing for each department (e.g., purchasing, production, transportation), and allowed each department to analyze and share data independently. Meanwhile, the system continuously monitored customer orders and calculated their impact on the inventory levels of goods to determine when it was necessary to increase production. As a result, the accuracy of forecasts increased by 13% in five consecutive months, lead times decreased by more than two weeks, and the costs of storage fell.[589]

***Consider Benefits of Blockchain Technology*:** Logging transactions along the supply chain as organizations continue to adopt new technologies and acquire additional data has become increasingly more complex, which has made blockchain technology appealing to industry. Blockchain is a distributed ledger that provides a digital database for recording all the transactions of the supply chain (refer to Section 4.5.4 on Blockchain). The use of blockchain technology can establish a digital database of transactions across the supply chain and make it easier for manufacturers to monitor the supply chain, which can limit interruptions and improve efficiency. This method has become more widely adopted in food (e.g., wine, tea, restaurants), agriculture (e.g., eggs, soybean farmers), and healthcare (e.g., pharmaceuticals) sectors due to its traceability system and enhanced data sharing capabilities.[590] The Defense Advanced Research Projects Agency (DARPA) has also been experimenting with blockchain technology in battlefield operations due to the technology's efficiency, robustness, and security,[591] as has the North Atlantic Treaty Organization (NATO), who used blockchain to secure military supply services.[592,593]

One non-regulating government agency suggested blockchain technology can also make it easier for the government to track certifications for suppliers.[446] Regulators currently manually track suppliers when certifying additive manufacturing processes for second- and third-tier suppliers.[446] This method is labor-intensive and costly for government agencies, but the digital database that blockchain technology generates can allow organizations to share this information with regulators to facilitate a more efficient and timely certification process. As the structure of blockchain technology allows for traceability, transparency, and trustworthiness through the irreversible tracking of information that is validated through the network, blockchain provides a governance structure that is a trusted and secure source of information that regulators can utilize.[594,595] With a more connected and increased global supplier network, blockchain technology allows end-to-end tracking through the product lifecycle—from material procurement through when the product reaches the end user. This traceability allows manufacturers to ensure that products meet required standards and provides more control over suppliers and contractors. For example, Renault, an automotive manufacturer, integrated a blockchain solution into the manufacturing process allowing them to easily share and oversee compliance standards across their entire supplier network.[596] During an interview, one non-regulatory government agency stated that they are focusing on the concept of traceability within the supply chain using blockchain technology to provide provenance through the entire lifecycle until the product reaches the customer and noted that traceability requirements have increased recently.[446]

Despite findings identified with blockchain performance limitations (see Section 4.5.4 on Blockchain), blockchain best practice applications include its ability to be developed for operation without any human intervention, which is known as a Decentralized Autonomous Organization (DAO). Bitcoin is a current example of a DAO that is autonomous and automatic.[597] In addition, blockchain began integrating uniform governance in its "adequate minimum viable ecosystem" where industry partners have certain uniform approaches to "publishing, capturing, and interpreting the data stored and accessed." This allows for decreased complexity of industry participation as blockchain is increasingly used within industry supply and service chains.[598] Integrating blockchain-based smart contracts into the supply chain saves time and resources; minimizes impacts to the manufacturing process; and simplifies the supply chain by providing data, documentation, and regulatory transparency.[597] Although decentralization is built into blockchain technology itself, there are still many opportunities for regulators to interact with the process, especially within cryptocurrency. Research indicated the U.S. Government Accountability Office (GAO) identified regulatory gaps and proposed recommendations for legislation providing federal oversight of blockchain technology, all of which have yet to be addressed.[599]

Considerations for FDA

Collaboration between advanced manufacturing efforts and supply chain efforts to share knowledge on how industry can use novel advanced manufacturing technologies to build a more resilient and agile supply chain may help generate valuable insights to promote the adoption of advanced manufacturing technologies, as well as support the safe development of products and a more resilient supply chain. This may also be done by hosting public information sessions aimed at eliciting challenges and best practices organizations have identified when utilizing advanced manufacturing technologies in their supply chains. These sessions can help inform oversight of the product supply chain and provide critical insights to drive future guidance and recommendations for industry. Holding events such as symposiums for products may help to provide the opportunity to share knowledge and help inform ongoing efforts to promote supply chain resiliency.

5.3.3 SHORT- AND LONG-TERM IMPACTS

Best Practices

***Evaluate Economic and Environmental Sustainability and Impact*:** Although it may be tempting for organizations to focus on short-term gains, it is also important for organizations to understand the long-term downstream economic and environmental effects of these technologies. For many organizations, their decision to implement these new technologies may depend on the potential of increasing returns and reducing risk and uncertainty.[136] One best practice organizations have found helpful is to conduct a vulnerability assessment to identify potential risks (e.g., shipping hazards, environmental effects, potential for natural disasters) and to develop corresponding mitigation strategies that promote sustainable and environmentally conscious decision making.[600]

Industry may also attempt to understand the economic and environmental implications of new technologies and minimize material consumption by utilizing data processing technologies and AI to improve decision making and make production more resource and environmentally efficient.[601,602] Organizations can reduce their material waste by optimizing manufacturing process parameters, but they also need to consider how to properly handle waste.[603] Drones and robots have leveraged AI to identify types of production waste and proper disposal methods.[604] However, changing materials or production methods may necessitate a change in waste disposal processes. For example, during one interview, a government agency working with toxic chemicals shared that a small substance change may require a new toxicity profile, and that the potential impacts of these changes can help organizations protect workers and consumers and comply with material and environmental standards.[605]

Assess the Environmental Impact of Materials*:* Material recyclability is another key issue and organizations may consider the future sourcing of critical materials, as well as materials' environmental, economic, and social impacts.[605] Material recyclability requirements vary by country. Some countries mandate that suppliers manage their product's lifecycle through end-of-life mandates and view a material's recyclability as a critical factor for qualification. Meanwhile, other countries do not have any requirements or consider recyclability when qualifying materials.[606] Organizations have found it beneficial to leverage technology to comply with environmental regulations and local environmental requirements. For example, several recycling companies have begun to incorporate AI and robotics to improve the potential recovery of recyclable items and the speed of the sorting process. As a result, some companies have seen up to 30% increases in their recovered materials and large cost reductions. One of the companies utilizes 3D-depth sensing cameras on the recycling conveyor lines, feeds the images into an AI software to differentiate the types of materials and packaging, and then prompts robotic arms to retrieve recyclable materials.[607] Similar efforts in manufacturing facilities could help organizations further reduce potential material waste and offset the cost of labor through an automated solution.

Considerations for FDA

As innovations emerge, there may be additional considerations regarding the potential environmental effects of new technologies and advanced materials used in medical products. In addition, vulnerability assessments may help identify risks and provide insights into mitigation strategies that promote decision making.

5.3.4 HORIZON SCANNING

Best Practices

Define a Digital Strategy: Strategic planning for novel technologies and applications can allow organizations to quickly react to innovations. Organizations have established roadmaps that outline a structured approach to their horizon scanning strategy along with the potential steps for either implementing new technology into the production line or modifying existing technology for a new use. Having a well-documented roadmap can help organizations stay abreast of technological developments and allow them to focus their evaluation efforts on technologies that solve business problems or improve the organization's competitiveness and overall performance.[445,608] They can leverage this insight to make more informed investment decisions and increase production quality, efficiency, and resource allocation.[445] One example of a collaborative roadmap is the AMSC Roadmap, which aimed to accelerate the development of industry-wide additive manufacturing standards and specifications and helped facilitate the growth of the additive manufacturing industry.[12,609]

In addition to developing roadmaps, organizations have created information systems to monitor their investments and compare them to their technological focus areas. The U.S. Department of Veterans Affairs (VA) and the DoD have found success utilizing this approach with the VA's Research and Development Information System (RDIS) (which tracks the project lifecycle of VA research projects) and the DoD's Readiness Reporting System (which tracks the readiness of components intended for defense applications).[610,611] Such systems consider elements like MRLs and TRLs and have allowed organizations to more effectively assess the lifecycle of new technologies and find maturity gaps in existing enterprises.[612]

Gather Consumer Feedback*:* While it is important for organizations to monitor technological trends across different industries, it is equally as important to listen to their consumer's needs. During interviews, one private industry manufacturer noted the importance of having consumer needs motivate technological development rather than having technological development motivate consumer needs.[570] Placing value on consumer-driven needs can allow organizations to be proactive in their service and product offerings to better serve existing and future consumers.[499] Organizations can use a feedback-driven approach to better understand the experiences of their consumers and identify their preferences and pain points. Ultimately, the value of this approach lies in its ability to give organizations the insights needed to identify and respond to consumer needs, drive continuous improvement, and promote consumer satisfaction.

Considerations for FDA

Taking a coordinated approach, such as a roadmap that defines a vision for advanced manufacturing, can help bring together resources, support understanding of advanced manufacturing technologies, and aid in a consistent approach to regulation and oversight across the different product centers. Industries have found it beneficial to coordinate their advanced manufacturing strategy across business units to get the most return on investment or benefit. Ongoing collaborations with industry offer opportunities to focus on understanding challenges organizations face when integrating new technologies into their production processes.

5.3.5 SCALABILITY

Challenges

***Lack of Information to Inform Scalability*:** Missed opportunities to scale up advanced manufacturing implementation can stem from a lack of available information. Research indicated there is a need to address how the next generation of technologies will impact industries once adopted.[613] For example, AI-based industry solutions lack sufficient evidence that identifies successful industrial applications because organizations are not sharing the insights they gather from implementing and adopting AI-based technologies.[614] Professional organizations agree that manufacturers can demonstrate confidence in the technology through data proof capabilities, since the costs and investments geared towards advanced manufacturing implementation can be limiting factors.[570] Limited examples of real-world applications can negatively impact other manufacturers' perception of advanced manufacturing due to the number of unknown variables. If organizations cannot properly evaluate the advantages of advanced manufacturing technologies compared to traditional approaches, and if industry does not share lessons learned from implementing or scaling up advanced manufacturing technologies, industry may continue to experience challenges when attempting to maximize the full potential of advanced manufacturing technologies.

Impact of Regulation on Technology Innovation*:* Regulations can provide industry with guidance on best practices and QC methodologies. However, research showed that some regulations can lag technological advancements, which can create challenges when industries are attempting to find guidance and certification of innovative technologies. For example, GAO reported in 2018 FAA implemented Part 23 Amendment 23-64, a new performance-based regulation, which shifted from prescriptive design requirements to performance-based regulations for small planes. With performance-based regulations, required results are specified but no specific method to achieve the required results are prescribed. Performance-based regulations were intended to improve safety, reduce burdens of regulatory costs, and increase innovation and adoption of small plane technology. However, when attempting to review industry applications under the new regulation, FAA experienced initial design review delays due to staff uncertainty with application level of detail, lack of guidance, and insufficient training on new application review processes. Within the report, staff noted general content provided in training leads to application delays and potential inconsistencies with application review and processing. FAA reviewed the existing process and looked to provide staff more inclusive training to reduce delays and inconsistences, in addition to develop guidance materials to provide staff with sufficient information for small plane designs on application. Doing so would hopefully reduce application delays and ensure small plane designs are fulfilling FAA's safety requirements.[615] Insight on how regulation processes can act as an adoption roadblock can aid industry in understanding the realistic timeframes required for rulemaking and certification of novel technologies. However, until lengthy regulatory processes are addressed and rectified, industry-wide adoption may continue to be negatively impacted (*Refer to* Workforce Planning and Development *for more examples)*.

Stakeholder-Suggested Solutions: To address the challenges identified with regulatory impacts to technology scalability, the following suggested solutions were provided by industry stakeholders:

- Assess available training resources for regulatory staff to ensure proper guidance of Agency-desired objectives are captured and for application review staff to ensure a thorough understanding of review processes are depicted.
- Derive a strategy to collect, address, and share information gathered from staff regarding the guidance for newly implemented regulations.[615]

Customizability Creates Complexity**:** Customized technology was found to be beneficial for organizations when manufacturing products tailored to specific consumer needs. However, findings indicate implementing customized technology into existing production lines may force organizations to augment their manufacturing processes (e.g., design, manufacturing, distribution) to become more flexible and agile.[616] An academic institution identified 3D printing as an increasingly popular method for manufacturers to support the fabricating of customized end products during an interview. However, the interviewee explained some industries have better outcomes when additive manufacturing is used to fabricate spare parts on demand versus using additive manufacturing for larger scale customized production, which has been easier to achieve with more traditional manufacturing processes.[487] Similarly, research also indicates when attempting to manufacture customized end products, 3D printing is still limited due to operational and supply challenges (e.g., material access, software tools, production workflow) that may arise when shifting to a mass customized business model.[618]

More customizable technologies can present challenges for industry when updating or maintaining existing technology. For example, some organizations may prefer to designate support staff or processes to maintain equipment. In these cases, introducing a novel, more customized technology into an existing system can create issues with regular maintenance. Findings indicate customized technologies can potentially limit the number of knowledgeable resources available to conduct equipment repairs, thus making it difficult to maintain and modify new technologies.[617] This increased reliance on external parties for equipment maintenance may make organizations less willing to adopt new technology. Additionally, ML models may require specific datasets to be effective for organization-specific scenarios, but studies encourage industry to focus on creating more generalized models since over customization can limit their attractiveness for adoption.[124] For example, when using DL models for fault diagnosis, attempting to use the same model for similar, but not identical, scenarios can potentially significantly reduce the diagnostic accuracy.[228]

Stakeholder-Suggested Solutions: To address challenges identified for customized technologies, the following suggestions were provided by industry stakeholders:

- Assess the technologies currently used on the production line to determine the capabilities supporting customized product fabrication or identify whether new equipment is needed to properly execute manufacturing demands prior to adopting.[618]
- Explore possible use of indirect 3D printing with customized molds to overcome challenges with mass customized product fabrication (i.e., wax castings used for customized jewelry).[618]

Best Practices

Apply an Agile Methodology to Production: Utilizing an Agile methodology has been found to be beneficial when scaling additional supporting novel advanced manufacturing technologies, supplemental technologies, and equipment across production lines. Some technologies are more challenging or cost-/resource intensive to implement, so organizations have added flexibility through "plug-n-play" products that ease user adoption and provide them more control over process parameters and workflows.[424] Organizations have also initially adopted technology on a smaller scale to better understand its benefits and effects on outputs before deciding whether or how to scale it across their organization. This phased approach can improve the long-term feasibility of these technologies and help future adopters develop more effective implementation strategies.[619] One study suggests more flexible, agile approaches overall can help organizations better respond to dynamic environmental conditions in their technology implementation strategies.[620] They can use frugal engineering/innovation principles (i.e., creating quality solutions in a resource-constrained setting that are accessible to low-income consumers) to enable more agile technology implementation and promote greater personalization to meet consumer demands.[620,621]

Considerations for FDA

Emerging technologies have the potential to rapidly scale within an organization and across industry. Organizations have worked to maximize the value of new technologies by scaling them across their production processes. Sharing information between industry and the government can be mutually beneficial for both parties and enable them to learn from one another's experiences and improve their strategies for technological scaling. Reviewing scalability challenges for advanced manufacturing technology across industries can provide insight on roadblocks for sustained growth.

5.4 Standards and Controls

Many new technologies involve unique procedures or involve new materials that may be unfamiliar to staff and present potential hazards. Standards and controls help to create consistent processes and keep operations and staff safe. However, the novelty of advanced manufacturing technologies has caused some technologies and processes to lack widespread safeguards. Industry has worked to develop internal materials (e.g., standard operating procedures [SOPs]) and leverage existing quality assurance processes in the interim, but this can lead to inconsistencies across organizations without a nationally recognized standard. Additionally, emerging technology can have unique applications across different industries, which can make it more difficult for organizations that manufacture products or components for multiple end users to identify, understand, and abide by relevant guidelines. This can create industry-wide uncertainty and deter manufacturers from entering the market, thus delaying the rate of implementation and adoption of novel capabilities across the ecosystem.

5.4.1 CONSISTENT GUIDELINES AND PROCEDURES

Challenges

***Inconsistencies in Performance*:** Repeatability and structural integrity of the advanced manufacturing technology's output generate challenges for widespread adoption. The ability to confirm the advanced manufacturing process is fully matured and understood to best provide a safe output is an overall obstacle expressed by non-regulatory agencies. [446] In addition, the failure to guarantee consistent dimensional accuracy for a given product was identified as a major challenge for advanced manufacturing adoption. Further, determining the mechanical behavior of some advanced manufacturing processes after implementation has yet to be thoroughly understood, which can become a challenge for industries looking to adopt.[98,446] Within the nuclear industry, the use of additive manufacturing is increasing, especially for legacy part replacements. However, component maintenance and operating conditions (e.g., radiation exposure, temperature) can lead to challenges with implementing 3D-fabricated parts due to possible defects or structural integrity.[622] The World Nuclear Association also indicated "challenges remain in demonstrating the quality and reliability of materials produced through advanced manufacturing techniques under both normal and accident conditions."[475]

The metal manufacturing industry was also identified as a field that commonly encounters challenges with consistency and repeatability. The multiple physical and chemical reactions with the complex metallurgical process that occurs when printing each layer causes difficulty with consistency for metal advanced manufacturing.[476] For example, PBF-LB and Wire Arc Additive Manufacturing (WAAM), are two processes that still require research to understand fabricating challenges, like metallurgical defects (e.g., pores), lack of fusion, and intermetallic formations generated from the process.[623,624] Literature indicates material properties and dimensional accuracy were a concern for manufacturers due to gaps in application knowledge.[115] Predicting the outcome from utilizing advanced manufacturing processes is often challenging due to variables that are currently out of the manufacturers' control. Workarounds to address end product integrity are being discussed within industries, primarily through monitoring and post-processing methods. DOE's Office of Energy Efficiency and Renewable Energy (EERE) Workshop participants suggested the increased use of ex-situ and in-situ testing, due to in-situ characterization tools' ability to detect defects during the manufacturing process.[108,625] However, research findings suggest greater efforts are needed towards developing simulation tools that can predict defects, which can help develop approaches to eliminate defects and build manufacturer confidence in technology reliability.[106]

Stakeholder-Suggested Solutions: To address issues related to validating technological processes and end products, industry identified the following solutions:

- Include a combination of in-situ experiments and multi-scale simulation to better understand the formation mechanisms and develop predictive capabilities.[106]
- Develop ML techniques and AI to complement the existing numerical simulations to aid in-process and post-process monitoring systems development.[623]

Underdeveloped Guidelines*:* Standards provide industry with technical guidelines to promote the accuracy of advanced manufacturing processes and assist with implementation and adoption. During interviews, one government agency acknowledged the challenges that knowledge gaps in some advanced manufacturing processes and applications can create for certain industries.[446] For example, stakeholders from the metal manufacturing industry exhibited knowledge gaps related to material properties and dimensional accuracy as a result of standards being either underdeveloped, nonexistent, or not aligning with emerging processes.[115,626] Findings also indicated many of these standards currently do not speak to or provide guidelines on advanced manufacturing components, thus keeping advanced manufacturing structural components at the laboratory level.[627] ASME is an example of a standards organization that provides specific standards and codes for industry (e.g., nuclear reactor pressure-retaining structural components). However, interviewees from one regulatory agency noted certain additive manufactured (e.g., PBF-LB, direct energy deposition (DED)) components that are novel to the industry have yet to be incorporated into ASME nuclear codes or standards.[444] In addition, the World Nuclear Association's Cooperation in Reactor Design and Licensing (CORDEL) working group's Advanced Manufacturing of Nuclear Components report discusses codes and standards related challenges. Within the report, CORDEL also indicated ASME is currently working on establishing criteria for qualifying and accepting additive manufactured components for pressure equipment—an example of how requirements to define some nuclear applications are a work in progress.[475] Interviewees also explained how the nuclear industry qualifies novel manufactured components prior to implementation in areas with high safety significance and noted the qualification process can be lengthy and costly due to the need for large amounts of data (e.g., long-time performance data) to determine component capabilities. However, interviewees did explain how engaging with other stakeholders from across the industry (e.g., research organizations, standards organizations) helps industry gain insights on other applications and identify challenges they have encountered in their use of advanced manufacturing technologies.[444]

Knowing that advanced manufacturing technology is available and beneficial, but has limited standards, may lead to frustration among manufacturers within certain industries (e.g., nuclear) and dissuade them from future implementation. However, identifying and understanding the standards, certifications, guidances, and/or regulations that apply to an industry can also be complex due to their potential specificity. This lack of clarity has made it challenging for organizations to meet certain technical standards.[499, 628] For example, a private semiconductor manufacturer noted their end products and associated uses can differ across industries (e.g., medical, automotive, aerospace). Rather than modifying its production process to align to each industry's specific guidelines, the manufacturer chooses to follow all applicable guidelines from all of its relevant industries for its entire production process. While this approach may limit the need for additional modification to fit each industry, the effort to identify all applicable guidelines and incorporate them into the production process can be cumbersome and unrealistic for organizations with limited resources (e.g., monetary, staffing).[481]

Differences in Standards Across Industries**:** Advanced manufacturing technologies may not yet have foundational standards established in a particular industry or across industries due to their inherent novelty. Utilizing existing frameworks to guide new technology applications may seem like a solution, however, since the standards are often process or application dependent, frameworks may benefit from tailoring.[629] The growing number of applications across industries make it difficult to identify and create new standards that can be applied to address the needs across stakeholders and industries. Organizations also need to consider that the users of products may differ and fall under different regulatory purviews depending on the application.[499] This can create even greater complexity since there may be different qualification criteria and performance standards depending on who the OEM is, as well as what the end-use of the output is further down the supply chain.

For example, while 3D printing technology has been around for decades, findings show that there is uncertainty and variability in its standards related to material properties, process controls and limitations, material supply chain, equipment configuration, and post-processing procedures.[467, 630] Industries currently utilizing metal additive manufacturing methods may encounter different QC requirements and device standards depending on the end product application and its level of criticality.[464] During an interview, one government agency mentioned aircraft parts fabricated using additive manufacturing methods can vary widely in criticality while a 3D-printed coat hanger, which has zero impact on safety, has a vastly different amount of oversight compared to a 3D-printed wire harness, which has a much higher level of safety impact.[473] These types of complexities and intricacies can be difficult for regulatory agencies to sufficiently address and are compounded by inconsistency in standards that regulatory bodies may wish to create guidance around.[464]

Additionally, advanced materials (e.g., traditional, smart, composite, rare-earth minerals) may have unique responses to the different 3D printing methods (e.g., binder jetting, biofabrication, material extrusion, powder bed fusion), and there is a need for specifications for such raw materials.[631] For instance, codes and standards for certain laser bed powder fusion materials lack robust definitions and procedures that define ranges for the structure and composition of end products or heat treatment requirements for before and after production.[632] Traditional metal standards have focused on processes like forging, casting, and machining, with guidelines for mechanical properties, chemical compositions, and tolerances related to traditional materials and methods.[633] These gaps in standards may deter adoption and could adversely impact the quality and safety of end products. For instance, there are standards that exist for metal additive manufacturing, but they may not be robust enough for usability.

Standards may be created by a community of researchers from various fields and industries that consider numerous materials (e.g., ISO 17864: "Corrosion of metals and alloys — Determination of the critical pitting temperature under potentiostatic control"). As a result, there may be contradictions between scientific committees who bring expertise from different areas since applications can vary significantly by industry. Without adequate considerations, materials may not properly endure corrosion environments or be properly evaluated.[634] For example, there are strict QCs for aerospace manufacturing, and these controls can be made more complex when organizations use advanced manufacturing technologies and processes. Studies have indicated 3D-printed products can demonstrate disparate mechanical properties, especially involving fatigue performance, which may necessitate further testing that can be time-consuming, expensive, and not comprehensive.[635] As part of the regulation process, regulatory agencies may benefit from studying examination techniques and these techniques' abilities to identify defects.

Correcting this gap is a common discussion topic for other governments (e.g., European Union (EU)), USG agencies, and SDOs. There is an overall desire to create standards and set baseline criteria to promote health and safety, as well as efficiency and cost savings. During interviews, both industry and USG agencies confirmed that conferences and panels have repeated discussions regarding the need for industry standards and material databases.[570] Without set standards, companies face the burden of proof and are relying on their own testing and qualification processes, which can be expensive and time-consuming.[446,570]

Stakeholder-Suggested Solutions: To address challenges pertaining to underdeveloped guidelines and differences in regulations, the following solutions were suggested by industry:

- Encourage collaborative efforts of industry and standards development organizations to aid in the development and consideration of safety guidelines and standards.[644]
- Consider implications for uniformity in developed standards and data use by encouraging data to be interoperable and usable, which may help to foster agency-to-industry trust in the data compilation process.[451]
- Provide high-level or broad direction for regulatory compliance, as industry may be confused about how to enact compliant practices in their specific use case. Regulatory bodies could communicate how to comply with quality and reliability requirements.[451]
- Create a range of modern standards to accommodate new technology applications.[491,636] More specifically, they could separate and define specific and custom processes and materials to clarify regulations.[451]
- Encourage traceability and accountability via blockchain to address issues related to equipment with limited field life.[499]
- Inspect facilities periodically and conduct in-service monitoring as a solution to limited qualification data.[444]
- Consider implementing in-situ data monitoring systems to fulfill regulatory requirements and avoid inefficiencies of previously used brute force statistical modeling techniques.[451]

Best Practices

Standardize Terminology: As more organizations adopt advanced manufacturing technologies, many have used different terminology to describe the technologies or how they work; however, standardizing this terminology across the industry can help to improve understanding and uptake. Developing and defining standards of terminology can help eliminate confusing terms and allow for efficient and accurate communication globally within the additive manufacturing ecosystem.[476] One example is ISO/ASTM 52900: "Additive manufacturing — General principles — Terminology," which provides an overview of the fundamental principles and terms of the additive manufacturing processes to facilitate easier communication between stakeholders from different industries.[340]

Define Internal Standards: The dynamic nature of advanced manufacturing technologies has made it difficult for regulators to develop guidelines or establish standard procedures for using and maintaining these new technologies across industries and their vast applications. This lag has led many organizations to establish internal (i.e., company-specific) standards intended to facilitate safe and correct use of these technologies. Regardless of the method or metric that an organization uses, industry may develop SOPs for their processes.[637,638,639] These SOPs may include the steps and materials involved in the manufacturing and monitoring processes (e.g., collecting, tagging, classifying, storing, managing data, materials), a schedule for routine maintenance and calibration, and a log of revisions to the written procedure with the rationale for the change.[637,640] This commitment to accountability is crucial to a consistent manufacturing process.

Organizations can improve their ability to implement internal standards by sharing and incorporating ideas and best practices related to QC and supply chain management from other areas.[32] This approach can also potentially help an organization reduce manufacturing costs, which may enable other organizations to enter the market. Additionally, developing quality frameworks across the value chain (e.g., design and simulation services, materials suppliers, OEMs, post-processing providers) can allow organizations to better identify current issues, adopt best practices, and implement continuous improvement.[476]

Evaluate Procedures to Keep Pace with Technological Change*:* The current environment for regulating advanced manufacturing is expanding to include new regulatory guidances as well as revisions of existing regulations. NRC understands the need to clarify the regulatory requirements surrounding advanced methods for manufacturing. As such, NRC drafted an action plan to prepare the Agency for reviewing technologies for manufactured nuclear components and outlined their expectations for use within industry.[481] NRC has developed an Action Plan for Advanced Manufacturing Technologies to target specific issues including the overall regulatory process, codes and standards development, properties of advanced technology materials, and service performance.[641] The NRC Action Plan for Advanced Manufacturing Technologies set the foundation for further advanced technology research. Following the release of the Action Plan for Advanced Manufacturing Technologies, Nuclear Energy Institute (NEI) published their own roadmap outlining the path for regulatory acceptance of advanced technologies and processes within the nuclear energy industry.[642] In response to certain tasks within the Action Plan, technical reports on various technologies within the nuclear industry, such as cold spray, were developed. These reports provide information such as current technology use, successful applications, limitations, relevant qualifications and standards, and prioritization of knowledge gaps that need further research for a wider application of the technology.[643] SDOs are also involved in the process of documenting new information and guidances. SDOs evaluate the knowledge gained from the implementation of advanced manufacturing technologies in various industries to refine existing standards and develop additional necessary standards based on lessons learned.[644] The goal of this worldwide effort is to document lessons learned so they can be applied to newer methods efficiently and assist with the creation of more formal regulation.

Focus Initial Efforts on Low Impact Areas**:** Initial industry and regulatory efforts will occasionally focus on low-risk or less critical areas when implementing or overseeing advanced manufacturing technologies and processes. This approach can minimize production disruption while allowing performers to collect information on how they affect safety and performance. This information can then be leveraged to develop standards, guidelines, and regulation for more risky and critical technologies and processes. Implementing technologies in areas of low criticality can provide opportunities for licensees to obtain experience with materials, better understand how the material will perform in certain environments, and evaluate the holistic manufacturing process. Once the manufacturing process and longevity of the product is established, the licensee can engage with a more safety-critical field before the technology is implemented across industry. NASA developed an Initial Criticality Assessment (ICA) to be a triage for individual components and determine if they can potentially cause loss of life, loss of flight vehicle, and/or loss of mission. For those components that meet these criteria, a FMEA must be conducted to determine if specific design guidelines are met. To perform this analysis, NASA requires high fidelity ground testing that simulates the environment that the component is intended to perform in. By testing in a low criticality area (ground as opposed to air), components can be preserved. Using an ICA is beneficial because it helps analysts with efficient use of their time by separating potential high criticality parts from low criticality. This allows analysts to properly analyze and test the high criticality parts, ensuring they meet requirements set.[645] By testing products that are applied in areas of low risk, manufacturers within industry increase familiarity with technologies and resolve issues before testing in safety-critical areas.[444] Regulators can focus on the data gained from implementation in areas of low criticality to create standards for use within more safety-critical areas.

***Promote Quality and Safety Standardization Across the Supply Chain*:** Many larger organizations have taken it upon themselves to develop their own testing and qualification criteria to keep pace with setting standards for quality and safety for novel advanced manufacturing technologies. The organizations then impose these internal criteria on their associated suppliers and distributors.[446,570] Using new technologies to modernize approaches to regulatory compliance can help improve the efficiency and quality of compliance testing. One multinational industrial manufacturer began using a proactive risk and compliance platform that leverages advanced algorithms and AI to detect risks and compliance issues. The manufacturer used the platform to conduct reviews of contracts and improved their ability to review documents for potential issues related to third-party payments.[646]

Where certification procedures do exist, many are not well-suited to handle existing uncertainties and variations in competencies across industries. Current certification procedures may affect the long-term competitiveness of the technology by limiting its ability to change or improve while remaining compliant. Balancing safety with innovation through adaptive certification rather than strict procedures can promote safety, while still leaving room for organizations to innovate.[467]

Considerations for FDA

Organizations, such as DOE (EERE Workshop) or World Nuclear Association (CORDEL working group), have seen benefits from creating opportunities to meet with stakeholders and discuss current regulation of advanced manufacturing technologies. Similar approaches may help identify differences in regulation across the manufacturing landscape and provide clarity for organizations that work in multiple industries. Currently, FDA participates on the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the International Pharmaceutical Regulators Programme, and the International Medical Device Regulators Forum, among others. These efforts provide FDA with an international perspective on medical product oversight and regulation.

5.4.2 QUALITY CONTROL (QC)

Challenges

***Limited Insight on Best Quality Control Processes*:** Some advanced manufacturing technologies may still independently produce inaccurate results, which leaves some industry stakeholder groups unsure about what the best QC procedures might be for different advanced technologies. For example, the DOE EERE held a QC workshop for different energy industry stakeholders to discuss existing challenges they observed with advanced manufacturing technologies. Workshop participants noted the energy industry's adoption of these technologies were slower compared to other industries (e.g., metal, automotive) and wanted to increase the energy industry's awareness of identified challenges from other industries.[625] Participants discussed the need for QC methods aligned with advanced processes for fuel cell fabrication and nanomanufacturing process metrology for energy technologies (e.g., photovoltaics). Participants also discussed a need for greater understanding of the effects device defects have on the long-term performance of technologies. Participants further noted there need to be improvements to sensor sensitivity, the accuracy of model algorithms used to detect device defects, the speed of QC data acquisition, and the cost of new QC technologies. To address some challenges with defect detection, participants suggested using cameras or software to evaluate end products. [625]

***Limited Insight on Monitoring and Control Techniques*:** When looking to validate advanced manufacturing processes or technology capabilities, literature indicated some stakeholders lack complete understanding of process monitoring technologies. Industry leaders (e.g., DoD) have requested more robust standards on in-situ monitoring to aid in the monitoring processes, improve defect detection, and reduce the amount of material waste and the need for post-processing treatments.[624,647] Some energy industry stakeholders have also expressed interest in using detailed in-situ testing to increase measurement system capabilities. Findings identified a limited understanding of how material defects may impact device performance, as well as concerns related to the different criticality of similar defects on different applications.[625] Energy industry stakeholders expressed interest in using in-situ testing to advance tools and methods for collecting, analyzing, storing, and using high volumes of in-line QC data to integrate into process control and feedback systems.[625] Determining monitoring process gaps can not only enhance the advanced manufacturing process but also the manufacturers' ability to validate these processes and increased likelihood for adoption. The use of additive manufacturing is increasing within the nuclear industry; however, legacy part replacements, component maintenance, and operating conditions can lead to challenges with implementing 3D fabricated parts due to possible defects.[622] The World Nuclear Association also indicated there are still challenges to demonstrating the quality and reliability produced through advanced manufacturing techniques.[475] Workarounds to address technology limitations were discussed, primarily through monitoring and post-processing methods. EERE Workshop participants suggested the increased use of ex-situ and in-situ testing, due to the ability of in-situ characterization tools to detect defects during the manufacturing process.[625] However, research findings suggest greater efforts are needed towards developing simulation tools that can predict defects and help develop approaches to eliminate defects, building manufacturer confidence in technology reliability.[106]

In addition to in-situ monitoring, trends are shifting more towards NDE in replacement of destructive detection methods. For example, the chemical manufacturing and food industries use PAT to conduct end product quality assurance and provide information on product properties, material flow properties, and/or operating conditions. However, some literature indicates PAT does not provide isolated measurements and requires interpretation to ensure product quality and safety using a soft sensor. PAT may ultimately require manufacturers to adopt a combination of technologies and reliance on IoT platform connectivity to support the PAT environment. For example, PAT sensors can require a physical twin (e.g., smart field device and connectivity) to provide data to a DT which then informs the smart sensor to instruct the overall PAT environment.[648] This can become a challenge if manufacturers' existing environments are unable to support a technology system of this complexity.

Findings also identified CT as an alternate NDE method to assist with defect detection and dimensional accuracy in advanced manufacturing parts.[106] However, NDE can experience limitations like decreased resolution, which can ultimately impact manufacturers' attempts to validate advanced manufacturing product quality.[225] Specifically, CT can be time and resource intensive in addition to presenting limited scan resolution, exhibiting inability to differentiate defect types, and lacking threshold robustness (e.g., scan noise, color thresholds).[103,109] CT also lacked efficient thermal imaging, potentially causing inefficient penetration and capturing only the temperature distribution of the fabricated product's upper surface, which is closer to the location of the thermal camera.[225] Some of these issues with CT have yet to be addressed, possibly leaving manufacturers with the decision to avoid CT altogether.[109]

Stakeholder-Suggested Solutions: To address challenges pertaining to process and QC techniques, the following solutions were suggested by industry:

- Develop and provide a QC technique catalog that includes information on QC capabilities, applications, and suppliers/developers, with insight from QC vendors and lab developers.
- Consider participating in government-supported industry/lab collaborations to discuss specific technical issues.
- Attend or hold webinars and post case studies on QC topics and techniques to enhance industry's understanding of QC capabilities and value to facilitate engagement between the material manufacturers, QC vendors, and lab researchers.[625]

Best Practices

Maintain Human Operators for Technology Oversight: Although many organizations use technologies to monitor their production process and identify errors, several manufacturers and researchers encouraged others to maintain a link between any advanced manufacturing technology and a human operator. Unless the production system can run completely error-free on its own, human operators and decision makers may find it advantageous to monitor the system and take over whenever it fails or malfunctions.[513] Industry has utilized this type of human oversight in manufacturing for decades. However, many organizations now utilize this existing practice with advanced technologies to not only validate that the technology performs correctly and produces accurate outputs, but also to identify malfunctions. Organizations use those malfunctions as a means of improving the performance of the technology and reducing error rates. In doing so, the operators help to push the novel technology toward a future where the technology can operate autonomously. One study, based on Canadian Nuclear Power Plants, created a framework in which an auto-linking approach (i.e., automatically detecting and linking objects from a 3D scan to an asset management repository) was used to move toward a digital twin of its legacy assets. The framework utilized DL object detection to read and locate equipment tags from a collection of digital images and then transformed the asset's 2D coordinates from the image data into 3D point clouds that it related to an asset management system. In the study, this method improved the efficiency of the initial system where operators manually geotagged each asset and had to search across point clouds to identify equipment ID tags that required a label. A human operator then used this detection system to validate the results and manually create links when the system makes a mistake, which led to reduced costs and greater efficiency than using RFID, barcodes, or a completely manual approach.[649] In the automotive industry, one South Korean manufacturer has a human operator overseeing a real-time monitoring system consisting of IoT-based sensors, big data, and a hybrid prediction model, which has led to improved accuracy and efficiency in detecting and responding to faults.[650] A machine turning center utilized a similar approach where an operator oversaw a tool wear monitoring system to confirm that the system correctly identified parts in need of replacement. If the algorithm made an incorrect indication, the operator adds the information to the training database to improve subsequent results and help create a more accurate algorithm.[120]

Develop Internal Quality Assurance Criteria and Processes: As novel or disruptive advanced manufacturing technologies are introduced quality assurance checks (e.g., certification checks) need to be conducted on the technology in a predictable and effective manner.[473,446] To confirm output safety and performance, most organizations have developed comprehensive internal quality assurance processes and certification criteria that align with set industry standards and include requirements for repeated testing to promote accuracy and safety in the manufacturing process.

Although modern QMSs focus more on maintaining consistency among all outputs, there needs to be additional quality management processes during the manufacturing process to validate all critical utilities, equipment, and processes; test methods appropriately; and ensure a minimum confidence level in the performance of the component.[651] This certification can come from either an internal process or from an external group.[652] NIST offers organizations such support, including the opportunity to request tailored training on various quality standards (e.g., AS9100: "Quality Systems - Aerospace - Model for Quality Assurance in Design, Development, Production, Installation and Servicing"; IATF 16949: "Automotive Quality Management Systems") as well as on-site assessments and implementation support.[653] One manufacturer requested assistance when looking to renew their ISO 9001: "Quality Management Systems" certification, and NIST's North Carolina Manufacturing Extension Partnership coordinated training to all the manufacturer's staff on quality control concepts and QMS implementation. The manufacturer was able to renew their certification and worked with an improvement specialist across multiple audits to identify operational issues, conduct root cause analyses to understand the cause of the problem, and correct the issue to prevent future occurrences. The effort led to the manufacturer retaining $500,000 in sales and led to $100,000 in new sales and $250,000 in costs savings.[654]

Considerations for FDA

Understanding industry's current processes can help verify if current processes provide sufficient quality assurance and help inform future guidance and policymaking. Interactions with academia, industry, and other government agencies provide experience with innovative technologies may help proactively develop benchmarks, metrics, and tools to evaluate these technologies and facilitate standards development and knowledge sharing.[655]

Assessing the feasibility of using additional advanced manufacturing technologies to understand how these technologies can improve production and product quality over time, especially with methods currently used for medical product development, such as smart and continuous manufacturing systems, as well as point-of-care manufacturing.[656]

5.4.3 DATA-DRIVEN STANDARDS AND CRITERIA

Best Practices

***Leverage Data to Inform Development of Standards*:** Regulators can use the information obtained from experimental data and measurement techniques to improve the effectiveness and interpretability of standards, define acceptable levels of risk, assist in policymaking, and define performance requirements. Within the field of additive manufacturing, requirements for safety-critical aircraft and engine parts are based on property variations and characteristics. This prevents safety incidents, such as when an undetected powder metallurgy characteristic ultimately resulted in the crash of a F-18 aircraft.[657] Manufacturers look to regulators to provide or inform performance requirements and define metrics. Regulators can work to outline and quantify these requirements to help promote compliance. One study noted a best practice was to develop regulations to mitigate risks associated with advanced technologies, especially regarding worker safety to protect their interests.[658] Autonomous technologies, such as AI, are considered more safety-critical as compared to some other technologies since they have the potential to be hacked or pose a cybersecurity threat. This indicates that safety-critical technologies may call for clearer and improved standards to enable proper regulatory oversight and compliance.[659] Although current standards exist, such as for additive manufacturing, the landscape for emerging technologies is rapidly changing. As more information and experience with technologies become available, requirements need to evolve as older requirements may not address current limitations in industry experience.[657]

Regulators can use the information (e.g., from certification and qualification processes) and models (e.g., DTs) to their advantage when developing standards for performance and data. Manufacturers within industry can develop certifications within their production processes to determine if their technologies meet pre-existing requirements before moving on to the regulatory review process. Within the field of additive manufacturing, test artifacts can be used to set benchmarks that are later used for evaluation and conduct comparisons of processes that assist with the determination of uniform machine or process values across the industry. Test artifacts are a method of conducting performance evaluations with the intent of determining a machine or process's functions, limitations, and property characterizations. Test artifacts also help to relate results to errors to improve future additive manufacturing.[464] By doing this, regulators and industry obtain baseline data that assist the regulatory review process, making it more efficient. The data gained from certifications and internal qualification processes not only determines if technologies meet requirements, but also helps to create a foundation for future regulation by providing valuable insights into how the technology performs and is used. Validating advanced manufacturing technologies that meet the appropriate requirements can be completed through the qualification process to include all parts of the product lifecycle, such as process qualification, post-processing, and evaluation.[476] DTs are an emerging approach for modeling, testing, and validating experimental procedures and devices. Because they can serve as digital models of many common devices, DTs are perfect environments for conducting numerous virtual experiments revealing weaknesses in a system. Validation of new technology is enabled when models are proven to meet performance standards of the real system.

Considerations for FDA

Conducting additional internal research and working with organizations that use advanced manufacturing technologies to develop and evaluate test artifacts that may provide insights on the performance of new technologies and its products or outputs. The data generated from these test artifacts can help better define standards and performance criteria to promote the safety of medical products and improve the efficiency of regulatory review.

FDA is an active participant in the development of standards and has Agency liaisons that coordinate with various international SDOs. These liaisons serve an important role as representatives of FDA's perspective on the types of guidelines and safeguards needed to protect the safety of workers and users of advanced manufacturing technology. Collaborating with stakeholders from industry and academia to maintain awareness of current best practices for safe and effective use of advanced manufacturing technologies may help inform perspectives on needed standards and help apply real-world experiences into its collaborative work to develop standards.

5.4.4 RISK ASSESSMENTS AND PREVENTION

Best Practices

***Identify and Mitigate Hazards*:** Understanding the potential hazards within a manufacturing system is not only key for preventing or mitigating exposure, but also for developing strategies to respond to any incidents. Progress in the design and application of innovative technologies, like SMRs, requires a comprehensive risk assessment template. This template can support well-informed decision making based on the magnitude of operational risks associated with the technology and prioritize predisposing risk factors and the most effective/efficient means of risk reduction.[224] ISO/ASTM 52909:2022 – "Additive manufacturing of metals — Finished part properties — Orientation and location dependence of mechanical properties for metal powder bed fusion" suggests that manufacturers conduct risk assessments and identify the presence of dangerous chemicals and materials and any potential opportunities workers could be exposed to these hazards. They also note that organizations may find it beneficial to clearly document hazards across the manufacturing process (i.e., prior to use, during use, end of use, post-processing, maintenance) and can define each step of the process, including the potential levels of exposure during routine operations (e.g., regular maintenance, production, cleaning) and occasional operations (e.g., ad hoc maintenance, accidents). [660]

Safety is the top concern for industry when it comes to the development and use of new technologies. In addition to potential safety concerns on the production line that existed in legacy systems, these technologies can also present cybersecurity risks (e.g., ransomware, third-party hacks) that can be detrimental to organizations leveraging digital systems to coordinate production. Cyberattacks can slowdown or halt production entirely, disrupt supply chains, and threaten consumer and worker safety. They have also led to major production issues, such as the attack on a Toyota supplier that forced them to stall domestic production and led to more than 13,000 cars being lost. Other events have led to major gas shortages or created major concerns for water purity, like the Colonial Pipeline hack and the Oldsmar water treatment plant attack, respectively.[661] However, maintaining up-to-date security software and protocols can help protect production systems, along with adopting best practices like implementing access controls, conducting regular software updates, segmenting networks to contain potential threats, and developing response plans to cyber incidents.[662]

During a NIST workshop on autonomous vehicles, industry stakeholders noted it would be helpful if regulators developed requirements for safety risks and defined appropriate baseline levels of risk. These stakeholders emphasized the importance of having these requirements be as specific as possible (e.g., specific wavelengths, luminosity thresholds) and the importance of having available metrics to measure safety.[663] These requirements and qualification and certification processes promote lowered risk. Regulators developing these processes collaboratively with industry stakeholders can help all parties understand broader industry perspectives and promote proper interpretation, adoption, and regulatory oversight.[663][664,665] Regulators can work with non-regulatory agencies that can supply experimental data on what common risks exist in different contexts and help develop further evaluation methods to influence policy.[663] Risk assessments are necessary to promote adherence to regulations and confirm that organizations are using technology appropriately.[664]

Organizations may find it beneficial to apply their findings from risk assessments to their implementation of risk reduction measures to eliminate the hazard or reduce the severity and probability of occurrence of harm. ISO 12100:2010 – "Safety of machinery - General principles for design - Risk assessment and risk reduction" suggests that industry apply risk reduction measures to best protect workers and production from harm, including leveraging safe design measures (i.e., eliminate hazards or reduce risks via design features), applying protective measures (i.e., reducing risk when it is not possible to eliminate a hazard), and providing information for use (e.g., safe working practices, training requirements, recommended PPE).[666] Additionally, ISO 20387:2018 – "Biotechnology - Biobanking - General requirements for biobanking" recommends steps for biobanking that have applications across various fields. They suggest that industry establish, document, and implement procedures for controlled implementation, safe handling, transport, storage, and planned maintenance of all equipment. They also recommend that organizations establish procedures for the safe handling, packaging, transport, and reception of materials that are compliant with relevant security and safety requirements.[640]

Employ Risk and Safety Controls: Innovative technologies can introduce new short-term and long-term risks to the manufacturing process and its associated workforce, such as cybersecurity risks, exposure to hazardous materials used to produce or power these technologies, more complex and powerful machinery, and environmental concerns from fuel consumption.[667] Organizations need to understand these risks and implement the needed controls to help protect themselves, their workers, and their production line from hazards. For many manufacturers, the best way to control the risks of hazardous materials in the workplace is preventing exposure by implementing engineering control techniques (e.g., eliminating or substituting the hazard, ventilation, filtration), administrative control systems (e.g., modifying work practices, minimizing the number of exposed workers), and PPE (e.g., masks, coveralls, gloves).[668]

For advanced manufacturing methods like 3D printing, adequate ventilation systems (e.g., local exhaust systems, snorkel fume extractors) are an important engineering control to help limit emissions, protect workers from exposure to harmful exhaust, and potentially reduce energy costs compared to general dilution ventilation.[669] Combining these with non-ventilation controls (e.g., guards and barricades, material treatment, additives) can provide additional protection for workers.[670] Organizations can further support their staff by developing and disseminating general knowledge related to hazards, exposure assessment methods, and adaptable risk assessment and risk management methods.[286] If an incident does occur, ISO/ASTM 52909:2022 – "Additive manufacturing of metals — Finished part properties — Orientation and location dependence of mechanical properties for metal powder bed fusion" encourages organizations to investigate the cause of the incident, report the equipment affected, analyze the effects, and provide recommendations for preventing a repeat of the incident.[660]

Considerations for FDA

Regulatory partnerships can be leveraged to improve risk assessment capabilities, determine best practices for preventing risk exposure and mitigating negative impacts, and collaborate on standards and regulation development to further protect patients. Establishing liaisons focused on risk prevention that can share resources and coordinate meetings between the different groups as needed can help to promote public health and the safety of workers and patients.

5.5 Weighing Regulation and Innovation

Research and comments from interviewees indicate that appropriate regulations should provide enough oversight to protect the public without becoming an unnecessary inhibitor to innovation and scientific advancement. To ensure emerging technologies are implemented successfully and safely, there risks must be addressed either through regulation best practices or standards. At the same time and allowing space for novel R&D to continue. While requirements must be met to validate technologies, using open-ended methods of compliance (i.e., subjective language) within the design, manufacturing, and validation lifecycles of a technology or process enables continuous innovation in tandem with reducing risk, increasing public safety, and maintaining trust in the validation process.

5.5.1 ETHICAL LAW AND LIABILITY

Challenges

Previously Unseen Ambiguities Within Emerging Technologies: For both regulators and manufacturers, ambiguity surrounding ethical or legal intricacies may create hesitancy to fully embrace technologies that are coming onto the market. For example, users of some robots are encountering controversial challenges when attempting to determine their legal classification. Challenges arise when attempting to determine if robots should be classified as "a natural person, legal person, animal or object."[671] This classification verbiage is especially impactful when it comes to potential ramifications for insurance claims, and there are questions whether accidents that occur from robots should mirror similar frameworks for accidents from vehicles.[671,672] As such, industry may express a desire for guidance or law, so they can create appropriate risk mitigation plans and consider insurances for fault or financial responsibility.

Ethical issues may also arise when emerging technologies are engaged in scenarios initiated from human behaviors. For example, there is ambiguity regarding how legal entities should consider instances when autonomous vehicles are used in criminal activities. Within a research discussion piece, hypothetical scenarios were presented about law enforcement's ability to identify responsible human parties that use fully autonomous vehicles for illegal drug trafficking. If the vehicle is abandoned, law enforcement can experience uncertainties when assigning fault since regulations have yet to explore applicable ethical conflicts. In addition to the autonomous vehicle example, as AI capabilities and user adoption expands, there is growing congressional and public interest surrounding the scope and level of human authorship in copyright claims for material produced using generative AI. In response, the U.S. Copyright Office launched a comprehensive AI Initiative in 2023 where they hosted public listening sessions, published a notice of inquiry, created an initiative website, and planned events for public engagement. The goal of this initiative is to analyze copyright law and policy issues created by the use of AI, and how copyrighted material is used within AI.[673] The expected impact of this initiative is to provide knowledge on the current state of copyright law and issues raised using AI to determine if there is potential for future regulatory action.[673] The Office also responded by issuing a statement of policy which provides registration guidance for AI-generated material; holding public educational webinars on generative AI; and engaging with stakeholders from academia, trade associations, creators, technology companies, and creative industries. These types of intricacies create additional considerations for industry seeking to implement novel technologies.[673]

Stakeholder-Suggested Solution: To address challenges identified in ethical law and liability, stakeholders suggested the following solution:

- Regulatory agencies should consider users' behaviors, needs, and problems when providing guidance relating to ethical issues.[671]

Considerations for FDA

As emerging technologies come to market, determinations need to be made as to how potential ethical implications of these technologies affect decision making related to regulation while balancing innovation, productivity, and social responsibility. Maintaining situational awareness of the ethical guidelines that may be important forregulatory decision making.

5.5.2 REQUIREMENTS AND FRAMEWORKS

Best Practices

Utilize Flexibility and Adaptability Within Regulation: Flexibility in subjective regulatory language that is informed by a multidisciplinary knowledge base of advanced technologies can allow industry to strike a balance between regulation to promote public safety and innovation. Experts from a regulatory agency stated that while they try to support and facilitate technological advancements, they understand the importance of reducing associated risks (e.g., due to lack of field, design, and/or manufacturing experience).[473] Regulators work to develop an understanding of emerging technologies and their risks, while proactively protecting patient safety within their regulatory oversight. Regulators that were interviewed noted that one of their primary responsibilities with emerging technologies is to understand them before and during the regulatory review process. Developing an understanding of technologies before they enter regulatory review processes can allow for increased efficiencies of the overall process. However, during the regulatory review process, they can tap into experts from different perspectives (e.g., production line staff, legal counsel) to help ensure a robust knowledge base for decision making. By creating regulation or regulatory guidance based on a collection of multidisciplinary knowledge, regulatory agencies can balance the competing risks and needs related to emerging technology. This can also have downstream benefits as other governmental agencies leverage the knowledge base already established because the regulatory frameworks were developed with a holistic perspective in mind (e.g., encompass the various aspects of the technology as used across industries).[451] The practice of leveraging previous knowledge to inform future regulation is a form of adaptive regulation where learning from the impact of previous regulatory decisions provides a background for future policy. Adaptive licensing is a method of implementing adaptive regulation where, for example, autonomous vehicles are approved for use within a certain demographic before wide approval. This enables regulators to learn from different use cases before developing overarching regulation for autonomous vehicles. The U.S. Clean Air Act is an example of adaptive regulation where air quality standards for air pollutants are reviewed every five years to determine if the Act needs revisions.[674,675] As another example, Australia developed the Gene Technology Act 2000 which stood up a governmental office to monitor genetic engineering research. Later on, in the 2011 Review of the Gene Technology Act, the office's responsibilities were revised to include advancements in synthetic biology, for example the use of genetically modified organisms (GMOs), in addition to gene engineering.[676] This example of adaptive regulation within the 2011 revision of the Act demonstrated that flexibility and adaptability can be built within regulation, leading to effective management of advancements in emerging technologies.[677]

Subjective terms used within regulation may allow innovation to continue without being limited by regulation.[286,475,678] In other words, the regulation can intrinsically expand as innovation and technology expand. While safety controls are necessary, it is also important that industry allow some flexibility to promote innovation and to allow them to adapt to rapid technological changes. Flexible safeguards or soft laws can allow these technologies to develop while also protecting human health and the environment. These safeguards and laws can also provide the public with confidence that the technology meets performance standards and that their products and outputs meet expectations.[194] "Soft law" measures (e.g., quasi-regulatory mechanisms like recommendations) are a way of introducing regulation without stopping the innovative process by filling gaps in regulation through flexible measures that provide a basis for formal regulation later on. These measures allow for trust in the technology validation process, provide a sense of safety and certainty regarding regulatory requirements, and affirm stakeholders will not feel burdened by regulations.[194] Performance standards are an example of providing flexibility within the regulatory environment, e.g., by stating that a standard must be met but without requiring a specific method of compliance.[674] This allows organizations to innovate in how they comply with the performance standards. Regulatory agencies can adopt the same practice where they provide a set of requirements to various organizations, and each organization can then determine their own method of compliance with the overarching requirement set. While it may not be beneficial to force organizations to use the same method of compliance across the board, having open-ended regulation allows for revisions to standards and regulations to include methods of compliance that are technology specific in the future.[473] Organizations can initially prioritize these flexible measures for areas that are less critical to the continued functioning of the system and present less potential risk. This allows the organization to gain experience with the technology, understand how it can perform, and assess how these measures may affect its usage. Organizations can then take this experience and leverage the lessons learned when applying standards for more critical areas of the production process.[444]

Adopt Responsive Regulation When Appropriate: One regulatory agency stated they intend to revise existing regulations and develop new ones to be specific to the method and material selected for the manufacturing process.

This means there will be an increased need to differentiate between regulatory requirements and methods of compliance. A practice that can assist with this is the adoption of responsive regulation where regulating agencies can promote requirements, reward compliance, and provide increased opportunities to stakeholders involved. Currently, responsive regulation occurs through voluntary compliance programs and, by engaging in responsive regulation, regulators offer industry the opportunity to self-regulate. For example, EPA previously had an online-based national performance tracking system that provided corporate transparency and accountability relating to sustainability. However, the system was terminated leading to individual states developing their own form of a decentralized performance tracking system. The Office of Inspector General determined EPA's lack of a central monitoring system led to an inability to adequately monitor the activities of the agency's Renewable Fuel Standard Program. By requiring provenance of requirements being fulfilled, EPA can easily monitor biofuel development activities. Monitoring allows for a responsive regulatory approach where sustainability programs can be evaluated and their successes can be quantified.[679] However, this approach requires industry participation, buy-in, and incentivization to be a viable method of promoting increased collaboration between regulators and industry when developing requirements.

Considerations for FDA

FDA frequently issues non-binding recommendations through guidance documents when regulations and statutes are not specific enough for a given technology or product area. Continuing to use these types of "soft" documents that allow flexibility can promote innovation while maintaining safety and compliance. The U.S. Clean Air Act is an example of an adaptable and revisable approach to regulation and provides lessons on how to routinely evaluate previous regulations, not just guidances, at periodic intervals. In addition, the EPA's former performance tracking system is an example of how to monitor advanced technologies. This can tie into lessons learned from Australia's response to genetic engineering research, where an adaptive regulation process or office can be utilized to monitor and facilitate the need for adaptive research. In addition, roadmaps have been beneficial for industries and regulatory agencies to increase predictability and preparation for emerging technologies (e.g., providing managing framework for a combination of "competition, innovation, and collaboration").

5.6 Workforce

With the advent of novel and disruptive technologies and processes, comes a corresponding need to educate and train a workforce on how to apply them safely and effectively. This goes for private industry as well as the governing agencies regulating the products manufactured by such novel technologies. There is an inherent challenge in organizations keeping ahead of this curve, as workforce planning, development, and skills training can often lag behind technological advancement. In addition, one recent study found the pandemic led to a loss of approximately 1.4 million U.S. manufacturing jobs, of which only 63% were recouped by the end of 2020. It was further found that the existing manufacturing skill gap in the U.S. has the potential to lead to 2.1 million jobs being unfilled by 2030.[680] Despite this dire outlook, research identified strategies that organizations have taken to acknowledge and proactively address this gap in their workforce.

5.6.1 WORKFORCE PLANNING AND DEVELOPMENT

Challenges

Gaps in Knowledge, Skills, and Abilities: There is a significant challenge created by a shortage of highly skilled subject matter experts, who are often required to operate advanced manufacturing technologies. In the same study referenced in the opening of this section, 77% of manufacturers claimed they will continue to experience difficulties in attracting and retaining workers, with executives reporting they "cannot even fill higher paying entry level production positions, let alone find and retain skilled workers for specialized roles".[680] For example, domain experts, AI engineers, and data scientists are all identified as personnel necessary to understand AI systems and components and data analysts and/or computer scientists are required for AI application development.[261,681] Metal manufacturing operators and service engineers were similarly identified by academic institutions as necessary roles, but harder to retain due to talent stealing between manufacturers.[487] Industry stakeholders noted there was once a time when training for advanced manufacturing credentials were made available but there was a limited need. Now the resulting lack of competencies has become a barrier for adoption.[451]

Research noted that once organizations understand the talent requirements for successful advanced manufacturing implementation, huge investments are being made to acquire and retain skilled talent. Exclusively internal trainings may be burdensome for some manufacturing companies, so those trainings may be pushed to external curricula from private training providers, professional or industry associations, and/or equipment suppliers. A 2017 survey of employers from an Australian Bureau of Statistics (ABS) Business Register indicated that 47% of manufacturing employers used unaccredited (structured without a formal credential) certification programs. Employers in this survey indicate choosing outside private training providers (e.g., professional or industry associations, equipment suppliers) due to their high levels of specialized knowledge and tailored curriculum.[682]

Research indicates that the regulatory workforce—both veteran staff and new hires—faces similar challenges and may require substantial amounts of technical training to stay up-to-date on the Knowledge, Skills, and Abilities (KSA's) needed to oversee and inspect products using novel and disruptive advanced manufacturing technologies and processes.[444] To compound this challenge, regulatory agencies may struggle to recruit and retain an adequate workforce, partially due to unclear job announcements, lengthy hiring processes, and high percentage of retirement-eligible employees, with the incoming skills and foundational know-how.[683] Furthermore, when tenured staff who primarily work independently leave their agency, that intellectual capital often leaves with them, which can create large knowledge gaps.[459] Similarly to private industry, such loss of talent and expertise can have downstream impacts on the quality of guidance documents and inspections.

Stakeholder-Suggested Solutions: To address challenges identified in workforce development, stakeholders suggested the following solutions:

- Focus on upskilling existing workforces on areas with identified shortages of personnel skilled in advanced manufacturing (e.g., automation, ML).[451]
- Initiate training by assessing current personnel's competencies towards operating advanced manufacturing technologies, then attempt to enhance specific skills tailored to specific solutions to address shortcomings.[451]
- Prioritize technical trainings to grow subject matter expertise on novel technologies and avoid expectations for workers to possess the knowledge upfront.[459]
- Foster training opportunities for both new and tenured regulatory workforces, which may lack the competencies needed to oversee and inspect advanced manufacturing technologies due to their novelty and/or complexity.[459]
- Pair tenured and new regulatory employees together with the goal of open knowledge sharing and encourage site visits, when applicable and possible.[459]
- Review existing HR practices geared towards attracting new talent and retaining existing talent when attempting to improve organization's worker retention.[684, 685] Identifying technical workers, offering development opportunities, and adopting strong talent management practices can help organizations improve their talent retainment efforts.[686]

Best Practices

Take a Sociotechnical Approach to Workforce Planning: Organizations have benefited from taking a sociotechnical approach to their workforce planning that considers both the human and technological implications of their role in the manufacturing process.[687] New technologies require more multiskilled and autonomous workers that possess both digital competencies (e.g., knowledge and skills required to use digital media effectively) and non-technical competencies (e.g., willingness to learn and change, teamwork, communication, initiative, curiosity, critical thinking).[688] Additionally, while some advanced technologies such as AI can reduce the need for certain traditional roles in the workforce, many organizations have subsequently repurposed their talent resources to use real-time data collected by the technology (e.g., equipment monitoring predictive maintenance) to help workers optimize machine performance and proactively identify potential failures.[617] A sociotechnical approach focuses on closing such skill gaps and promotes adoption among workers by encouraging an inclusive and holistic perspective when implementing new technologies that effectively integrates variables of skills training, culture, production, processes, infrastructure, and goals.[689]

Upskill and Reskill the Existing Workforce: To overcome limited expert availability, industry identified workforce upskilling and reskilling opportunities as key to understanding new systems and equipment, enhancing data literacy, and facilitating the successful transition to and utilization of innovative technologies.[131, 690] Upskilling provides individuals with more advanced skills through additional education and training, while reskilling provides the opportunity to learn new abilities to facilitate a transition to a different role.[691] A survey of HR professionals across a variety of industries (e.g., healthcare and social assistance, manufacturing, construction) found that 52% offer upskilling training, and nearly 60% of respondents felt that skill-based training can provide a return on investment, address skills gaps and changing business needs, and improve worker retention.[692]

These types of upskilling and reskilling opportunities can be supplemented with visual resources and aids. Specifically, job aides have been found to be successful in the evaluation of an MRO (i.e., maintenance, repair, overhaul) and can be used for additively manufactured replacement components. For example, the FAA found such resources to be helpful for their Flight Standards Services personnel and for maintenance and alteration of aircraft and their parts.[630] When integrating new technology, organizations such as General Electric (GE) have acknowledged that incorporating training initiatives and upskilling of its workforce into their strategic change management approach has resulted in more positive workforce reactions and production operations.[693]

Recruit and Train New Talent: When recruiting new employees, organizations can recruit employees with non-technical skills, knowing they can gain skills and trainings on the job. While hiring of manufacturing workers—even at entry level positions—has been identified as a challenge across multiple aforementioned studies, taking an upskilling approach has also been found to be a successful best practice in addressing such a challenge. For example, the MassBridge project aims to plan and develop advanced manufacturing programs for non-technical individuals enrolled in high school and community colleges in Massachusetts.[694] Several regulatory agencies and governmental bodies have employed similar initiatives.[695] For example, NIST's Manufacturing Extension Partnership (MEP) Centers offer company-tailored training and skills development for manufacturers and supervisors to ultimately help companies attract and retain manufacturing talent. These offerings include assistance creating a systematic onboarding process for new employees and supporting skill building for current employees.[696] Additionally, some professional organizations have begun to team up to improve North America's workforce challenges. For example, in September of 2023, the Association for Manufacturing Technology and the Society for Manufacturing Engineers announced a strategic partnership for workforce development alongside Tooling U-SME, a development solution provider.[697] While there is no direct evidence to support this, our analysis might suggest that the success of such hiring initiatives and training programs is no small feat and may depend on the level of investment (time, money, resources) placed in such efforts, many of which are very targeted in their mission. Examples of successful execution include those that are well-structured, many of which have partnerships that share the initial burdens, as well as the fruits of program success.

Invest in the Next-Generation Workforce: Industry can help to promote the manufacturing space and foster skills in younger generations by collaborating with educational institutions (e.g., grade schools, high school, colleges and universities, trade schools) to share knowledge on their processes and the technologies that they use. Workforce development programs are supported by science, technology, engineering, and mathematics (STEM) education and related workforce training and development programs, with programs beginning as early as the elementary age group.[3] Project Lead the Way offers a series of programs designed to teach students about the importance and usefulness of STEM education. The organization offers curriculum tailored to different age groups (e.g., pre-kindergarten through 5 years old, 6 years old through 8 years old, 9 years old to 12 years old) and aims to empower students to explore their interests and use their imagination to solve real-world problems.[698] The organization For Inspiration and Recognition of Science and Technology conducts similar work and offers mentor-based in-school and after school programs that provide pre-kindergarten through high school students with exposure and education on robotics and other STEM disciplines.[699] Programs like these reinforce the education, trainings, and connection for the future manufacturing workforce.

These types of training programs can not only support the manufacturing industry as a whole, but can also support specific applications of emerging technology. For example, in order to support integrations of AI and big data, industry can collaborate with educational institutions to align curricula with the skills needed to understand and effectively integrate the technology into the workplace upon graduation.[700] There is also a need for more students to graduate with majors related to AI and for more programs to offer coursework on AI. Denmark has sought to address this gap by launching a large initiative called the Danish Technology Pact (DTP) to increase the number of STEM professionals by 20% by 2025.[701] The DTP aims to prepare the population for a more technical and digital future and provide them with the skills and knowledge to succeed in fields relying on technology and digital innovation. Through partnerships with industry, academic, and government stakeholders, the DTP provides a national platform for evaluating, developing, adopting, and expanding educational initiatives aimed at improving STEM education at all levels, promoting interest in STEM, and providing Danes of all ages with STEM competencies.[702] Similar efforts could help more students be better prepared to enter the workforce and provide industry with a larger talent pool of specialized and qualified staff.

NSF's Advanced Technological Education (ATE) Program supports education of technicians for high-technology fields, including advanced manufacturing technologies, through partnerships with academic institutions (grades 7-12 and two-year Institutions of Higher Education [IHEs]). ATE sponsors research proposals, while also offering curriculum development, instructor professional development, and career pathway initiatives.[703] Additionally, the Manufacturing USA institutes offer partnership with educational institutions and industry and aim to support advanced manufacturing technology education and workforce development. During an interview for this report, individuals from one organization highlighted their approach to workforce development which serves as a bridge into industry. The organization brings in graduate students and places them on various projects to upskill them by providing education on different technologies and industries. The program provides new hires with on-the-job training on multiple projects while they finish their graduate programs. In doing so, many emerge from the program more prepared to enter industry and make meaningful contributions sooner.[461] Workforce development programs, such as these examples above, support industry product and process improvement for advanced manufacturing as a whole.[704] As new and existing staff develop their expertise, providing opportunities for them to share knowledge both within the organization and with stakeholders can help build a more robust base of intellectual capital for the next generation of manufacturers.

Considerations for FDA

Many of the workforce strategies above emphasized developing a next-generation workforce. Partnering with programs to develop young talent can enhance skills and knowledge of regulatory oversight principles for emerging advanced manufacturing technologies and processes. These programs could be valuable for multiple technologies, including ones used in FDA-regulated products but especially focused on longer timeframe concepts with future potential relevance and impact (e.g., advanced robotics, quantum computing) for which FDA may need workforce expertise.

Partnership(s) with universities or other non-regulating government agencies (e.g., NIST MEP) that already have programs to develop advanced manufacturing talent could be established to facilitate the career aspirations of the upcoming workforce and reinforce interest in advanced manufacturing specialization. Such programs can potentially provide students with paid schooling or training in advanced manufacturing and in return, individuals make a commitment of employment for a certain number of years, allowing them to contribute their enhanced skills and knowledge back to the medical manufacturing industry or government. The U.S. military employs such a concept in covering the costs of medical school for students who then owe the military one year of active-duty service for each year of support they receive, following residency.[705]

6 INDICATORS OF CURRENT USAGE AND FUTURE GROWTH

Monitoring potential indicators of current usage of emerging and adopted advanced manufacturing technologies can provide valuable insight into forecasting future growth (i.e., rates of implementation and corresponding adoption success). Indicators do not necessarily imply a direct correlation but are potential signals for an organization to make informed business decisions and for regulatory agencies to be better prepared to protect public safety, respond to ethical considerations, and enact oversight. Table 6-1 describes potential indicators of usage and future growth in advanced manufacturing technologies and observations as to why they may be worth tracking.

Table 6-1: Potential Indicators of Usage and Future Growth

Potential Indicators	Observations of Current Usage and Future Growth
Academic and Industry Research or Testing	Academia and industry also invest heavily in emerging and disruptive advanced manufacturing technologies and processes, which can indicate growing interest in usage and anticipated future growth. For example, 3D printing generated interest within the research community to explore benefits and applications. Private manufacturers, like GE and Boeing, among many others, simultaneously invested in research programs to further identify 3D printing advantages, opportunities, and applicability within the aerospace industry.[706] Nuclear industry leaders are now designing and testing 3D-printed components to implement into nuclear facilities. Westinghouse, a commercial nuclear vendor, subsequently allocated resources to design, develop, and test advanced manufacturing produced fuel components with hopes of future adoption.[707] These examples are intended to illustrate how research and testing can quickly build confidence and drive further investment in support of a specific technology across industries. The interest in capabilities of 3D-printed spare parts tripled over a ten-year time span, which further underscores the growing interest surrounding 3D-printed spare part utilization.[708] Private industry also continues to increase efforts directed towards ML application techniques to control advanced manufacturing performance phases and defect detection for metal manufacturing.[504]
Creation of Industry Standards	Industry leaders seek technical standards to aid in efficient implementation, and so establishing or revising standards to encompass disruptive or emerging technology can indicate there is enough current usage (or criticality of that usage) to desire consensus for standard implementation. As an example, growing interest sparked collaborations between DOE and nuclear industry leaders to develop standards that can incorporate advanced manufacturing processes within NPPs.[707] If an advanced manufacturing technology or process warrants standards, it is a good sign there is a future for it in the marketplace. Within the aerospace industry, NASA maintains a consistent cadence creating standards outlining their requirements for 3D printing to facilitate safe design manufacturing.[678] They continue to be at the forefront of utilizing 3D printing technology in their industry. In the nuclear industry by comparison, literature and interviews with government agencies indicate a disconnect in standards for emerging technologies and an irregularity in existing standards. As such, the nuclear industry is self-admittedly behind other industries in their implementation and usage of the same or similar 3D printing capabilities.[444] As articulated in Section 4, the rate of emergence and adoption of any given technology can range across industries. The creation of standards for novel technologies and their applications can signal confidence in current usage and potential for further growth—in one industry or across many.
Government Investment	Increasing USG investments in R&D, production and utilization, and training can be an indicator of growing interest of an advanced manufacturing technology's future expansion. These investments can dictate technologies that receive resources (e.g., funding, personnel, prioritization) and ultimately expand in use or come to market soonest.[3] ***Research and Development (R&D)***

Potential Indicators	Observations of Current Usage and Future Growth
	USG commitment to emerging technology R&D is evident from the allocation of funds towards government-run research efforts at the federal and international levels. The following examples highlight USG R&D efforts to increase development of novel advanced manufacturing technologies: • The U.S. Airforce Research Laboratory (AFRL) funds public-private partnership research projects, like America Makes Institute, geared towards additive manufacturing R&D, and air force applications (e.g., aircraft part replacement).[709] • In 2021, Congress passed the Creating Helpful Incentives to Produce Semiconductors (CHIPS) for America to support the semiconductor industry within the framework of the National Defense Authorization Act (NDAA). This series of programs promotes the research, development, and production of semiconductors in the U.S., and reaffirms the importance of future growth in the semiconductor industry to both the civilian and military sectors.[217] • The DOE Office of Nuclear Energy (DOE-NE) developed research programs aimed at innovative manufacturing processes to reduce costly and timely nuclear power plant construction and to increase the reliability of advanced manufacturing components.[627] • The DOE awarded Semiplastics, a contract for research to test coal-enhanced filaments and resins with 3D printing.[710] • The U.S. military currently finances research to explore advanced robotics and the potential utilization of exoskeletons to carry loads.[536] • The U.S. military also currently finances DTs to assist in the ongoing evaluation of components and predict failures of F-35 fighters. Additionally, the DTs will examine the aircraft's performance, life expectancy, and failure rates.[253] • The U.S. Army Combat Capabilities Development Command Aviation & Missile Center partnered with Wichita State University's National Institute for Aviation Research (NIAR), a research center that promotes safety, research, manufacturing, and design in the aviation industry through specialized advanced manufacturing laboratories.[711] This shared initiative sought to create a 3D modeling and simulation environment. This environment enables experts to evaluate systems and the integrity of repairs, and develop criteria to identify a list of parts to be manufactured through advanced additive manufacturing processes. This analysis helps show a path for future advanced manufacturing efforts in the Army aviation enterprise.[253,712] In addition to domestic investments, the U.S. also engages in programs to further R&D with their international partners. For example: • In 2015, USG agencies partnered with Israel's Binational Industrial Research and Development (BIRD) Program, which supports U.S. and Israeli joint research aimed at advancing homeland security technologies. The program focuses on a platform for airports and air traffic that will provide continuous cyber visibility, real-time monitoring, and data traffic detection to minimize risks and boost compliance with regulations.[713] This program was also referenced during an interview with NIST, as just such an example of international government investments signaling prioritization and confidence in certain technologies.[462] • The U.S. and the United Kingdom participated in a joint program aimed at researching and developing a prototype for heads-up display for military divers.[267,] ***Production and Utilization*** Growing government interest in advanced manufacturing technology also manifests through the increased investments in office facilities and production site creation, joint agency initiatives, and industry group formation. Increasing presence through the establishment of programmatic offices and working group initiatives continues to demonstrate the perceived anticipation for future use of advanced manufacturing technology implementation. Examples of such investments include: • The U.S. Navy currently invests in unmanned underwater vehicles and has 60 active additive manufacturing workshops which created roughly 20 underwater vehicles.[714,715] • DARPA utilizes blockchain for battlefield operation management, while NATO employs blockchain for secure military procurement and improved traceability in supply logistics.[716] • Project Maven, a flagship AI project started in 2017, focuses on adapting commercial AI algorithms to military functions and optimized decision making. In May 2021, the Deputy Secretary of Defense issued a memo that established the Department's approach to AI and established priorities for implementation.[717] • In February of 2022, DoD established a command structure, the Office of Digital Technologies and AI, which in the future will be responsible for strengthening and integrating big data, AI, and digital solutions in the military department.[217]

Potential Indicators	Observations of Current Usage and Future Growth
	• National laboratories supported by the DOE produce cars, wind turbine blade molds, and live cells through additive manufacturing.[718] • Collaborative initiatives span across several defense agencies, including the creation of a Joint DoD advanced manufacturing roadmap in 2016 and establishment other joint agency development projects and working groups.[719] • Institute for Advanced Composites Manufacturing Innovation (IACMI), Institute for Reducing Embodied Energy And Decreasing Emissions (REMADE), the American Composites Manufacturers Association (ACMA), and the Electric Power Research Institute (EPRI) support advanced recycling techniques.[720] Governmental investment towards advanced manufacturing technology application also occurs on an international scale. In 2017, China passed New Generation Artificial Intelligence Development Plan to foster its goal of turning China into a leader in AI by 2030. In 2019, Russia passed the National Strategy for the Development of AI to "close the gap in the AI field and achieve global leadership in certain AI-related areas."[217] Both domestic and international stakeholders are investing more into creating and applying advanced manufacturing technologies across industries and continue to develop innovative ways to increase implementation. ***Training*** Investments toward workforce training of emerging technologies by the USG can signal a priority of upskilling to target an anticipated demand that will impact the workforce. For example, DoD developed internal additive manufacturing courses and leadership development training, given the increased rate of the technology's current usage and trajectory of future growth.[719] The USG also prioritizes workforce development of advanced manufacturing techniques. DoD's Manufacturing Technology Program (DoD ManTech) partnered with the state of Massachusetts to develop a state-based advanced manufacturing technician training program and career pathway model.[721] The Integrated NSF Support Promoting Interdisciplinary Research and Education (INSPIRE) was also established to address innate and pressing scientific problems, and aims to advance NSF's strategic goal of making investments that lead to emerging new fields of science and engineering and shifts in existing fields.[722] Investing in training of certain emerging technologies can signal a long-term commitment governmental agencies have towards preparing for increased use of advanced manufacturing techniques and their processes.
Increased Utilization Across Multiple Industries	Widespread adoption of advanced manufacturing technologies across multiple industries translates to a positive indicator for continued success. Domestic and international manufacturers continue to phase advanced manufacturing technologies into their existing systems and make investments to continue scaling, especially in the military and defense, environmental monitoring, and energy industries. Autonomous robots (e.g., drones) serve as an example of a technology originally utilized in a niche market primarily for military and high-security clearance institutions. Now drone usage has expanded to other fields. For instance, in meteorology they are used to assist with weather performance monitoring.[723] The transportation industry also initiated the usage of autonomous technologies, primarily within car manufacturing. Google and Apple expressed interest in manufacturing and released their first autonomous vehicle. The private manufacturers—in addition to public transportation and commercial vehicle organizations—also initiated discussions pertaining to implementing autonomous vehicles for public service and on-demand use.[724] WSNs also expanded to include more markets, like military, industrial, and environmental monitoring, and enhance their advanced manufacturing capabilities.[725] The recycling industry adopted wireless sensor networks to assist with their waste sorting systems, and the energy and environmental monitoring industries adopted photonics for its instrumentation and measurement capabilities.[233,244]
Industry Awards	Recognition can represent confidence in or promise of a particular innovation and help propel its continued growth. Industry awards can provide a level of validation of the viability of novel technologies, as the recognition is often from experts in the field. They can also provide insight on the latest industry trends, innovations, and organizational benchmarks that indicate their achievements. For instance, NIST's Advanced Manufacturing Awards Organization presents Best Design Innovation and Product Development, Best Technology Disrupting the Production Process, and Best Automation and Robotic Integration. The private sectors also give recognition to the latest, most successful emerging disruptive technologies.[306]
Industry and Consumer Demand	As the market broadens to implement more advanced manufacturing technologies, demand across industries and consumers increases as well. This interest to implement advanced manufacturing technologies in various fields of study derives—at least in part—from increasing consumer and industry demand, which is observed across many technologies such as IoT, photonics, AI, and 5G communication.[233,726] VR has also peaked industry's interest in recent years because of its cost-effectiveness and accessibility to consumers (e.g., monitoring and maintenance of construction projects).[727] As one example of demand driving growth and expansion, the nuclear industry globally

Potential Indicators	Observations of Current Usage and Future Growth
	identified a market demand for nuclear power plant part replacements and is making financial investments to expand its manufacturing of advanced structural materials and utilization of 3D printing processes.[449,728] Despite the high costs associated with advanced manufacturing investments, some academic institutions that closely monitor the field concur that increased interest and demand will eventually drive down costs associated with advanced manufacturing.[306]
Inter- and Intra-Industry Partnerships	New and continued relationships within and across industries demonstrate the desire to drive a specific advanced manufacturing technology or process to market, e.g., when chemical producers and printing manufacturers came together to create innovative 3D-printed materials.[729] As another example, aviation organizations worked with 3D printing manufacturers to design and produce extruded polymer components for aircraft.[706] Such joint efforts and cross-pollination of expertise fosters risk-sharing, signals to industry and regulators about potential technology readiness, and indicates the development lifecycle is potentially one step closer to initial commercialization or market expansion.
International Interest, Investment, and Implementation	Increased interest, investment, and implementation by international counterparts can signal potential for more widespread advanced manufacturing utilization and adoption. It can also impact global competitive advantage in market sectors, which can drive U.S. (or other global leaders) to look further into such technologies. The following are examples of a few large international efforts towards advanced manufacturing implementation that may indicate some emerging trends and potential areas of future growth: • Glasgow, Scotland implemented a system of sensors that communicate to the traffic lights to assist with traffic control and to minimize travel time.[621] • Russia's energy sector is implementing SG technology and smart infrastructure as a top priority for future growth.[324] • Both China and the EU allocated funds to increase engagement in quantum computing. In 2017, the EU funded a quantum computing technology-based program ($1 billion), and China spent $10 billion towards building a National Laboratory for Quantum Information Sciences.[217] • Made in China 2025 is an initiative to comprehensively upgrade Chinese industry. The initiative currently draws direct inspiration from Germany's "Industry 4.0" plan. The goal of the Made in China program focuses on comprehensively upgrading the Chinese industry, making it more efficient and integrated so that it can occupy the highest parts of global production chains.[730] • An Australian iron ore mining company and a 3D printing company announced a twelve-month agreement to further develop 3D printing across their mining industry. • Brazil has identified monetary advantages from advanced manufacturing adoption and estimated to reduce supply chain cost to at least $19 billion per year.[731] • Overall, the global machine vision market expanded in 2018 to being worth roughly $9 billion and growth is expected to reach $14 billion by 2025.[207] The International Data Corporation (IDC) projected global spending for AI system development is expected to increase from $85 billion in 2021 to $204 billion in 2025.[217]
Private Investments	Both domestically and internationally, industry stakeholders (e.g., private organizations, manufacturers) contribute large financial investments to better understand advanced manufacturing technologies. An interviewee from one government agency indicated that major private capital investments may be an indicator for emerging manufacturing technology.[446] These investments in newly established businesses, like start-ups, are an example of enabling opportunities for innovation, quick adaption to market shifts, and niche focus for emerging technologies or novel applications. Although existing small businesses may not have the investment dollars to adopt emerging technologies compared to large businesses, a small subset provide innovation and create advanced technologies. Industry leaders have drawn more interest in start-ups' potential to generate niche research opportunities. Globally, there are approximately two hundred fifty start-ups, with about 45% of these in the U.S. and Canada focusing primarily on quantum programming, quantum communication, and computers.[217] R&D funding for quantum computing continues to rise and attract the attention of many venture capitalists. In 2020, funding for various start-ups working on quantum computing (e.g., D-Wave Systems, Rigetti Computing, PsiQuantum) received over $500 million from companies like Google, IBM and Microsoft, which allowed them to create their own quantum computers.[732] Though start-ups may carry certain risks, increased funds directed towards promotion of advanced manufacturing technologies displays a strong belief in their growing success.

7 INFLUENCING FACTORS

Research indicates there are several contributing factors that can potentially influence how emerging technologies may be implemented and adopted across the market space, as well as how their corresponding regulations may be applied and integrated into industry. These factors vary in their level of influence depending on the industry, the specific technology and its application(s), or the amalgamation of different factors. Identified factors (Table 7-1) have been summarized into nine themes: crisis events, environmental impact concerns, geography and weather, limited government regulatory resources, organizational readiness, public and market demand, safety and security concerns, technology readiness, and variability in application.

Table 7-1: Potential Influencing Factors

Potential Influencing Factors	Observations of Influence
Crisis Events	Global crises can affect the rate of emergence and implementation or the success of adoption because such crises may create sudden demand for novel technologies or processes or, alternatively, stall them indefinitely. Industry may switch to local or domestically sourced materials instead of sourcing internationally. For example, as supply chain issues slowed global production of metals, industry has pivoted to avoid future supply chain issues and enabled U.S.-based 3D metal printing and other 3D printing technologies to speed up production and lower costs.[733] Industry may also replace materials if a global crisis cripples support or hinders the distributed manufacturing supply chain. As unforeseen events (e.g., pandemics, shifts in financial, supply chain, or food supply changes, weather events) occur, industries may alter the technologies used to accommodate or offset impacts. In these emergency situations, lack of funding and personnel can negatively affect an organization's supply chain and ability to roll out new technologies.[451] Industries must forecast to determine the next steps in replenishing future supply chain when enabling new technologies into their manufacturing space.[605] In addition to large crises, weather patterns (e.g., natural disasters, hurricanes, extreme storms) may slow adoption due to supply chain disruptions, making the raw materials necessary to implement new technologies unavailable.[614,487] For example, as severe storms and droughts impact the agriculture industry, farming groups began using wearable sensor technology and digital monitoring systems to improve irrigation, minimize the loss of water and fertilizer, and adopt drones and robotics that apply herbicides and pesticides.[79] The availability of natural resources or cost of electricity in an area could slow down adoption (e.g., too expensive to transport materials to a more remote area, too expensive to generate sufficient energy to use certain processes).
Environmental Impact Concerns	Industries that want to transition to more environmentally friendly solutions could drive implementation of new technologies that address such concerns. According to the U.S. Energy Information Administration, renewable energy sources are growing year over year.[734] The International Trade Organization reports that the U.S. has a growing demand for clean energy in conjunction with the market's falling costs and government-backed incentive programs and, as a result, the market demand for environmentally friendly technology is expected to grow into the 2030s.[735] The World Economic Forum, based from non-governmental and international companies, published a governance document that provides the sentiment that companies are more than their economic impact and that they should focus on the social and environmental outputs.[736,737] As new technologies that address environmental concerns or clean energy emerge, the public may push to adopt and replace technologies that are less harmful to the climate and environment. For example, renewable energy harvesting is emerging across industries. Because it is addressing environmental impacts, the demand for replacing non-renewable energy (e.g., setting up renewable energy grids, the rise of electric cars) may put pressure on organizations to adopt and regulators to develop standards to shape the renewable energy marketplace.[80] General industry and consumers may not always understand the depth or broad-spanning impacts of a novel technology on environmental health. For example, novel technologies such as synthetic biology, surface modification, and nanotechnology may have concerns about unknown potential ramifications of accidental or intentional release of organisms into the environment.[76,194,398] There may also be concerns with how standards are enforced across industries and the impacts to human health. NIOSH provides Recommended Exposure Limits (RELs) to guide industry on safe limits for workers' safety and health. However, these RELs are based on guidance values which are not enforceable or mandatory.[738] The inability to provide consistent and meaningful oversight can present challenges with misinterpreting the purpose of the guidance and negatively impacting implementation. This inconsistency with enforcement may lead to unsafe workplaces which may inhibit adoption of technologies with similar lack of structured reinforcement. Until more research is completed about the downstream effects of advanced manufacturing technologies (e.g., synthetic biology, surface modification, nanotechnology), industry and regulators may be slow to advance novel technologies.

Potential Influencing Factors	Observations of Influence
Geography and Weather	Topography of the land where technology is built may impact how successful the technology works. When implementing novel multi-sensor data fusion technology, the equipment must be able to gather signals from multiple sensors. If the sensors pick up noise/EMI, industry may be slow to adopt this technology in certain geographic locations due to the topographic constraints.[154, 739] There are also instances where technology (e.g., drones, sensors) utilized in various topographic conditions (e.g., deserts, high elevation) could be negatively impacted by the weather.[740] Other technologies (e.g. quantum computing) may be sensitive to environmental disturbances such as temperature and dust.[216] Industry and organizations may have issues controlling these types of environmental factors and slower to adopt new technologies that are sensitive to disturbances.
Limited Government Regulatory Resources	When government resources (e.g., funding, subject matter experts, time) are limited, regulatory bodies must prioritize and focus on areas of high risk or impact to safety. This could potentially limit the presence or awareness of regulations in lesser used or emerging technologies or processes. Because creation and updating of regulations and standards is time-intensive, it may be burdensome for governments and regulatory bodies to quickly adjust to evolving technologies.[446,563] Regulations may be created or updated, but industry may not know how to apply a broad regulation or standard to their specific technology or product.[741] This disconnect between formal regulatory information and application could inhibit the adoption or growth of new technologies.
Organizational Readiness	Organizational readiness is defined as the members' collective resolve to implement or integrate a change.[742] There are many ways in which organizational readiness may positively and negatively impact industry and regulation implementation. Organizations may be too small or immature, not prepared, lack motivation, or lack funding to integrate novel technologies.[200] If a technology is in the early stages of emergence, it may be expensive to implement, which can discourage organizations from adopting it until it becomes more widespread and affordable.[83] Industry may not have the capacity to adopt technology due to leadership or resource constraints.[83] There may be a lack of competency or resources familiar with the novel technology (i.e., limited number of subject matter experts trained on the technology), especially in certain geographic areas.[451,456,461] Industry or regulators are often ready to implement a technology or update a regulation, respectively, based on three factors: task demands, resource availability, and situational factors. For organizations to be ready for a change, additional change management factors are considered: how the group understands the need for change, how involved the group is related to the change, and how engaged the group is to own the design or implementation of the change.[743] When a group is ready for change, members are more likely to initiate conversations, complete transition activities, and cooperate with others to ensure the change is made.[742,742] Regulators may be more willing to enact a change in adopting or regulating a novel technology if they perceive there is sufficient organizational readiness for that technology across the industry. For example, the waste, aerospace, and agriculture industries have enabled machine vision to utilize AI and sensors to interpret visual information (e.g., take measurements, monitor equipment). The industries may have been ready to adopt these technologies because organizations were functional, ready, and able to support such innovations.
Public and Market Demand	Regulatory bodies may assess public needs to determine where to enact or update regulations related to advanced manufacturing technologies. Governments may rely on more formal public requests (e.g., public advocacy groups, adverse event reporting, public comment periods) to gather and understand collective concerns. However, research has shown that public groups that petition for governmental change through the use of social media outlets can also impact market demand. For example, if a technology is shown or perceived to have a negative impact on the public's safety or health, the population may share their concerns via collective methods that include social media, which may provide opportunities for groups to both share and learn more around emerging advanced manufacturing technologies.[744] When groups are exposed to high-engagement posts, "they perceive greater crisis severity, which in turn increases their responsibility attribution to the company and to social systems."[745] For example, researchers studied the social media response to integration of AI technology. The responses indicated that the public had negative attitudes toward the immaturity of the technology and mistrust in organizations implementing AI.[746] Public interest groups' targeted efforts and initiatives may drive demand for certain novel technologies or share dissatisfaction with current technologies via social media, thus influencing novel emergence and successful adoption. Positive perception may enable growth whereas negative perception may inhibit technologies from being adopted.
Safety and Security Concerns	As new technologies emerge, there may be unknown or unstandardized physical hazards (e.g., machinery or infrastructure) with potential to harm users or other groups. These risks—or even perceived risks—can affect how quickly a technology is adopted or how technologies are rejected due to their risk factors. When safety or environmental risks

Potential Influencing Factors	Observations of Influence
	associated with technologies are identified or perceived by the public, industry, or government, regulators may move to create or enhance guidelines to protect public health. For example, as novel biological-related technologies emerge, there may be concern about exposure impacting human health. Until more research is conducted related to these issues, such as toxicity, industry may be hesitant or inhibit adoption of such novel technology. Because minimal information is currently available on dominant exposure routes, potential exposure levels, and material toxicity related to novel technology (e.g., human exposure to nanomaterials or nanoprocessing materials), there may not be sufficient information for regulators to update guidance or safety measures.[71,75] Emerging technologies may also identify security concerns, such as how data is stored, the ability for outsiders hacking into a server or network, or other breaches to personal or proprietary information.[630,747] For example, new technologies such as biosensors, AI systems, SGs, cloud-based computing, and robotics present security risks related to data privacy, vulnerabilities in the networks, and autonomous control, which may limit adoption until regulations are standardized.[27,206,249,665] These concerns may not always stop implementation as industry moves forward innovating new technologies, but they may factor into how organizations and regulatory bodies weigh risks prior to implementation, as well as the rate of adoption by organizations or the public. If current, adopted technology is proven or perceived to be unsafe, public outcry or demand may influence the rate of implementation or adoption of more novel technologies to mitigate the unsafe conditions. For example, when health concerns related to the agriculture or military industry were identified, industry moved to produce advanced robotics and exoskeletons to automate tasks, improve efficiency, and protect workers' health and safety.[297] Construction, farming, and other industries enable these technologies due to the positive perception of safety. Regulating agencies that see a public safety concern may also propose new or revised guidance or regulation to limit the use of the riskier technology.
Technology Readiness	The readiness—or maturity—of a technology can enable or inhibit its rate of growth and adoption. There can be any number of subfactors that may contribute towards such readiness (e.g., resources, competition, supply chain disruptions, investment levels, implementation costs) and may limit or slow scalability as industries adopt the new technology.[445,451,484] There may also be lags in anticipating risks for technology implementation (e.g., speed to market) and planning to understand the scaling required for a technology to move from the testing to industrialized level, both of which can limit the rate of adoption.[451,484,521] As new technologies emerge, many industries use the Technology Readiness Levels (TRL) or MRL rating systems and their defined criteria to evaluate the maturity or readiness of the advanced manufacturing technology or process.[14] Regulators may also evaluate contributing factors (e.g., lack of resources, adaptability, functional need for technology) to determine the areas(s) of focus or cadence of regulatory updates. Alternatively, if a technology demonstrates that it can be regulated, industry may be more likely to adopt and implement it. For example, the nuclear industry has made improvements in technology readiness to align with nuclear regulatory requirements, which may lead to more widespread adoption of novel nuclear technologies and lead regulatory bodies to update nuclear regulations.[748]
Variability in Application	As industries need or demand innovation, they may implement technologies at varying times and in different ways (e.g., application). Research indicates that variability in technologies may impact how both industry and regulators incorporate novel technologies into their current operations. For instance, industry or regulators may be inconsistently documenting their procedures or infrequently conducting audits to verify compliance. With differing internal processes, certain industries may not be able to successfully integrate certain emerging technologies or processes over others, which can inhibit overall growth and industry adoption.[749] These variations make standardization and regulation difficult to implement across industries. Multiple organizations (e.g., ASME, ASTM Standards Committee) are working to build standards for novel advanced manufacturing technologies and processes.

8 APPENDICES

8.1 Appendix A: Acronyms

Table 8-1: Acronym List

Acronym	Definition
μSXCT	Synchrotron-Based Micro-Computed Tomography
2D	Two-Dimensional
3D	Three-Dimensional
4D	Four-Dimensional
5G	Fifth Generation
6G	Sixth Generation
ABS	Australian Bureau of Statistics
ACMA	American Composites Manufacturers Association
AEM	Association of Equipment Manufacturers
AFRL	Air Force Research Laboratory
AFTIM	Air Force Technical Interchange Meeting
AI	Artificial Intelligence
AIA	Aerospace Industries Association
AIChE	American Institute of Chemical Engineers
AMI	Advanced Metering Infrastructure
AMMD	Additive Manufacturing Material Database
AMMTO	Advanced Materials and Manufacturing Technologies Office
AMNPO	Advanced Manufacturing National Program Office
AMSC	Additive Manufacturing Standardization Collaborative
AMT	Association of Manufacturing Technology
AMTA	Additive Manufacturing Trade Association
ANSI	American National Standards Institute
APC	Advanced Process Control
APG	Alpha Precision Group
API	Application Programming Interface
APL	Applied Physics Laboratory
AR	Augmented Reality
ARM	Advanced Robotics for Manufacturing
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
ATE	Advanced Technological Education
AV	Advanced Visualization
BIRD	Binational Industrial Research and Development
CAD	Computer-Aided Design
CAMAL	Center for Additive Manufacturing and Logistics
CAM-LEM	Computer-Aided Manufacturing of Laminated Engineering Materials
CAPA	Corrective and Preventive Actions
CBAM	Composite Based Additive Manufacturing
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention

Acronym	Definition
CDD	Common Data Dictionary
CDER	Center for Drug Evaluation and Research
CDM	Common Data Model
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CGI	Corporate Green Investment (CGI)
CHIPS	Creating Helpful Incentives to Produce Semiconductors
CISA	Cybersecurity and Infrastructure Security Agency
CIM	Ceramic Injection Molding
CM	Continuous Manufacturing
CMfg	Cloud Manufacturing
CMM	Coordinate Measuring Machine
CNC	Computer Numerical Control
CORDEL	Cooperation in Reactor Design Evaluation and Licensing
CPS	Cyber-Physical System
CPSC	Consumer Product Safety Commission
CSET	Center for Security and Emerging Technology
CT	Computed Tomography
DAO	Decentralized Autonomous Organization
DARPA	Defense Advanced Research Projects Agency
DCI	Data Collection Instrument
DCM	Data-Constrained Modeling
DDoS	Distributed Denial of Service
DED	Directed Energy Deposition
DfAM	Design for Additive Manufacturing
DHS	Department of Homeland Security
DL	Deep Learning
DLP	Digital Light Processing
DMAP	Data Modernization Action Plan
DMF	Digital Microfluidics
DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOE	Department of Energy
DOE-NE	Department of Energy Office of Nuclear Energy
DOL	Department of Labor
DOT	Department of Transportation
DON	Department of the Navy
DPT	Dye-Penetrant Inspection
DSS	Decision Support System
DT	Digital Twin
DTP	Danish Technology Pact
EDXS	Energy-Dispersive X-Ray Spectroscopy
EELS	Electron Energy Loss Spectroscopy
EERE	Office of Energy Efficiency and Renewable Energy
ELP	Experiential Learning Program
EMI	Electromagnetic Interference

Acronym	Definition
EPA	Environmental Protection Agency
EPRI	Electric Power Research Institute
ETP	Emerging Technology Program
EU	European Union
EV	Electric Vehicle
FAA	Federal Aviation Administration
FBG	Fiber Bragg Gratings
FCC	Federal Communications Commission
FDA	Food and Drug Administration
FDM	Fused Deposition Modeling
FEA	Finite Element Analysis
FEM	Finite Element Modeling
FERC	Federal Energy Regulatory Commission
FFF	Fused Filament Fabrication
FMEA	Failure Modes and Effects Analysis
FTC	Federal Trade Commission
FTIR	Fourier Transform Infrared
GAO	Government Accountability Office
GE	General Electric
GMO	Genetically Modified Organism
GPS	Global Positioning System
HHS	Health and Human Services
HPP	High Pressure Processing
HR	Human Resources
IAAE	International Association for Applied Econometrics
IACMI	Institute for Advanced Composites Manufacturing Innovation
IAEA	International Atomic Energy Agency
I-AM	Indirect Additive Manufacturing
IBM	International Business Machines Corporation
IC	Integrated Circuit
ICA	Initial Criticality Assessment
IDC	International Data Corporation
IDSP	Industry Data for Society Partnership
IDSS	Intelligent Decision Support Systems
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
IHE	Institution of Higher Education
IIoT	Industrial Internet of Things
INSPIRE	Integrated NSF Support Promoting Interdisciplinary Research and Education
IoCPT	Internet of Cyber-Physical Things
IoT	Internet of Things
IP	Intellectual Property
IR	Infrared
IRB	Institutional Review Board
IRPA AI	Institute for Robotic Process Automation and Artificial Intelligence
ISE	Industrial and Systems Engineering

Acronym	Definition
ISIE	International Society of Interdisciplinary Engineers
ISO	International Organization for Standardization
ISR	Intelligence, Surveillance, and Reconnaissance
IT	Information Technology
I-TEAM	Innovative Technologies and Advanced Manufacturing
JAMWG	Joint Additive Manufacturing Working Group
KSA	Knowledge, Skills, and Abilities
LLC	Limited Liability Company
LOM	Laminated Object Manufacturing
LoRaWAN	Long Range Wide Area Network
LPT	Liquid Penetrant Testing
LTE	Long-Term Evolution
MAM	Mobile Additive Manufacturing
ManTech	Manufacturing Technology
MEP	Manufacturing Extension Partnership
MII	Manufacturing Innovation Institute
MIM	Metal Injection Molding
MINER	Mine Improvement and New Emergency Response
ML	Machine Learning
MR	Mixed Reality
MRL	Manufacturing Readiness Level
MRO	Maintenance, Repair, Overhaul
MRTO	Multiple Remote Tower Operations
MSFC	Marshall Space Flight Center
MSHA	Mine Safety and Health Administration
mW	Milliwatt
NAICS	North American Industry Classification System
NAIIO	National Artificial Intelligence Initiative Office
NAIRR	National AI Research Resource
NAM	National Association of Manufacturers
NAMA	National Additive Manufacturing Association
NAMTI	Naval Additive Manufacturing Technology Interchange
NASA	National Aeronautics and Space Administration
NATO	North Atlantic Treaty Organization
NC	North Carolina
NCCoE	National Cybersecurity Center of Excellence
NDAA	National Defense Authorization Act
NDE	Non-Destructive Evaluation
NDT	Non-Destructive Testing
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NHSI	Nuclear Harmonization and Standardization Initiative
NHTSA	National Highway Traffic Safety Administration
NIAR	National Institute for Aviation Research
NIH	National Institutes of Health
NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals

Acronym	Definition
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLP	Natural Language Processing
NMI	Non-medical Industry
NPP	Nuclear Power Plant
NRC	Nuclear Regulatory Commission
NSF	National Science Foundation
NSTC	National Science and Technology Council
nW	Nanowatt
OAM	Office of Advanced Manufacturing
OC	Office of the Commissioner
OCET	Office of Counterterrorism and Emerging Threats
OCS	Office of the Chief Scientist
ODI	Open Data Institute
OEA	Office of Economics and Analysis
OECD	Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
OPQ	Office of Pharmaceutical Quality
ORNL	Oak Ridge National Laboratory
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
OT	Operational Technology
OWI	Office of Workforce Investment
PAT	Process Analytical Technology
PBF	Powder Bed Fusion
PBF-LB	Laser Beam Powder Bed Fusion
PCM	Phase Change Material
PCR	Polymerase Chain Reaction
PETG	Polyethylene Terephthalate Glycol
PEV	Plug-n-play Electric Vehicles
PIM	Powder Injection Molding
PLA	Polylactic Acid
PLM	Product Lifecycle Management
PPE	Personal Protective Equipment
PRR	Production Readiness Review
PSL	Plastic Sheet Lamination
QC	Quality Control
QDCA	Quantum-Dot Cellular Automata
QMS	Quality Management System
R&D	Research and Development
RAI	Responsible Artificial Intelligence
RAM	Random Access Memory
RAPID	Rapid Advancement in Process Intensification Deployment
RDIS	Research and Development Information System
REL	Recommended Exposure Limit
REMADE	Reducing Embodied Energy And Decreasing Emissions

Acronym	Definition
RF	Radio Frequency
RFID	Radio Frequency Identification
RIA	Regulatory Impact Analysis
S&I	Strategy and Implementation
SaaS	Software-as-a-Service
SAE	Society of Automotive Engineers
SBS	Sensor-Based Sorting
SCADA	Supervisory Control and Data Acquisition
S-CAP	Standards and Conformity Assessment Program
SDL	Selective Deposition Lamination
SDO	Standards Developing Organizations
SDR	Spinning Disc Reactor
SG	Smart Grid
SLCOM	Selective Lamination Composite Object Manufacturing
SLM	Selective Laser Melting
SMDR	Spinning Mesh Disc Reactions
SME	Society of Manufacturing Engineers
SMR	Small Modular Reactor
SOP	Standard Operating Procedure
SPO	Scanned Probe Oxidation
STEM	Science, Technology, Engineering and Mathematics
TMAP	Technology Modernization Action Plan
TRL	Technology Readiness Level
TV	Television
UAM	Ultrasonic Additive Manufacturing
UARC	University Affiliated Research Center
UAV	Unmanned Aerial Vehicle
U.S.	United States
USA	United States of America
USDA	United States Department of Agriculture
USG	U.S. Government
UV	Ultra-violet
V2G	Vehicle-to-Grid
VA	Veterans Affairs
VR	Virtual Reality
VRNT	Variable Rate Nitrogen Application Technology
VRT	Variable Rate Technology
WAAM	Wire Arc Additive Manufacturing
WM	Waste Management
WSN	Wireless Sensor Network
XPS	X-Ray Photoelectron
XR	Extended Reality

8.2 Appendix B: Non-Medical Industries

The NAICS[750] was utilized to identify and define potential industries to include in this analysis. NAICS is an industry classification system that groups establishments into industries based on the similarity of their production processes. It is a comprehensive system covering all economic activities and grouped by production criterion across 20 sectors, 96 subsectors, and 1,012 industries in the U.S. While each industry is expansive, the industry names (some of which were derived by NAICS sector or subsector titles) and descriptions below are scoped as they apply to this landscape scan. One exception is for AI, which to date, does not have its own industry code but is included in the description of the "Research and Development in the Physical, Engineering, and Life Sciences" industry. In addition, while consumer product safety is an illustrative example of the industry titled "Other Justice, Public Order, and Safety Activities", neither consumer nor worker safety are referenced within the NAICS. In identifying industries for this report, we felt AI and safety were pertinent areas to be included.

Aerospace Research, Technology, and Development: Aerospace manufacturing encompasses aircrafts, missiles, space vehicles, aerospace components and products, and aircraft conversions, overhauls, and rebuilds.[327]

Agriculture: The agriculture industry involves growing and harvesting crops and raising animals. The industry can be broken up into two areas: 1) agricultural production, and 2) agricultural support activities associated with farm operation (e.g., soil preparation, planting, harvesting, and management). This industry does not include agricultural research or government regulated lands (e.g., national parks).[750,751]

Artificial Intelligence (AI): Manufacturing and Technology: AI represents the "ability of computers to perform cognitive functions associated with human minds, such as perceiving, reasoning, learning, and problem solving."[490] With modern manufacturing systems generating copious amounts of data (e.g., environmental, process, operational, measurement), AI can collect these data and translate them into actionable outputs that provide organizations with critical insights to increase the efficiency and quality of production, improve the resiliency of their supply chains, and protect sensitive information from cyberthreats.[122,222,490] AI includes multiple subfields (e.g., ML, NLP, image processing, and data mining).[752] Recent substantial increases in the usability and sophistication of AI and its subfields have enabled industry to identify additional current and future applications to leverage AI for robotics, transportation, healthcare, education, and others.[177,753]

Air Transportation: The aviation industry involves air transportation of passengers and/or cargo using aircrafts (e.g., airplanes, helicopters, spacecraft). However, the aviation industry excludes air transportation related to sightseeing and air courier services.[751]

Chemical Manufacturing: Chemical manufacturing industry transforms organic and inorganic raw materials using a chemical process to formulate products. It includes several sub-manufacturing processes: basic chemical manufacturing (e.g., petrochemical, industrial gas, synthetic dye); resin, synthetic rubber, and artificial and synthetic fibers and filaments manufacturing; pesticide, fertilizer, and other agricultural chemical manufacturing; pharmaceutical and medicine manufacturing; paint, coating, and adhesive manufacturing; soap, cleaning compound, and toilet preparation manufacturing; and other chemical product and preparation manufacturing (e.g., printer ink, explosives).[751]

Construction: The construction industry deals with the construction of buildings, infrastructure (e.g., highway systems, utility systems), and construction/building sites. Industry activities include new builds, modifications, and maintenance of buildings and infrastructure, and also involve the use of specialty trade contractors, and smaller or specific work on construction such as painting, electrical work, and flooring. Construction is divided into three subcategories: Construction of Buildings, Heavy and Civil Engineering Construction (e.g., infrastructure), and Specialty Trade Contractors. Force account construction is not included as part of the construction industry unless the work is performed by the construction sector of a company. Maintenance of telecommunications and utility systems are also not included unless the work is completed by independent contractors.[751]

Data Processing: Data processing organizations use data supplied by clients or automated data entry services to provide processing and specialized reports.[751]

Defense: National defense agencies and the private-sector defense industry are developing advanced technologies that improve military agility, including silicon photonics (i.e., silicon integrated circuits and semiconductor lasers for data transfer speed), computer modeling for defense product defects, and additive manufacturing.[751]

Energy: Electric and Nuclear: The energy industry engages in electrical power generation, transmission, and distribution. Electrical energy is generated from various sources that include "waterpower (i.e., hydroelectric), fossil fuels, nuclear power, and solar power. The energy industry can undertake one or more of the following activities: "(1) operate generation facilities that produce electric energy; (2) operate transmission systems that convey the electricity from the generation facility to the distribution system; and (3) operate distribution systems that convey electric power received from the generation facility or the transmission system to the final consumer."[751]

Life Sciences: The life sciences industry primarily relates to nanotechnology and biotechnology and the overall improvement of the lives of organisms.[751]

Metal Manufacturing: The metal manufacturing industry includes organizations that "smelt and/or refine ferrous and nonferrous metals from ore, pig, or scrap, using electrometallurgical and other process metallurgical techniques". Metal manufacturing can create several metal products (i.e., bars, rods, and wires) in addition to alloys and superalloys. However, metal manufacturing does not include the use of coke ovens or manufacturing of "ferrous and nonferrous forgings (except ferrous forgings made in steel mills) and stampings."[751]

Mining (Except Oil, Gas, and Uranium): The mining industry partakes in the mining and beneficiating (i.e., preparing) of metallic and nonmetallic minerals in addition to mine site development. The term "mining" can include the following activities that typically occur at a mining site: ore extraction, quarrying, and beneficiating (e.g., crushing, screening, washing, sizing, concentrating, and flotation).[751]

Motor Vehicle Manufacturing: Motor vehicle manufacturing encompasses organizations engaged in: "1) manufacturing complete automobiles, light duty motor vehicles (e.g., trucks, vans, pickup trucks, minivans and sport utility vehicles), and heavy-duty trucks (e.g., trucks, buses, motor homes); or (2) manufacturing motor vehicle chassis only".[751] A trend within this industry is towards manufacturing environmentally sustainable components and cars, as well as a future trend towards research, development, and implementation of autonomous vehicles.[751]

Petroleum and Coal Products: The petroleum and coal products manufacturing industry transforms crude petroleum and coal into usable products. Its dominant process is "petroleum refining that involves the separation of crude petroleum into component products through such techniques as cracking and distillation." In addition, the industry includes "establishments that primarily further process refined petroleum and coal products and produce products, such as asphalt coatings and petroleum lubricating oils. However, establishments that manufacture petrochemicals from refined petroleum are classified [separately]."[751]

Safety: Consumer and Worker: The consumer and worker safety industry is focused on best practices and standards for various consumer products including robotics and sensors to compensate for human error, PPE, and advanced raw materials (e.g., antimicrobial materials). Advanced manufacturing within this industry focuses on streamlining safety processes and protocols for workers and using AI for digital transformation.[3,751]

Telecommunication: The telecommunication industry provides all forms of telecommunication (e.g., telephones, internet, cable, satellite television) and includes companies such as internet providers and cell phone carriers. The industry engages in providing and or operating facility access of the transmission of voice, data, text, sound, and video. However, telecommunication systems construction and/or maintenance is not an included activity.[751]

Uranium Mining, Processing, and Atomic Energy: Uranium mining and processing refers to the life cycle of developing mine sites, "mining, and/or beneficiating (i.e., preparing) metal ores." Although atomic energy is closely related to the "Nuclear Electric Power Generation" industry listed within NAICS, atomic energy here refers to the technologies, processes, and methods in which uranium and uranium derivatives are utilized.[751]

Waste Management and Remediation Services: The waste management and remediation services industry collects, treats, and disposes of material waste. Waste management industry activities also include material operation, material sorting (e.g., recyclable materials versus trash materials), remediation service and septic pumping and other miscellaneous waste management services. Activities are separated into three groups: waste collection, waste treatment and disposal, and remediation and other waste management. Waste management activities do not include hauling waste materials long distances, sewer systems and sewage treatment facilities services, and tangential waste management activities (e.g., waste management consulting).[751]

8.3 Appendix C: Mega Search String Terms

Mega search strings were developed to capture research articles that are within scope and aligned to research questions for this landscape analysis. These strings were created by incorporating terms from Columns A, B, C, D, E, and F in Table 8-2 with Boolean operators (AND, OR). Within Table 8-2, Column A was intentionally left blank since search terms varied and were industry dependent. Each individual string included keywords specific to each of the 18 non-medical industries addressed in this report. The following combinations were included:

- A+B+C (i.e., industry terms + innovation terms + manufacturing processes)
- A+B+D (i.e., industry terms + innovation terms + enabling technologies)
- A+B+E (i.e., industry terms + innovation terms + manufacturing technologies)
- A+B+F (i.e., industry terms + innovation terms + additional terms recommended by OCET)

For example, ***A+B+C*** mega search string, would be entered as:

(“Aerospace” OR “Aerospace research” OR “Aerospace technology” OR “Aerospace manufacturing” OR “Space engineering” OR “Space research” OR “Space technology” OR “Space exploration” OR “Space manufacturing” OR “Aeronautics” OR “Astronautics” OR “Aerospace engineering” OR “Hybrid-electric aircraft”)

AND

(“Novel manufacturing” OR “Innovative manufacturing” OR “Enabling technology” OR “Advanced analytical technologies” OR “Advanced computational technique” OR “Advanced sensing technology” OR “Advanced manufacturing” OR “Innovative technology” OR “Digitalization” OR “Digital transformation” OR “Innovative process” OR “Enabling innovation” OR “Emerging technology” OR “Disruptive technology” OR “Industry 4.0”)

AND

(“Automated manufacturing” OR “Continuous manufacturing” OR “Distributed manufacturing” OR “Flexible manufacturing” OR “Smart manufacturing” OR “Modular system” OR “Personalized manufacturing” OR “End-to-end continuous manufacturing” OR “Smart factory” OR “Rapid manufacturing” OR “Rapid prototyping” OR “Next-generation manufacturing” OR “Digital thread”)

Table 8-2: Mega Search String Terms for Web of Science Literature Search

Column A Industry Terms *Terms Vary By Industry*	Column B Innovation Terms	Column C Manufacturing Processes	Column D Enabling Technologies	Column E Manufacturing Technologies	Column F Additional Terms Recommended by OCET
	• Novel manufacturing • Innovative manufacturing • Enabling technology • Advanced analytical technologies • Advanced computational technique • Advanced sensing technology • Advanced manufacturing • Innovative technology	• Automated manufacturing • Continuous manufacturing • Distributed Manufacturing • Flexible manufacturing • Smart manufacturing • Modular system • Personalized manufacturing • End-to-end continuous manufacturing • Smart factory	• Advanced computation and analytics approaches • Advanced robotics • In-line sensing and process control • Artificial intelligence • AI • Machine learning • ML • Virtual reality • VR • Big data • Data cloud • Cloud computing • Robotics • Computer-aided design	• Additive manufacturing • 3D printing • Automated closed-loop system • Biofabrication • Bioprinting • Bioreactor • Controlled-ice nucleation • Lyophilization • Digital twin • Electron beam • High pressure processing • Hot melt extrusion • Metal injection molding • Microwave-assisted thermal sterilization	• Sterility • Sterile • Water absorption • Soil absorption • Education • Training • Paper manufacturing • Packaging • Material Extrusion • FFF • Fused Filament Fabrication • Vat photopolymerization • Direct energy deposition • Sheet Lamination

Column A Industry Terms *Terms Vary By Industry*	Column B Innovation Terms	Column C Manufacturing Processes	Column D Enabling Technologies	Column E Manufacturing Technologies	Column F Additional Terms Recommended by OCET
	• Digitalization • Digital Transformation • Innovative process • Enabling innovation • Emerging technology • Disruptive Technology • Industry 4.0	• Rapid Manufacturing • Rapid Prototyping • Next-Generation Manufacturing • Digital Thread	• CAD • Computational modeling and simulation • Connectivity and edge processes • Process analytical technology • Process control • Digital checkpoint • In-line sensing • Single-use technologies • Isolator technology • Nanotechnology • Augmented Reality • AR • Laminated Object Manufacturing • LOM • Smart robotics • Smart • Internet of things • IoT • Collaborative robot • Cobot • Prototype • Directed energy deposition • Intelligent production systems • Advanced sensor technologies • Topology Optimization • DfAM • Design for Additive Manufacturing	• Microwave-assisted pasteurization system • Multi-attribute method • Parametric release • Plasma activated water • Radio frequency heating • Single-use systems • Novel container • Novel closure system • Fused deposition modeling • FDM • Pressure-assisted microsyringe • PAM • Stereolithography • Binder jetting • Powder bed fusion • Selective laser melting • SLM • Inkjet printing • 4D printing • Metal shape memory alloy • Closed system manufacturing • Graphene • Polymer coating • Spectrometry • Spectrophotometry • Liquid chromatography • Smart biomaterial • Biocompatibility testing • Direct metal laser sintering • Free-form fabrication • Selective laser sintering • Material jetting • Digital light synthesis • Direct laser melting • Semiconductor • Advanced materials	

8.4 Appendix D: Non-Medical Industry Stakeholders

A non-exhaustive, illustrative list was compiled to identify non-medical industry stakeholders and their role towards progressing the research, development, and/or integration of advanced manufacturing. Within agencies (e.g., EPA, United States Department of Agriculture [USDA], FDA), there may be overlapping product areas with coordinated regulatory frameworks to facilitate transparent interactions.

Table 8-3: Regulatory Agency Stakeholders

Regulatory Agencies	Description
Consumer Product Safety Commission (CPSC)	CPSC works to "protect the public against unreasonable risks of injury associated with consumer products" by creating laws and regulations (i.e., Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Child Safety Protection Act) related to consumer products.[754]
Department of Labor's Mine Safety and Health Administration (MSHA)	MSHA focuses on the prevention of mining related deaths, illnesses, and injuries by promoting safe and healthful workplaces for U.S. miners.[755] Through the Federal Mine Safety and Health Act of 1977 (Mine Act), as amended by the Mine Improvement and New Emergency Response (MINER) Act of 2006, the Secretary of Labor has the "authority to develop, promulgate, and revise health or safety standards for the protection of life and prevention of injuries in the nation's mines."[756]
Department of Labor: Occupational Safety and Health Administration (OSHA)	OSHA works to set and enforce standards to ensure employees have a safe and healthful work environment. They also provide training, outreach, education, and assistance. OSHA conducts inspections (i.e., imminent danger situation, fatality, or a worker complaint) to enforce their regulations and to ensure employers are complying with all applicable OSHA standards.[757]
Environmental Protection Agency (EPA)	EPA works to protect the health of humans and the environment by creating and issuing environmental regulations that span across the agriculture, automotive, construction, energy/electric utilities, oil and gas, and transportation industries.[758] The areas of regulation can include, but are not limited to, pesticides, toxic substances, waste and its various forms, water, and air (i.e., emissions, pollutants).[759,760]
Federal Aviation Administration (FAA)	FAA works towards becoming the most safe and efficient aerospace system in the world by regulating all civil aviation activities and air traffic management in U.S. airspace. FAA is responsible for issuing and enforcing regulations related to the manufacturing, operation, and maintenance of aircrafts. They also certify airmen and airports that serve air carriers.[761]
Federal Energy Regulatory Commission (FERC)	FERC serves as an independent agency responsible for regulating the interstate transmission of natural gas, oil, electricity, and hydropower projects. Through the appropriate collaborative efforts, regulatory, and market means, FERC assists consumers in obtaining reliable, safe, secure, and economically efficient energy services.[762]
Nuclear Regulatory Commission (NRC)	NRC provides reasonable assurance of adequate public health protection and safety and promotes common defense and security to protect the environment. NRC is responsible for the regulation of nuclear reactors, nuclear materials, and nuclear waste, as well as licensing the nation's civilian use of radioactive materials. [763]

Table 8-4: Non-regulatory Agency Stakeholders

Non-regulatory Agencies	Description
Air Force	The U.S. Air Force serves as the nation's air and space defense and is responsible for developing war fighting technology.[764,765]
Department of Defense (DoD)	DoD serves as the largest U.S. government agency responsible for protecting the nation's security by providing the necessary military forces to deter war.[766]

Non-regulatory Agencies	Description
Department of Energy (DOE)	DOE works to ensure the security and prosperity of America by utilizing transformative science and technology solutions to address energy, nuclear, and environmental challenges.[767] To increase U.S. industrial competitiveness and drive economy-wide decarbonization, DOE's Advanced Materials and Manufacturing Technologies Office (AMMTO) conducts research and develops and demonstrates next-generation materials and manufacturing technologies. AMMTO focuses on driving material and manufacturing innovations and transformations for America's future energy use.[768]
DOE: Oak Ridge National Laboratory (ORNL)	DOE ORNL serves as one of the nation's largest multi-program science and technology laboratories that focuses on scientific and technical discoveries in energy and national security.[769] ORNL serves as a leader for R&D related to supercomputing, advanced manufacturing, materials research, neutron science, clean energy, national security, AI, bioenergy technologies, energy storage, grid security, and waterpower technologies.[770,771]
National Aeronautics and Space Administration (NASA)	NASA serves as the global leader in space exploration and America's civil space program. NASA's research covers the Earth and its climate, the sun, and the solar system. They also research and test for advance aeronautics development.[772]
National Institute for Occupational Safety and Health (NIOSH)	NIOSH is a research agency within the CDC that aims "to develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice." NIOSH's focus pertains to several areas in relation to occupational safety (i.e., motor vehicles, robotics, maritime work, and older age workers).[773]
National Institute of Standards and Technology (NIST)	NIST works to promote innovative and industrial competitiveness through the advancement of measurement science, standards, and technology that enhances economic security and improves the quality of life within the U.S.[774] • The NIST MEP works to strengthen and empower U.S. manufacturers through federal, state, and local level collaborative partnerships and increased access to available resources. MEP works with manufacturers "to develop new products and customers, expand and diversify markets, adopt new technology, and enhance value within supply chains."[775] MEP resides within NIST's Department of Commerce and is comprised of a MEP Advisory Board, MEP Center boards, the Foundation for Manufacturing Excellence, 51 Centers, and 430 MEP service locations. Additionally, MEP employs approximately 1,450 trusted advisors and experts to further support U.S. manufacturers' needs.[776] • NIST's Office of Advanced Manufacturing (OAM) is responsible for managing NIST's outreach geared towards advanced manufacturing. OAM provides federal financial assistance in programs (i.e., AMTech and open-topic competition Manufacturing USA institutes) and serves as the headquarters for the interagency Advanced Manufacturing National Program Office (AMNPO). AMNPO has representation from manufacturing-focused federal agencies (e.g., NASA, DoD, DOE), academia, and private manufacturers.[777]
National Science Foundation (NSF)	NSF works to advance the nation's health, prosperity, and welfare by funding research focused on the progression of science and securing the nation's defense. NSF-funded research includes topics related to science, engineering, and education, as well as research areas related to strengthening national defense (i.e., cryptography, cybersecurity, novel materials, advanced analytics for massive datasets, AI, environmental change, quantum information systems, and advanced manufacturing).[778]
National Science and Technology Council (NSTC)	NSTC advises the President on policy decisions and implementation activities related to science and technology. Established in 1993, NSTC is comprised of cabinet-level advisors that ensure the science and technology policy decisions are aligned with the President's policy priorities. NSTC has six main committees (i.e., Science and Technology Enterprise, Environment, Homeland and National Security, Science, STEM Education, and Technology) and a specific committee, the Select Committee on AI, focusing specifically on AI.[779]
National Artificial Intelligence Initiative Office (NAIIO)	NAIIO serves as support to both the Select Committee on AI and the National AI Initiative Advisory Committee and acts as a point of contact for multiple stakeholders (e.g., federal departments and agencies, academia, industry, nonprofit organizations, professional societies) when addressing technical and programmatic AI-related initiatives. NAIIO is also responsible for conducting regularly scheduled stakeholder outreach and promoting their expertise on topics related to technology access, best practices, and innovations.[780]

Table 8-5: Private Manufacturer Stakeholders

Private Manufacturers	Description
General Electric Company (GE)	GE serves as a U.S. private manufacturing, multinational company heavily focused on delivering solutions related to additive manufacturing, materials science, and data analytics within industries such as power, renewable energy, aviation, and healthcare.[781]
Lockheed Martin	Lockheed Martin is a global company that focuses on security and aerospace research, design, development, manufacture, integration, and sustainment of advanced technology systems, products, and services. Lockheed Martin's capabilities and technology focus areas include, but are not limited to, autonomous and unmanned systems, cyber technology, directed energy, electronic warfare, energy storage solutions, radar, sensors, and weapon systems.[782]
Northrop Grumman	Northrop Grumman serves as a global company focusing on aerospace, defense, and security industries.[783] Northrop Grumman is comprised of four business sectors: Aeronautics Systems, Defense Systems, Mission Systems, and Space Systems.[784] Northrop Grumman has experience in digital transformation, space technologies, AI, advanced manufacturing, and environmental technology, as well as development of autonomous underwater vehicles and digital defenses for physical assets.[785]
Siemens	Siemens serves as a global technology group focused on the automation and digitalization of the manufacturing industry's processes. Siemens' four business sectors include digital industries, smart infrastructure, mobility, and medical technology through their Siemens Healthineers company.[786,787] Siemens' research areas include, but are not limited to, additive manufacturing and materials, sustainable energy infrastructures, AI, cybersecurity and trust, automation, connectivity and edge, sustainable energy infrastructure cybersecurity and trust, and data analytics.[788,789]

Table 8-6: Academic Institution Stakeholders

Academic Institutions	Description
North Carolina State University - Industrial and Systems Engineering (ISE) - AM Department	The ISE AM Department's is comprised of students and faculty members focused on research that advances modern manufacturing system technologies. Their industrial engineers work in subject areas related to big data, automation, robotics, nanotechnology, 3D printing, automotive, aerospace, power electronics, and microscale/nanoscale materials and processes.[9] Within the ISE AM Department is the Center for Additive Manufacturing and Logistics (CAMAL). Initiated in 2014, CAMAL aims to become a leader in advanced manufacturing and rapid prototyping R&D.[790] CAMAL conducts research pertaining to material development, biomedical, hybrid manufacturing, and logistics and supply chain.[791]
Wichita State University National Institute for Aviation Research (NIAR)	Wichita State University's NIAR is a unique aviation-based R&D facility that provides research, design, testing, certification, and training for aviation and manufacturing-related industries. They are known for their expertise in composites and advanced material, DT, and advanced manufacturing technologies, like automated and additive manufacturing.[792]

Table 8-7: Public-Private Partnership Stakeholders

Public-Private Partnership	Description
America Makes	Founded in 2012 by the DoD, America Makes serves as the leading public-private partnership for additive manufacturing processes and education. America Makes is comprised of members from industry, academia, government, and organizations working together to accelerate the nation's adoption of additive manufacturing and global manufacturing competitiveness.[793]
American Institute of Chemical Engineers (AIChE)	AIChE serves as the world's leading organization for chemical engineering professionals. AIChE is comprised of over 60,000 members from over 110 countries from different technical groups across the manufacturing industry.[794] Organizations engaged with AIChE can include, but are not limited to, Rapid Advancement in Process Intensification Deployment (RAPID) Manufacturing Institute, Design Institute for Physical Properties, Advanced Manufacturing and Processing Society, Nanoscale Science & Engineering Forum, and Pharmaceutical Discovery, Development and Manufacturing Forum.[795]

Public-Private Partnership	Description
BioMADE	BioMADE is a DoD sponsored Manufacturing Innovation Institute (MII) and a member of Manufacturing USA®. BioMADE focuses on accelerating the commercialization of modern biotechnology products and identifying domestic supplies of important materials by focusing on the pilot-scale MRLs 4-7. BioMADE de-risks the process of bringing new products to market and stimulates investment in biomanufacturing. The direct outcome of these R&D efforts will be to develop and expand industrial and defense-related biomanufacturing in U.S. public-private partnerships, such as BioMADE, to generate IP and create solutions to problems broadly impacting the bio-industrial manufacturing ecosystem.[796,797]
International Atomic Energy Agency (IAEA)	IAEA serves as an independent, intergovernmental science and technology-based organization for the nuclear industry. IAEA focuses on the safe use of nuclear science and technology. Additionally, IAEA assists Member States with social and economic goals related to nuclear technology utilization planning, knowledge and transfer, and nuclear safety standards development. IAEA also conducts inspections to verify Member States comply with their commitments and use nuclear materials and facilities for only peaceful purposes.[798]
Institute of Electrical and Electronic Engineers (IEEE)	IEEE serves as the world's largest technical professional organization. IEEE aims to "foster technological innovation and excellence for the benefit of humanity." IEEE is considered a trusted, unbiased source for technical information. IEEE encourages broad information sharing and education of fundamental activities, community building, and partnerships. Additionally, IEEE looks to advance technical interests and inform public policy.[799]
World Nuclear Association	World Nuclear Association is an international organization that represents the global nuclear industry and works to promote a wider understanding of nuclear energy among key international influencers. World Nuclear Association produces authoritative information, develops common industry positions, and contributes to the international energy debate. Their three strategic areas of focus relate to "nuclear industry cooperation (e.g., working groups, forums, meetings), nuclear information management, and nuclear energy communication."[800]

Table 8-8: Trade Association Stakeholders

Trade Associations	Description
Aerospace Industries Association (AIA)	Since 1919, AIA has served as an advocate and leader towards shaping policy, providing insight on the aerospace industry's impact and how to fortify its future. AIA advocacy influences federal investments, accelerates innovative technologies development, advances policies geared towards enhancing global competitiveness, and supports recruitment and workforce retention efforts.[801]
National Association of Manufacturers (NAM)	NAM serves as an advocate and resource for the nation's manufacturers industry-wide. NAM is comprised of 14,000 organizations, with 90% of the members being small to medium-sized organizations.[802]

Table 8-9: Standards Organization Stakeholders

Standards Organizations	Description
American National Standards Institute (ANSI)	Founded in 1918, ANSI serves as a private, nonprofit organization responsible for administering and coordinating the U.S. voluntary standards and conformity assessment system. ANSI collaborates with industry and government stakeholders "to identify and develop standards- and conformance-based solutions to national and global priorities."[803]
American Society for Testing Materials (ASTM) International	ASTM International is a global standards organization focused on the development and enhancement of technical quality standards across multiple industries (e.g., energy, aerospace, construction, chemical, metal manufacturing, healthcare). ASTM partners with different stakeholder groups (e.g., industry, government, and academia) in over 140 participating countries to help advance the use and understanding of over 12,500 global ASTM standards created for innovative products and services.[804]

Standards Organizations	Description
International Electrotechnical Commission (IEC)	IEC is a not-for-profit, global organization with a focus in electrical and electronic goods' quality infrastructure and international trade. IEC is responsible for facilitating "technical innovations, affordable infrastructure development, efficient and sustainable energy access, smart urbanization and transportation systems, climate change mitigation, and increases the safety of people and the environment." IEC provides a global, neutral, and independent standardization platform to approximately 20,000 global experts, spanning 170 countries. IEC International Standards are used when testing, certifying, and verifying that manufacturers upheld their promise. IEC publishes around 10,000 IEC International Standards and administers four conformity assessment systems for members to certify devices, systems, installations, services, and people conduct work as required. Both resources provide technical frameworks to government and companies when attempting to build quality infrastructures, as well as buy and sell safe and reliable products.[805]
International Organization for Standardization (ISO)	ISO is an independent, non-governmental international organization that engages experts to share knowledge and develop international standards that are consensus-based and market relevant. These standards are geared towards supporting innovation and providing solutions to global challenges. ISO is comprised of a global network of 168 national standard bodies with one member per country to represent their nation's standards.[806]

Table 8-10: Professional Organization Stakeholders

Professional Organizations	Description
Association of Manufacturing Technology (AMT)	AMT works to advance manufacturing technology by providing support to their members and industry. AMT provides industry services related to the facilitation of transformative technologies adoption. These services aid in enhancing industry knowledge, fostering community and partnerships, holding events to create new business opportunities, and supporting global business growth.[807]
American Society of Mechanical Engineers (ASME)	Founded in 1880, ASME is as a not-for-profit professional organization that serves the global engineering community and assists in developing solutions for real-world challenges, knowledge sharing, and skill development. ASME provides a foundation for technical knowledge advancement through their ASME codes and standards, publications, conferences, continuing education, and professional development programs.[808]
Society of Manufacturing Engineers (SME)	Established in 1932, SME serves as a nonprofit organization dedicated to manufacturing advancements. SME looks to elevate manufacturing stakeholders (i.e., manufacturers, academia, and communities) by creating new ways to understand and solve problems and believes "manufacturing holds the key to economic growth and prosperity."[809]

8.5 Appendix E: 3D Printing Subtypes

3D PRINTING: BINDER JETTING

Description: Binder jetting is a layer-by-layer 3D printing manufacturing method that distributes powder in a fine layer, then distributes a binding fluid applied via an inkjet print head.[810] The printer repeats the layering process with powder and binding fluid to build up layers. Once complete, the printed item is cured using convection ovens or IR light, which removes the solvent and solidifies the layers.[811]

Applications: Binder jetting has been leveraged to cast patterns, molds, cores, prototypes, full-color decorative objects, and jewelry. Binder jetting has also been utilized for aerospace for part development and other heavy industries. Materials such as polymers, biomaterials, ceramics, and metals have been used in 3D printing via binder jetting for applications including electronics and tissue engineering.[810]

Key Benefits: Binder jetting provides faster print speeds, lower costs, flexibility in material use due to powder form, increased build platform volume, and reduced risk of part warping. Since support structures are not required, it allows multiple parts to be fabricated in one powder bed simultaneously, which is ideal for low to medium batch production. Further, binder jetting with print heads that contain color allows production of complex and full-color designs.[812]

Limitations and/or Risks: Binder jetting often requires post-processing (e.g., curing, bronze infiltration, sintering) to strengthen parts due to the lack of mechanical functionality, which may require additional time and costs.[812]

Stage of Emergence or Adoption: Binder jetting aligns with the adoption stage, as binder jetting appears to be integrated into the market.

3D PRINTING: BIOFABRICATION AND BIOPRINTING

Description: Biofabrication (including bioprinting) refers to the process of using living cells as an alternative to traditional synthetic chemistry to synthesize and assemble materials in a layer-by-layer construction method.[3,539,813] Specific modalities are available for various applications, including several 3D printing methods such as extrusion-based 3D printing, droplet-based bioprinting (e.g., inkjet printing), and laser-based bioprinting (e.g., stereolithography).[814]

Applications: Bioprinting is used in non-biomedical contexts to build environmental sensors and remediations (e.g., immobilizing bioluminescent bacteria in alginate beads to sense explosive material; immobilizing *Bacillus velezensis* on a microsphere of sodium alginate to treat slaughterhouse wastewater).[814] Bioprinting is commonly used in biomedical manufacturing for in vitro tissue models, healthcare research, drug screening in toxicology studies, cell research, and wound regeneration.[539] Biofabrication has also been used to engineer vaccines and therapeutics such as intervertebral disc (IVD) scaffolds.[815] Drop-on-demand printing creates 3D hypercellular constructs to enhance the homology to native tissues and/or organs.[539]

Key Benefits: Bioprinting provides the option to utilize genetically engineered self-repairing systems (i.e., cells) to respond to environmental stimuli in a prescribed way. It enables the production of highly complex structures with minimal labor, straightforward operating conditions, and simple equipment and materials.[810]

Limitations and/or Risks: Bioprinting may emit harmful chemicals during the bioprinting process. It has equipment restrictions such as high viscosity bioinks, which cause inaccurate printing constructs, as well as a lack of precise droplet placement.[816] Bioprinting technology can be time-consuming and challenging for cells to survive due to viscoelasticity, stabilization, and fluidity of bioinks used in printing.[817]

Stage of Emergence or Adoption: Bioprinting is considered to be in the late stage of emergence and early stages of adoption. This technology is used in some industries, but novel applications may emerge as new chemistry and other techniques are integrated (e.g., environmental sensors and remediations).

3D PRINTING: DIRECT ENERGY DEPOSITION (DED)

Description: DED is an additive manufacturing process in which focused thermal energy is used to fuse materials by melting as they are being deposited.[603] This method is similar to welding, and because metal powder or wire is deposited onto the base plate, it can also be used to repair damaged parts.[818]

Applications: DED can be used to repair metallic parts by depositing new material on complex surfaces and providing manufacturers with near net shape parts. Additionally, DED can be used on composite or hybrid parts and print with different materials simultaneously. A blend of compatible materials can go into the printed item, and its composition can even vary throughout the print.[343]

Key Benefits: DED is a popular method for effectively repairing and refurbishing defective and damaged high-tech components (e.g., turbine blades) due to metallurgical bonding, controllable heat input, and minimal stress and distortion.[603] DED is also capable of creating large objects. The extra degrees of motion make it capable of deposition on complex substrates, allowing for selective feature addition on wrought material and repair or repurposing of worn components.[96]

Limitations and/or Risks: DED can be time-intensive and requires a large amount of material. Additional risks arise when attempting to design and remove the support structures after the completion of the part building, which can cause damage to the fabricated part.[101]

Stage of Emergence or Adoption: DED aligns with the adoption stage, as AI QC and new detected light fabrication technologies show new applications of growth.

3D PRINTING: MATERIAL EXTRUSION

Description: Material extrusion is an additive manufacturing technique that uses a nozzle to deposit material layer-by-layer to build 3D parts.[819]

Applications: Material extrusion can be applied using material such as plastics to create product prototypes, (i.e., Polylactic acid [PLA], Acrylonitrile butadiene styrene, Polyethylene terephthalate glycol [PETG], and Nylon), ceramics, concrete, metal, and even chocolate. Material extrusion can be utilized in fused filament fabrication (FFF). Construction companies may use material extrusion via concrete extrusion to strengthen and build buildings.

Key Benefits: Material extrusion is considered environmentally friendly, decreases manufacturing costs, and reduces the manufacturing lifecycle by combining multiple steps into one (i.e., rapid prototyping). Additionally, material extrusion uses less energy and raw materials.[820,821]

Limitations and/or Risks: Challenges with extrusion head malfunctions and surface finish (e.g., visible layer lines, bumpy material, warping) may be experienced. If these printing issues occur, it may result in lengthier printing times and require more support.[822]

Stage of Emergence or Adoption: Material extrusion aligns with the adoption stage. It is used within certain industries but has novel applications as new, stronger materials emerge and more energy-efficient processes are used.

3D PRINTING: MATERIAL JETTING

Description: Material jetting is an additive manufacturing technique that uses liquid photopolymer to build functional 3D parts.[823] Material jetting creates objects in a similar method to that of a 2D ink jet printer, and it is also capable of full-color models and multi-material printing.[341]

Applications: Material jetting is used in photopolymer jetting where droplets are jetted into the build platform and then solidified via an UV light. It is used in Nanoparticle Jetting whereby powdered material (e.g., metal, ceramic) is jetted to build parts. The 3D printing technique has been used for the fabrication of anatomical models. Material jetting has also been used to build casting patterns for fine components, like jewelry.[824] Nanoparticle Jetting is also used to create high-temperature and friction-resistant parts for aerospace and automotive industries (including pistons used in racing), and sensors for the electrical industry.[825]

Key Benefits: Material jetting produces 3D products with minimal surface roughness and high dimensional accuracy, and is an effective printing method for building small or fine-detailed parts with thin layers.[823,824]

Limitations and/or Risks: Material jetting materials can be expensive and exhibit light sensitivity and degradation in high-UV environments. Additionally, equipment for material jetting can be costly to purchase, operate, and maintain after each build, which can lead to material waste.[824] Material jetting also lacks the ability to print overhangs (i.e., 3D geometric shapes), so all fabricated structures require supports that need to be accessible in order to remove.[826,827]

Stage of Emergence or Adoption: Material jetting aligns with the adoption stage. Material jetting is relatively new but has potential for novel applications (e.g., in the nanoscale manufacturing space).

3D PRINTING: POWDER BED FUSION (PBF)

Description: PBF is a manufacturing process in which thermal energy (e.g., laser or electron beam) selectively consolidates regions of a powder bed into 3D objects.[340] There are various types of PBF, including selective laser sintering/melting, direct metal laser sintering, and electron beam melting.[828]

Applications: PBF can be used in the military and commercial aerospace industries to build components for engines and aircraft. PBF has also been used to manufacture car parts such as turbocharger housings, exhaust components, air ducts, and interior car mirrors.[829]

Key Benefits: PBF techniques can provide the best reproduction and dimensional accuracy across metal additive manufacturing production.[106] Laser PBF can produce metal or polymer parts with complex shapes in a shorter timeframe and with reduced waste over traditional manufacturing techniques (e.g., machining, casting, rolling).[830] PBF can handle a wide range of materials to build 3D printed objects with desired mechanical properties.[831] Electron beam additive manufacturing has also shown the ability to control local microstructure, depending on the process parameters used during the build process.[96]

Limitations and/or Risks: PBF does not assess the 3D printed object's quality, so additional resources are needed for QC.[148] The PBF layering process can lead to defects that impact the geometric and mechanical properties of the 3D printed object due to residual stress from the process. [832] This can lead to the process becoming costly and time-consuming. [833] PBF can generate heterogenous data which can cause downstream effects of API connections, processing, and handling of the data.[832] If the lasers used in PBF are used incorrectly (e.g., part distortion, insufficient powder, powder capacity), they can melt the materials, causing incomplete fusion, cracks, surface deformation, irregularities in re-coating, balling, and porosity issues.[98,834]

Stage of Emergence or Adoption: PBF aligns with the adoption stage. This technique is used in industry but can have novel applications for stronger or more energy-efficient methods.

3D PRINTING: SHEET LAMINATION

Description: Sheet lamination, one of seven types of additive manufacturing processes as indicated by ISO/ASTM 52900-2021, involves stacking and laminating (e.g., brazing, bonding, ultrasonic welding) thin sheets of material to build a 3D object. Layer thickness, which depends on the process and machine used, impacts final quality. Laser cutting or CNC machines provide the final shape in sheet lamination.[835] Sheet lamination may apply a bond process (e.g., within computer-aided manufacturing of laminated engineering materials [CAM-LEM], sheet material is cut prior to being bonded to the previous layer) or bond then form process (e.g., within selective deposition lamination [SDL] and ultrasonic additive manufacturing [UAM], sheet material is bonded prior to cutting into the shape).[835]

Applications: The seven types of sheet lamination include: UAM, plastic sheet lamination (PSL), laminated object manufacturing (LOM), CAM-LEM, selective lamination composite object manufacturing (SLCOM), SDL, and composite based additive manufacturing (CBAM).[835]

Key Benefits: Sheet lamination provides more rapid print times, eases handling of materials, lowers costs, and integrates with hybrid manufacturing systems and OEM components. Sheet lamination provides a larger working area, removes the need for support structures, and allows for full-color printing.[835,836]

Limitations and/or Risks: The process of sheet lamination produces parts with lower additive resolution (linked to sheet thickness) and requires post-processing, which may make the process time inefficient compared to other additive manufacturing processes. There are fewer material options and greater waste generated, challenges when producing hollow parts and removing excess material, and limited bond strength for certain techniques.[835]

Stage of Emergence or Adoption: Sheet lamination aligns with the adoption stage. The first applications of sheet lamination became popular in the 1990s; therefore, the process is relatively new. However, sheet lamination still has a great deal of potential (e.g., material scalability).

3D PRINTING: VAT PHOTOPOLYMERIZATION

Description: Vat photopolymerization, also known as stereolithography, is a 3D printing method in which a light-emitting device (e.g., laser beam or projector) is focused on the free surface of a photosensitive liquid, inducing polymerization of that liquid, and transforming it layer-by-layer into a solid 3D component (thermosetting plastic).[837] The process utilizes highly viscous materials that must be cured to develop a hard texture and form the desired object. Vat polymerization can be subdivided into stereolithography, digital light processing (DLP), liquid crystal display, continuous liquid interface production, two-photon 3D printing, and computed axial lithography.[339,838]

Applications: There are limited current applications of vat polymerization in non-medical industries. It is used in the construction industry to build molds for injection molding and create plastic tools including insulation, flooring, walls, windows, roofing, and piping.[839,840]

Key Benefits: Vat photopolymerization provides a cost-effective method that is highly accurate for printing products with uniform quality and surface finish.[339,841,842]

Limitations and/or Risks: Vat photopolymerization products require long curing times and post-processing techniques.[843] One of the biggest disadvantages of Vat photopolymerization is the material suitability, which limits the applicable materials to special photopolymer resins.[841]

Stage of Emergence or Adoption: Vat photopolymerization aligns with the adopted stage as it has been utilized in the metamaterial and dentistry industries for several decades.[844] However, there are emerging applications, including multi-material vat photopolymerization to print living cell structures and print in 4D and fabricating superhydrophobic objects for water remediation and treatment.[845]

8.6 Appendix F: Referenced Programs and Documents

A list was compiled of programs and documents referenced within this report.

Table 8-14: List of Referenced Programs and Guides

Program Title	Brief Description
America Makes & ANSI Additive Manufacturing Standardization Collaborative (AMSC) Roadmap	A roadmap describing the current and desired future standardization landscape for additive manufacturing (AM) and focusing on industrial market sectors using AM technologies.
Department of Energy (DOE) Office of Energy Efficiency and Renewable Energy (EERE) Workshop	Workshop to explore the future of building energy codes. The purpose of the workshop is to highlight leading advancements in energy codes, bringing together key stakeholders from across the design and construction industry to discuss recent code updates, upcoming trends, as well as opportunities and challenges facing code implementation.
Environmental Protection Agency (EPA) Renewable Fuel Standard Program	Program created to reduce greenhouse gas emissions and expand the nation's renewable fuels sector while reducing reliance on imported oil.
Federal Energy Regulatory Commission (FERC) WorkshOPP Program	A specialized office that offers virtual workshops and guidance on how to submit public comments effectively, which can improve outcomes not only for commenters, but also for the agency.
Massachusetts Center for Advanced Manufacturing MassBridge Project	Project aims to plan and develop advanced manufacturing programs for non-technical individuals enrolled in high school and community colleges in Massachusetts.
North American Industry Classification System (NAICS) Manual	The North American Industry Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy.
National Institute for Occupational Safety and Health (NIOSH) "Approaches to Safe Nanotechnology" workplace Guidance	A summary of current nanotechnology research and safety guidelines to help produce valuable science-based data, inform future guidance and policymaking, and identify policy challenges related to this technology.
National Science Foundation (NSF) "GoodNanoGuide"	A repository of good practices for safely handling nanomaterials that can be used and contributed to by researchers internationally.
NSF Advanced Technological Education (ATE) Program	Program that supports education of technicians for high-technology fields, including advanced manufacturing technologies, through partnerships with academic institutions.
National Institute of Standards and Technology (NIST) Cyber Security Best Practice Guide	A guide that provides targeted information to assist manufacturers in the protection of their manufacturing control systems and the integrity of their systems, information, and data by providing guidance. The guide encourages organizations to safeguard their historical system data; block the execution of unapproved software; identify any unusual behavior in the network and any hardware, software, or firmware alterations; support secure remote access; and authenticate and authorize safe system users.
NIST Manufacturing Extension Partnership (MEP) Centers	A public-private partnership that offers company-tailored training and skills development for manufacturers and supervisors to ultimately help companies attract and retain manufacturing talent.
White House Office of Science and Technology Policy (OSTP) National AI Research Resource (NAIRR) Task Force	Task force to promote collaboration, innovation, and economic prosperity with AI.

8.7 Appendix G: Illustrative Standards and Frameworks in Non-Medical Industries (NMIs)

A series of industry and government documentation provide direction and guidance across various aspects of the manufacturing ecosystem. These standards, guides, and frameworks bolster advanced manufacturing by ensuring consistency in quality and processes and promote safety of workers and users.

America Makes and ANSI: Standardization Roadmap for Additive Manufacturing

This roadmap describes the current and future landscape, as well as gaps of standardization for additive manufacturing across industries using AM technologies. In addition to identifying standardization gaps, it provides corresponding recommendations throughout the AM lifecycle and notes relevant published and in-development standards.[846]

ASME Criteria for Powder Bed Fusion (PBF) Additive Manufacturing

This ASME document describes the criteria for using additive manufacturing PBF technology to create metallic pressure-retaining equipment. The criteria specify material, design, fabrication, examination, inspection, testing, and QC requirements following the applicable ASME Construction Code or Standard.

Manufacturing Readiness Levels (MRLs)

MRLs are criteria used to assess the level of readiness for a product or system to be manufactured. They were created to determine maturity, quality, and issues throughout the manufacturing process. MRLs provide insight into a nominal level of technology readiness, potential risks to the technology, processes, and the overall system.[480]

NASA - Marshall Space Flight Center (MSFC) Technical Standard

NASA MSFC Technical Standard defines the additive manufacturing requirements for using L-PBF technology to build metals and parts in spacecrafts or other applications.[847]

NASA Standard 6030

NASA Technical Standard 6030 defines the minimum requirements for additive manufacturing processes used to produce spaceflight systems (e.g., additive manufacturing of hardware used in robotics, spacecrafts, launch vehicles, landers).[848]

NASA Standard 6033

NASA Technical Standard 6033 defines the minimum requirements for advanced manufacturing facilities, equipment, and processes used to produce spaceflight systems (e.g., advanced manufacturing of hardware used in spacecrafts, launch vehicles, extraterrestrial surface systems).[849]

NIST Special Publication (SP) 1800-10

NIST SP1800-100, *Protecting Information and System Integrity in Industrial Control System Environments: Cybersecurity for the Manufacturing Sector,* is a new Cybersecurity Practice Guide created by NIST's National NCCoE specifically for the manufacturing sector.[850]

NRC 10 Code of Federal Regulations (CFR) 50.59

NRC 10 CFR 50.59 defines the process when a license amendment is required prior to making changes to facilities, advanced manufacturing technologies, or procedures. This regulation is followed to determine the safety of a planned change to a component, test, or experiment.[851]

Responsible Artificial Intelligence (AI) Strategy and Implementation Pathway

This document describes the DoD's Responsible AI (RAI) Strategy and Implementation (S&I) Pathway for using AI in an ethical and lawful way. Its purpose is to detail how AI is used, standardized, mitigated for risks, communicated, and defined throughout government work.

Technology Readiness Levels (TRLs)

TRLs are criteria used to assess the maturity of a particular technology. TRLs evaluate and compare the maturity between different types of technology, provide a readiness rating, and track technologies development and scalability. The TRL approach has been widely used as the technology maturity measurement by NASA and DoD programs.[480]

8.8 Appendix H: Figure Descriptions for Assistive Technology Users

Figure 1-1: Assessment Findings

Influencing factors are crisis events; environmental impact concerns; geography and weather; limited government regulatory resources; organizational readiness; public and market demand; safety and security concerns; technology readiness; and variability in application.

Challenges, best practices, and considerations include six themes, with subthemes in each. the first theme is collaboration and engagement, with subthemes of knowledge sharing and transparency, risk tolerance, and resistance to change, understanding, compliance and integration, and international counterparts. the second theme is data and information, with subthemes of availability and access, interoperability, integration, and quality, interpretability of outputs, and data security. the third theme is economic impact, with subthemes of value proposition, supply chain resiliency, short- and long-term impacts, horizon scanning, and scalability. the forth theme is standards and controls, with subthemes of consistent guidelines and procedures, quality control, data-driven standards and criteria, and risk assessments and prevention. the fifth theme is weighing regulation and innovation, with subthemes of ethical law and liability, and requirements and frameworks. the sixth theme is workforce, with a subtheme of workforce planning and development.

Indicators of current usage and future growth are academic and industry research or testing; creation of industry standards; government investment; increased utilization across multiple industries; industry awards; industry and consumer demand; inter- and intra-industry partnerships; international interest, investment, and implementation; and private investments.

Figure 3-1: Evaluation Framework

Technology phase inputs included document reviews, data reviews, system reviews, and interviews. Analysis looked at whether technology was adopted or emerging. Outputs were a catalog of technologies and processes.

Assessment phase inputs included document reviews, data reviews, system reviews, interviews, and regulations and policies. Analysis focused on applicability to FDA and included technology usage and future growth; implementation strategies; validation of technology; process improvement activities; facilitation of regulation; and promotion and implementation conditions, approaches, and processes. Outputs included challenges; best practices; considerations for FDA; indicators of current usage and future growth; and influencing factors.

Outcomes and impact of the evaluation:
1. Support the regulation and validation of medical advanced manufacturing technology to facilitate adoption and implementation by industry
2. Inform and enhance FDA regulatory programs
3. Strengthen overall FDA advanced manufacturing capabilities and oversight

Figure 3-2: Illustrative Organizations per Stakeholder Group

Illustrative organizations per stakeholder group are as follows:

Academic Institutions:
- Wichita State University’s National Institute for Aviation Research (NIAR)
- North Carolina State University- Industrial and Systems Engineering (ISE)

Public-Private Partnerships

- DoD: America Makes
- American Institute of Chemical Engineers (AIChE)
- BioMADE
- Institute of Electrical and Electronic Engineers (IEEE)
- International Atomic Energy Agency (IAEA)
- World Nuclear Association

Private Manufacturers

- General Electric (GE)
- Lockheed Martin
- Northrop Grumman
- Siemens

US Government Non-Regulating Agencies

- Centers for Disease Control and Prevention CDC: National Institute for Occupational Safety and Health (NIOSH)
- U.S. Air Force
- National Aeronautics and Space Administration (NASA)
- National Science and Technology Council (NSTC)
- National Institute of Standards and Technology (NIST)
- National Science Foundation (NSF)
- Department of Defense (DOD)
- National Artificial Intelligence Initiative Office (NAIIO)
- Department of Energy (DOE)
- DOE: Oak Ridge National Laboratory (ORNL)

Trade Associations

- Aerospace Industries Association (AIA)
- National Association of Manufacturers (NAM)

Standards Organizations

- American National Standards Institute (ANSI)
- American Society for Testing Materials (ASTM) International
- International Electrotechnical Commission (IEC)
- International Organization for Standardization (ISO)

Professional Organizations

- American Society of Mechanical Engineers (ASME)
- Society of Manufacturing Engineers (SME)
- Association of Manufacturing Technology (AMT)

US Government Regulating Agencies:

- Environmental Protection Agency (EPA)
- Federal Aviation Administration (FAA)
- Mine Safety and Health Administrations (MSHA)
- Nuclear Regulatory Commission (NRC)
- Consumer Product Safety Commission (CPSC)
- Federal Energy Regulatory Commission (FERC)
- Occupational Safety and Health Administration (OSHA)

Figure 4-1: Catalog of Advanced Manufacturing Technologies in Non-Medical Industries

Advanced Manufacturing in non-medical industries includes methodologies, platforms, technologies, and processes.

Methodologies are a form of advanced manufacturing that includes conceptual approaches for how manufacturers build or create products. Identified methodologies include additive manufacturing, automated manufacturing, biomanufacturing, cloud manufacturing, circular manufacturing, continuous manufacturing, distributed manufacturing, flexible manufacturing, green manufacturing, hybrid manufacturing, lean manufacturing, nanomanufacturing, and smart manufacturing.

Platforms are forums or opportunities to connect, communicate, share, organize, or obtain ideas data, information, and knowledge. Identified platforms include application programming interface (API), automated closed-loop systems, advanced metering infrastructure (AMI), blockchain, cyber physical system (CPS), long range wide area network (LoRaWan), digital microfluidics, wireless sensor network (WSN).

Technologies are a form of advanced manufacturing that innovates or automates existing techniques, or combines with other technologies to improve manufacturing speed, efficiency, and quality. This may encompass analytical techniques, tools, or software, etc. Identified technologies include 3D optical scanning, advanced visualization (AV), computed tomography (CT), deep learning, intelligent decision support Systems (IDSS), machine vision, multi-sensor data fusion, natural language processing, pattern recognition, predictive maintenance, bioreactors (indicated as emerging), synthetic biology, centrifugation, cloud-based computing (indicated as emerging), quantum computing (indicated as emerging), advanced metrology, photonics, smart sensors (indicated as emerging), digital twins (DTs), extended reality (XR), energy harvesting, advanced robotics, networking technologies that include fifth generation (5G) and sixth generation (6G), and smart grid (SG); vehicle-to-grid (V2G), and semiconductor chips/integrated circuits.

Processes are a form of advanced manufacturing that includes approaches, techniques, and production methods used to manufacture products. Identified processes include 3D modeling, 3D printing (3DP), 4D printing (indicated as emerging), indirect additive manufacturing (I-AM), mobile additive manufacturing (MAM), flow cytometry, microfluidics, cloud-based monitoring, spectroscopy, variable rate technology (VRT), material processing, nanoprocessing, nondestructive testing and evaluation (NDT/NDE), and surface modification.

Figure 4-2: Common Types of 3D Printing

Eight common 3D printing types were identified.

Binder jetting is a process in which a liquid bonding agent is selectively deposited to join powder materials. The printer repeats the layering process with powder and binding fluid to build layers. Once complete, the printed item is cured using convection or sintering ovens or infrared light, which removes the solvent and solidifies the layers. The most common type of binder jetting is selective deposition modeling (SDM).

Direct Energy Deposition (DED) is a process in which focused thermal energy (e.g., laser, electron beam, plasma jet, electric arc) is used to fuse materials by melting them as they are being deposited. DED adopts the same principle as powder bed fusion, but instead of fusing material on an existing bed of powder, the powder (or in other cases wire) is simultaneously fed through the nozzle and fused to melt and deposit it onto the build platform.

Biofabrication/Bioprinting is A process of using living cells as an alternative to traditional synthetic chemistry to synthesize and assemble materials in a layer-by-layer construction method. Biofabrication, or bioprinting, uses various types of 3D printing methods, such as material extrusion, material jetting, and laser-based stereolithography.

Material extrusion is a process in which a continuous material filament is selectively dispensed through a nozzle or orifice to deposit material layer by layer to build 3D parts. An example is fused deposition modeling (FDM), also known as fused filament fabrication (FFF).

Material Jetting is a process in which droplets of feedstock material (e.g., liquid photopolymer resin, wax) are selectively deposited and solidified under ultraviolet light to build functional 3D parts. Material jetting create objects in a similar method to that of a two-dimensional ink jet printer and is capable of full-color models and multi-material printing. Commonly known as photopolymer jetting, new novel applications include nanoparticle jetting (NPJ).

Powder Bed Fusion (PBF) is a process in which thermal energy (e.g., laser, electron beam) selectively consolidates regions of a powder bed into 3D objects. There are various types, including selective laser sintering/melting, direct metal laser sintering, multi-jet fusion, and electron beam melting.

Sheet Lamination is a process in which thin sheets of material are stacked and laminated (e.g., brazing, bonding, ultrasonic welding) to build a 3D object. The process often uses Laminated Object Manufacturing (LOM) to alternate layers of material and adhesive for visual and aesthetic appeal, or Ultrasonic Additive Manufacturing (UAM), which employs ultrasonic vibrations to weld layers of material together.

Vat Polymerization/Resin 3D Printing is a process in which highly viscous liquid photopolymer in a vat is selectively cured by light-activated polymerization to develop a hard texture and form the desire object. Common subtypes are stereolithography (SLA), masked stereolithography (mSLA), digital light processing (DLP), liquid crystal display, continuous liquid interface production, two-photon 3D printing, and computed axial lithography.

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