Center for Drug Evaluation and Research (CDER) Presentation

Office of Pharmaceutical Quality

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Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user – drugs are no different.

Patients expect safe and effective medicine with every dose they take.

Pharmaceutical quality is assuring *every* dose is safe and effective, free of contamination and defects.

It is what gives patients confidence in their *next* dose of medicine.

Office of Pharmaceutical Quality (OPQ)
Office of Quality Surveillance (OQS)

Research Goals to Advance Quality Surveillance

Office of Quality Surveillance: Sleuths for Drug Quality!

- Use intelligence, analytics, and GMP assessments to help OPQ assure drug quality and availability:
  - Provide oversight of quality throughout product lifecycle
  - Understand and model supply chains
  - Characterize site quality AND product quality
  - Collaborate with internal FDA business partners:
    - Assign inspections, investigations, and sampling
    - Identify and escalate signals for follow-up and potential enforcement
    - Prevent supply disruptions and mitigate drug shortages

Focus Area 1:
Better Understanding of Global Supply Chains

- How can site and product quality be characterized?
- How can FDA capitalize on new sources of data (CARES amount reporting, NIPP, Quality Management Maturity, Quality Metrics) to describe supply chains?
- How can postmarket defect data (FAR, BPDR, MW, consumer complaints) enhance our understanding of supply chains?
- How can data and analytics improve prevention of, and response to, potential drug shortages and supply chain interruptions.
- How can diverse data sources (social media, laboratory data, regulatory submissions, global events and natural disasters) complement each other to improve the supply chain picture?

Focus Area 2:
Quality Management Maturity (QMM)

- What are potential unintended consequences (blind spots) of QMM implementation?
- How can we improve our understanding about the link between robust quality management practices and robust supply chains?
- How can Quality Metrics complement the implementation of QMM?
- What metrics should be evaluated for QMM program success?
- How can manufacturing sites build supply chain resilience?
- How can the current state of QMM be benchmarked across the industry or by sector?

Reference for BAA Announcement: Key Areas of OQS Research Interest

- II.D.1.a, b, c, and d (reporting tools for active surveillance)
  - Support development of QMM and QM
  - Evaluate product quality defect reports with other data to identify signals
  - Use data analytics to characterize the quality of sites and products
- II.D.2.b (surveillance and scientific approaches to evaluate generic drugs) – combine surveillance tools and laboratory data to identify quality signals in generic products
- III.H.1.b (analysis of global data to manage risks)
  - data mining inspection reports and other information sources
  - better understanding global supply chains, predicitve models to identify quality risk signals across supply chain

Reference for BAA Announcement: Additional Areas of Potential OQS Research Interest

- I.A.1.a (methods development for product quality) – evaluate quality of biological products
- I.B.1.e (AM for product quality) – evaluate impact of AM on quality/process controls & supply chains
- I.B.2.a.iii (raw material quality control) – characterize raw material (excipients & packaging) quality
- I.C.1.f and g (tools for data analytics and visualization) – how to best harness CARES amount reporting data, NIPP, and visualizing, analyzing, and understanding supply chains
- I.C.5 (data analysis techniques for human drug regulatory operations) – better methods for data processing and data curation
- I.K.1 (data standards and data infrastructure) – design and optimize data infrastructure to facilitate information/data exchange, management, and extraction
- II.A.1.a (methods for analysis of pre-market and post-market data) – support quality signal detection
- II.B.2.a (AI/ML for data analytics on big data) – prioritizing adverse events with FAERS II data
- II.H.1.a (guidelines for data quality standards) – enabling consistent data assessment and data sharing
- III.H.4 (import operations) –using data management technologies to better understand supply chains

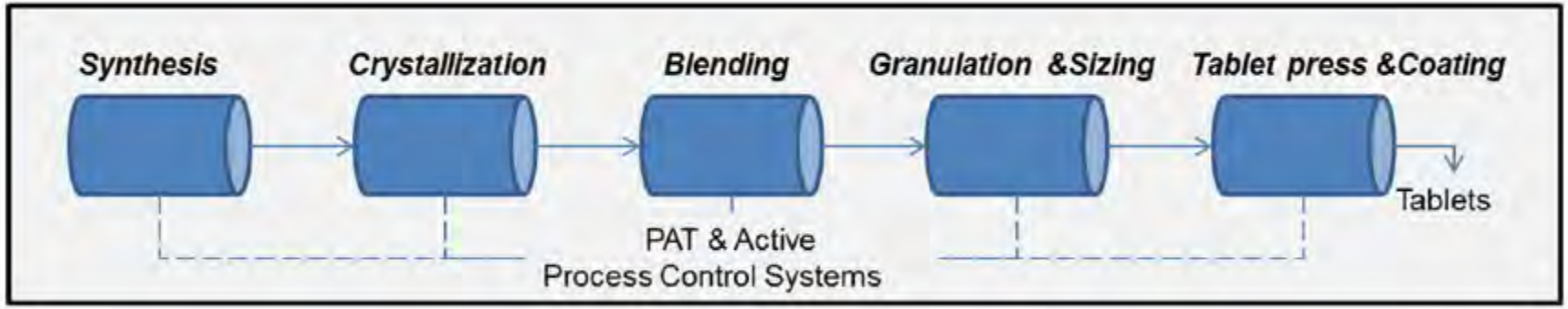
What is Advanced Manufacturing

- Novel **manufacturing methods** to improve process robustness and efficiency
- Novel **dosage forms** or delivery systems to improve drug delivery and targeting
- Novel **analytical tools** to improve product characterization, quality testing, process monitoring and/or control

Advanced Manufacturing Benefits

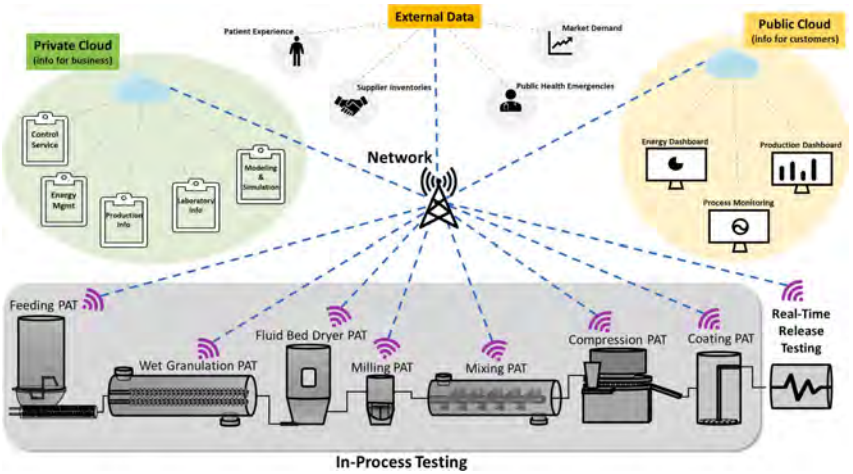
- **Produce better quality medicine.** Facilitates six-sigma operation, no more than 3.4 defects per 1M opportunities.
- **Re-shore drug manufacturing facilities.** Helps domestic drug manufacturers compete in a global market.
- **Develop drugs rapidly.** Speeds the development of novel or patient-focused therapeutics.
- **Prevent drug shortages.** Reduces today's quality-related manufacturing issues causing 62% of drug shortages.
- **Improve emergency preparedness.** Provides more agility and flexibility to help pivot in a public health emergency.

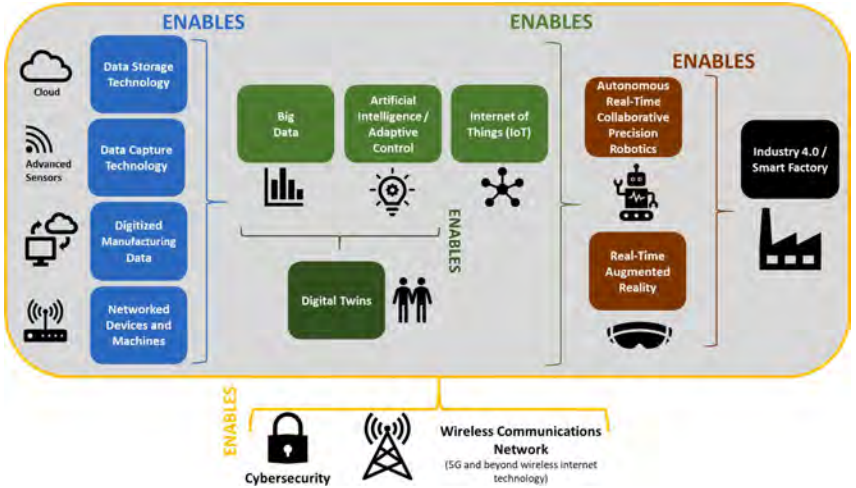
Innovations in Manufacturing



- Validation and maintenance of automated or semi-automated in-process monitoring and control systems and methods
- In-process measurements for hard to measure quality attributes
  - Rapid sterility measurements

Industry 4.0





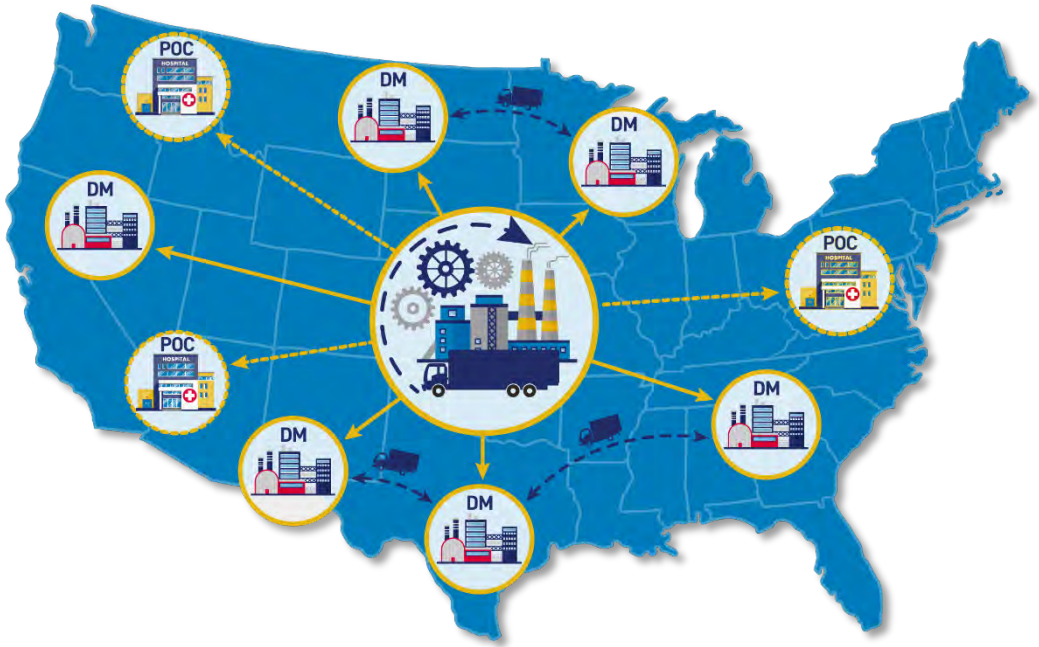
Development of improved methods and tools for the validation and lifecycle maintenance of digital technologies (digital tools, AI, adaptive controls etc.)

*Arden, N. Sarah, et al. "Industry 4.0 for Pharmaceutical Manufacturing: Preparing for the Smart Factories of the Future." *Int J Pharm* (2021): 120554.

Distributed Manufacturing (DM)

DM: A decentralized manufacturing strategy consisting of a manufacturing platform comprising manufacturing units deployed to multiple locations.

Investigate the effects in supply chain of implementing distributed manufacturing

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