Impact Expansion

USP will expand its public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.

Year 2 Update

USP continued to expand its impact internationally through a range of approaches and workstreams to increase the resilience of the global medicines supply chain, including through its efforts to support risk-based postmarketing surveillance; strengthen public procurement; develop standards for good distribution practices; lower barriers to adoption of pharmaceutical continuous manufacturing; and prevent, detect, and eliminate substandard and falsified medicines. USP’s broader work to advance adoption of USP quality standards, guidelines, and best practices reached more people in more regions of the world, helping to strengthen the global medicines supply chain and improve patient safety and public health.

Key areas of progress over the past fiscal year include:

Impurities – USP engaged stakeholders around the world through its solutions to help control the risk of impurities in medicines, including through related USP standards and training.

- USP initiated a pilot project on testing for nitrosamine impurities with the Vietnam National Institute of Drug Quality Control. The collaborative project assisted the country in strengthening postmarketing surveillance to detect nitrosamine impurities in angiotensin receptor antagonists (sartans).
- USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority. USP provided the lab with nitrosamine impurities Reference Standards as well as training on nitrosamine testing in line with USP standards.
- USP expanded stakeholder engagement with its Nitrosamines Exchange online community, more than doubling its user base to 1,600 across 60+ countries and 22 language capabilities. The Nitrosamines Exchange is a focused forum for global pharmaceutical stakeholders and experts to share up-to-date information and facilitate real-time conversations.
on nitrosamine impurities. The site debuted in year one of the cycle with risk assessments as the primary focus, and evolved in year two to all things related to nitrosamines as community members deepened their engagement through activities including user-driven collaborative projects and publications. Examples include the co-development of specific nitrosamine impurity analytical methods leveraging external resources, and a peer-reviewed article on the complex nitrosamines landscape.

▶ USP’s Promoting the Quality of Medicines Plus (PQM+) program to improve access to quality-assured medicines in low- and middle-income countries (LMICs), funded by the U.S. Agency for International Development, finalized a technical brief describing impurities in chlorhexidine and how manufacturers can address them during production. The brief will help local manufacturers increase the supply of quality-assured chlorhexidine gel to prevent umbilical cord infections in newborns.

Multi-Attribute Methods Exchange – USP launched a pilot Multi-Attribute Methods Exchange online community to facilitate knowledge sharing and real-time conversations globally on the emerging quality control analytical techniques. Since its debut in October 2021, the community has grown to 300+ users from 30+ countries, and includes scientists from industry, contract research organizations, and instrumentation companies, among other stakeholders.

Pharmaceutical Continuous Manufacturing in Asia – During the China Pharmaceutical Association of Plant Engineering Annual Meeting, USP collaborated with regulatory bodies and industry to address challenges and opportunities in the adoption of pharmaceutical continuous manufacturing (PCM) as a means to bolster medicines supply chain resilience. The event was attended by key regulatory agencies from China and 200+ industry participants. Similarly, USP collaborated with the Indian Pharmaceutical Alliance on a PCM conference in India for global stakeholders in the field. Featuring speakers from industry, academia, and regulatory authorities including the U.S. FDA and European Directorate for the Quality of Medicines & HealthCare, the event drew 260+ participants.

Substandard and Falsified Medicines in Asia – USP worked with stakeholders across the region to advance efforts to prevent, detect, and eliminate substandard and falsified medicines.

▶ In collaboration with the Asia-Pacific Economic Cooperation (APEC) forum, the USP-APEC Supply Chain Center of Excellence hosted an event on “Confronting Substandard and Falsified COVID-19 Vaccines and Treatments” in partnership with the Pharmaceutical Security Institute, Moderna, and Sanofi. The workshop was attended by 75+ regulators and other key stakeholders across Asia and the Americas. USP also led the APEC Task Force on Post-Market Surveillance and contributed to the APEC Task Force on Internet Pharmacies led by the Alliance for Safe Online Pharmacies to help support access to quality-assured medicines across the region.

▶ USP partnered with the Association of Southeast Asian Nations in an initiative led by Cambodia to combat substandard and falsified medicines in the region.
USP supported the Philippine FDA’s National Consciousness Week on Anti-Counterfeiting campaign to increase awareness of the issue.

**Strengthening Public Procurement in Asia and Africa** – In collaboration with the World Health Organization’s Southeast Asia regional office, USP provided technical support for self-assessments by public procurement agencies – including in the Indian states of Tamilnadu and Gujarat, and 10 other countries in Southeast Asia – to help strengthen public procurement practices in the region. Separately, PQM+ helped Rwanda and Nepal develop and implement procurement guidelines that incorporate medical product quality considerations.

**China Engagement on Metal Packaging Standards** – USP formed a joint working group on metal packaging standards with the Chinese Pharmacopoeia (ChP) that aims to outline a related pharmacopeial general chapter.

**Regulatory Capability Building in LMICs** – USP continued to advance regulatory capability building in LMICs through a range of initiatives during the year.

- USP’s Preferential Access for Regulators program provided regulators in at least 38 countries with no-cost or subsidized access to USP educational courses, documentary standards, and reference standards to help those countries ensure access to quality medicines and support medicines supply chain resilience.
- PQM+ helped the regulatory authorities of several countries (e.g., Bangladesh, Ethiopia, Kazakhstan, Kenya, Mozambique, Pakistan, and Rwanda) on their journeys toward more advanced levels of regulatory maturity. More broadly, PQM+ efforts in 21 countries were focused on building the capacity of the regulatory authority and/or its quality control laboratory.
- USP facilitated efforts by the Egyptian Drug Authority to develop guidelines for risk-based postmarket surveillance by sharing related resources and organizing discussions to help guide the agency’s work.
- USP collaborated with the Colombian regulatory agency INVIMA on an educational session on vaccine quality attributes to improve related regulatory capabilities, drawing 75+ regulatory officials.
- USP shared with the Peruvian Regulatory Authority and National Laboratory USP resources on ensuring the quality of cannabis for medical use to help improve their capabilities in the field.

**Global Stakeholder Education and Engagement** – USP engaged thousands of stakeholders globally around our standards and related solutions through educational courses, webinars, and workshops.

- USP co-led a workshop on good distribution practices for finished drug products with the trade association Sindusfarma in Brazil and the Brazilian Academy of Pharmaceutical Sciences. Over 800 participants, including regulators, trade associations, distributors, transporters, and regulatory affairs professionals, attended the event.
- USP co-led a workshop on dietary supplements with the Brazilian regulatory agency ANVISA and Sindusfarma. The event drew 1,400+ participants, including industry, academia, public laboratories, and regulators from across Latin America, for discussion on Brazil’s regulatory framework and standards-setting process for supplements.
USP organized the 6th Annual Workshop on Biologics and Peptides to facilitate knowledge-sharing on these rapidly growing product classes among 290+ global regulatory, industry, and academia stakeholder attendees.

USP collaborated with the Centre of Regulatory Excellence at Duke-NUS Medical School in Singapore to provide training on postmarketing surveillance through a “good reliance practices” workshop.

USP collaborated with South Korea’s National Institute of Food and Drug Safety Evaluation on a joint workshop to identify challenges and provide solutions to expand development of advanced therapies.

USP worked with the Indian Pharmacopoeia Commission to organize an industry training workshop on the fundamentals of drug dissolution, drawing 330+ participants from 149 companies.

USP worked to strengthen pharmaceutical compounding in the Philippines by providing education and training to the Food and Drug Administration Philippines.

USP organized a workshop on sterility testing in Indonesia in collaboration with the Indonesian FDA that provided hands-on training to provincial laboratories to help ensure drug safety in the country, drawing 400+ participants.

USP delivered training courses and organized educational workshops to build regulatory capabilities in the Middle East. The effort included working with the Egyptian Drug Authority on data integrity and monograph-setting processes; the Saudi FDA on biologics; and the Jordanian FDA on biosimilars.

Collaboration with FDA Internationally – USP worked with the U.S. FDA’s office in India on activities related to regulatory strengthening, addressing nitrosamine impurities and anti-microbial resistance, and lowering barriers to adoption of advanced manufacturing technologies. Separately, PQM+ collaborated with the U.S. FDA to organize an online workshop for representatives of national medicines regulatory authorities from high-burden TB countries to share experiences with the regulatory review of new medicines, including TB medicines.

Planned for Year 3

USP will continue to expand regulatory engagement internationally – including through formal memorandums of understanding – to advance capability building and medicines supply chain resilience. Specific focus areas will include pharmaceutical impurities and dietary supplement quality.

USP will continue to advance stakeholder engagement – including through Convention Regional Chapters – to share knowledge and expertise, and to learn from diverse perspectives around shared priorities on topics ranging from pharmaceutical impurities to adoption of advanced manufacturing technologies.

USP will continue to advance capability building solutions to ensure proper storage and transportation of finished drugs.

USP will continue to engage global regulatory authorities to increase awareness of the opportunities and challenges of advanced manufacturing technologies, lower barriers to adoption, and explore options to provide related training.
USP will collaborate with FDA and other APEC partners to convene an in-person event on the medical product supply chain during the APEC USA 2023 host year.

**Contact**
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