Quality Standards

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.

Year 2 Update

USP has prioritized revision and development of new quality standards that can have a greater public health impact. Leveraging the standards engagement model implemented in year one of the five-year cycle, USP revised and created standards that are timely and fit for purpose. As USP worked on these standards, we also worked to advance stakeholder adoption. These efforts help to ensure a resilient medicines supply chain by enabling consistency and uniformity in the production of safe, quality medicines from raw materials through packaging, distribution, and delivery.

Key progress areas over the past fiscal year include:

Priority Standards – USP advanced revisions and development of multiple standards, guidelines, and best practices in areas where they are most needed:

- **USP General Chapter <1469> Nitrosamine Impurities** became official on December 1, 2021. This chapter provides information, tools, and recommendations to help users understand potential sources of nitrosamine impurities, assess risk, and establish strategies and suitable methods to control nitrosamines in pharmaceutical products. USP also expanded its education and training activities in this area.

- Proposed new **USP General Chapter <477> User-Determined Reporting Thresholds**, published in the *Pharmacopeial Forum (PF)*, outlines an approach for determining the appropriate numeric reporting threshold value for impurities in chromatographic test procedures when referenced in individual monographs.

- USP announced a format change for presenting relative retention times for organic impurities in monographs.

- USP revised and published General Chapters <761> Nuclear Magnetic Resonance Spectroscopy and <1761> Applications of Nuclear Magnetic
Resonance Spectroscopy to support the use of quantitative nuclear magnetic resonance (qNMR) technology to help ensure quality.

- A proposed revision to USP General Chapter <711> Dissolution published in PF would replace existing USP Reference Standard (RS) Prednisone Tablets with a new USP Dissolution Performance Verification Standard – Prednisone RS.

- USP continued to develop monographs to ensure the quality of products on FDA’s lists of bulk drug substances that can be used in compounding drug products. During the year, USP published five draft compounded preparation monographs (CPMs) in PF for public comment, and six new CPMs in USP-NF. In addition, USP continued work with stakeholders on revisions to USP General Chapters <795> Pharmaceutical Compounding – Nonsterile Preparations, and <797> Pharmaceutical Compounding – Sterile Preparations to help ensure the supply of quality compounded drugs. (See Compounding Resolution update.)

- Technical guides on control strategy, as well as three proposed new standards for the physical properties of material used in pharmaceutical continuous manufacturing, have been identified for development. USP anticipates that these and future guides could be developed into documentary standards as they mature in industry, potentially positioning USP as the industry leader in control strategy development.

- USP released a series of draft guidelines, including “Analytical Procedures for mRNA Vaccines Quality” and “Analytical Procedures for Viral Vectored Vaccine Quality” that help build trust and confidence in innovative vaccine products.

- USP’s U.S. COVID-19 Vaccine Handling Toolkit and International COVID-19 Vaccine Handling Guide, as well as the COVID-19 Vaccine Quality Assessment Toolkits, were updated to reflect new vaccine information and enhanced practitioner guidance. The vaccine handling toolkit and guide provide operational strategies to address potential efficiency gaps in vaccine delivery and to accelerate the pace of vaccinations while maintaining safety and quality. The quality assessment toolkits serve as a resource for laboratories that need to develop and validate assays for the assessment of quality attributes of vaccines.

Iterative Standards Approach – USP published a Stimuli article titled USP’s Iterative Approach to Standards Development and the “Emerging Standards” Concept. The paper outlines USP’s iterative approach, through which 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. By accelerating the development of relevant, timely resources and public quality standards, the iterative approach can help USP fulfill its important role in ensuring availability of quality-assured medicines. The article also introduces the concept of an “emerging standard” as a standard under development that is made available at an earlier stage for stakeholder input and contributions. The first two examples of emerging standards (for acetaminophen injection and palbociclib) were published along with the article.

Standards Engagement Model – Additional progress was made on the new approach for engaging volunteers and stakeholders in standards development that helps ensure
that the right individuals are engaged at the right time to support a more iterative approach. (See Efficiency in Standards Development and Revision Resolution update).

**Science Quality Framework** – USP made significant progress developing standards and solutions guided by USP’s Science Quality Framework, which comprises five strategic pillars that cover evolving and expanding standards, product and substance performance, emerging modalities, advanced technologies, and the quality environment. (See Efficiency in Standards Development and Revision Resolution update).

**Health Equity Initiative** – USP continued to advance this initiative, which aims to address long-standing public health challenges that have contributed to inequitable access to quality medicines. During the year, USP formed the Health Equity Advisory Group to provide ongoing counsel for the initiative and explore ways Expert Volunteers can incorporate health equity metrics into our standards development and prioritization work for enhanced public health impact.

**Critical Resources – Information Sharing Priorities** – USP continued to make progress on Critical Resources - Information Sharing Priorities (CRISP) objectives, working with FDA to increase information exchange between the agency, USP, and industry for critical standards development.

- USP and FDA continued to discuss the incorporation of language into FDA communications with industry during the drug application process, with the goal of helping industry to understand how to work with USP to develop standards.

**Planned for Year 3**
- USP will continue to prioritize standards development and to advance initiatives to address key topics, including impurities, complex generics, and dissolution.
- USP will conduct outreach to stakeholders with additional information in preparation for the planned revision to *USP General Chapter <711>*.
- USP will continue to engage with FDA and other stakeholders to facilitate approaches that support efficiency through greater and earlier information sharing. This will include holding a joint webinar on information sharing and standards development with FDA and the Association for Accessible Medicines.
- USP will continue to address health equity principles in standards setting. This will include efforts to continue to broaden inclusion of independent Expert Volunteers by expanding USP’s Call for Candidates and the Scientific Expert Fellowship program.

**Contact**
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