



# Resolution

## 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 3 Update

USP has revised and created quality standards and solutions that help strengthen the resilience of the medicines supply chain and ensure access to quality medicines people can trust. This has included a focus on priority standards that represent major milestones in compounding and dissolution performance verification testing, as well as tools and solutions that support quality assessments, address concerns about impurities, and help build trust and confidence in specific product areas. Efforts like these help to ensure a resilient medicines supply chain by enabling consistency and uniformity in the production of quality medicines from raw materials, manufacturing, packaging, distribution, and delivery.

Key progress areas over the past fiscal year include:

**Standards and Solutions** – USP advanced revisions and development of multiple standards, guidelines, and best practices in

areas where they are most needed. This work was guided by USP’s Science Quality Framework, which comprises five strategic pillars that cover evolving and expanding standards, product and substance performance, emerging modalities, new analytical and manufacturing technologies, and quality environments. Related progress includes:

- ▶ Revisions to *USP* General Chapter <711> *Dissolution*, with the new USP Dissolution Performance Verification Standard—Prednisone Reference Standard (RS). This RS has been shown to have lower tablet-to-tablet variability, more consistent performance, and a more stable shelf life than the previous RS.
- ▶ USP delivered the final versions of the revised compounding chapters. These include *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—*

*Sterile Preparations*. Both chapters are available in the *United States Pharmacopeia–National Formulary (USP–NF)* and through the *USP Compounding Compendium*. USP continued to support their early adoption by stakeholders through outreach, resources, and training. (See *Compounding* Resolution update.)

- ▶ Proposed new *USP* General Chapter <477> *User-Determined Reporting Thresholds* was developed to provide a flexible approach for reporting unspecified impurities referenced in *USP–NF* monographs.
- ▶ New *USP* General Chapter <901> *Detection of Asbestos in Pharmaceutical Talc* and *USP* General Chapter <1901> *Theory and Practice of Asbestos Detection in Pharmaceutical Talc* were developed, along with an updated *Talc* monograph, to help ensure that tests for asbestos have adequate specificity.
- ▶ Proposed *USP* General Chapter <1568> *Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research* includes specifications for quality attributes that are fundamental to characterizing materials for clinical research. (See *Cannabis* Resolution update.)
- ▶ *USP* is working to modernize *USP* General Chapter <660> *Containers—Glass* to address public health concerns regarding global glass production and the potential for resulting drug shortages.
- ▶ *USP* also revised or developed guides and draft guidelines that help build trust and confidence in specific product areas. *USP* developed a “Guide to Food Ingredient Standards and Solutions for the Infant Formula Industry” to help address overall

concerns about infant formula quality. *USP* published its “Monoclonal Antibody (mAb) Analytical Guide,” which outlines testing needs at various phases of development and provides *USP* resources on mAb quality. In addition, *USP* published a revised second edition of the “Analytical Procedures for mRNA Vaccine Quality (Draft Guidelines),” which incorporates public comments and donated methods.

- ▶ *USP*’s new or updated toolkits during the year included: *USP*’s toolkit for measuring and controlling levels of diethylene glycol and ethylene glycol contamination associated with allergy, cold, and cough medicines; updated *USP* COVID-19 Vaccine Quality Assessment Toolkits and COVID-19 Vaccine Handling Toolkit to help stakeholders navigate relevant documentary standards; and cannabis toolkits in four volumes that provide scientists, manufacturers, and regulators with the resources needed to help protect public health by establishing a framework for the consistent characterization of cannabis for medical use.

**Iterative Standards Approach –** *USP* continued to develop its iterative approach to standards development, outlined in Fiscal Year 2022.

- ▶ The iterative standards approach includes the concept of an “emerging standard,” wherein a potential standard not yet under development is made available at an early stage for stakeholder input, prior to formal notice and comment through publication in *Pharmacopeial Forum*. As part of this effort, *USP* launched the Emerging Standards Concept website with links to emerging standards.

- ▶ USP launched the Nitrosamine Exchange Analytical Hub, which is an online repository containing downloadable, non-compendial analytical procedures (i.e., analytical notes) for the testing of nitrosamine impurities and related substances. The hub is an active online community where pharmaceutical professionals and other experts exchange key information on this developing quality and safety issue.
- ▶ USP launched the Novel Excipients Knowledge Hub Pilot, which is an online community for stakeholders to exchange knowledge, best practices, and challenges working with novel excipients, in multiple languages.

### **Critical Resources – Information Sharing**

**Priorities** – USP continued to make progress on its 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 the FDA Center for Drug Evaluation and Research continued development of a memorandum of understanding (MOU) to facilitate the timely sharing of information on standards development.
- ▶ USP and FDA collaborated to incorporate relevant messaging into communications coming from FDA during the drug application process, helping industry understand how to work with USP to develop standards.
- ▶ USP, FDA, and the Association for Accessible Medicines began development of a joint information-sharing webinar on standards development with FDA.

### **Planned for Remainder of the Cycle**

- ▶ USP will onboard the newly formed Diversity, Equity, Inclusion, and Belonging Expert Panel, which will report to the Council of Experts and advise Expert Volunteer leadership and USP staff on strategies and best practices to establish a diverse and inclusive environment that fosters strong collaboration.
- ▶ USP will expand its portfolio of quality materials, including non-RS materials, and will work with customers at key points of their product life cycle in USP's Materials Program to help increase the global supply of quality medicines.
- ▶ USP's strategic collaboration with ATCC, a nonprofit global biological materials and information resource and standards organization, will jointly provide co-branded reference materials and reference standards that will serve to advance the quality and development of biologic medicines and therapies.
- ▶ USP will continue to address barriers to adoption of pharmaceutical continuous manufacturing and other advanced manufacturing technologies by exploring opportunities to develop related guidelines, best practices, and quality-focused solutions.
- ▶ USP will expand its portfolio of standards for monoclonal antibodies, which remain the largest modality for biotherapeutics.
- ▶ USP will expand its portfolio of small molecule documentary standards and develop new approaches to controlling impurities.
- ▶ USP's Dietary Supplements and Herbal Medicines team will highlight issues associated with impurities, contaminants, and adulteration through documentary standards and publications that help industry

manage the related risks to the supply chain.

- ▶ USP will accelerate Healthcare Quality and Safety standards development to fill key gaps in the supply chain, medication safety, and e-prescriptions.
- ▶ USP will prioritize development of standards for excipients used in high-priority small molecule formulations, complex generics, injectables, and vaccines.
- ▶ USP will identify and prioritize new, high-impact *Food Chemicals Codex (FCC)* standards for development and will reconsider its *FCC* Analytical Materials strategy.

- ▶ USP will continue to explore and evaluate new testing methodologies and technologies to help improve the quality of medicines.
- ▶ USP will continue to engage with FDA and other stakeholders on approaches that support efficiency through greater and earlier information sharing. This will include developing resources that increase awareness of USP and its standards-development process.

### **Contact**

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