From Visibility to Resilience: an end-to-end framework

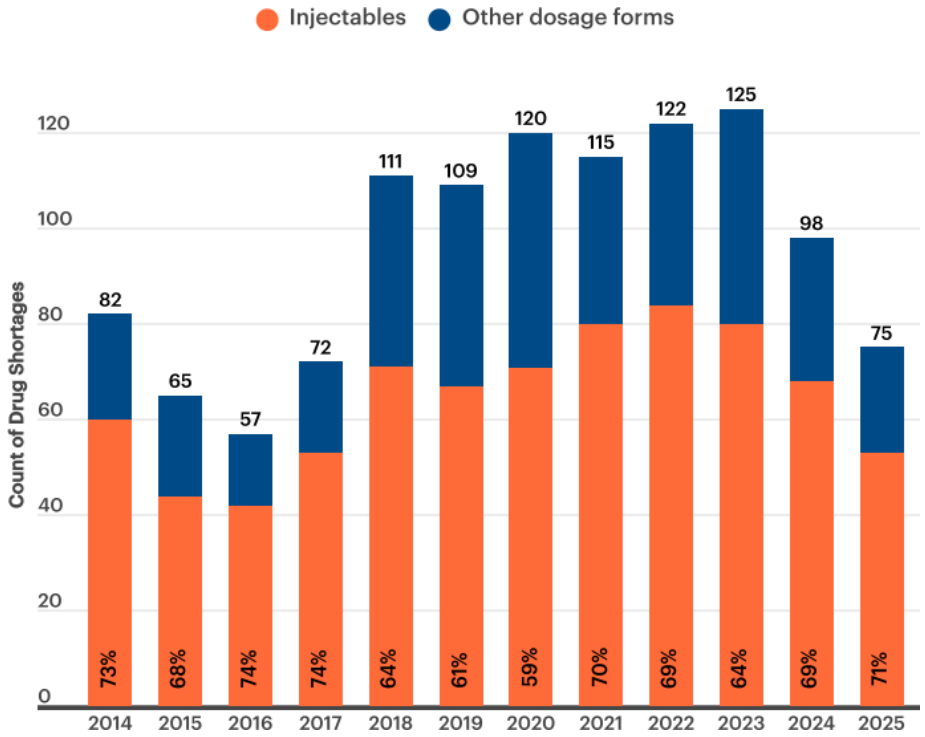
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GRx Biosimilars Conference
2 November 2026

Navigating an unpredictable landscape

Annual Ongoing Drug Shortages



Source: USP Medicine Supply Map, 2026

- **Increased volatility in supply chain environments**
- **Key risks:**
  - Natural disasters
  - Geopolitical events
  - Geographic concentration
  - **Foundational weaknesses**
- **Disruptions are more frequent and harder to predict and affect:**
  - Patient care
  - Economic stability
  - National security

Need for visibility and proactive insights!

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America's and the global medicine supply relies heavily on China and India for critical starting materials, leaving it vulnerable to disruptions



HEALTH

The New York Times

America Is Heavily Reliant on China for Raw Materials in Medicines

A new analysis found that nearly 700 drugs approved for use in the United States depend on chemicals solely produced in China.

By Rebecca Robbins



PRINT EDITION America Relies Heavily on China for Raw Materials in Drugs | October 18, 2025, Page B1

News Pharmaceuticals

Raw materials from overseas fuel the production of medicines used in the US

Regardless of where the drugs are made, key chemicals often come from China or India

by Aayushi Pratap

October 22, 2025 • 4 min read

A US Pharmacopeia study shows that the US is heavily dependent on China for raw materials needed to make important medicines



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Identify risks

Use existing early warning capabilities and invest to fill in supply chain gaps



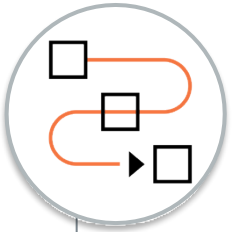
Incentivize resilience

Reward medicine manufacturers for investments in quality, resilience, and reliability with meaningful payment reforms and committed long-term contracts



Diversify manufacturing

Advance broader geographic diversification of manufacturing including incentives to advance more U.S.-based medicine production



Bolster capacity

Tools, standards, and incentives can help facilitate adoption of advanced manufacturing technologies (AMTs) that improve manufacturing efficiency, reduce production costs, and support supply chain resilience.

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Pharmaceutical supply chain is complex, intricate, and highly fragmented

> 50,000 formulations

2,908 US - approved APIs

916
Biologic (32%)

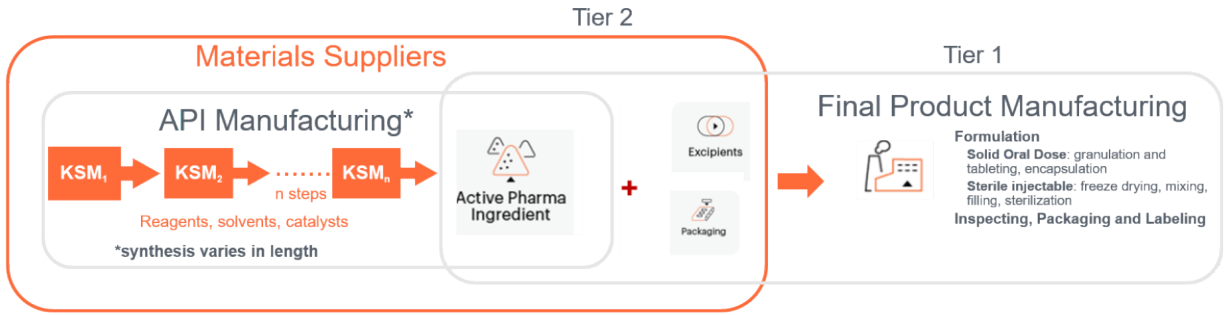
1,992
Small molecule (68%)

1,839 Organic

153 Inorganic

>6,000 KSMs

> 20,000 suppliers



Tiers 1-3

Manufacturing Technologies, Capacity, Expertise, Workforce
Regulations (FDA, EHS)
Market Dynamics (incl Gov't incentives, geopolitical, consumer/patient, etc)

Sources: USP data and analysis

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USP Resiliency Framework: Informing Practical Paths to Adoption

Identify and Understand → **Determine and Evaluate Levers** → **Mitigate and Solve**

WHERE?



Medicines Supply Map

AI-powered supply chain mapping

- End-to-end segmentation
- Commercial KSM identification
- Global visibility across supply chain segments

WHY?



Foundational Factor Analysis

In-depth analysis of supply drivers and risks

- KSM-API-excipient manufacturing evaluation
- Geographic & technoeconomic analysis
- Data-driven, feasible recommendations

HOW?



Mitigation Strategies & Long-term Resilience

Enabling strategic on/re/allied-shoring

Mitigate

- Formulary substitution
- Multi-sourcing & strategic stockpiling
- Domestic capacity optimization and utilization

Solve

- Advanced synthetic route and manufacturing development
- Pharmaceutical quality testing and ingredient verification
- CMC and Regulatory
- Resilience benchmarking

Convene, Collaborate, and Advocate

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Thank you

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The standard of trust