200 years of building trust

Proposed Resolution 3

Quality Standards

Resolution white paper developed by USP staff, with input from the Council of the Convention

200 usp The standard of trust | Convention The 2020 Meeting

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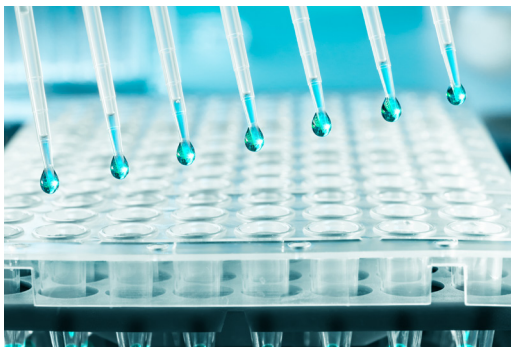
Quality Standards



USP will be a definitive source and a recognized leader in quality standards to help protect patient and consumer safety and to meet the needs of regulators and policymakers, healthcare practitioners, and industry working in evolving global regulatory environments.

Summary

The quality of medicines is fundamental to treating disease and maintaining health. Through its public quality standards, USP helps build a safety net across the industry and healthcare system to preserve the well-being of patients. Standards help ensure that medicines meet quality expectations from the time they are made until the moment they are taken by a patient. As scientific understanding evolves, so too must USP standards. This Resolution proposes that USP should evolve its approach to setting standards so it can continue to protect patient safety and public health in a way that reflects new and emerging science, while understanding the impact of USP standards on regulators, policymakers, healthcare practitioners, industry, and patients. As a recognized leader and definitive source of high-quality, timely, fit-for-purpose standards that reflect the best expertise available from around the world, USP will maintain and even strengthen its cadre of expert volunteers, ensuring that this group of experts reflects the stakeholder community. USP will also work to maximize opportunities for volunteer engagement beyond the classic five-year fixed-term model. To ensure its standards are timely and

fit for purpose, USP will identify and implement ways to accelerate the standards-setting process while reflecting an understanding of the priorities of users and the impact of new or revised standards. Additionally, USP will disseminate relevant scientific findings in more flexible ways than it has in the past to allow earlier and broader access to valuable information, data, and methods. Finally, being a definitive source not only means that USP standards are of high quality, timely, and fit for purpose, but also that USP is creating the right standards. USP will prioritize standards that have the most relevance for stakeholders while simultaneously anticipating new technology and products. Engaging stakeholders will be essential to establishing priorities that reflect the needs of users while always keeping patient safety and public health top of mind.

Background

USP's core contribution to public health is the comprehensive set of well-established, broadly trusted public quality standards that USP establishes for medicines, dietary supplements, and foods. USP deploys a thorough, rigorous, and open process to develop its quality standards, leveraging the knowledge and expertise of leading scientific experts around the world. In this way, USP's expert volunteers form the foundation of the quality standards.

As part of the process, USP makes available several venues for the public to participate and provide input, including stakeholder forums, roundtables, and workshops. For example, the public is invited to review and comment on proposed standards through the *Pharmacopeial Forum*[1] and the *Food Chemicals Codex Forum*.[2] These opportunities allow stakeholders beyond those serving on USP's Expert Committees to contribute their knowledge, ideas, or concerns to the process. By providing time for public review—and similarly by opening Expert Committee, Expert Panel, and other official meetings to the public—USP ensures that its process is robust, transparent, and collaborative.

Since the 2015 Convention, USP has made strides toward increasingly modernized and up-to-date standards, launched new education and training programs to support users of USP standards, and increased efforts to connect with global stakeholders. USP made these efforts in response to rapidly evolving science, transformational advancements in healthcare, and the growing number of countries that are developing or manufacturing medicines and making regulatory decisions for medical products. Expert volunteers and the scientific understanding they represent are the foundation of quality standards. In recognition of their valuable contribution to the mission of the organization, USP will adopt a new and nimbler approach in the next cycle that increases efficiencies and better reflects the needs and priorities of stakeholders while sharing scientific knowledge in flexible, innovative ways.[3]

The USP Expert Volunteer Model

Expert volunteers are crucial for preserving public trust in USP standards. More than 1,000 scientific experts—representing the healthcare practitioner, industry, academic, public health, and regulatory communities—compose the committees that develop, refine, and approve USP standards. USP volunteers possess the critical expertise, state-of-the-science understanding, and ability to apply their knowledge in the standards-setting framework. Every five years, USP invites qualified candidates to apply for expert volunteer positions where they can serve as decision makers on its Council of Experts (CoE), Expert Committees, and Expert Panels.

- ***Council of Experts:*** This body oversees USP's scientific and standards-setting decisions. The USP Convention Membership elects CoE members every five years. Each member serves as the Chair of an Expert Committee for a five-year term. The Chairs, in turn, select the members of the Expert Committees.
- ***Expert Committees:*** These committees develop and revise standards that constitute the USP compendia: *USP–NF, USP Compounding Compendium, Herbal Medicines Compendium, Dietary Supplements Compendium, and Food Chemicals Codex*. They also approve USP Reference Standards specified for use with the compendia. Each Expert Committee focuses on a different area of standards for medicines (including chemical medicines, biologic medicines, excipients, and compounded preparations), dietary supplements, and food ingredients. Expert Committees engage in scientific deliberation to develop proposed standards, solicit feedback on these proposals from the public, then review and consider the input received, adjusting the standards accordingly and adopting them by a majority vote.
- ***Expert Panels:*** Expert Panels are formed to support the Expert Committees by providing additional expertise on a particular compendial topic. Each

Expert Panel has a specific charge (including scope of work, deliverables, and timeline for completion) and dissolves when its task is completed. Each Expert Panel advises one or more Expert Committees. Expert Panels are not decision-making bodies.

USP recognizes that the time commitment of serving on an Expert Committee or Expert Panel may prevent some experts from volunteering. To address this, USP is reimagining the volunteer model, seeking ways to appeal to scientists who have the requisite interest and expertise to participate in the standards-setting process, but who may not have the time or ability to commit to full Committee or Panel service These efforts will draw and retain experts who will help address current and future changes in healthcare and industry, including a complex global supply chain, the explosion of new medicine modalities, and innovative manufacturing technologies.

USP envisions that a more flexible volunteer model will help attract a broader, more diverse group and increase volunteer engagement. To that end, USP will launch a volunteer model pilot project in which six Expert Committees will test a more agile and flexible model to engage and convene expert volunteers in a new role referred to as Expert Advisors. Participating committees will be encouraged to leverage the Expert Advisors, who can share their expertise in a more ad hoc, flexible way without committing to a five-year cycle or being required to participate in mandatory balloting activities.

USP will collect data throughout the pilot project to identify best practices and lessons learned. Ultimately, USP hopes the project outcome will be that potential volunteers view USP as the "go-to" scientific organization because it offers an engaging volunteer experience that makes the most of their time and expertise.

Timely and Fit-for-Purpose Standards

USP will continue to fulfill its mission of creating timely and fit-for-purpose standards while simultaneously identifying ways to accelerate the standards-setting process, engage stakeholders in an effective and responsive fashion, and disseminate USP scientific findings in more flexible and agile ways. These approaches align with USP's strategy of focusing on standards and building capabilities.

USP will accelerate the standards-setting process, without sacrificing quality, in a way that reflects an understanding of the priorities and needs of users. Because USP creates standards with requirements that impact stakeholders, USP requests prompt stakeholder feedback to ensure that the organization can develop and, if necessary, revise the

USP Standards: Quality, Timely, and Fit for Purpose

As a definitive source and recognized leader in high-quality, timely, and fit-for-purpose standards, USP is committed to ensuring that its standards are:

Useful:

USP is focused on developing solutions that provide the most value to public health and to stakeholders. These solutions incorporate emerging and established science to ensure quality medicines and food ingredients.

Recognized:

USP staff and expert volunteers are scientific thought leaders; thus, the organization is a resource for quality standards recognized throughout the regulatory, industry, scientific, and healthcare communities.

Comprehensive:

USP data assets provide a critical mass of broadly applicable and definitive standards—including monographs and General Chapters—ensuring that the standards align with current, rigorous science and fully support the needs of stakeholders.

standards to closely reflect user needs and constraints and ultimately improve fit for purpose.

In 2019, USP launched the Public Input Lifecycle and Impact Project (PILIP), which covers the lifecycle of a standard encompassing problem definition, solution development, identification of affected stakeholders, public notice and comment, and communication about outcomes. PILIP touches everything that goes through the *Pharmacopeial Forum and Food Chemicals Codex Forum*, including monographs, general chapters, and *Stimuli* articles. Implementing PILIP will help USP engage stakeholders in an effective and timely fashion.

Through PILIP, USP staff will develop new, research-based tools and comment mechanisms that integrate the public input processes/systems with the transformation of standards-development processes/systems to benefit everyone who uses USP standards. PILIP explores stakeholder engagement throughout the lifecycle of a standard and questions assumptions about policies and processes. Because USP standards have a broad stakeholder base, tailoring solutions to meet all needs while proactively engaging across a diverse group of stakeholders will be challenging but ultimately worthwhile. Currently, USP staff are implementing projects identified during the analysis phase of PILIP. These projects aim to enhance stakeholder engagement throughout the standards-setting process to ensure that stakeholder input and needs are reflected. Increased stakeholder engagement yields better standards, ultimately leading to improved patient safety and access to quality medicines.

USP will disseminate its relevant scientific findings in more flexible ways to allow earlier and broader access to valuable information, data, and methods. USP conducts rigorous experiments and develops innovative scientific approaches (especially in new or emerging areas of science) that are shared through the traditional, peer-reviewed journal pathway. Additionally, internally developed and vetted white papers help explain USP positions on an array of related topics, such as advancing compounding quality or combating antimicrobial resistance. Future steps might entail growing USP's presence in the digital realm, thereby increasing the visibility and flexibility of USP data as well as USP's ability to quickly marshal resources to address risks and create solutions.

In the next five-year cycle, USP will devote resources to increasing efficiency in publicly sharing the scientific expertise and knowledge developed by staff and committee-led activities in national and international forums.[4] Interactive workshops and trainings are another opportunity for USP to engage more directly with stakeholders who rely on USP standards, both to share the knowledge gained by staff and expert volunteers and to gather feedback that may inform revisions to USP standards. The goal is to increase access to the knowledge gained through USP's scientific approaches as well as to stimulate the scientific community to engage with USP.

Developing the Right Standards

Being a definitive source not only means that USP standards are of high quality, timely, and fit for purpose, but also that USP is creating the right standards. To this end, USP will prioritize standards that have the most relevance for stakeholders such as industry and regulators[5] while anticipating new technology and products. USP recognizes that the key to this process is engaging stakeholders in different ways to identify priorities that reflect the needs of users while always keeping patient safety and public health top of mind.

Developing the right standards does not mean creating standards for every product in an area. The approach should, and will, differ for different fields. New standards will be created where they can contribute the most value for patients. For most of its 200-year history, USP has focused primarily on end products. Going forward, the organization will reimagine what a standard can be—moving beyond monographs and reference standards—including how to better deliver them and connect to users. USP is seeking and finding innovative opportunities for quality standards to support the lifecycle of medical products beyond quality control testing. For example, to increase access to biologics, USP performance standards will support analytical testing throughout the product lifecycle.

Following the 2015 Convention, USP embarked on an ambitious journey to ensure that all USP standards are up to date and reflect current scientific understanding. In that time, USP expert committees have created 400 new monographs, modernized 900 monographs, and eliminated 400 monographs. In the next five years, USP will address new and emerging therapeutic classes, including biologics and biosimilars, and others. More information on these approaches can be found in the proposed Resolution on Innovation. As a scientific organization, USP will begin any new approach by collecting data on what has been done already to identify a baseline, measure impact, and identify opportunities for improvement. To ensure that USP's compendial

science work reflects the needs and resources of the industry and regulatory communities, the organization will adopt a more flexible, agile, and iterative approach to standards development and delivery that reflects the needs of industry and regulators as well as end users.[6] For more information about PILIP, please read the proposed Resolution white paper on Quality Standards.

Alignment with USP Mission

As standards are revised or created, USP must build stakeholders' resolve to adopt and use those standards and support their capabilities to do so. USP has a strong foundation—200 years of deep expertise—that makes it uniquely qualified to collaborate with its stakeholders to create quality standards that ensure medicine and food ingredient quality, thereby boosting consumer confidence in medicines, foods, and dietary supplements. As USP embarks on the next five years, an enhanced focus on capability building will help the organization to prioritize standards that are most needed and reflect the input of expert volunteers. Building on the open, transparent public process that has been the hallmark of USP standards, a reimagined expert volunteer model will catalyze a focus on creating the right standards and ensuring they are of high quality, timely, and fit for purpose.

Resource Assessment

Additional resources required to supplement resources that are currently in place.

Identification and development of standards that meet stakeholder needs is integrated into USP program unit planning. The current CoE Expert Committee structure and the proposed structure for the next cycle will support this work.

References and Notes

[1] *The Pharmacopeial Forum* (*PF*) is a free bimonthly online journal in which USP publishes proposed revisions to *USP–NF* for public review and comment. A new issue is posted online every two months at the beginning of the month. The comment period lasts 90 days and ends on the last day of the month.

[2] *The Food Chemicals Codex Forum* (*FCCF*) is a free online resource in which proposed revisions to the *FCC* compendium are published for public review and comment. All comments are made available to all interested parties to ensure a transparent and scientifically rigorous process.

[3] To learn more about USP's efforts to align with other national and international compendia, please review the proposed Resolution paper on Harmonization.

[4] Adapted from a Resolution proposal submitted by Roger Clemens, University of Southern California School of Pharmacy.

[5] Adapted from Resolution proposals submitted by Hany Demian, U.S. Food and Drug Administration, and Tina Morris, Parenteral Drug Association.

[6] Adapted from Resolution proposals submitted by Hany Demian, U.S. Food and Drug Administration, and Priscilla Zawislak, DuPont Nutrition & Biosciences.