FDA Innovative Technologies and Advanced Manufacturing Hub

FDA I-TEAM Hub

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Abstract

The I-TEAM Hub is a space for FDA to research, train, and experience cross-cutting innovative technologies.

The FDA Innovative Technologies and Advanced Manufacturing Hub (I-TEAM Hub) is an FDA-wide resource for research and collaboration containing state-of-the-art manufacturing, sensing, and cross-cutting technology platforms that enable the manufacture and characterization of many FDA-regulated products. Managed by the **Office of Regulatory and Emerging Science (ORES)** in the Office of the Chief Scientist, the I-TEAM Hub works closely with HHS, industry, academia, and other government partners to identify innovative technologies that may be used to make the next generation of medical products. We bring technologies and partners to the Hub, host research collaborations, perform training, and advance the FDA's collective regulatory science knowledge.

Advanced Manufacturing Landscape

The 2022 National Strategy for Advanced Manufacturing defines "advanced manufacturing" as

"the innovation of improved methods for manufacturing existing products, and the production of new products enabled by advanced technologies." [1]

Production techniques and processes considered advanced manufacturing are often:

- ✓ Integrating novel approaches,
- ✓ Used in a new or innovative way, or
- ✓ Applied in a new domain without defined best practices or experience.

The ORES Innovative Technologies Team aims to create a cross-cutting environment in the I-TEAM Hub to augment Center-based research and collaboration.

Individual Center programs such as CDER ETP, CBER CATT, and the CDRH Digital Health CoE evaluate, understand, and provide suggestions to industry to promote the adoption of novel technologies in their specific product areas.

Emerging technologies and processes anticipated to evolve over the next 5-10 years.

Understanding the advanced manufacturing landscape is essential for the FDA to promote reliable manufacturing practices, encourage supply-chain resilience, and continue its support of safe and effective regulated products. A landscape analysis of non-medical industries sponsored by ORES and conducted by Booze Allen Hamilton, identified **six major considerations** for implementing advanced manufacturing.[2]

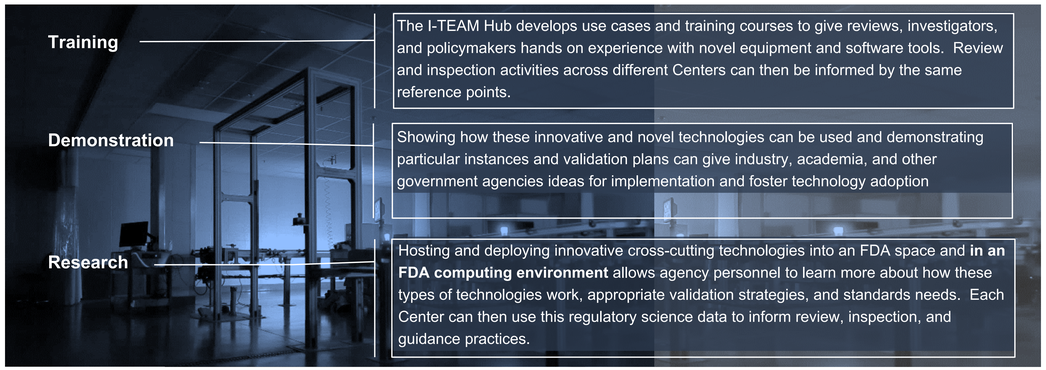
Collaboration and Engagement
Data and Information
Economic Impact
Standards and Controls
Regulation and Innovation
Workforce Development

See ORES landscape on the web for insights into challenges and best practices for implementing innovative technologies.

I-TEAM Hub Facility Overview

The I-TEAM Hub is a ***shared resource***, initially supported in a collaboration between FDA and the Assistant Secretary for Preparedness and Response (ASPR) and operated by the Office of Regulatory and Emerging Science (ORES). It is focused on the technologies that are enhancing manufacturing processes, sensors, and quality control algorithms used to produce multiple types of FDA-regulated products. Located at FDA's Laurel campus, the I-TEAM Hub is a cross-cutting program focusing on advanced and emerging technologies, complementing the Agency's Center-based product-specific programs.

The I-TEAM Hub supports the ORES Innovative Technologies Program through three primary goals:



Projects and Partnerships

The I-TEAM Hub is committed to fostering innovative collaborations through a variety of key projects and partnerships that enhance our mission. Partnerships include cross-functional teams within FDA and external collaborations with academic institutions, industry leaders, and government agencies. These joint efforts are all aimed at driving innovation in advanced manufacturing.

Biofoundry: Automated cell-based manufacturing

Engaging in a collaborative initiative with ARMI to establish an automated, closed-loop, modular system aimed at advancing biomanufacturing capabilities and enabling scalable production of engineered tissues and organ systems.[3]

ASPR Collaborations

Collaborations with ASPR groups such as Industrial Base Management and Supply Chain (IBMSC) and BARDA TechWatch provide insights and horizon scanning for new technologies

CERSI (UMD):

- *Applying Additive Manufacturing for Continuous Production of Extracellular Vesicle Products*[4]
- *Noninvasive PAT for Manufacturing Automation*
- *X-Ray Based inline Probe for Real-time Process Monitoring of the Crystallization of Active Pharmaceutical Ingredients (API) in Manufacturing Drug Products*

Initiative to Benchmark and Profile Antibody and Large Biomolecule Stability

*IAA with NIST and **CDER** experts to assess and benchmark the stability of monoclonal antibodies and large biomolecules, enhancing production and storage process.*[5]

Smart Design and Manufacturing Pilot

*A joint pilot project with **CDRH** to explore smart manufacturing processes and design innovations for streamlined production.*[6]

FDA-VHA MOU for a Digital Stockpile Response Network Roadmap

Collaborating among cross-functional teams to develop a roadmap for a robust digital network for managing emergency stockpiles and response capabilities.[7]

Securing Manufacturing Technology

All the connected industrial pieces of equipment that make up a production facility – devices, software, and technologies – are *operational technology (OT).*

Enabling different technologies to integrate and interoperate efficiently as a single cohesive system allows businesses to improve efficiency, reduce errors, cut costs, enhance workflows and gain measurable competitive advantages compared to legacy processes and systems. **FDA implemented OT within the I-TEAM Hub.**

There are unique cybersecurity considerations for OT.

The presence of legacy equipment, initial prioritization of functionality over cybersecurity in equipment design, and lack of visibility and control in industrial networks all play a role in the security of products which may differ from standard software products.

In our implementation of manufacturing technology, FDA discovered over 243 cybersecurity vulnerabilities and 1 entire product which was not compliant with Federal Information Processing Standards.

The FDA I-TEAM Hub has learned to secure OT for scientific and engineering usage.

Through implementation of architecture and infrastructure best practices, conducting continuous security monitoring, and a deep understanding of network communications required for OT functionality, FDA can help to ensure the safety, security, and quality of manufacturing for medical products for the American public.

Opportunities

The I-TEAM Hub is an FDA-wide resource open to collaboration.

- Expand collaborations with internal and external partners.
- Drive technological advances by researching innovative solutions like digital twin systems to enhance manufacturing processes.
- Accelerate the adoption of emerging technologies, including innovative manufacturing techniques, across the FDA to enhance safety, quality, and efficacy.
- Develop and perform targeted training for innovative and emerging technologies

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