



# VIII Resolution

## Year 1 Resolution Update: Regulatory Systems Strengthening

### Resolution

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

### Alignment with USP's Mission

USP will continue to work with key stakeholders, including national medicines regulatory authorities (NMRAs), national quality control laboratories, academic institutions, regional regulatory systems, and international organizations to strengthen regulatory systems. By promoting collaboration and engagement across key sectors, USP will build capabilities among NMRAs to help ensure medicine quality while expanding patient access to essential medicines in countries around the world.

### Year 1 Update

Key progress on regulatory systems strengthening efforts over the past fiscal year include:

**Promoting the Quality of Medicines Plus Program Expansion** – This year, USP's flagship "Promoting the Quality of Medicines Plus" (PQM+) program to improve access to quality-assured medicines in low- and middle-income countries, funded by the U.S.

Agency for International Development, added Guinea, Mozambique, the Democratic Republic of the Congo, Madagascar, and Tajikistan. The Mozambique project includes the first PQM+ funding under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Funding for USP regulatory system strengthening efforts also comes from the World Bank to support the strengthening of lab capacity in Chad, Mali, Niger, and the Democratic Republic of the Congo, as well as from the Australian Department of Foreign Affairs and Trade, and World Health Organization (WHO).

**PQM+ Partner Engagement** – USP engaged 13 PQM+ consortium partners to amplify our reach and strengthen our offerings under the program. We are continuing to expand our circle of donors and partners to further amplify our ability to strengthen regulatory systems in low- and middle-income countries.

**Risk-Based Post-Marketing Surveillance** – USP deployed risk-based post-market surveillance implementation guidelines and associated Medicines Risk-based Surveillance (MedRS) tools to 20 countries.

**Regional Harmonization and Coordination** – USP provided the following support to key stakeholders for regional harmonization and coordination efforts:

- ▶ USP provided support to regional technical groups and economic development bodies to strengthen coordination across key geographies and facilitate mutual reliance in regulatory efforts. These organizations included: the Intergovernmental Authority on Development secretariat, the African Union Development Agency-New Partnership for Africa's Development, the Regional Development Mission for Asia regional program, and the Economic Community of West African States.
- ▶ USP collaborated with the Pan American Health Organization on efforts to strengthen regulatory capacity of the Caribbean Public Health Agency, which implemented key regulatory functions in the Caribbean Regulatory System. This resulted in development of guidance, policies, and documents on regulatory inspections and post-market surveillance.
- ▶ USP supported key Asia-Pacific Economic Cooperation (APEC) forum-related events, and the group endorsed USP as a Center of Excellence in Advanced Therapies. We led an APEC workshop on raw materials used in manufacturing cell and gene therapies attended by 125+ regulators from 21 countries. USP also co-led a workshop and webinar series on good distribution practices and track-and-trace with the Malaysia Ministry of Health and Taylor's University, attended by 400+ government regulators and industry representatives from 31 countries.

#### **Brazilian Dietary Supplement Standards –**

USP co-led a workshop on Dietary Supplements with the Brazilian regulatory agency ANVISA and local trade association Sindusfarma with 1,000+ participants from

industry, academia, public laboratories, and regulators who discussed the country's regulatory framework and standards-setting process for supplements.

**COVID-19 Response –** USP regulatory system strengthening activities included the following global efforts responding to the pandemic.

- ▶ PQM+ is providing critical support for safety and quality surveillance of vaccines, treatments, and preventatives, and for emergency use authorization pathways for vaccines and treatments. PQM+ is implementing COVID-19 programs in seven countries: Bangladesh, Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan, and Uzbekistan.
- ▶ USP webinars supporting access to quality-assured COVID-19 vaccines, treatments, and preventatives attracted large numbers of regulators and public health officials from low- and middle-income countries. These webinars included: "Safeguarding Populations from Poor Quality COVID-19 Vaccine Products: Toolkits for the Assessment of Quality Attributes," and "Storage and Distribution of Vaccines."
- ▶ To address potential methanol contamination of alcohol-based hand sanitizers, USP supported revision of methanol testing requirements for medical products by China's National Medical Products Administration. China is implementing method verification and sample testing using the "Limit of Methanol" test from the USP monograph.

#### **Planned for Year 2**

- ▶ USP will continue to support regulatory system strengthening interventions, including through our collaboration with the WHO as an independent, non-state actor in official relations with WHO.



- ▶ USP will continue to provide support for COVID-19 response through the PQM+ approved work plan activities to strengthen product quality and safety surveillance, immunization readiness and implementation, as well as to support laboratory systems.

- ▶ USP will continue to support global expansion of COVID-19 vaccine manufacturing capacity.

### **Contact**

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