The Future of Quality and Maintaining a Reliable Supply Chain

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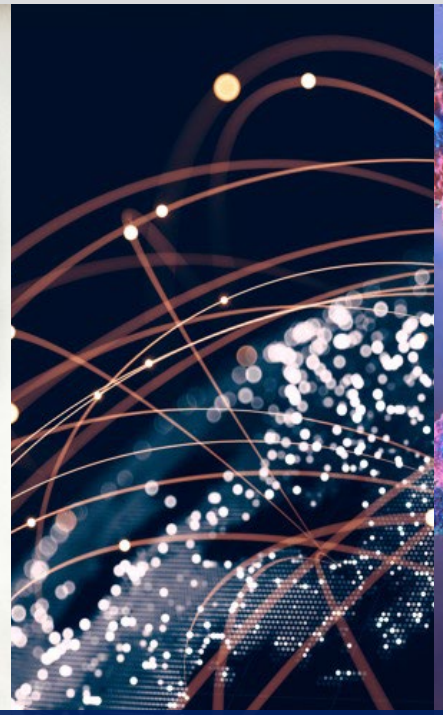
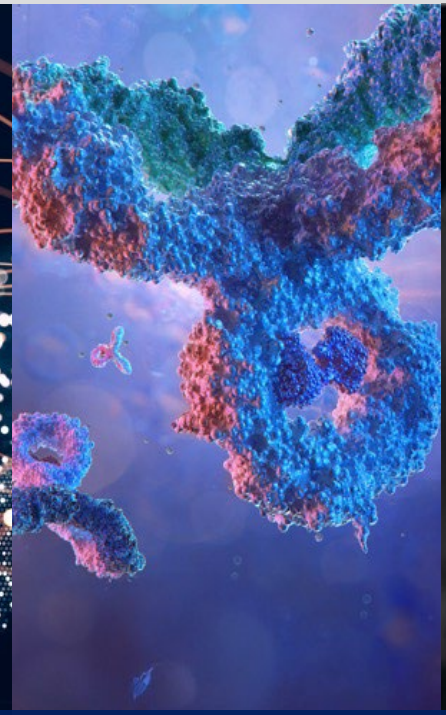
USP's 2025-2030 cycle mission commitments





Enable greater availability of the world's most relied-upon medicines

Solve pervasive quality challenges that impact medicines, supplements, and foods

Strengthen resilience of the global pharmaceutical supply chain

Expand global availability of and access to quality-assured biologics products

Advance quality through the increased use of digital technologies

Foster environmental sustainability across the pharmaceutical life cycle

Supply Chain Resilience depends on Visibility and Mitigation

- **Visibility -** insights into supply chain vulnerabilities
- **Mitigations -** solutions that are deployed with agility and flexibility to safeguard supply chain disruptions.

Bringing visibility to the supply chain

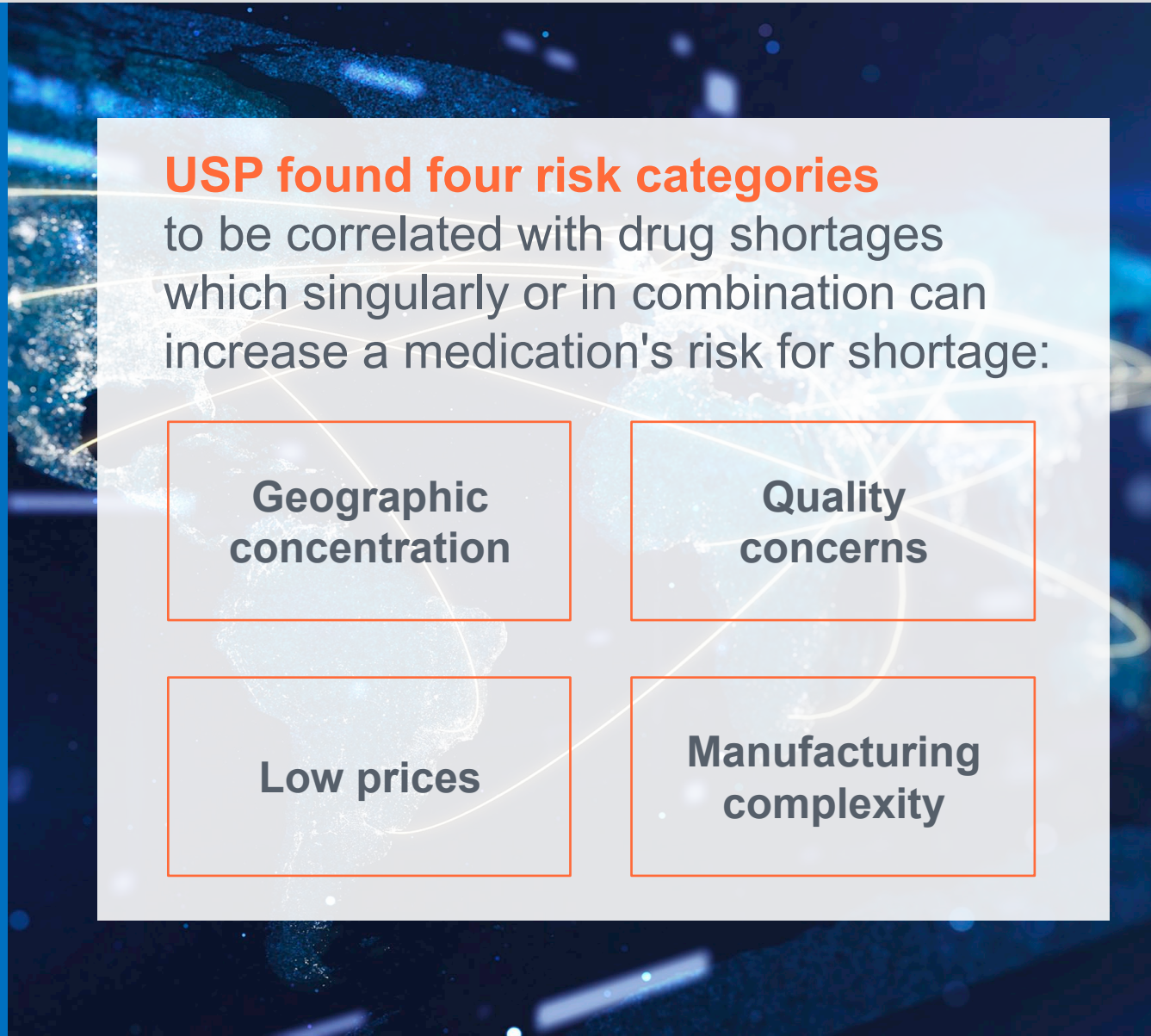
Trust and Visibility are essential for a secure global supply chain.

USP Medicine Supply Map: A data intelligence platform that:

- Identifies, characterizes, and quantifies risks in the upstream pharmaceutical supply chain
- Helps prioritize investments in supply chain resilience
- Proactively mitigate drug shortages
- Enables informed decisions through AI-driven insights

Supply chain vulnerability scores

Over 100 factors back tested against actual shortages recorded by the U.S. Food and Drug Administration (FDA) and American Society of Health-System Pharmacists (ASHP) to select the most important factors.



USP found four risk categories to be correlated with drug shortages which singularly or in combination can increase a medication's risk for shortage:

- **Geographic concentration**
- **Quality concerns**
- **Low prices**
- **Manufacturing complexity**

USP Medicine Supply Map: KSM Module

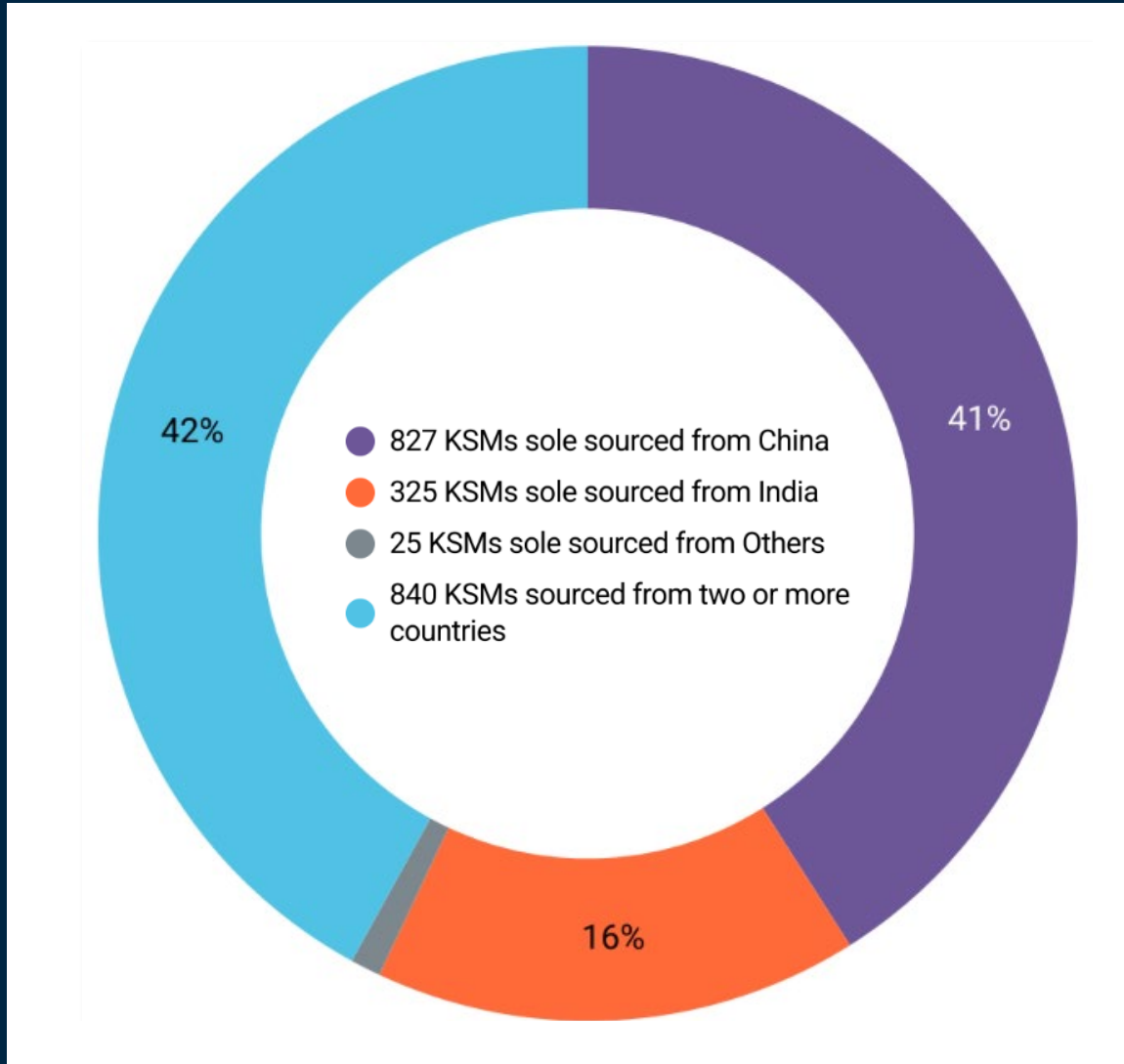
USP manufacturing scientists analyzed all APIs for US approved Medicines to understand KSM sourcing.

Category	Count
Total US APIs (Rx, OTC, Veterinary)	**2,908**
Less Biologics (no KSMs)	(916)
Less Inorganic (no KSMs)	(153)
Total APIs Included in Analysis	**1,839**
APIs with commercial KSMs	1,438
APIs with no identified KSMs	
• Natural APIs (no KSMs, e.g., made via fermentation)	140
• APIs without commercial KSMs (made in-house)	261

A majority of KSMs are sourced solely from a single country

58% of KSMs for US APIs are sole-sourced from a single country (see right)

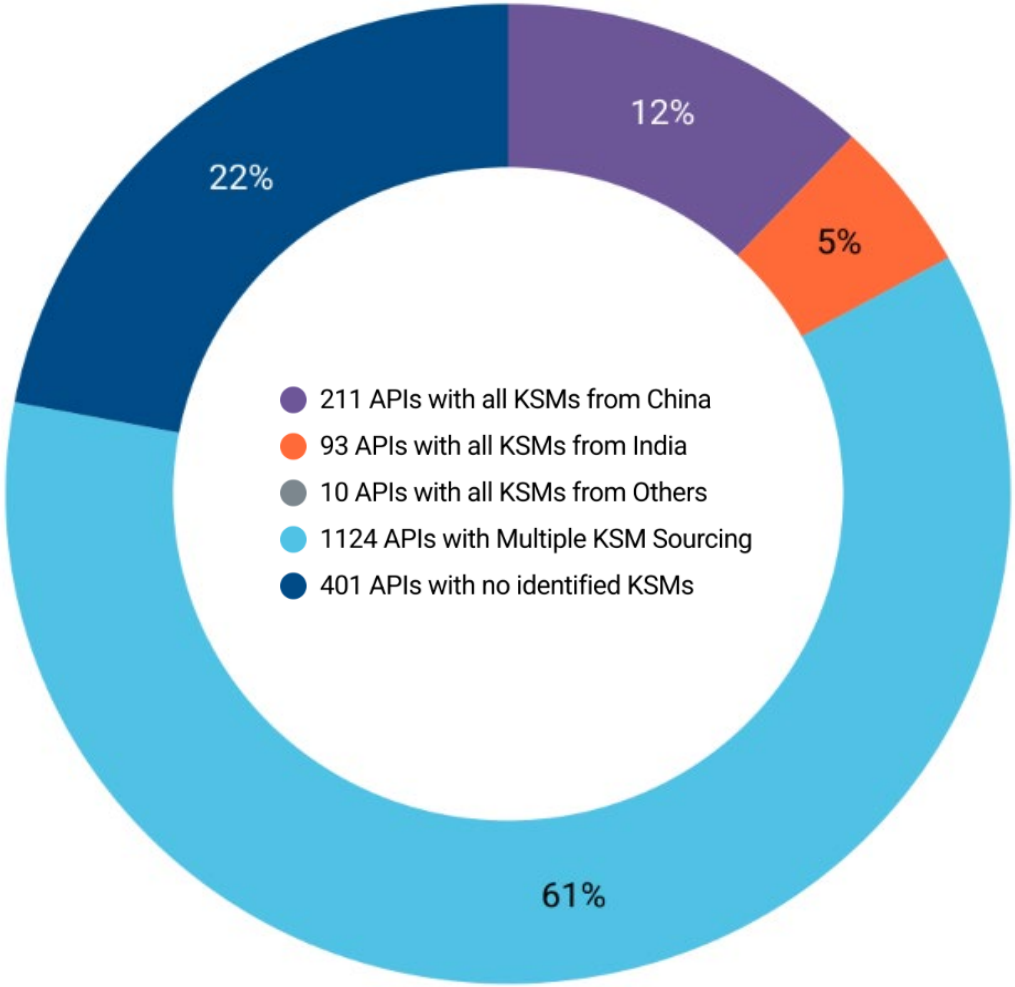
- **41%** of KSMs used in U.S.-approved APIs are sole sourced from China
- **16%** of KSMs used in U.S.-approved APIs are sole sourced from India
- **1%** of KSMs are sole sourced from other countries, including **4 KSMs** that are sole sourced from the U.S.



Many APIs for US approved Medicines rely on a single country for all KSMs

17% of US APIs rely on a single country for all KSMs
(see right)

- **12%** of APIs rely on China for all KSMs
- **5%** of APIs rely on India for all KSMs
- Less than 1% of APIs (10) rely on other countries (Indonesia, Taiwan, EU) for all their KSMs



USP Pharmaceutical Product Quality Testing Program

A look back at factors that have disrupted the system

- The quality of medical products became a recognized global concern during the pandemic
- Generic drug price erosion continues to undermine industry stability
- Disruption to overseas inspections (due to pandemic and other external factors)
- Conflation of drug shortages, overseas manufacturing, and concerns described as "quality issues"
- Proliferation of third-party product quality testing using unvalidated test methods, yielding misleading results

USP offers a solution

USP's Pharmaceutical Product Quality Testing (PPQT)

- Voluntary post marketing testing program for generic medicines that enables purchasers, suppliers, and manufacturers to showcase their commitment to quality medicines in the last mile
- Utilizes scientifically validated quality testing methods, either those found in USP's public quality standards or those accepted by the FDA
- USP works with the manufacturer for program implementation

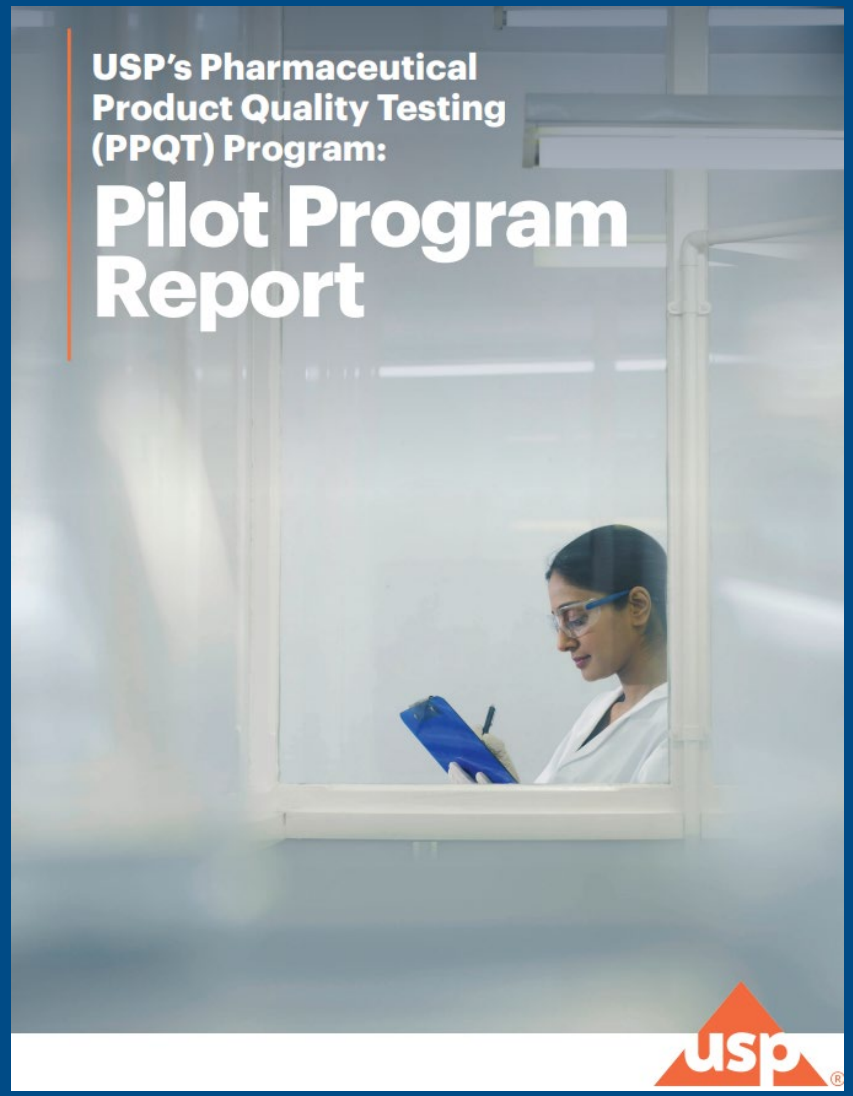
Potential benefits

- **Quality-assured sourcing and transparency:**
  - Independent data to evaluate supplier quality, fostering accountability and informed formulary decisions without relying on manufacturer claims.
  - Provides verified passing results to guide procurement, enabling selection of reliable generics
  - Purchaser can request participation in program.
- **Cost savings**: Minimizes shortage-related expenses by prioritizing compliant suppliers, aligning with value-based contracting and budget impact models for sustainable affordability.
- **Risk mitigation**: Early detection of issues prevents distribution disruptions, supporting payer goals for safe, equitable access to therapies.
- **Scalable and risk-based** for purchaser to target products for inclusion

Critical attributes of the USP's PPQT Program

- Voluntary
- Market-based testing (non-CGMP)
- Validated methods consistent with FDA approvals
- Results distributed freely to purchasers to inform their decisions
- Lean and efficient
  - Does not result in delays in meeting market access requirements
  - Cost-effective
- Easily and rapidly scalable

For more information on PPQT, read the Pilot Program Report below:



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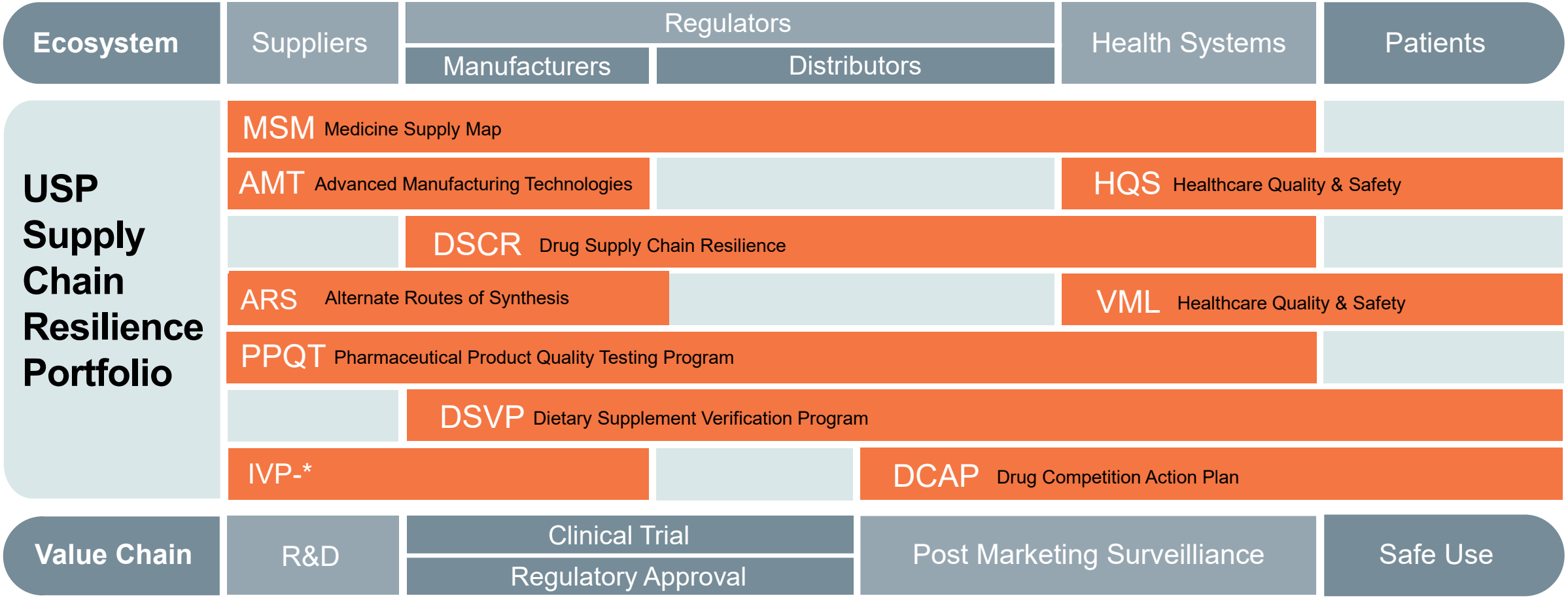
USP's Supply Chain Portfolio of Programs



USP Supply Chain Quality Standards – More than 330 General Chapters supporting manufacturing, regulation, and distribution of medicines

* Ingredient Verification Programs for Dietary Ingredients, Excipients, and Active Pharmaceutical Ingredients (IVP-DI, IVP-E, IVP-API)

Leucovorin Drug Journey

USP Supply Chain Program shortage response

Abbreviations

AMT	Advanced Manufacturing Technologies
API	Active Pharmaceutical Ingredient
DSCR	Drug Supply Chain Resilience
FDF	Finished Dosage Form
GPO LTA	Group Purchasing Organization-Long Term
HQS	Healthcare Quality & Safety
KSM	Key Starting Material
MSM	Medicine Supply Map
PPQT	Pharmaceutical Product Quality Testing Program
VML	Vulnerable Medicines List

MSM produces drug shortage list, VML

Leucovorin shortage projected due to demand surge

MSM identifies KSM, API, and FDF risks

Investigate current manufacturers and locations for API-folic acid, FDF-leucovorin
Identify current manufacturing capacities and demand surge for folic acid and leucovorin

AMT conducts Foundational Factor Analysis (F2A), reviews manufacturing solutions, reviews KSM/API alternate synthesis

Investigate the fermentation/enzymatic pathway for the synthesis of pteroylglutamic acid
Explore alternate synthesis and raw materials e.g., GTP, PABA, l-glutamate

DSCR reviews supply and demand practices

Investigate current procurement, price change & demand surge, stockpiling, redistribution/reverse logistics, production ramp-up
Quantify needs and review utilization patterns – Leucovorin inj rescue after HD Methotrexate; prenatal prevention of NTD, fortified food & nutraceutical demand.

PPQT – drug quality market testing

Review for recent quality concerns - January 2024 GAO report found quality issues in 11 of 12 prenatal supplements, with OOS folic acid amounts
Test methods are available, independent testing to support procurement decisions.

HQS identifies USP compounded preparation monograph candidates

Develop compounding monographs – Leucovorin calcium compounded inj; oral susp, tab.
Formulary review for alternatives

Supply Chain Quality Stds – packaged to support vulnerable medicines candidates

Bundle monographs, Leucovorin has OTC and Rx drugs and offered in many different FDF formats. Linking the quality requirements with the type of product and assuring standards are properly adhered to is important.
Relevant General Chapters available availability on related GMP topics – sterility, dosage forms, etc.

For more information, visit: USP.org/MedicineSupplyMap

Or use this QR code to read the KSM report

Annual Report on Drug Shortages

Scan the QR code
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