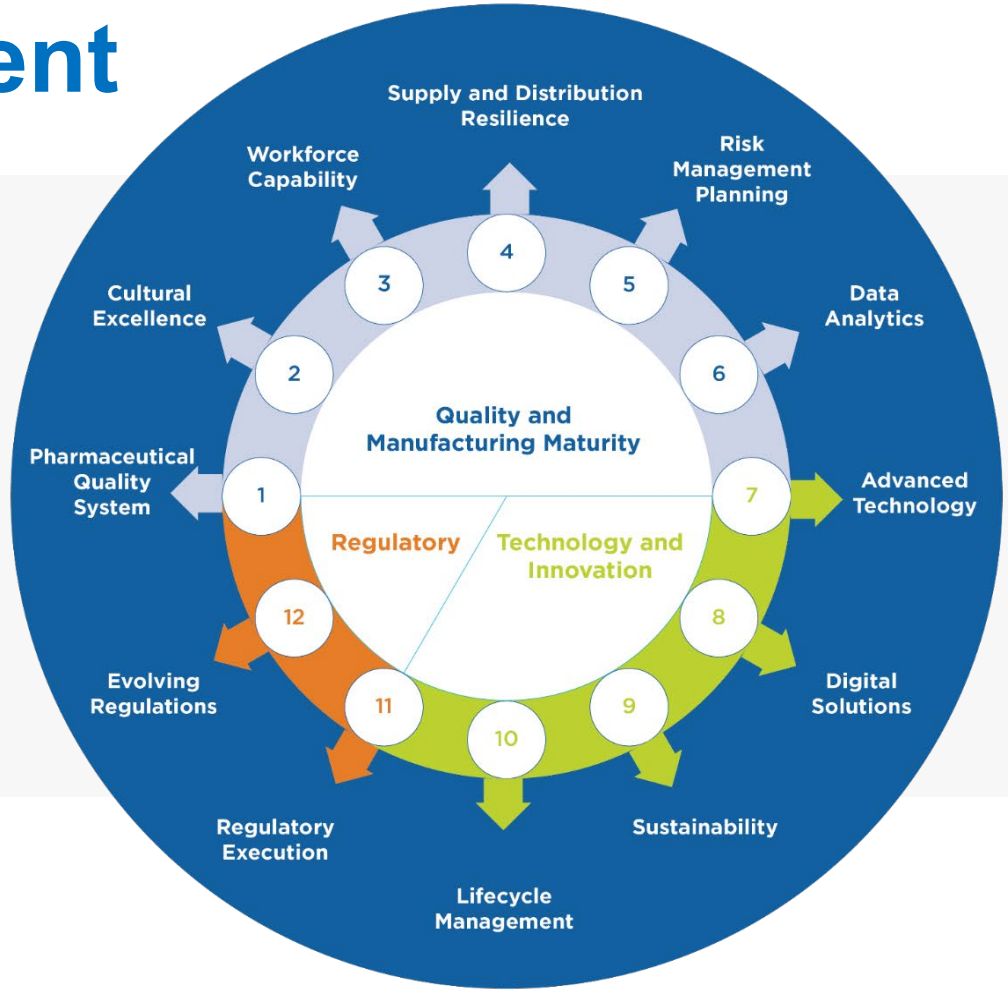
Addressing Drug Shortages in the United States

Insights from ISPE and Its Global Membership

ISPE

ISPE Commitment

Advancing progress in drug shortage prevention through industry guidance and health authority interactions since 2012



Seeking opportunities within ISPE areas of expertise

Technical, Quality, and Regulatory topics

global supply chain complex problem

Reflecting on the Panel Questions

1. Why proposals haven’t scaled,
2. the barriers that keep returning,
3. how market dynamics influence reliability, and
4. what lessons suggest a better path forward.

Why haven’t solutions scaled?

1. *Complexity of the global supply chain footprint and international regulations*

2. *E2E Digitalization of Supply Chain not yet achieved*

What are the persistent barriers?

How	
Example	**Challenges**
Onshoring	Global regulatory changes, US economic headwinds, Operational logistics
Stockpiling	Market-specific stockpiling increases burden on resources and raw materials – potentially impacting access, increasing administrative oversight and/or discards

What	
Example	**Enablers (not inclusive)**
A supply chain footprint that anticipates, withstands, and quickly recovers from disruptions	Onshoring, friendshoring, flexible manufacturing (modular, pods), advanced manufacturing, redundancy, safety stock, stockpiling, Rapid alert/issues management system, improved forecasting, Pharmaceutical Quality System (ICH8-10), Risk management (ICHQ9R1), Knowledge management, geographic diversity, optimized operational logistics

Can we shift focus from 'how' to 'what' is needed to allow manufacturers to adapt their approach for best outcomes for each product and over time?

ISPE

How do market dynamics influence reliability?

- Economics matter
  - Business failure cuts patient supply
- Buy on price and reliability
- Resiliency requires significant investment in discretionary safeguards
- Can we explore targeted incentives and regulatory agility?

Cost to Build New Pharmaceutical Manufacturing Facilities

Average costs:$200 million-$2 billion
Timeline: 5-10 years
Biopharmaceutical Manufacturing | PhRMA

Cost of Changing Contract Manufacturing Organizations (CMO)

Typical switching costs: Over $5 million
Timeline: 6-30 months depending on complexity
Tech Transfers in Pharma: Definitions and Key Processes in Technology Transfers – PharmaSource
12 Critical Questions and Answers for a Successful Tech Transfer--Propharma

ISPE

Surfaced Opportunities

Simplify

- one small, clear priority product list
- Move from “how” to “what”
- Leverage existing government records

Surfaced Opportunities

Simplify

- one small, clear priority product list
- Move from “how” to “what”
- Leverage existing government records

Race to the Top

- Create regulatory fast track
- Meaningfully reduce requirements for high performance

Surfaced Opportunities

Simplify

- one small, clear priority product list
- Move from “how” to “what”
- Leverage existing government records

Race to the Top

- Create regulatory fast track
- Meaningfully reduce requirements for high performance

↑Digital Capability

- Explore E2E digital view
- Generate agility with eLabeling

Surfaced Opportunities

Simplify

- one small, clear priority product list
- Move from “how” to “what”
- Leverage existing government records

Race to the Top

- Create regulatory fast track
- Meaningfully reduce requirements for high performance

↑Digital Capability

- Explore E2E digital view
- Generate agility with eLabeling

Coordinate Globally

- Lead development of a global fast track for certain critical medicines in certain situations

Thank You

"…supply resiliency is a journey."

Recommendations Summary

- *Simplify*
- *Strengthen risk-based regulatory approaches*
- *Amplify digital tools*
- *Lead global partnerships*

ISPE®