USP Science and Standards: 2025-2030

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USP Mission: Over 200 years of building trust



To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.



Responding to today's public health challenges through coordinated standards, advocacy, and capability building







To be a definitive source of standards for the supply of quality medicines

Advocacy

To be the global institutional leader advancing the supply of quality medicines

Capability Building

To be a leading provider of services that advance the supply of quality medicines to improve the health and well-being of people and patients

USP: a Definitive Source of Quality Standards



- Lead standardization of new scientific approaches (e.g. risk-based, performance-based, predictive, flexible)
- Provide knowledge on complicated (e.g. complex Gx) and emerging modalities
- Facilitate establishing equivalence for evolving analytical technologies and advanced manufacturing to lower adoption barriers
- Continuously evolve our standards and processes to stay relevant and impact supply of quality medicine
- Generate and increase availability of interoperable data on supply of quality medicine



eople Quality Digital Investment and Sustainability

Focus on products and technologies with the most utility to our stakeholders and greatest impact on patient and consumer health

Powered by a knowledge engine in the supply of quality medicines and leveraging an engaged scientific and healthcare community

Defined broadly, encompassing different physical, digital or documentary formats that make information accessible

More than 9,000 USP standards providing quality benchmarks



\longleftarrow USP offer solutions across the supply chain \longrightarrow



Collaborating to address shared challenges





USP provides more than just standards





Engagement

Identify and build community Constructive debate and dialogue Individual scientific input



Standard Setting

Monographs General Chapters Reference Standards and Materials Guidelines



Education

Build awareness Education, training, tools



USP provides flexible solutions





Reference Standards

- Usually referenced in USP-NF methods
- Tested in multi-lab studies and approved by USP Expert Committees
- Potential uses: compendial or in-house methods, assay control, control material for method development, standardization testing across laboratories, method transfer, stability testing

Analytical Reference Materials (ARMs)

- Not required for compliance with USP-NF methods but sometimes important for verification of methods
- Fit-for-purpose assessments
- Details on testing/application on Product Information Sheet or application notes

USP Supports Innovation

New Products and Modalities

- Complex generics
- Gene and Cell Therapies
- Combination Products

New Technologies

- Advanced manufacturing
- Process Analytical Technologies
- Advanced analyticsl technologies (qNMR, UPLC, MAM)

Digital tools and solutions





USP Science Quality Framework



Evolving	Product	Emerging	Novel	Quality
Standards	Performance	Modalities	Technologies	Environment
 Flexible content Risk-based Performance-based Analytical Procedure Lifecycle New approaches to establish standards Impurities Materials Emerging Standards Release testing 	 Future of performance testing Mini vessels Continuous Manufacturing Extended and modified release New advancements in product performance testing (NAPPT) New delivery systems Liposomes Nanomaterials Excipient performance 	 Personalized medicine Compounding Digital Therapeutics Precision Therapies Gene Therapies Cell Therapies Combination Products Complex generics Novel Excipients Biomarkers Novel Vaccine Platforms & Adjuvants Microbiome therapeutics 	 Manufacturing technologies Advanced manufacturing Continuous manufacturing 3D printing Single use/disposable manufacturing equipment Nanotechnology Packaging Analytical technologies QNMR Spectroscopy Optical image analysis UHPLC MS PAT Rapid micro testing 	 • Quality culture • Quality maturity model • Quality Metrics • Quality Management • GMP • Product Development Practices • Quality by design • Supply chain • Supplier qualification • Quality screening for adulterants

USP's 2025-2030 Cycle Mission Commitments







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



- StrengthenEresilience ofathe globalapharmaceuticalqusupply chaina
 - 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

Enhancing availability of global medicines





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

- Continuing our mission to support stakeholders with standards that help ensure the quality medicines to meet the needs of patients globally
 - Developing new public standards for medicines that will have the greatest impact and ensure the relevancy of USP (~1300 monographs/~10 years)
 - Improving the design of standards to increase their effectiveness at ensuring medicine quality
 - e.g. mutagenic impurities, complex generic products
 - Evolving standards to make them easier to use, provide more information, allow greater flexibility (when appropriate) to ensure medicine quality
 - Creating new approaches/tools beyond traditional standards (e.g. emerging standards)

Fostering Environmental Sustainability





Note: Focus on environmental efforts; access to medicines and DEIB related initiatives are excluded. Source: Interviews of ESG Leads, Sept 2022

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





Pervasive challenges such as sterility, adulteration and impurities, persist across the supply chain

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Expert Volunteers help power USP's impact on global public health

Serving on Expert Committees, Panels and Sub-Committees, they collaborate to develop quality standards and other solutions that help build a more resilient supply of quality medicines.



Apply and amplify your impact

Thank You



The standard of trust