Regulatory Systems Strengthening

USP will collaborate with global regulators and other partners to strengthen regulatory systems.

Year 2 Update

From initial product reviews and inspections of manufacturing facilities, to preventing, detecting, and responding to substandard and falsified medical products, regulatory systems play an essential role in ensuring access to supplies of quality-assured medical products. USP works in 40+ countries with national regulatory authorities and other stakeholders to strengthen capabilities in these areas. Much of this work is supported by donors, including the U.S. Agency for International Development (USAID), the Australian Department of Foreign Affairs and Trade, the Global Fund, the World Bank, and the World Health Organization (WHO).

Key areas of progress over the past fiscal year include:

Promoting the Quality of Medicines Plus Program – This year, the Promoting the Quality of Medicines Plus (PQM+) program, funded by USAID, marked the completion of the first half of USP’s current five-year agreement. PQM+ works to improve access to quality-assured medicines in low- and middle-income countries (LMICs). Highlights for the year include expansion of technical assistance to support regulators in the areas of vaccines and medical device quality, as well as support for pharmacovigilance and lot release functions, particularly for COVID-19 vaccines. Building on earlier efforts, PQM+ also supported numerous countries (e.g., Bangladesh, Ethiopia, Kazakhstan, Nigeria, Pakistan, and Rwanda) on their journey to strengthen their regulatory systems.


- Practical guidance documents on emergency use authorizations for vaccines and in vitro diagnostics were finalized and disseminated.
- To further support safe deployment of COVID-19 vaccines, PQM+ worked with several countries to strengthen systems for monitoring adverse events following immunization. During the year, we assisted Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan, and Uzbekistan in developing pharmacovigilance procedures and reporting systems.
- In Bangladesh, PQM+ collaborated with the National Control Laboratory to
develop guidelines for vaccine lot release.

Regional Harmonization and Coordination – USP continued to promote efforts to advance mutual recognition, reliance, and regulatory convergence.

- In Uzbekistan, PQM+ successfully advocated for and guided the use of the WHO Collaborative Registration Procedure for accelerated registration of two WHO-prequalified tuberculosis (TB) medicines.
- USP worked in partnership with four technical committees of the African Medicines Regulatory Harmonization initiative to promote regional coordination and regulatory excellence.
- USP, via PQM+, is providing guidance and planning support toward the formation of the African Medicines Agency, a continent-wide regulatory body that is meant to complement existing regional initiatives and national regulatory authorities.

Partnerships and Thought Leadership – USP advanced key partnerships in Africa, Europe, South America, and Asia.

- USP signed a Memorandum of Understanding with the South African Health Products Regulatory Authority to advance risk-based inspections and post-marketing surveillance; strengthen quality control laboratories for medicines, biologics, and medical devices; and advance regional harmonization.
- USP is working with regulators in Europe, Brazil, China, Saudi Arabia, and elsewhere to improve detection and mitigation of nitrosamine impurities through workshops, access to the USP Nitrosamines Exchange, and preferential access to nitrosamine reference standards.

- PQM+ is supporting a multifaceted approach to developing Uzbekistan’s pharmaceutical sector that includes economic incentives, strengthening regulatory systems, and building workforce capabilities. During the year, USP hosted the inaugural U.S.-Uzbek Pharmaceutical Summit, supported by PQM+, which aimed to catalyze partnership, collaboration, and investment opportunities.

Asia-Pacific Economic Cooperation – As part of the Asia-Pacific Economic Cooperation (APEC) Forum, USP convened two critical workshops under the auspices of the USP-APEC Center of Excellence (COE) on Securing Medical Product Quality through the Supply Chain and the COE on Advanced Therapies. The first workshop, on “Confronting Substandard and Falsified COVID-19 Vaccines and Treatments,” drew 75+ regulators. The second workshop, on “Development and Validation of Bioassays for Advanced Therapies,” was attended by 150+ regulators. USP also now leads the Task Force on Post-Market Surveillance and joined the Task Force on Internet Pharmacies.

Planned for Year 3

- In August 2022, USP announced that $7.1 million is being provided to the PQM+ program to help expand access to COVID-19 vaccines. The additional funding is part of the U.S. government’s Global VAX initiative and will be used in FY23 to support the strengthening of regulatory systems in six African countries toward WHO maturity level three.
- USP and the PQM+ program will support an FDA webinar on “Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines” to share information with regulators in LMICs.
USP will disseminate a paper entitled “A Holistic View of the Global Medicines Supply Chain and Recommendations to Improve Resilience and Ensure Access to Quality Medicines.” The paper will be informed by broad perspectives based on dialogue and gathered evidence, and will include lessons learned during the pandemic as well as policy recommendations targeted at improving supply chain resilience and strengthening regulatory systems.

USP is collaborating 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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