

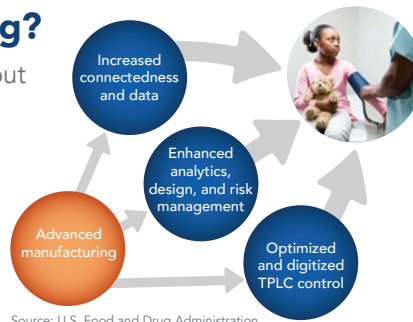


ADVANCE MANUFACTURING CLEARING HOUSE

Advanced Manufacturing in medical devices is an approach that uses innovative techniques that applies the use of electronic information, computer technology, machinery, materials, and tech-enabled management to improve the quality and process of production. Each organization has unique needs and starting points in the journey toward an advanced manufacturing process.

Why Advanced Manufacturing?

- Ensure safe, effective and compliant output
- Improve product quality and yield
- Maintain and improve process controls
- Increase operational effectiveness
- Reduce unplanned downtime
- Enable educated decisions
- Increase product intelligence
- Improve after-market support



Source: U.S. Food and Drug Administration

Medical Device Innovation Consortium with the FDA will be piloting an Advanced Manufacturing Clearing House program with the goal of contributing expertise and capital to implement advanced manufacturing technologies into the production process for device manufacturers.

Objectives include improving design, supply, production, distribution, tracking, device reliability, overall quality, and safety across the product life cycle.

Examples of technologies include additive and generative part design, digital twins, and digital threads (e.g., modeling and simulation for virtual design verification, validation and design transfer), and data-driven closed-loop quality.

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

LEARN MORE ABOUT THE ADVANCED MANUFACTURING CLEARING HOUSE TEAM

For further information contact the MDIC Case for Quality Team at AMCH@mdic.org.

