



Resolution

Year 1 Resolution Update: Quality Standards

Resolution

USP will be a definitive source and a recognized scientific leader in public quality standards to help protect patient and consumer safety, and to meet the needs of regulators, policy makers, healthcare practitioners, and industry working in evolving global regulatory environments. In doing so, USP will work to identify emerging trends; align with analytical, manufacturing and other technological advances; and develop innovative and agile approaches to address current and future needs of industry, regulators, practitioners, consumers, and patients.

Alignment with USP's Mission

As standards are revised or created, USP must build stakeholders' resolve to adopt those standards and support their capabilities to use them. USP has a strong foundation—200 years of deep expertise—that makes us uniquely qualified to create relevant and impactful quality standards. USP's enhanced focus to prioritize standards that are most needed, and its reimagined standards engagement model, will help create the right standards at the right time, and ensure that they are high quality, timely, and fit for purpose.

Year 1 Update

Key progress areas over the past fiscal year include:

Priority Standards – USP worked to advance priority standards. This included development of vaccine and complex carbohydrate standards, as well as tools and solutions to address nitrosamine impurities and the COVID-19 pandemic, among other priorities.

- ▶ USP developed an outline for a new informational general chapter on messenger RNA (mRNA) vaccines. This included best practices for establishing critical quality attributes such as identity, molecular size, purity, potency, capping efficiency, and impurities. Physical standards to support vaccines were also a priority, including to support quality assessment of CRM-197, a carrier protein found in many polysaccharide-protein conjugate vaccines.
- ▶ USP provided tools and solutions that address the hazards of unacceptable levels of nitrosamine impurities, the presence of which has been reported in widely used prescription and over-the-counter medications. We developed a new general chapter on nitrosamine impurities (*USP General Chapter <1469> Nitrosamine Impurities*), and we created associated reference standards and educational

webcasts to help drug manufacturers and regulators analyze, monitor, and control for nitrosamine impurities.

- ▶ USP developed a range of tools and resources to respond to the COVID-19 pandemic. To address public health risks associated with potential methanol contamination of alcohol-based hand sanitizers used to help protect against disease transmission, and in response to a request from FDA, USP worked quickly to issue Revision Bulletins requiring the “Limit of Methanol” identification test in monographs for alcohol. Since alcohols are widely used as pharmaceutical ingredients, the revisions also address contamination risks to the supply chain beyond hand sanitizers. USP also posted a *Food Chemicals Codex* Ethyl Alcohol Immediate Standard revision to address FDA concern about hand sanitizers labeled to contain ethanol but that tested positive for methanol. In addition, USP collaborated with other international pharmacopeias on an interactive dashboard of monographs mapped to medicines investigated as COVID-19 treatments.

Standards Engagement Model – USP implemented a new approach for engaging volunteers and stakeholders in standards development. We transitioned to Expert Committees (ECs) that are smaller, more agile, and that hold more frequent and shorter meetings, with leaner work plans focused on key issues. We encouraged ECs to leverage Expert Advisors who can share their expertise as needed, without having to commit to a five-year cycle or participate in balloting activities. Our aspiration is that our new flexible model will help USP attract broader, more diverse participation, and increase volunteer engagement.

Science Quality Framework – USP’s Council of Experts helped to develop the Science Quality Framework, which comprises five strategic pillars covering the following areas: Evolving and Expanding Standards, Product and Substance Performance, Emerging Modalities, Advanced Technologies, and the Quality Environment. These focal points form the foundation for USP’s Global Science and Standards Division work during this cycle to advance our vision, become more iterative in creating standards and disseminating knowledge of quality, and to be a definitive source of quality standards.

Iterative Standards Approach – Under USP’s “iterative standards” approach, we aim to share our preliminary work on standards to build stakeholder communities, stimulate early discussion and contribution, and enable more rapid, dynamic development of standards. Iterative approaches were employed, for instance, in developing USP’s “Methods to Assist in Detecting Falsified Remdesivir.” By accelerating the development of such relevant, timely resources and public quality standards, this model can help USP fulfill its important role in ensuring availability of quality-assured medicines.

Critical Resources - Information Sharing Priorities – We completed our 2021 Critical Resources - Information Sharing Priorities (CRISP) reanalysis showing the impact of the original CRISP roadmap, demonstrated by improved deferral rates. We built an overall narrative of CRISP into various USP and FDA engagements, including senior FDA-USP leadership discussions, to drive improved information sharing through the agency’s Center for Drug Evaluation and Research.

FDA’s Drug Competition Action Plan – We successfully mapped new USP monographs



to FDA's list of "Off-Patent, Off-Exclusivity Drugs without an Approved Generic" (the OPOE list) under FDA's Drug Competition Action Plan (DCAP) to help support development of new generic drug products and demonstrate USP's commitment to FDA's DCAP initiative. We also prioritized drug monographs associated with drug products on the OPOE list.

Health Equity Initiative – In alignment with our commitment to support global public health and access to quality medicines, USP continued its work developing a Health Equity Initiative and exploring ways Expert Volunteers can incorporate health equity into standards for enhanced public health impact. USP's Council of Experts has supported a phased approach, starting with formation of a Health Equity Advisory Group to provide ongoing counsel for the initiative.

Planned for Year 2

- ▶ USP will continue to prioritize standards development and engage with FDA on approaches that support efficiency through greater and earlier information sharing.
- ▶ USP will continue to advance initiatives to address key topics, including dissolution, impurities, and complex generics.
- ▶ USP will continue to evolve and implement the standards engagement model.
- ▶ USP will conduct a virtual workshop in fall 2021 to address the causes of health disparities and help identify potential solutions that can be applied to USP standards.

Contact

For additional information on this Resolution, contact Jennifer Devine at jad@usp.org.

