

## ADVANCED/INNOVATIVE MANUFACTURING 101

FDA defines advanced/innovative manufacturing as a collective term for new medical product manufacturing technologies that can improve drug quality, address medicine shortages, and speed time-to-market.



### Qualifications:

- Integrates novel technological approaches;
- Uses established techniques in a new or innovative way; **OR**
- Applies production methods to a new domain where there are no defined best practices or experience



### Real-world examples used in biologics, cell, and/or gene therapies:

- Continuous manufacturing
- Process digital twins
- Advanced analytics, “big data,” and machine learning
- Real-time release (RTR) testing
- Portable biomanufacturing
- 3D printing



### Potential benefits of advanced/innovative manufacturing technologies:

#### Promote efficiency and scalability by:

- Creating new pathways for drug synthesis
- Shortening supply chains, increasing manufacturing resilience, and reducing costs long term
- Increasing consistency in product quality assurance

#### Improve public health and global impact by:

- Increasing availability of emerging therapies
- Mitigating drug shortages and supply chain challenges
- Increasing environmental sustainability
- Enabling treatment personalization capabilities



### Current challenges to implementation:

- Large capital requirements, resource investments, and workforce up-skilling
- More robust CMC submission requirements than current technologies
- Uncertain regulatory expectations and pathways
- Limited opportunities for discussion on implementation requirements
- Utilization of CMOs without clear regulatory guidance/acceptance
- Limited sourcing