

Resilient and Flexible Biopharmaceutical Supply Networks

Workshop Proposal

Biopharmaceutical supply chains, covering raw materials to patient delivery, are uniquely complex, customized for each product (e.g., mAb, mRNA, cell/gene therapy), and globally dispersed. The COVID-19 pandemic underscored their vulnerabilities, with disruptions revealing risks in numerous areas above and beyond just-in-time inventory and minimal idle capacity. Resilient supply chains are recognized as critical to business success. Advanced risk management and data-driven, real-time contingency planning tools are essential to staying ahead.

Vision for Resilient Supply Chains:

To address these challenges, a robust, real-time digital infrastructure is needed for seamless data exchange across supply networks. Such a system would provide real-time visibility into the quality and status of materials and products, enabling agile decision-making, reducing waste, and improving throughput. Key components include:

- ✓ Standardized Supply Chain Data Exchange for real-time visibility and interoperability.
- ✓ Resilience Toolkit for enhanced visibility, cybersecurity, and crisis response.
- ✓ Common Taxonomy and Governance to establish trust and incentivize adoption.
- ✓ Proven Implementation through interoperability pilots in normal and crisis scenarios.
- ✓ Community of Practice to ensure ongoing collaboration and solution sustainability.

Key Challenges in Biopharma Supply Chains

- ⓘ Shortages or quality issues in critical raw materials (e.g., excipients, adjuvants, enzymes).
- ⓘ Failures in single-use systems and drug product components (e.g., bioreactors, vials, syringes, filters).
- ⓘ Delays from unmet analytical specifications for raw and in-process materials.
- ⓘ Disruptions at manufacturing or storage sites (e.g., natural disasters, power failures).
- ⓘ Limited regional capacity for unexpected demand or loss of production facilities.



Workshop Objectives:

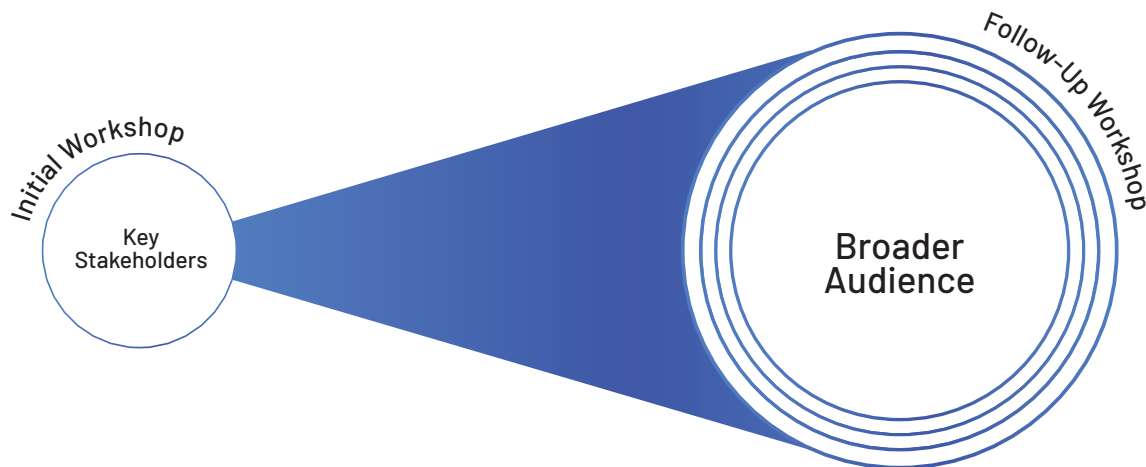
The workshop aims to bring together manufacturers, suppliers, technology providers, and academic experts to explore a collaborative path toward developing and implementing a Supply Chain Data Exchange framework. CESMII proposes leveraging its Smart Manufacturing Supply Chain model to:



Workshop Structure:

Initial Workshop: Engage leading manufacturers, federal agencies and non-profits to identify critical use cases and opportunities for collaboration.

Follow-Up Workshop: Expand the audience to include subject matter experts, technology providers, and additional stakeholders to define a roadmap, refine objectives, and outline required resources.



Anticipated Outcomes:

By implementing this framework, manufacturers can improve supply chain robustness, quality, and efficiency, reducing costs and waste. These advancements will enhance the accessibility of lifesaving biotherapeutics and vaccines globally, benefiting both developed and developing nations.

