

USP's Work to Help Build Supply Chain Resilience Expanding the Supply of Quality Medicines

A resilient supply chain withstands acute disruptions so that safe, effective, and quality medicines can be supplied to patients around the globe, in adequate quantities, when they are needed. USP standards and solutions are critical tools supporting global medicines supply chain resilience, enabling consistency and uniformity in the production of safe, quality medicines from raw materials through packaging, distribution and delivery, building trust in medicines.

Information and Innovation

Medicine Supply Map: Identifies, characterizes, and quantifies risk in the upstream supply chain, developing insights from over 250 million data points from more than 40 sources.

Advanced Manufacturing Technologies (AMT) Workforce Development: Training in applications to help upskill staff to implement AMT.

USP Pharmaceutical Continuous Manufacturing (PCM) Knowledge Center: Captures and shares PCM knowledge across six domains of knowledge from R&D through manufacturing and regulatory affairs.

Collaboration

Regulatory Capability Building: USAID-funded PQM+ program works in low- and middle-income countries building capabilities to help ensure the supply of quality medicines in their countries.

USP-APEC Center of Excellence:

Convenes regulators from 21 economies from Pacific rim countries focused on supply chain quality. Sponsored by the U.S. FDA.

Advancing Preparedness: USP is an active participant in Biden Administration formal advisory committees for the HHS Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA).

Global Pandemic Prevention and Biodefense Center: USP participation in cross-sectoral initiative to develop Monoclonal antibodies (mAbs) for the world's top 100 pathogens most likely to cause a future pandemic.

Policy Development and Advocacy

Congressional Engagement: Advocacy through comments and letters to Congress and Federal Agencies focused on upstream supply chain insights to reduce shortages, combat antimicrobial resistance (AMR), and reduce the barriers to adoption of pharmaceutical continuous manufacturing.

Public Policy White

Papers: AMR, falsified and substandard vaccines, and supply chain resiliency were the focus of USP white papers to inform policy dialogues.

USP Quality Institute:

Research to inform policy related to supply chain risk perception, AMR and its link to quality, and medical product procurement.

Joint Policy Recommendations: USP collaborated with the American Medical Association, American Society of Anesthesiologists, American Society of Health-System Pharmacists, and Association for Clinical Oncology to develop policy recommendations to improve the resiliency of the U.S. supply chain and mitigate medical supply shortages.

Distribution

Storage and

Distribution

Key Initiatives

Essential Standards

Development Formulation (R&D)

- Medicines Patent Pool (MPP): - USP's Center for Flow collaboration with UN's MPP on **Chemistry Research and** Good Manufacturing Practices to help generic drug synthesis routes to localize manufacturers achieve starting materials for critical prequalification of products under Volume License Agreements (VLA) with
- Monoclonal Antibody (mAbs) **Standards** to support new therapy development

materials

- Cell-based Advanced **Therapies and Tissue-based Products standards**

originators

Process Development

- API manufacturing support at the USP Center for Flow Chemistry Research and Development by producing analytical methods and process chemistry methods.
- USP Quality Verification of Ingredients and Excipients

Creation

- Active Pharmaceutical - Analytical Procedure Lifecycle **Development** standards Ingredients (API), Excipients, **Cell Banking Practices** standards for key starting - Good Manufacturing Practices
 - Excipients standards - Standards for dosage forms (e.g., transdermal, injectable,

for Bulk Pharmaceutical

Regulatory Filings and Compliance

- Regulatory Advisory Services for LMICs (e.g., Prequalification services; Dossier preparation/filing; Product registration; Mock inspections/audits)
- COVID-19 vaccines quality assessment tools
- Nomenclature Standards and guidelines
- API and Drug Product **Identification Tests**
- Assays and supporting physical reference standards

Manufacturing

- DNA, mRNA, and viral-vectored vaccines standards and resources to support their development

Production/Manufacturing

- - Support for the development of traditional and complex generics through Standards, including Dissolution, Inhalation and Nasal Drug Products,
 - Products for Nebulization, Characterization Tests, APSD Measurement Data for Orally Inhaled Products, and Excipient Performance

Microbial Control and Sterility **Assurance Standards**

- Supplier Qualification

Standards

Sourcing

- Good Manufacturing Practices Standards for Bulk Pharmaceutical Excipients, including sourcing
- - - Nomenclature Standards

Products

- Packaging and Storage Requirements Standards

- Good Storage and Distribution

Practices Standards for Drug

- Extractables and Leachables Standards
- Vaccine handling guidelines, including vaccine transport and support for COVID-19 and monkeypox vaccines

- Compounding Standards

Consumption

Point of Care/

Administration

Substandard/falsified and

safety surveillance support for

- Dispensing Standards including Stability Considerations in Dispensing Practice

- Labeling Standards: Prescription Container Labeling, Physical Environments that Promote Safe Medication Use, Injections, Labeling on Ferrules and Cap Overseals