

2020 USP Resolutions

The Resolutions below reflect the discussion and decisions made by the Council of the Convention following the Open Hearing on Resolutions on May 4, 2020.

Resolution 1 – Collaboration with FDA and Other Stakeholders on Health Priorities: USP will continue its commitment to collaboration with the U.S. Food and Drug Administration (FDA), industry, and other stakeholders by identifying shared priorities, based on scientific principles, and leveraging USP's capabilities to help advance patient safety, public health, innovation, and access to quality medicines.

Resolution 2 – Efficiency in Standards Development and Revision: USP will proactively evaluate and enhance the process for developing and updating monographs and other standards to maintain and continuously optimize their impact. In doing so, USP will consider the perspectives and implications of process modifications from FDA, industry, and other stakeholders. A focus of this work will be to explore new approaches for the efficient sharing of information that is critical to standards development, along with the information needed for the evaluation of fit-for-purpose analytical methods and specifications, and the integration of appropriate scientific and manufacturing advances into USP standards.

Resolution 3 – 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 ~~the~~ current and future needs of industry, regulators, practitioners, ~~and~~ consumers, and patients needs.

Resolution 4 – Access to Biologics: USP will develop standards and other solutions to support innovation in the efficient development and manufacturing of quality biologics and advanced therapies to increase patient and health system access to these medicines.

Resolution 5 – Innovation: USP will explore the development of quality standards and other fit-for-purpose solutions to help stakeholders safeguard the quality of promising healthcare innovations that address patient and public health needs.

Resolution 6 – Digital Transformation of Standards: USP will create interoperable core digital solutions that leverage USP data and standards to improve public health through global access to quality medicines.

Resolution 7 -- Education and Training for Industry and Healthcare Professionals: USP will build and strengthen capabilities fundamental for industry and healthcare practitioners to utilize USP standards through efficient, effective, and measurable training and education programs.

Resolution 8 – Regulatory Systems Strengthening: USP will collaborate with global regulators and other partners to strengthen regulatory systems.

Resolution 9 – Compounding: USP will continue to collaborate with stakeholders on standards to help ensure the quality of compounded drug preparations. New and revised standards for compounding, including beyond-use dates, will be developed utilizing-based on data, scientific evidence, and input from recognized healthcare professionals and state and federal regulators.

Resolution 10 – Cannabis: USP will leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions that will help address quality-related and public safety concerns as well as support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

Resolution 11 – Pharmacopeial Cooperation and Convergence: USP will lead efforts to advance convergence around robust science-based standards across pharmacopeias. USP will focus efforts on those standards where convergence will have the most impact on global access to quality medicines.

Resolution 12 – Evidence Generation to Inform Policy: USP will generate and disseminate evidence upon which informed choices can be made for investment in regulatory and quality systems, and reforms to regulatory paradigms that advance quality, patient safety and public health.

Resolution 13 – Coalition Building: USP will lead and power a stakeholder movement for quality to advance public health and patient safety.

Resolution 14 – Culture of Excellence: USP will model operational excellence, continuous improvement, stakeholder responsiveness, and transparency.

Resolution 15 – Impact Expansion: USP will expand its public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.