



XV

Resolution

Year 1 Resolution Update: Impact Expansion

Resolution

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

Alignment with USP's Mission

The complexities of our interconnected world impact patient safety and public health globally. This is especially true for the medicine supply chain, which is global for all countries, making adherence to science-based standards more important than ever. Globalization has also brought shared societal public health risks that can accompany medicine quality challenges. By cultivating critical success factors that focus on people, continuous improvement, digital optimization, and investment and sustainability, USP advances its mission and expands its impact, reaching more people in more areas around the world.

Year 1 Update

Key progress areas over the past fiscal year include:

Nitrosamines Initiative – USP engaged thousands of stakeholders globally around our solutions to help control the risk of nitrosamine impurities in medicines through

USP standards, educational courses, webinars, and workshops. Piloting a new online community approach to sharing knowledge on risk assessments, USP launched the Nitrosamine Exchange and engaged 400+ members to date from 63 countries. We also engaged numerous regulatory agencies and pharmacopeias on the topic.

China Methanol Standards – 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.

South Asia Engagement – USP collaborated with the Centre of Regulatory Excellence at Duke-NUS Medical School in Singapore on "good reliance practices" and to address risk-based post-market surveillance as a key regulatory function through a session attended by 43 regulators from 15 countries across the South Asia and other global regions.

Asia-Pacific Economic Cooperation – USP worked to develop resources to support post-market surveillance and monitoring as components of the Asia-Pacific Economic



Cooperation (APEC) Supply Chain Security Toolkit.

Promoting the Quality of Medicines Plus Program – 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 (USAID), this year added Guinea, Mozambique, the Democratic Republic of the Congo, Madagascar, and Tajikistan. USP also engaged 13 PQM+ consortium partners to amplify our reach and strengthen our offerings under the program.

Convention Regional Chapters – The USP Convention launched regional chapters for convention members. They provide a consistent and structured way for regional members to share their perspectives, expertise, and input on USP’s work. We launched regional chapters in Latin America, South Asia, Greater China, and the Asia Pacific. To further expand our reach, USP actively engaged with regulatory agencies across the Middle East and North Africa (MENA) region to renew collaborations with Turkey, the United Arab Emirates, Saudi Arabia, Oman, Pakistan, Egypt, Kenya, Ethiopia, Sudan, Jordan, Tunisia, and Morocco, and worked toward an anticipated launch of USP’s MENA regional chapter.

Virtual Stakeholder Engagement – The COVID-19 pandemic’s requirement for social distancing ushered in changes to the way USP interacts with customers and stakeholders globally, including new ways to work virtually. As a result, we more than doubled the number of global attendees for USP events, including workshops, forums, roundtables, and webinars. We estimate attendance at USP events by those outside of North America almost tripled.

Education – USP hosted industry, regulatory, and healthcare professional education and training for over 20,000 attendees during the year, with significant participation by those outside the U.S. Attendees shared high marks (88%) when asked if the course they took would have a positive impact on the quality of their work.

Pharmatech Acquisition – USP acquired Pharmatech Associates, creating a foundation for increasing our global impact through consulting services that will assist manufacturers in meeting quality standards across the product lifecycle.

Planned for Year 2

- ▶ USP will apply learnings from its work on nitrosamines to strengthen global engagement on other initiatives.
- ▶ USP will continue to expand regulatory engagement with authorities in Brazil, South Korea, India, and Russia through formal memorandums of understanding on capability building, pharmaceutical impurities, cell and gene therapies, vaccines, and dietary supplement quality.
- ▶ USP will continue to engage regulatory authorities in Asia, Egypt, and Latin America to advocate for risk-based post-market surveillance programs and explore opportunities to provide related trainings.
- ▶ USP will launch the MENA regional chapter for convention members and continue to build engagement through all the regional chapters.
- ▶ USP will continue to translate our scientific materials and content into more languages, including Spanish, Mandarin, Portuguese, Russian, and Korean, to facilitate global stakeholder engagement.
- ▶ USP will continue to learn how best to leverage virtual tools to strengthen global engagement.



- ▶ USP will work to expand Pharmatech's geographic reach to increase global impact.

Contact

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