Convention 2025 Meeting

2020–2025 Cycle

Resolutions Outcomes Report


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A Note from the USP Convention President and Secretary

This report highlights the outcomes USP achieved in meeting the objectives of the 15 Resolutions adopted by the USP Convention Membership for the 2020-2025 cycle. Together, these outcomes helped safeguard the integrity of the pharmaceutical supply chain and increase the global supply of quality medicines people can trust. Our progress and impact this cycle required agility to continue to deliver the public quality standards that industry and regulators rely upon, and to meet the unique imperative to respond to a shifting public health environment amid the COVID-19 pandemic that commenced at the start of the cycle in 2020.

Like each cycle that came before, USP's accomplishments were powered by the individuals and organizations that collaborate to deliver on our mission. We are especially grateful for the contributions of USP's many Expert Committee Members who volunteered countless hours to develop USP standards, along with USP Convention Member organizations that enthusiastically engaged in the USP Convention Sectors and Regional Chapters to make them an outstanding success. This commitment to the USP mission enabled the USP community to deliver impact through standards development, advocacy, and capability building that advanced the supply and quality of medicines and the quality of dietary supplements and food ingredients for more people in more places.

The cycle began just a couple of months into the COVID-19 pandemic, and it was clear that USP's response to the crisis would be an organizational priority. USP staff, Expert Volunteers, and Convention Member organizations quickly mobilized, working with stakeholders around the world to help maximize the doses of vaccine from vials, collaborating with the U.S. FDA to support the production of safe hand sanitizer, and fostering more visibility into the upstream pharmaceutical supply chain. But these efforts did not distract us from our commitment to deliver on the 15 cycle Resolutions adopted by the Convention Membership. Resilience, a relentless focus on mission, and a stakeholder-focused mindset shaped the cycle and drove our impact on public health.

Select Outcome Highlights from the 2020-2025 Cycle

- **Standards portfolio expansion:** USP strengthened the medicines supply chain through new standards, guidelines, best practices, and related programs. Key topics included medicines compounding, impurities (including nitrosamines), vaccines, complex generics, biosimilars, cell and gene therapies, new analytical techniques, and other priorities, addressed in the updates to Resolutions 1, 3, 4, 5, 9, and 15.
- **Solutions to supply chain vulnerabilities:** USP advanced solutions to address ongoing medicines supply chain vulnerabilities, launching the USP Medicine Supply Map to enhance visibility into the upstream medicines supply chain, and working to reduce barriers to the adoption of advanced manufacturing technologies that can help make more medicines in more places. More information about this work can be found in the updates to Resolutions 1, 5, and 12.
- **Leadership in convening national regulators on supply chain challenges and solutions:** USP, in collaboration with the U.S. FDA, convened stakeholders from Asia, the Americas, and Australia to advance capability building, knowledge-sharing and discussion, which further bolstered medicines supply chain resilience. This included co-hosting the Asia-Pacific Economic Cooperation (APEC) forum Medical Product Supply Chain Dialogue as part of the U.S.'s 2023 APEC host year activities, gathering stakeholders from 45 economies; and convening a summit in São Paulo, Brazil on improving supply chain resilience, which included regulators, industry, academia, and other stakeholders from across the region. Information about this work can be found in the updates to Resolutions 1, 8, 13, and 15.

- **Advancing regulatory systems in low- and middle-income countries through PQM+:** USP expanded the supply of quality-assured medicines in low- and middle-income countries through the USAID-funded Promoting the Quality of Medicines Plus (PQM+) program, addressed in the update on Resolution 8.
- **Digitization and transition to modern platforms:** USP accelerated and amplified its digitally enabled public health initiatives to make more content available through digital processes. This included development of solutions to efficiently deliver standards and related resources as structured data directly into stakeholders' digital environments, described within the updates to Resolutions 6 and 14.
- **Vastly expanded engagements with regulators and other USP stakeholders:** USP broadened and deepened stakeholder collaboration and engagement. We achieved this by further strengthening our collaborations with regulators, especially the U.S. FDA, including through consistent dialogue, and by convening on an annual to quarterly basis the Convention's six Sectors and seven Regional Chapters through which Convention Members share knowledge, perspectives, and expertise. Additional information is shared in the updates to Resolutions 1 and 13.

Additional details on USP's outcomes across each of the 15 Resolutions are included in the pages that follow.

As we look ahead to the next five years, we appreciate the foundation that we can build upon from this cycle. At the same time, we are mindful that the pace of change across the globe along with advances in science and technology offer both challenges and opportunities to further leverage USP standards, programs, and the USP stakeholder network to advance our mission. Together, we executed our commitments for the 2020-2025 USP cycle. And, with continued and collective commitment, we will once again deliver for patients and consumers over the next five years.

Thank you for your ongoing commitment to the USP mission.

Sincerely,

Dennis E. Doherty, M.D.
President, USP Convention

Anthony Lakavage, J.D.
Secretary, USP Convention

Resolution 1

Collaboration with FDA and Other Stakeholders on Health Priorities

USP will continue its commitment to collaboration with 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.

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Advancing patient safety and increasing the supply of quality medicines are both as complex as they are critical. To maximize USP's impact in these efforts, the organization prioritized expanded collaboration with a wide range of stakeholders – including FDA and regulators in other nations, industry, and healthcare providers – to identify, seek alignment on, and address shared priorities. As global medicines supply chain complexity increased and biomedical advancements accelerated, such collaboration strengthened USP standards development, public and regulatory policy engagement, educational outreach, and crisis response efforts. The results helped to bolster supply chain resilience, support innovation, and increase availability of quality medicines to improve patients' health. Additionally, USP's relationship with FDA and other stakeholders was strengthened, helping USP to continue to address ongoing healthcare challenges and opportunities.

Key outcomes during the cycle include:

FDA Engagement on Standards Development – USP and FDA strengthened their collaboration on development of standards that support medicines quality and public health.

- FDA included a new section in its drug approval letters encouraging manufacturers of generics and new medicines to engage with USP directly to enhance the flow of information that's essential to standards development and revision. This is significantly enhancing the efficiency of new standards development and standards revision efforts.
- FDA signed a memorandum of understanding with USP on a formal framework for streamlined interactions on standards development to increase efficiency and the alignment of USP standards with evolving regulatory frameworks.
- USP developed over two dozen new monographs for drugs on FDA's list of Off-Patent, Off-Exclusivity Drugs without an Approved Generic to help increase patient access to important generic drug therapies, and nine of those monographs progressed to official status during the cycle.
- USP began a new collaboration with FDA's Office of Generic Drugs, providing our expertise to help strengthen regulatory science for complex generics.
- USP initiated discussions with FDA to begin a new collaboration to develop tailored, standards-related resources for agency reviewers and inspectors, bolstering the real-time impact of USP quality standards.

Engagement with Policymakers – USP engaged with policymakers to advocate that key USP recommendations for improving medicines supply chain resilience – including recommendations developed in collaboration with other stakeholders – be considered for inclusion in legislative proposals. USP provided congressional testimony and submitted comments, letters of support, and statements for the record to legislative bodies and federal agencies to address critical pharmaceutical supply chain challenges.

- USP recommendations developed in collaboration with key stakeholders influenced the inclusion of key provisions in legislative proposals such as the PREVENTS Act and the Consolidated Appropriations Act of 2023, which aimed to strengthen the availability of essential medicines.
- USP testified before the Senate Homeland Security and Governmental Affairs Committee on the capabilities of the USP Medicine Supply Map and in support of policies to increase supply chain resiliency and prevent drug shortages. USP also regularly shared data and data-derived insights from the Medicine Supply Map with the White House, FDA, and the Administration for Strategic Preparedness and Response to inform policy decisions and legislative proposals. We supported the introduction of the Mapping America's Pharmaceutical Supply Chain Act in the Senate, and our advocacy resulted in the development of a bipartisan House companion bill. (See *Evidence Generation to Inform Policy* Resolution update.)
- USP worked with the American Cancer Society Cancer Action Network to convene a 22-organization Drug Shortage Task Force to prevent and mitigate drug shortages. The Task Force hosted a briefing

on Capitol Hill – and provided related information to the White House and others – to help policy makers better understand the root causes, complexities, and pervasiveness of drug shortages and the urgency for comprehensive solutions. (See *Coalition Building* Resolution update.)

Collaborating on Education and Combatting Misinformation – FDA and USP collaborated on educational efforts to advance key health priorities:

- USP and FDA co-developed and launched an educational infographic to inform dialogue between patients and healthcare providers on the quality of biosimilars. Created with input from a broad range of Convention Members, including patient advocacy groups and industry organizations, this valuable resource helped address an FDA priority to combat misinformation.
- FDA subject matter experts participated in numerous USP-led events, including workshops on cell and gene therapies, nitrosamine impurities, complex generics, dietary supplements, and more. Broad stakeholder participation helped ensure the events provided valuable insights to industry leaders and others to help address emerging challenges.

Global Supply Chain Engagement – USP engaged with stakeholders from across the globe to better understand their supply chain challenges. This engagement fostered dialogue that helped increase policymaker understanding of global supply chain vulnerabilities and their potential impact on the availability of quality medicines and raised awareness of USP solutions. Key impact areas representing a significant part of our work this cycle included USP collaborations with the Asia Pacific Economic Cooperation (APEC) forum and with FDA in support of innovation and medicines quality around the world.

- USP engagement with APEC led to USP's designation as an APEC Center of Excellence in two areas: advanced therapies to support patient access to innovation through trainings and capacity building; and securing medical product quality through the supply chain. The latter implemented updates to good distribution practices and launched a web-based version of the APEC Supply Chain Security Toolkit, which played a critical role in reinforcing the integrity of the medicines supply chain in the Asia-Pacific region.
- USP and FDA co-hosted the APEC Medical Product Supply Chain Dialogue in 2023 as part of the U.S.'s APEC forum host year. Over 45 economies were represented at the 2-day meeting centered on knowledge sharing and dialogue to advance supply chain resilience.
- USP expanded collaboration with FDA's offices around the world to strengthen supply chain resilience and support global public health. USP worked with FDA's India office to conduct workshops and training to address nitrosamine impurities and support adoption of advanced manufacturing technologies. USP also partnered with FDA's China office and the agency's Office of Dietary Supplement Programs at the FDA Human Foods Program to co-host workshops to increase regional awareness of U.S. dietary supplement regulations and critical supply chain considerations for quality and security.
- USP collaborated with FDA and others to develop and populate the Global Substance Registration System. The system helps address growing complexities of the global supply chain and inco nsistencies in the use of chemical nomenclature by classifying substances based on standardized scientific descriptions. The result facilitates regulatory processes and supply chain transparency to support medicines quality and public health.

Global Engagement on Emerging Quality Issues – USP engaged stakeholders globally around solutions to address emerging medicines quality issues, including the risk of impurities, and substandard and falsified medical products. (See *Impact Expansion* Resolution update.)

- **Nitrosamines:** USP launched its *Nitrosamine Exchange* online community to provide a forum for global

pharmaceutical stakeholders and experts to share up-to-date information and facilitate real-time conversations on nitrosamine impurities in medicines and related risk-mitigation efforts. The platform grew to include 5,000 users from 80 countries from across industry, regulatory bodies, and academia. USP also worked with global regulators and other stakeholders to address the challenges posed by potential nitrosamine impurities in medicines around the world, and to build awareness of compendial and non-compendial solutions.

- **Diethylene glycol and ethylene glycol contamination:** USP collaborated with FDA and global regulators to develop mitigation strategies and a toolkit for manufacturers, regulators, and other pharmacopeias to address the potential for diethylene glycol and ethylene glycol contamination of medicines, which was initially associated with certain allergy, cold, and cough medicines identified in The Gambia, Indonesia, Uzbekistan, and several other countries.
- **Methanol contamination in hand sanitizers:** USP worked closely with FDA to address the potential for methanol contamination in certain alcohol-based hand sanitizers, including through issuance of Revision Bulletins requiring a "limit of methanol" identification test in various alcohol monographs. This swift action helped mitigate public health risks associated with contaminated sanitizers and ensure the safety of alcohols used in other pharmaceutical products.
- **COVID-19 vaccines:** USP worked with global stakeholders to respond to the COVID-19 pandemic by developing a range of resources, including COVID-19 Vaccine Quality Assessment Toolkits to facilitate assessments of vaccine quality attributes. USP also developed the COVID-19 Vaccine Handling Toolkit to help healthcare providers address potential efficiency gaps, maximize doses per vial, and accelerate the pace of vaccinations while maintaining safety and quality.

Sohail Mosaddegh
Senior Director, U.S. Regulatory Affairs

USP standards and the FDA regulatory framework go hand in hand to support availability of safe, effective, quality medicines that save and improve patients' lives. With this in mind, USP collaborated with FDA throughout the cycle on shared priorities across our organization. From addressing emerging quality issues like the risk of impurities to combatting misinformation on biosimilars quality to development of standards that increased patient access to essential generic drugs, our collaborative achievements supported public trust and set the stage for continued progress for the benefit of patients."

Efficiency in Standards Development and Revision

Resolution 2

USP will proactively evaluate and enhance the process for developing and updating standards to maintain and continuously optimize their impact. In doing so, USP will consider the perspectives and implications of process modifications from FDA, industry, practitioners, 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.


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As USP standards are key to the resilience of the global medicines supply chain, we worked to enhance and streamline processes for developing and revising quality standards and to maintain a modernized *U.S. Pharmacopeia-National Formulary* (*USP-NF*) while further optimizing the impact of USP standards. USP consistently and strategically engaged with FDA, industry, healthcare practitioners, and other stakeholders throughout the cycle to inform and advance these efforts. This engagement led to collaborative development of new approaches for sharing the information needed for efficient standards setting, including enhanced transparency, to help advance access to quality medicines and protect patients.

Key outcomes during the cycle include:

Adapt-Transform-Progress – USP implemented its Adapt-Transform-Progress initiative, designed to increase the efficiency, consistency, and effectiveness of the standards development process and systems. This initiative leveraged technology, workflow automation, and case-based staffing to help ensure a strategic, optimized approach.

- USP deployed a Business Process Management (BPM) platform for documentary and reference standard development, which facilitated automation of select workflow processes and achieved increased consistency and control along with workflow optimization. Iterative enhancements were made based on real-time data and stakeholder feedback, allowing USP to further refine standards development processes progressively in response to evolving stakeholder needs.
- USP operationalized a case-based approach to staffing standards development efforts, which enhanced flexibility and resource alignment, and improved scalability and efficiency, with opportunities to reduce response times.
- USP established the Business Model, Process & Data Design office to help drive lasting impact by advancing process and data modeling for both documentary standard and reference standard value streams. The new office facilitated more effective IT-business alignment, improved decision-making based on process analysis, and leveraged efficient reuse of models for deploying new products and process improvements.

Standards Engagement Model – Applying a more iterative approach to standards development, USP helped ensure that the right Expert Volunteers and stakeholders were engaged at the right time. During the cycle, the approach evolved to enable more timely and inclusive stakeholder engagement throughout a standard's lifecycle while promoting closer alignment with evolving industry and regulatory needs.

- USP developed a structured approach to stakeholder involvement across key phases of standards development – including early, pre-compendial, compendial, and post-publication phases – to facilitate stakeholder input, foster transparency, and help capture key insights at each stage.
- USP deployed new stakeholder engagement tools including open forums, as well as roundtables, webinars, and workshops, to streamline and enhance approaches for direct stakeholder engagement. Drawing thousands of stakeholders throughout the cycle, these events targeted specific challenges and standards-setting topic areas like biologics, medicines compounding, and quantitative nuclear magnetic resonance (qNMR) technology.
- USP integrated principles of diversity, equity, inclusion, and belonging (DEIB) across its Council of Experts and collaborative groups, and throughout the Expert Volunteer Recruitment process for the 2025 – 2030 cycle. Achieved in part through related USP trainings, the results included increased understanding and engagement with DEIB-related best practices to

help interrupt bias, ensure equitable processes, and further integrate DEIB principles into USP standards setting. At the same time, these efforts helped ensure a transparent and equitable process for appointing Expert Committee chairs and recruiting Expert Volunteers. This process is attracting a highly qualified, robust, and globally diverse cohort of Expert Volunteers for the next cycle.

Science Quality Framework – The Science Quality Framework guided USP's science priorities and the work of our Expert Committees throughout the cycle. Its five strategic pillars, which cover evolving and expanding standards, product and substance performance, emerging modalities, new analytical and manufacturing technologies, and quality environments, provided focus areas and principles that helped fulfil USP's commitment to develop innovative, fit-for-purpose standards that respond to emerging scientific and regulatory needs.

- USP prioritized complex generics to facilitate manufacturers' access to quality-related resources supporting this burgeoning product category. USP identified more than 100 candidate materials for development – including documentary standards needed by manufacturers and vendors – to support products with complex active pharmaceutical ingredients, formulations, and delivery mechanisms.
- USP advanced impurity detection and mitigation efforts, including through new *USP* General Chapter <477> *User-Determined Reporting Thresholds*, which became official in 2024 to provide a flexible approach for reporting thresholds for organic impurities. USP also prioritized mitigation of nitrosamine impurities, including through development of a catalog of nitrosamine reference standards and Nitrosamine Drug Substance Related Impurities – which are reference materials not available as official USP reference standards – to help detect, identify, and measure nitrosamines in medicines.
- USP worked to lower potential industry barriers to widespread adoption of pharmaceutical continuous manufacturing (PCM), including through development of technical guides on control strategy, process modelling, and dissolution modeling, and several proposed new standards for the physical properties of materials used in PCM. USP launched the Continuous Manufacturing Knowledge Center to facilitate related stakeholder engagement.
- USP helped safeguard the integrity of the pharmaceutical supply chain through new *USP* General Chapter <1083> *Supplier Qualification*, which became official in 2023. The standard helps product manufacturers to qualify suppliers of raw materials, ingredients, and services for medicines, as well as dietary supplements and food ingredients, by providing a framework for vetting, approving, and monitoring suppliers. This can help ensure quality and mitigate potential supply chain disruptions, from product development to manufacturing and distribution.
- USP prepared for the continual evolution of digitization in the pharmaceutical sciences by creating the Digital Standards Working Group. The group was tasked with developing policies and processes for the inclusion of digital standards into the USP compendia; debuting the USP-ID quantitative nuclear magnetic resonance (qNMR) analysis software platform, which automates identity, strength, and purity analysis of molecules in complex mixtures; and launching incubation projects to optimize qNMR parameters to support broader adoption of digital reference standards. (See *Digital Transformation of Standards* Resolution update.)
- USP innovated standards for microbiology and packaging. Highlights included new *USP* General Chapter <86> *Bacterial Endotoxins Test Using Recombinant Reagents*, slated to become official in May 2025 to support endotoxin testing using non-animal derived reagents, and revised General Chapters <660> *Containers-Glass* and <1660> *Evaluation of the Inner Surface Durability of Glass Containers*, published for public comment in *Pharmacopeial Forum* in 2024 to enhance the evaluation of glass packaging for pharmaceuticals in response to related public health concerns. (See *Quality Standards* Resolution update.)

Government Liaison Program – Government liaisons including FDA staff members serve across USP's expert

bodies in support of USP standards-setting activities. During the cycle, liaison program collaboration between USP and FDA focused on shared priorities and standards development that responds appropriately to regulatory expectations and industry needs.

- USP progressively increased FDA government liaison appointments within USP's expert bodies throughout the cycle, fostering greater FDA collaboration and improved alignment of standards-setting activities with stakeholder expectations and needs.
- USP signed a memorandum of understanding with FDA on a formal framework for streamlined information exchange and collaboration, enabling more efficient quality standards development and improved transparency.
- USP provided training on USP standards and processes for FDA staff, including reviewers of FDA applications and inspectors, to facilitate understanding and improved collaboration on standards development.
- USP partnered with FDA and the Association for Accessible Medicines to develop joint webinars on standards development to further aid alignment of industry practices with USP standards to support public health.

Information Sharing – USP strengthened information exchange with FDA and industry partners to advance quality standards development and impact. A key development was USP's collaboration with FDA for the addition of a new section to the agency's drug approval letters encouraging manufacturers of generics and new medicines to engage with USP to enhance the flow of quality-related information and thus increase the efficiency of new standards development efforts. In addition, USP launched its Nitrosamine Exchange online community to provide a dedicated platform for stakeholders to share up-to-date information and real-time conversations on nitrosamine impurities in medicines and related risk mitigation efforts. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)

Quality Standards

Resolution 3.0

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.

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USP revised and created quality standards and solutions that helped strengthen the resilience of the medicines supply chain and increase access to quality medicines that people can trust. This 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. These efforts helped enable consistency and uniformity in the production of quality medicines from raw materials to manufacturing, packaging, distribution, and delivery.

Key outcomes during the cycle include:

Standards and Solutions – USP developed and revised numerous quality standards, guidelines, tools, and other quality-focused solutions in alignment with identified priorities. This work was guided in part by USP's Science Quality Framework, comprising five strategic pillars that cover evolving and expanding standards, product and substance performance, emerging modalities, new analytical and manufacturing technologies, and quality environments.

- USP achieved a major milestone in the quality and safety of compounded preparations when the revised *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* became official in Fiscal Year 2024. The revisions incorporated extensive stakeholder feedback and reflect advancements in science and practice to help ensure the quality of compounded preparations, promote public health, and support healthcare provider safety. (See *Compounding* Resolution update.)

- USP modernized its widely used standards for dissolution. *USP* General Chapter <711> *Dissolution*, with the new USP Dissolution Performance Verification Standard—Prednisone Reference Standard (RS), became official in 2023. The new RS has lower tablet-to-tablet variability, more consistent performance, and a more stable shelf life than its predecessor.

- USP helped safeguard the integrity of the pharmaceutical supply chain through new *USP* General Chapter <1083> *Supplier Qualification*, which became official in 2023. The standard helps qualify suppliers of raw materials, ingredients, and services for medicines, as well as dietary supplements and food ingredients, by providing a framework for vetting, approving, and monitoring suppliers. This can help ensure quality and mitigate potential supply chain disruptions, from product development to manufacturing and distribution.

- USP addressed the risk of nitrosamines and other impurities in pharmaceutical products, including through *USP* General Chapter <1469> *Nitrosamine Impurities*, which became official in 2021. New *USP* General Chapter <477> *User-Determined Reporting Thresholds* subsequently became official in 2024 to provide a flexible approach for reporting unspecified impurities referenced in *U.S. Pharmacopeia-National Formulary* (*USP-NF*) monographs. USP also developed certain Pharmaceutical Analytical Impurities—which are impurities not available as official USP reference standards—to help detect, identify, and measure impurities and ensure quality. USP provided education and training to help stakeholders understand potential sources of impurities, assess related risks, and establish strategies and methods to control impurities.

- To address the potential for contamination and adulteration of dietary supplements, USP developed the proposed new informational General Chapter <2760> *Impurities and Contaminants in Dietary Ingredients and Dietary Supplements*. USP anticipates presenting the proposal in 2025 to support manufacturers with approaches to testing for and limiting contamination.

- USP developed new and revised documentary standards to help ensure that tests for asbestos have adequate specificity. New *USP* General Chapters <901> *Detection of Asbestos in Pharmaceutical Talc* and <1901> *Theory and Practice of Asbestos Detection in Pharmaceutical Talc* became official in 2023. A related talc monograph revision is anticipated to become official in December 2025.

- USP worked to support biodiversity through expanded use of animal-free testing methods. To support pharmaceutical product endotoxin testing using non-animal derived reagents, USP published in 2023 new *USP* General Chapter <86> *Bacterial Endotoxins Test Using Recombinant Reagents*. The standard is slated to become official in May 2025.

- To respond to public health concerns regarding reported shortages of certain glass vials used to package medications and the potential for resulting drug shortages, USP modernized *USP* General Chapter <660> *Containers—Glass*, which became official in 2023. The revision focused on container performance characteristics to support additional flexibility in the use of suitable glass compositions. To further enhance the evaluation and standards for glass packaging systems used for pharmaceuticals, USP proposed additional revisions to General Chapter <660> and its supporting General Chapter <1660> *Evaluation of the Inner Surface Durability of Glass Containers*, which were published for public comment in *Pharmacopeial Forum* (*PF*) in 2024.

- USP developed and published new General Chapter <1220> *Analytical Procedure Lifecycle*, which describes a holistic approach for the development, implementation, and validation of analytical procedures – driven by quality by design principles – that can help prevent errors, control variability, and reduce resource consumption in quality testing. USP developed a related educational course on <1220> and analytical quality by design principles.

- USP developed and revised a range of toolkits, guides, and other quality-focused resources to help build trust and confidence in specific product areas, mitigate or prevent potential drug shortages, build medicines supply chain resilience, and protect public health. These included: toolkits and guides to address quality challenges and efficiency gaps in delivering COVID-19 vaccines, treatments, and preventatives; draft guidelines on analytical procedures to help build trust in the quality of innovative vaccine products; resources for preventing, detecting, and responding to substandard and falsified vaccines, particularly in low- and middle-income countries; a toolkit for measuring and controlling levels of diethylene glycol and ethylene glycol contamination associated with certain allergy, cold, and cough medicines; a guide to food ingredient standards and solutions to address concerns about infant formula quality; toolkits to establish a framework for characterizing cannabis for medical use; and a guide that outlines testing for, and provides USP resources on, monoclonal antibody quality.

- USP continued to identify, explore, and support the advancement of new production and distribution methods, new medicine modalities, emerging analytical technologies, and informatics trends and applications. This included addressing industry barriers to adoption of advanced manufacturing technologies including pharmaceutical continuous manufacturing and advancing multiple initiatives leveraging nuclear magnetic resonance spectroscopy technology for use in quality assurance. (See *Innovations* Resolution update.)

- USP also developed a range of additional standards and quality-focused solutions spotlighted elsewhere in this report, including those on biologics and cannabis. (See *Access to Biologics* Resolution update, and *Cannabis* Resolution update.)

Iterative Standards and Information Exchange – USP developed a framework for a more iterative and agile approach to the development of USP resources, including potential quality standards, and for related information exchange to address the evolving needs of industry, regulators, healthcare practitioners, and patients.

- USP advanced the iterative standards approach, which includes the concept of an "emerging standard," wherein a potential standard or related early idea is shared with the scientific community for stakeholder input prior to any formal notice and comment through publication in *PF*. To aid stakeholder participation, USP launched the Emerging Standards website, where links to emerging standards can be accessed.

- USP launched several online communities to facilitate stakeholder information exchange on important medicines quality, safety, and technology-related

issues. These active online communities, including the Nitrosamine Exchange Analytical Hub, Novel Excipients Knowledge Hub, Quantitative Nuclear Magnetic Resonance Knowledge Hub, and Continuous Manufacturing Knowledge Center, engaged and empowered stakeholders to share insights, best practices, and other information that supports supply chain resilience and the availability of quality-assured medicines.

- USP developed collaborations with FDA that strengthened regulatory science through the resolution of several long-standing and critical scientific issues involving complex generics, genotoxic impurities, impurity reporting thresholds, and commenting procedures. This work is helping to bring pending monographs to fruition, facilitating development of future standards and related solutions, and further positioning USP as a source of scientific and regulatory expertise. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)

Standards Development Acceleration – To expedite development of new standards for highly utilized medicines that currently lack a USP monograph, USP recruited additional scientific staff through an Inclusive Excellence in Hiring pilot that attracted a large, qualified, and diverse pool of candidates. USP also launched the Small Molecules Relevancy Initiative to significantly increase new monograph development overall. These efforts bolstered USP's capability to develop important new monographs while ensuring that the existing compendia continue to keep pace with scientific advances and meet evolving stakeholder needs. (See *Efficiency in Standards Development and Revision* Resolution update.)

Farah Towfic
Senior Director, Healthcare Quality and Safety Center of Excellence

During the COVID-19 pandemic, USP's most immediate impact came through solutions like revisions to USP alcohol monographs to help ensure the quality of hand sanitizers, and development of USP's COVID-19 Vaccine Handling Toolkit. The toolkit addressed challenges in vaccine preparation at a mass scale to help healthcare practitioners maximize available doses per vial at a time when supplies were limited. While not itself a compendial standard, the toolkit's operational strategies pulled together key components of USP standards, the expertise of multiple USP Expert Committees, and input from pharmacists, government agencies, and others racing against time to get more shots in more arms. Such actions helped to support trust, improve public health, and ultimately save lives."


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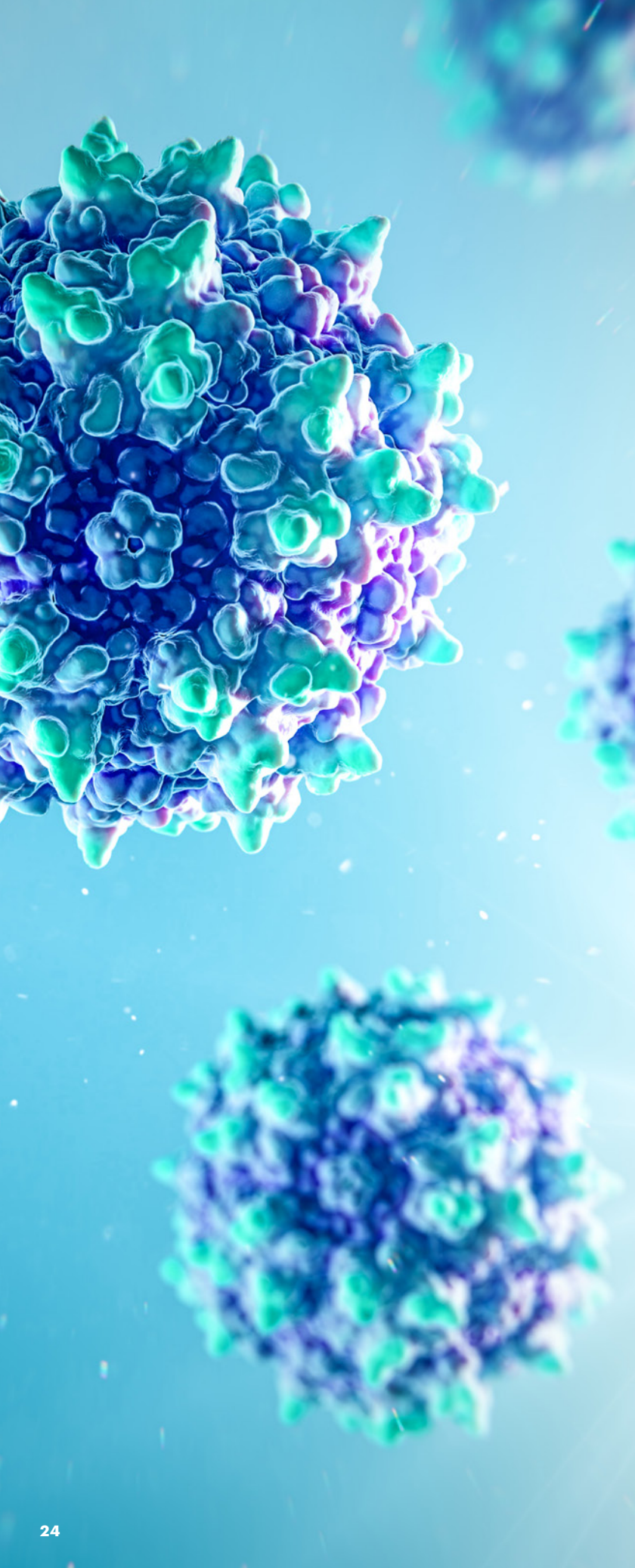
Access to Biologics

Resolution 4

USP will develop standards and other solutions to support innovation in the efficient development and manufacturing of quality biologics and advanced therapies to increase access to these medicines.



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USP expanded its portfolio of standards, best practices, and tools to support the quality and consistency of biologics such as vaccines, peptides, oligonucleotides, tissues, cell and gene therapies, and recombinant therapeutic proteins including monoclonal antibodies (mAbs). USP invested in the development of solutions that support quality across the product lifecycle, from quality assessment of raw materials through process development, material characterization, and release testing. Moreover, USP engaged with stakeholders on emerging biologics modalities to help build a common understanding of relevant quality attributes and test methods, and to develop new general chapters, reference standards, and analytical reference materials that support quality and consistency. Such tools also helped support industry efficiencies for product development and regulatory review processes. In addition, USP convened stakeholders to identify best practices that support adoption of advanced manufacturing technologies and analytics that have the potential to increase the supply of biologics and enable more decentralized manufacturing, which remains a key principle of supply chain resilience.

Key outcomes during the cycle include:

Microbiological Quality Control – Preventing potential microbiological contamination of medicines is essential to ensure quality during pharmaceutical production and preparation. In 2024, USP expanded its ability to make microbial contamination control solutions offerings through the acquisition of microbial preservation technology with broad applications across pharmaceuticals including biologics and compounded medications. In combination with USP standards, the acquisition increased USP's ability to address potential gaps in existing industry microbial contamination control strategies, help mitigate risks of product contamination, and support availability of quality medicines.

Monoclonal Antibodies and Therapeutic Proteins – USP expanded its portfolio of solutions to support quality assessment of mAbs and other therapeutic proteins, including new standards and other resources to support more efficient and informative quality assessment.

- USP released several new reference standards and analytical reference materials (ARMs) that support quality testing of an entire class of products, including three new mAb reference standards and several ARMs for host cell protein impurities.
- USP developed and published in the *U.S. Pharmacopeia-National Formulary* (*USP-NF*) two new general chapters on advanced analytical methods to support the quality of therapeutic proteins, including General Chapter <1060> *Mass Spectrometry-Based Multi-Attribute Method for Therapeutic Proteins*, and General Chapter <1132.1> *Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry*.
- USP completed a two-year, $1.5 million regulatory research grant program under the FDA Biosimilars User Fee Act III to enhance biosimilars development and regulatory science. The research focused on assessment of the multi-attribute method, an emerging analytical method that has the potential to provide more detailed information on product quality and increase the efficiency of biosimilars development.

Cell and Gene Therapies – Based on feedback from stakeholders through roundtables, stakeholder forums, and discussions with global manufacturers and regulators, USP expanded its portfolio of standards and solutions to support the quality of advanced therapies, with particular focus on adeno-associated virus (AAV)-based gene therapies and lentiviral vectors for gene modified cell therapies.

- New USP standards on best practices for advanced therapies include *USP* General Chapter <1040> *Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies*, which was published

in *Pharmacopeial Forum* (*PF*). A general chapter on manufacturing and control of AAV-based gene therapies is expected to publish in *PF* in 2025, and a general chapter on lentivirus-based therapies is in development.

- After conducting a successful pilot training program in 2021 on quality expectations for starting and raw materials for advanced therapies, USP was endorsed by the Asia-Pacific Economic Cooperation (APEC) forum as a Center of Excellence for Advanced Therapies. Since then, two training workshops were held for regulators, including one on best practices for development and validation of bioassays to support cell and gene therapy products and another on chimeric antigen receptor (CAR) T-cell therapies.
- USP continued to expand the portfolio of materials to support analytical testing of cell and gene therapies and has 12 new advanced therapy reference standards or reference materials that are completing collaborative studies.
- USP collaborated with the National Institute for Innovation in Manufacturing Biopharmaceuticals and the National Institute of Standards and Technology to conduct a multi-laboratory study comparing analytical techniques for AAV capsid content and empty-full ratio. Results were published in the journal *Human Gene Therapy*.

Peptide and Oligonucleotide Therapeutics – USP expanded its portfolio of standards and tools to support peptide therapeutics through development of ARMs for peptide impurities. USP also initiated development of its first standards to support oligonucleotide therapeutics, a broad family that includes aptamers, antisense oligonucleotides, and interfering RNA.

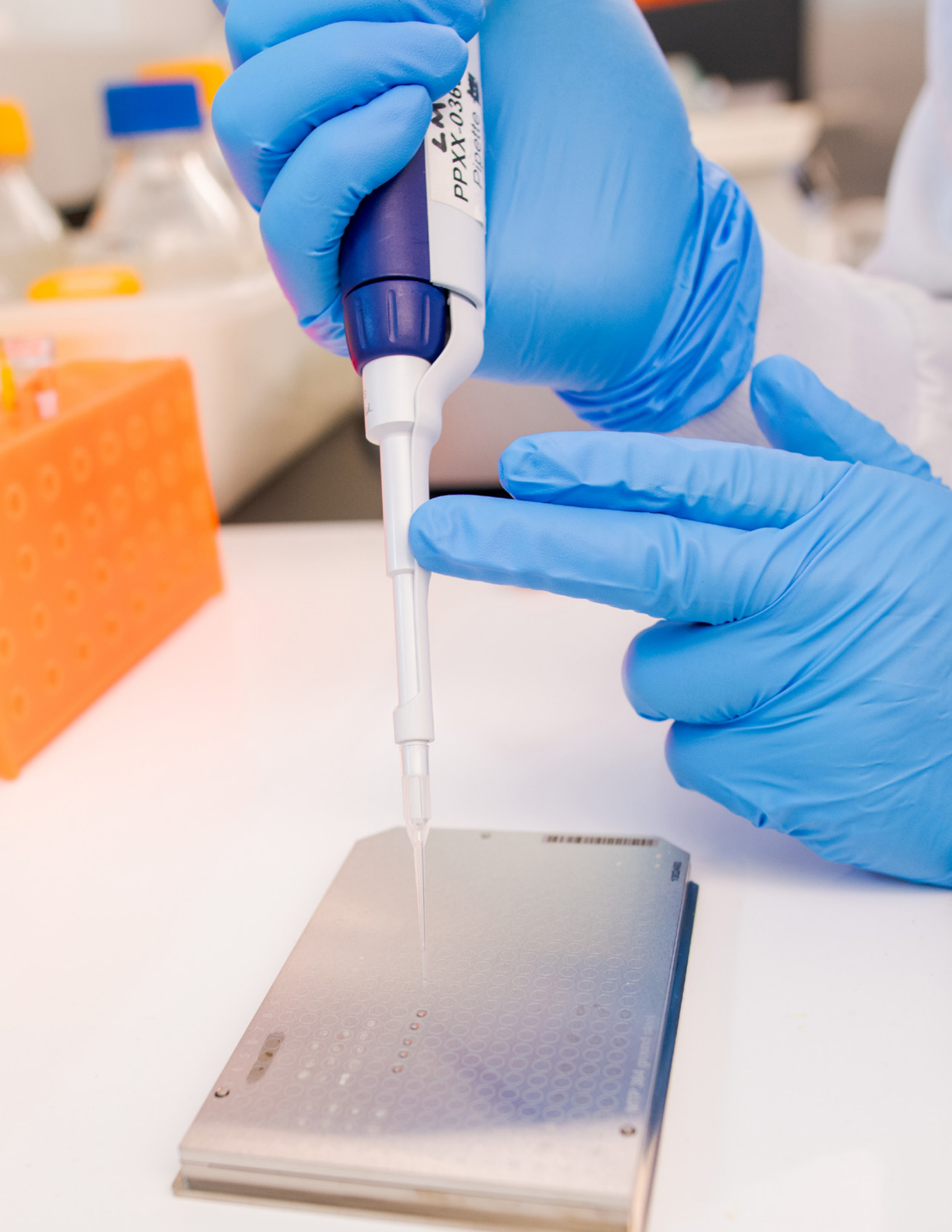
- USP developed over 40 new ARMs to support identification and control of common degradation-related impurities in peptide therapeutics. These new ARMs add authentic impurities to support current peptide monograph offerings.
- USP developed new reference standards to support quality assessment of phosphoramidites, which are critical raw materials for oligonucleotide therapeutics. The USP Biologics 1 Expert Committee submitted a publication on the quality of raw materials as an initial step towards development of a related general chapter.
- USP held two workshops on chemistry, manufacturing, and controls expectations for peptide and oligonucleotide therapeutics, convening industry representatives, regulators, and researchers to help solve common analytical challenges for these rapidly evolving therapeutic modalities.

Vaccine Quality – USP continued its efforts to support the quality and consistency of vaccines through publication of new tools and educational offerings, as well as related engagement with global stakeholders.

- USP developed vaccine quality toolkits for assessing the quality of vaccines using general and compendial tests. The first version, released in 2021, included major vaccine types to combat COVID-19, including mRNA, viral vectored, and inactivated vaccines. The toolkits were later expanded to include subunit, DNA, virus-like particle, and attenuated virus vaccines.
- To support a common understanding of quality attributes for mRNA vaccines and viral-vectored vaccines, USP developed and published draft guidelines on quality attributes and related analytical methods for these new vaccine modalities in 2022. The guidelines were later expanded and refined in response to stakeholder feedback suggesting that USP incorporate new and alternative analytical methods.
- USP initiated a new Expert Panel on mRNA vaccines and therapies that is drafting a general chapter on best practices for manufacturing and control of mRNA-based products. In addition, USP laboratories have evaluated several methods from the draft guidelines and are working towards validating platform methods and developing associated reference standards.

Advanced Manufacturing and Analytics – USP responded to stakeholder feedback on challenges in implementing advanced manufacturing methods and associated in-line/at-line analytical testing by convening stakeholders to share experiences and help develop best practices.

- USP held a hybrid workshop on Biopharmaceutical Continuous Manufacturing in December 2022 at USP headquarters in collaboration with BioPhorum. The workshop was well attended by industry, academia, and regulators. A summary of key themes from the workshop was published in the July/August 2023 issue of *Pharmaceutical Engineering*.
- Following feedback gathered from the 2021 USP Biologics Stakeholder Forum on innovative analytical and digital solutions to advance biomanufacturing and product quality, USP formed a new Expert Panel. Currently working on guidelines and best practices on in-line/at-line monitoring and real-time release testing, the new panel aims to develop a proposed general chapter to provide guidance on the application of process analytical technology and provide a summary of related technologies, including their strengths and weaknesses.



Innovations

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 51

2020 – 2025 Cycle Update

USP standards help build trust and confidence in healthcare breakthroughs, support market access, and advance the quality of medical products, strengthening the supply of quality medicines. Given the abundance of new medicine modalities and manufacturing advances, the opportunity is significant for USP standards and related programs to help ensure quality – from product development to manufacturing, distribution, and delivery – in support of supply chain resilience. To achieve this goal and better anticipate and support stakeholder needs, USP has bolstered its ability to identify and evaluate early technologies and prioritize emerging ideas and trends in pharmaceutical development.

Key outcomes during the cycle include:

Advanced Manufacturing Technologies – USP advanced work on multiple fronts to identify and address industry barriers to adoption of advanced manufacturing technologies (AMT) including pharmaceutical continuous manufacturing (PCM), which can facilitate medicines supply chain resilience through efficiencies that make it more practical to make more medicines in more places, alongside traditional batch manufacturing. USP also evaluated quality considerations for 3D printing (3DP) of pharmaceuticals to help unlock its potential to enable production of smaller batches of medicines with tailored dosages, shapes, sizes, and release characteristics to facilitate personalized medicine.

- USP opened dedicated AMT laboratory facilities focused on technologies and processes used in PCM – including process analytical technology (PAT), flow chemistry, digital controls, and other solutions – as well as 3DP. These laboratory capabilities are focused on development and qualification of methods to help ensure the quality of medicines made with AMT and to support wider adoption.
- USP's AMT team collaborated through a strategic alliance to develop new analytical methods for five critical active pharmaceutical ingredients (APIs) for the Biomedical Advanced Research and Development Authority (BARDA) Strategic API Reserve for essential medicines.
- USP secured and/or executed on more than $11 million in U.S. government funding to advance the use of applied AMT and related supply chain solutions in partnership with BARDA; the Administration for Strategic Preparedness and Response; the Advanced Research Projects Agency for Health; the Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense; the Economic Development Administration; the National Science Foundation; and the White House Office of Pandemic Preparedness and Response Policy.
- USP developed a more cost-effective manufacturing process using flow chemistry for the tuberculosis (TB) drug rifapentine, and transferred the technology to a local manufacturer of APIs in South Africa via USP's Promoting the Quality of Medicines Plus (PQM+) program, funded by the U.S. Agency for International Development (USAID), to facilitate supply chain resilience for this critical medicine.
- USP developed three technical guides to help ensure the quality of medicines made with PCM, including guides on control strategies, process modelling, and in vitro dissolution modeling. Two additional technical guides under development address material characterization and control strategy for drug substance manufacturing.
- USP launched the Continuous Manufacturing Knowledge Center (CMKC) online platform to facilitate stakeholder information exchange and help address potential knowledge gaps by providing rapid access to the latest information.
- USP organized multiple PCM workshops, including a July 2023 event on identifying and addressing barriers to PCM adoption that convened 150 stakeholders from industry, academia, and FDA.
- USP began development of a proposed general chapter on PAT to facilitate effective integration,

real-time monitoring, and product quality assurance, including case studies and examples of PAT applications in continuous manufacturing.

- USP collaborated with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) on development of the ICH guideline Q13 on continuous manufacturing of drug substances and drug products, and contributed to the development of training materials on PCM implemented in many countries.
- USP supported scientific research and co-developed five peer-reviewed articles in various scientific publications to advance the field of continuous manufacturing, covering topics that included residence time distribution studies and a predictive model for dissolution testing. USP also presented scientific findings on PCM-related topics at numerous international conferences.

Advanced Technology Evaluations – USP continued to identify, explore, and support the advancement of new production and distribution methods, new medicine modalities, emerging analytical technologies, and informatics trends and applications. This included identification and exploration of over 130 technologies and areas of emerging science in our research and incubation portfolio.

- USP conducted research to inform its understanding of green chemistry and other tools to optimize the use of resources and reduce pharmaceutical environmental impact. This included research into analytical methods and technologies that rely on fewer resources and/or more eco-friendly alternatives for the quality testing of medicines – such as supercritical fluid chromatography and solvent substitution liquid chromatography – as well as recycled solvents and alternatives to animal testing in quality standards. The research was informed through stakeholder engagement on specific needs for improving the pharmaceutical environmental footprint during a 2022 roundtable and 2023 open forum.
- USP explored the potential for standards development in emerging areas such as synthetic biology, smart materials, and bacteriophage treatments, as well as medical spas as a growing point of services.
- USP continued to advance polymer material characterization through applications of light-scattering technologies as well as other characterization modalities.

Complex Generics – Defined as drug products that have a complex active ingredient, formulation, or route of delivery, or are part of a drug/device combination, complex generics are becoming increasingly common, and generic entry has become increasingly challenging. During the cycle, USP advanced stakeholder engagement initiatives to develop a deeper understanding of gaps and opportunities to meet evolving stakeholder needs, and to identify appropriate standards, materials, and solutions. Notable accomplishments included:

- USP formed two Expert Panels to help develop new General Chapters <1155> *Iron Colloidal Formulations* and <1156> *Microspheres* to support related complex generic products.
- USP advanced plans to develop new standards for the testing of complex drugs for extractables and leachables, which are a subset of impurities derived from manufacturing systems, container-closure systems, drug product delivery systems, and other packaging material. The plans include development of proposed new General Chapters <1664.2> *Parenteral Drug Products*, <1664.3> *Ophthalmic Drug Products*, and <1664.4> *Topical & Transdermal Drug Products*.
- USP convened an open forum to understand the technical challenges in the analysis of extractables and leachables in complex generic products, including 1,100+ global registrants from industry, contract development organizations, and regulatory bodies.
- USP created analytical reference materials (ARMs) and a supporting application note for the analysis of

rubber oligomer leachables, which can arise through the interaction of elastomeric materials with drugs or during drug manufacturing.

- USP created a technical guide detailing strategies to deformulate a brand complex injectable reference listed drug to help the complex generic industry quickly test the brand product to identify the complex poly-lactic-co-glycolic acid (PLGA) polymers and make a similar generic product.
- USP convened a complex injectables roundtable that welcomed 800+ global registrants, including those from industry, regulators, and other stakeholders, to explore ways to support stakeholders in the development of complex injectables.

Nuclear Magnetic Resonance Spectroscopy – USP advanced multiple initiatives leveraging nuclear magnetic resonance (NMR) spectroscopy technology and quantitative NMR (qNMR) techniques for use in quality assurance. Key milestones included:

- USP revised General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Applications of Nuclear Magnetic Resonance Spectroscopy* in response to public comments and to enhance the application of NMR as a robust analytical tool for demonstrating quality. To facilitate adoption of the revisions and related NMR techniques, USP developed related educational courses.
- USP initiated General Chapter <1762> *Solid-State Nuclear Magnetic Resonance Spectroscopy – Theory and Practice* to incorporate modern technologies and contemporary practices of NMR spectroscopy.
- USP revised two monographs to support qNMR quality testing, including those for nicotinamide riboside chloride and enoxaparin sodium.
- USP convened multiple qNMR summits, bringing together experts and stakeholders in the field to discuss advancements and applications. USP also established the qNMR Community in China (qNMR-C) to further support global adoption. Notable events included three symposia and 12 webinars hosted by qNMR-C touching on scientific evaluations for potential compendial discussion.
- USP created the qNMR Knowledge Hub as a platform for stakeholders to exchange related information. It debuted in 2023 at the third USP qNMR Symposium in Shanghai. More than 70 members registered, with over 17,000 page views recorded.
- USP and the National Institute of Food and Drugs Control in China conducted discussions toward a possible memorandum of understanding to support collaboration on qNMR and other analytical techniques, and initiated an incubation project to evaluate a qNMR platform method for the generation of digital reference spectra.
- USP launched an automated NMR analysis software solution called USP-ID, which allows for the automatic identification and quantification of complex mixtures by applying a sophisticated algorithm to a database of high-quality chemical references. (See *Digital Transformation of Standards* Resolution update.)

Drug Dissolution – USP conducted studies aimed at optimizing dissolution testing using a reduced volume of dissolution media. The change would reduce the environmental impact of dissolution testing while accelerating the process and expanding test applications. The studies included collaboration with the New Jersey Institute of Technology to characterize the hydrodynamics of reduced-volume dissolution systems using particle image velocimetry technologies. USP submitted a related scientific article for publication in the International Journal of Pharmaceutics. USP also engaged the Equipment Subgroup of the American Association of Pharmaceutical Scientists' In Vitro Release and Dissolution Testing Community with the aim of forming a consortium of industry stakeholders, academic institutions, pharmaceutical industry researchers, regulators, and other stakeholders to map out a path to develop small- and reduced-volume dissolution guidelines.

Graph Database and Artificial Intelligence Capabilities – USP accelerated its understanding of graph databases and targeted artificial intelligence (AI) capabilities, including large language models (LLM), and their potential to uncover hidden connections and anomalies across complex data assets and create data-driven predictions and personalized recommendations to meet stakeholder needs.

- USP's exploration of the potential to integrate AI into USP quality-related programs included creation of an AI trend tracker to identify and explore use cases that keep pace with rapid advancements in this promising and potentially disruptive field. One example of a use case for graph databases and AI is their ability to enable stakeholders to better understand the interconnectedness of USP standards and related information, potentially facilitating increased utilization of USP products and services, transformation of USP into a more digitally enabled organization, and improved customer experiences.
- USP completed more than 12 prototypes, leveraging an iterative approach, stakeholder collaboration, and innovative solutions to assess the feasibility and value of AI in addressing stakeholder needs. This effort included scaling AI capabilities to enhance data, processes, and systems to support future applications.
- USP developed an internal AI policy to encourage appropriate staff experimentation with AI tools to help identify possible applications with the potential to increase efficiency and effectiveness of USP work processes.

Dennis Hall
Vice President, Advanced Manufacturing Technologies

"Technological advances like pharmaceutical continuous manufacturing (PCM) offer many potential benefits, but there are barriers to widespread adoption. As USP strives to identify and mitigate those barriers, collaboration is critical. It increases our access to expertise, funding sources, and valuable stakeholder input that strengthens USP solutions. **Throughout the cycle, we've broadened collaboration within the U.S. federal government, with manufacturers, and with other non-profit organizations."**

Digital Transformation of Standards

resolution 6

USP will create interoperable core digital solutions that leverage USP data and standards to improve public health through global access to quality medicines.

2020 – 2025 Cycle Update

In a rapidly evolving, increasingly digital and interconnected world, USP worked to transform quality standards into interoperable digital components of the healthcare ecosystem. This work aims to facilitate the ability of manufacturers, regulators, healthcare professionals, and other stakeholders to deliver quality medicines and help ensure a resilient medicines supply chain. To advance this goal, USP structured its content for enhanced machine readability, transitioned to a more modern clinical informatics platform, modernized the *U.S. Pharmacopeia-National Formulary* (*USP-NF*) delivery platform, advanced the development of digital reference standards, and leveraged advanced analytics to enhance visibility into the upstream medicines supply chain.

Key outcomes during the cycle include:

Transition to Modern Platforms – USP formed the Digital & Innovation Division (D&I) to accelerate and amplify our digitally enabled public health initiatives and digital fluency for long-term public health impact, and to help make more of USP's content available through digital processes. This effort has included working to curate and disseminate scientific content as machine-readable, structured data. It has also included developing solutions to efficiently deliver standards and related resources as structured data directly into stakeholders' digital environments. The result will improve efficiencies through increased automation and facilitate the ongoing industry modernization and digitization evolution known as "Pharma 4.0" for long-term public health impact.

- **Laboratory digitization:** Since the start of the cycle, USP has worked to address two key issues through digitization: the shortage of experienced chemists to translate USP monograph standards into routine lab procedures and the lack of integration of *USP-NF* methods into digitized lab environments. To address both issues, USP launched prototype software and data solutions, and began assessment of customer feedback to support broader availability. One solution combines content from USP monographs and general chapters with USP laboratory standard operating procedures to provide end users with guided workflows. The other solution allows the same content to be integrated directly into existing digital platforms in use by stakeholders.
- **Compendial platform modernization:** USP modernized the content-hosting infrastructure supporting *USP-NF* and other USP compendia to significantly improve the user experience. Typical search and content display times decreased from 12-15 seconds to as little as 1-2 seconds. In addition, the time required to validate and publish new and updated content was cut from an average of three weeks to just 2-3 days. The latter changes are intended to support transition to a more frequent publication model with bi-monthly updates by the end of Fiscal Year 2025. The infrastructure modernization, combined with "machine translation" technology, also increased the efficiency of translating subsets of *USP-NF* content into different languages.
- **Informatics for quality and safety:** USP leveraged a platform that connects into various health IT systems to offer the USP Drug Classification System (USP DC) and Medicare Model Guidelines, which are used by health plans in developing formularies. An enhanced version of USP DC enables a user to link to multiple pharmaceutical databases. A prototype Compounding Prescription Information Exchange tool was also developed to facilitate consistent and safe preparation of compounded medicines.
- **Chemical substance information:** USP implemented the Global Substance Registration System (GSRS) as the single source of record for chemical substance information at USP. GSRS is an open-source chemical informatics platform developed by the National Institutes of Health and FDA.

Digital Reference Standards – USP launched nuclear magnetic resonance (NMR) technology-based digital references and marked substantial progress in advancing digital reference standards.

- USP launched an automated NMR analysis software solution called USP-ID, which allows for the automatic identification and quantification of complex mixtures by applying a sophisticated algorithm to a database of high-quality chemical references.
- USP developed nearly 1,000 digital analytical reference materials (dARMs), leveraging NMR and quantum mechanics to enable digital delivery of chemical reference materials to customers. The portfolio

encompasses small molecules, excipients, dietary supplement ingredients, food ingredients, as well as focused libraries for biofermentation, controlled and illicit substance screening, and adulteration screening.

- USP worked on revisions to General Chapter <11> *USP Reference Standards* and *General Notices* to include language supporting the use of digital reference standards in compendial tests.
- USP-ID and/or digital reference standards were referenced in three peer-reviewed journal articles, five conference presentations, two posters, and one white paper, helping to inform scientific audiences and advance public understanding of these digital innovations. Of these items, USP either authored or contributed to two of the three journal articles, four of the five conference presentations, and each of the remaining materials.
- USP worked to develop various technologies for future use in digital reference standards, including infrared, mass spectrometry, liquid chromatography, artificial intelligence, and machine learning technology.

Medicine Supply Map – USP developed the Medicine Supply Map drug shortage intelligence tool, which harnesses millions of data points to help predict drug shortages and empower stakeholders to take proactive measures to prevent and mitigate their impact. The Medicine Supply Map provided insights into the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines, such as antimicrobials and cancer medicines. Such insights can assist stakeholders, including U.S. federal agencies, Congress, and pharmaceutical manufacturers, in their efforts to identify, characterize, and quantify vulnerabilities in the upstream pharmaceutical supply chain, guide risk mitigation strategies and investments, and help inform policy changes and legislation aimed at bolstering supply chain resilience. Such insights were shared with multiple stakeholders, including through USP testimony to the U.S. Senate Homeland Security & Governmental Affairs Committee. (See *Evidence Generation to Inform Policy* Resolution update.)

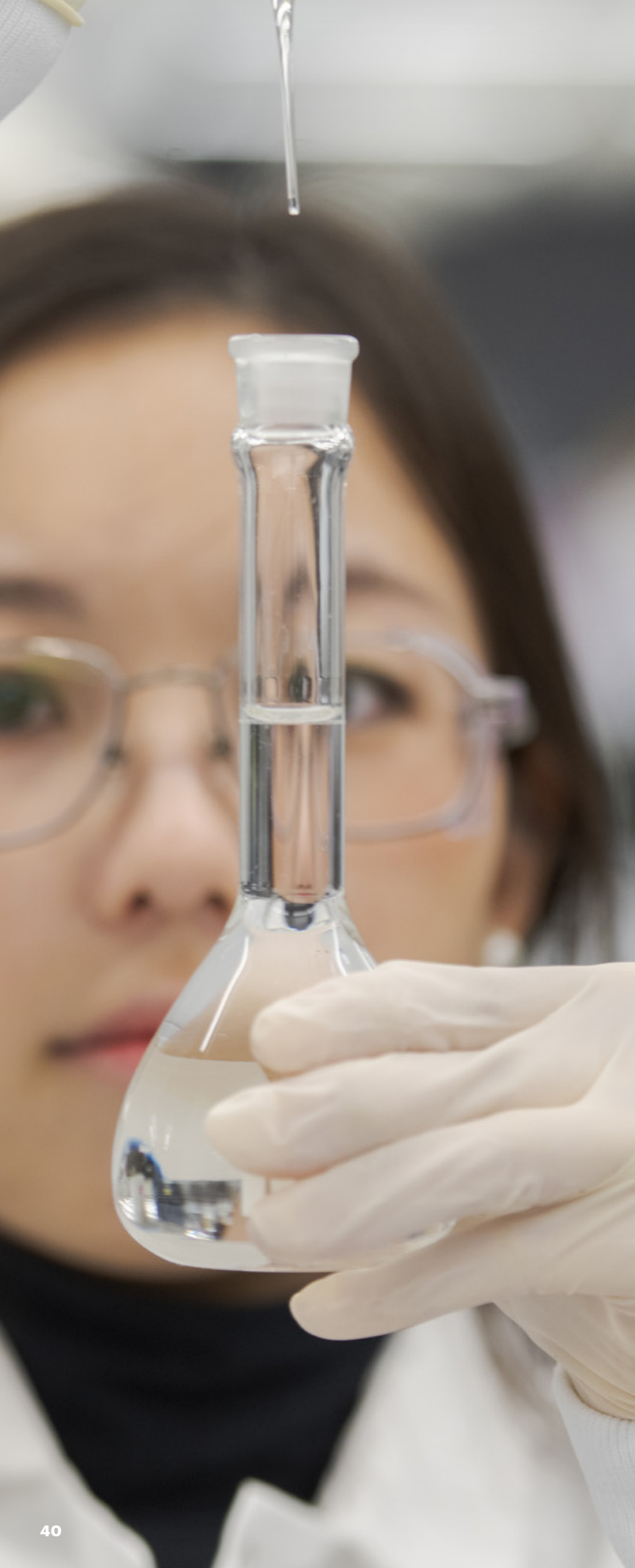
Michael Ambrose
Director, Product Quality and Analytical Methods, Digital and Innovation Division

"Digitalization in pharmaceutical sciences is accelerating innovation and increasing efficiencies across the healthcare ecosystem. To harness the potential of digital standards in this transformation and improve global health, USP formed the Digital Standards Working Group. Simply put, the group works to identify ways to facilitate incorporation of digital standards into the USP compendia. It's also **driving impact by facilitating integration of USP standards into digitized lab workflows. This increases access to USP standards, provides efficiencies, supports innovation, and helps ensure the quality of medicines."**

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



2020 – 2025 Cycle Update

USP provided education and training to more than 100,000 registrants to support adoption and implementation of USP quality standards and solutions. Addressing both new and revised standards, these efforts helped accelerate innovation, build trust and confidence in medical breakthroughs, advance the quality of medical products, and ensure a resilient medicines supply chain. USP's wide range of education and trainings leveraged state-of-the-art technologies to reach diverse audiences in a variety of settings. USP further supported standards utilization by improving the timeliness of its educational offerings, prioritizing real-world practice in course development, and expanding program reach around the world.

Key outcomes during the cycle include:

Expanded Program Reach – USP increased participation in education and training at a compound annual growth rate of over 20% through Fiscal Year 2024. Key contributing factors included an expanded course catalog; increased use of online, on-demand offerings (which grew to consistently represent two-thirds of total program attendance); licensing of USP courses to third parties; and strong geographic expansion of program offerings in China, Latin America, and the U.S.

- USP established free access to all self-paced courses for national regulatory bodies. Regulators' participation in the free-access program, which helped equip them with resources to ensure the quality of medicines, quadrupled since its inception to over 1,300 in Fiscal Year 2024.
- USP content was integrated into the internal training programs of universities, regulatory bodies, and manufacturers through licensing programs. As of Fiscal Year 2024, 8% of USP's education-and-training-program reach was achieved through licensing to other organizations.
- USP introduced an education subscription model to facilitate ongoing learning opportunities for stakeholders. The program reached a dozen subscriber organizations by Fiscal Year 2024, including a China-authorized distributor that offered it as a value-added service to customers. The distributor achieved a 25% increase in engagement with USP products and services among participating organizations.
- USP offered its courses in more languages and increased the language options for informational resources on priority standards to help expand global access.
- USP responded to increased demand for tailored educational offerings, including through creation of a classroom program for the Saudi FDA, development of a dedicated South Asia portal for self-paced learning, and a dedicated course for National Association of Boards of Pharmacy compounding inspectors to help U.S. state pharmacy boards ensure standards compliance.
- USP added briefer course offerings on key topics like biologics, particulate matter standards, and continuous manufacturing. Shorter, free content in such areas where standards are still emerging enabled USP to respond more quickly to evolving topics and further increase stakeholder engagement.
- USP broadened educational support beyond standards to facilitate adoption of USP's Medicine Supply Map and USP-ID products (See *Evidence Generation to Inform Policy* and *Digital Transformation of Standards* Resolution updates.)

Impact and Real-World Practice – USP focused on ensuring the impact of its courses on real-world practice, which was measurably recognized by course attendees. In post-course surveys conducted during the cycle, an average of 88% of attendees indicated USP courses and materials will have a positive impact on their quality of work. The results reflect increased use of real-world case studies, supported by online, digital, and interactive tools that helped increase participation and engagement.

Improved Timeliness – USP substantially reduced the timeframe between publication of a new USP standard and launch of a supporting educational course by implementing a Curriculum Roadmap process. The process identified early those quality standards for which educational programming would likely be most impactful in support of stakeholder adoption and implementation, enabling development of educational materials to begin earlier. Marking steady improvement each year, in Fiscal Year 2024 the process led to educational materials being available within a month of the launch of standards initially identified as being particularly consequential, down from a previous range of up to six to 12 months.

Solution 08

Regulatory Systems Strengthening

USP will collaborate with global regulators and other partners to strengthen regulatory systems.


APEC Medical Product Supply Chain Dialog
LAURA BRAY
ANTHONY SARDELLA


usp

2020 – 2025 Cycle Update

Throughout the cycle, scientific and technological innovations continued to push the boundaries of what is possible for preventing, treating, and curing medical conditions, and for saving and improving patients' lives. These innovations, combined with increasingly complex global supply chains and emerging public health issues, presented challenges for national and regional regulators tasked with ensuring the safety, efficacy, and quality of medical products, particularly in low- and middle-income countries (LMICs). To address these challenges, USP worked with national, regional, and continent-wide regulatory bodies from Africa to Asia and across the globe to strengthen and advance the maturity of regulatory systems and help increase the availability of quality-assured medical products. Much of this work was supported by government agencies and other organizations with global reach, such as the Asia-Pacific Economic Cooperation (APEC) forum, the Australian Department of Foreign Affairs and Trade, the Gates Foundation, the Global Fund, the Pan American Health Organization (PAHO), the U.S. Agency for International Development (USAID), the World Bank, and many others.

Key outcomes during the cycle include:

Regulatory Capability Building in LMICs – Through its global health programs and regulatory affairs outreach, USP supported the advancement of 50+ national regulatory authorities in strengthening their regulatory functions and regulatory maturity levels. During the cycle, USP continued to expand its global health programs and collaboration with regulators, launching new programs with regulatory capacity-building components in multiple countries across Asia, Africa, and Latin America, including in the past year in Cambodia, the Democratic Republic of the Congo, and Ghana.

Regional Harmonization and Coordination – Across multiple countries and regions, USP's work to support regulatory efficiencies and capability building included advancement of cross-border regulatory harmonization and convergence initiatives.

- Through USP's Promoting the Quality of Medicines Plus (PQM+) program, USP served as a technical partner on eight technical committees of the African Medicines Regulatory Harmonization (AMRH) initiative, which is serving as the foundation for the African Medicines Agency (AMA) – a continent-wide regulatory body designed to complement existing regional initiatives and national regulatory authorities. Further bolstering emergence of the AMA and harmonization in the region, PQM+ supported establishment of the Network of African National Reliance Laboratories (NARL) to support lot release and quality testing for vaccines and to harmonize related standards and practices across the continent. NARL was then expanded by local stakeholders with USP support to align quality testing for all medicines and medical devices.
- USP expanded its partnership with the Corporate Council on Africa (CCA), serving as a key sponsor for the annual U.S. Africa Business Summit, securing the appointment of a USP staff member to the CCA board, and serving as a collaborator and sponsor of the CCA-led Regulatory Harmonization Workshop Series. These regional dialogues brought together private and public stakeholders to collaborate on and advance regional harmonization initiatives across the African continent.
- USP contributed to development of the Americas RISE for Health (RISE) forum, a public-private initiative focused on health issues across the Americas, by providing thought leadership on the importance of regulatory convergence as part of the group's policy agenda. Through PQM+, USP also supported delivery of pilot regional training programs for regulators in the Western Hemisphere as part of RISE's regulatory improvements pillar.
- USP collaboration with PAHO included joining its member states and partners at the 2024 Pan American Network for Drug Regulatory Harmonization (PANDRH) conference to develop recommendations for advancing regulatory harmonization, convergence, and reliance to facilitate medicines supply chain resilience and reliability. USP similarly participated in the International Conference of Drug Regulatory Authorities in support of regulatory systems strengthening, cooperation, and convergence.

Asia-Pacific Economic Cooperation Forum – USP engagement with the Asia-Pacific Economic Cooperation (APEC) forum led to USP's designation in 2021 as an APEC Center of Excellence (CoE) for Advanced Therapies. This work supported APEC in developing tools and guides to

enhance global regulatory harmonization and convergence in support of increased availability of quality-assured, innovative treatments. A key highlight was a two-day virtual training in 2023 with more than 150 regulators from APEC and beyond focused on chemistry, manufacturing, and control challenges in chimeric antigen receptor (CAR) T-cell therapy to address knowledge gaps in real world applications. Separately, USP's service as an APEC CoE in global medical product quality and pharmaceutical supply chain security produced updates to good distribution practices and a web-based version of the APEC Supply Chain Security Toolkit, which played a critical role in reinforcing the integrity of the medicines supply chain in the Asia-Pacific region. USP and FDA also co-hosted the APEC Medical Product Supply Chain Dialogue in 2023 as part of the U.S.'s APEC forum host year. Over 45 economies were represented at the two-day meeting centered on knowledge sharing and dialogue to advance supply chain resilience.

Collaboration on Emerging Public Health Issues – USP provided guidance, thought leadership, technical advice, and capacity-building support to help national regulators address critical emerging issues.

- **COVID-19:** USP's response to global regulatory challenges posed by the pandemic included development of toolkits aimed at improving vaccine handling and dose maximization, increasing availability of quality hand sanitizer products, and combatting substandard and falsified vaccines. Through the PQM+ program, USP supported activities to strengthen capacity for vaccine manufacturing and regulation in six African countries. As part of that project, USP held workshops in South Africa and India in collaboration with local partners to increase the vaccine production competency of industry, regulators, and academia, and provide a forum for advocacy. Importantly, USP also issued practical guidance on emergency use authorizations for vaccines and in vitro diagnostics to help speed availability of and access to critical COVID-19 therapeutics and diagnostics.
- **Diethylene glycol and ethylene glycol:** After certain pediatric medicines in multiple countries were found to contain unsafe amounts of the contaminants diethylene glycol (DEG) and ethylene glycol (EG), USP issued a free toolkit for manufacturers, regulators, and other pharmacopeias to address DEG and EG contamination.
- **Nitrosamines:** During the cycle, the discovery of nitrosamine impurities in a variety of different drugs triggered major efforts by regulators and industry to reduce or eliminate their presence in the drug supply chain. USP worked with regulators in Europe, Brazil, China, Saudi Arabia, and elsewhere to improve detection and mitigation of nitrosamine impurities through workshops, access to the USP Nitrosamines Exchange online community, and preferential access to nitrosamine reference standards. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update).

Jude Nwokike
Vice President, Promoting the Quality of Medicines Plus

USP collaborated with national and regional regulatory bodies this cycle to strengthen regulatory systems, thereby increasing supply chain resilience and improving access to quality-assured medicines and vaccines. By working with stakeholders like the African Union and the Association of Southeast Asian Nations, and with funding from multiple donors, USP strengthened the capacity of many national medicines regulatory authorities to review drugs and protect populations from poor-quality medicines, support national control and diagnostics labs to meet global standards, and advance quality production for dozens of medical products. This work also bolstered environments for regional manufacturing to help make more quality medicines in more places to strengthen the supply chain."

Compounding

Resolution 9

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 based on data, scientific evidence, and input from recognized healthcare professionals, and state and federal regulators.

2020 – 2025 Cycle Update

Millions of medicines are compounded each year to meet the unique needs of patients who otherwise may not have access to their treatment in the concentration or dosage they need. Compounding also addresses cases where During the cycle, USP developed revised general chapters, best practices, and related resources to help ensure access to a supply of quality compounded medicines and to maintain public trust in compounded preparations.

Key outcomes during the cycle include:

Revised Compounding Chapters – USP revised general chapters on compounding to help ensure a resilient supply of quality compounded medicines. Revised *USP* General Chapter <795> *Pharmaceutical Compounding – Nonsterile Preparations* and <797> *Pharmaceutical Compounding – Sterile Preparations* were published in the *U.S. Pharmacopeia–National Formulary* (*USP–NF*) in 2022 and became official in 2023. Representing the culmination of 12 years of work by the USP Compounding Expert Committee (CMP EC), the revisions reflect extensive feedback gleaned from 15,000+ comments received over three public comment periods from a diverse group of stakeholders including healthcare practitioners, state and federal regulators, academicians, and industry.

- To support implementation, USP staff and expert volunteers presented at over two dozen stakeholder meetings on compounding, including open forums, webinars, workshops, and conferences. These included USP workshops that addressed topics arising from the revision work, with key sessions on developing stability studies, understanding certificates of analysis, container closure systems, and global perspectives on compounding.
- USP created multiple supplementary documents with details on scientific concepts and compounding-related topics that emerged during the revision process, several of which were published in *Pharmacopeial Forum* for public comment. The documents addressed formulation development, considerations when determining the stability of compounded preparations, assigning beyond-use dates, the addition of flavoring to conventionally manufactured nonsterile products, and responses to more than 450 frequently asked questions.
- USP updated its education courses on compounding to reflect the revised general chapters. USP also created related educational resources on the interpretation of USP compounded preparation monographs as well as pharmaceutical calculations.
- USP established several new CMP EC subcommittees to address compounding-related topics that emerged during the revision process, including the need for additional information and/or standards on the application of alternative technologies in compounding, quality assurance in compounding, and parenteral nutrition.

Monograph Development – USP developed 24 new monographs and revised 61 monographs for specific compounded preparations to help ensure the quality of formulations for which there is no suitable commercially available product. The new monographs were identified as top priorities following engagement with pediatric pharmacists and veterinary practitioners. The revised monographs adjusted for changes in General Chapters <795> and <797>. USP's monograph development efforts were facilitated by 99 donations of materials – consisting of ingredients and formulations used by compounders – that were received from compounding member support organizations, component suppliers, universities, and academic medical centers.

Resources for Compounders – USP worked with stakeholders to create and update resources to support compounders in responding to patient safety and public health emergencies. These resources included toolkits and guides with operational strategies, as well as related responses to frequently asked questions, with thousands of downloads.

- During the COVID-19 pandemic, USP produced and regularly updated resources including the COVID-19 Vaccine Handling Toolkit to facilitate safe and efficient

vaccine handling; Operational Considerations for Sterile Compounding to ensure consistency with changes made to the packaging of conventionally manufactured COVID-19 treatments; USP's Response to Shortages of Garb and Personal Protective Equipment for Sterile Compounding; and recommendations for compounding and use of alcohol-based hand sanitizers intended to reduce the risk of COVID-19 transmission.

- During a protracted shortage of conventionally manufactured amoxicillin formulations for pediatric patients, USP produced a guide with recommendations for compounders to consider when preparing amoxicillin compounded oral suspension.
- Following a disruption of supply chains for large-volume sterile intravenous fluids due to regional U.S. hurricane damage, USP developed an operational considerations document to facilitate compounding during public health emergencies.

Supporting Safe Compounding Around the World – USP worked to build capability in various countries to support equitable access to quality compounded medicines.

- USP entered a memorandum of understanding (MOU) with the Brazilian National Association of Compounding Pharmacists (ANFARMAG) to support the use of USP standards. The MOU addresses related needs for educational resources, webinars, exhibitions, and donations of formulations for development of USP compounded preparation monographs.
- USP provided free online training to over 200 inspectors of the Philippines FDA on USP compounding standards at the agency's request.
- Through USP's Promoting the Quality of Medicines Plus program, USP engaged with the Pharmacy Council of Nigeria to develop a project concept to revive and accelerate the practice of compounding in Nigeria.
- USP met with the Saudi Industrial Development Fund at their request to facilitate understanding of the U.S. framework for compounding and USP's role, and to advance sterile compounding in Saudi Arabia.

Brian Serumaga
Director, Personalized Medicines

The revised compounding General Chapters <795> and <797> reflect extensive USP engagement with healthcare practitioners, regulators, and other stakeholders over several years to maximize the revisions' impact in the real-world environments in which they're applied for the benefit of patients. The revisions aim to enhance the quality of compounded medications by integrating the latest scientific advancements and best practices impacting pharmaceutical compounding. This includes key areas such as facility design, environmental control, quality management systems, and stability considerations."

Cannabis

10

Resolution

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 concerns as well as support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

2020 – 2025 Cycle Update

To help reduce the potential for patient harm and support the consistent quality of cannabis products, USP provided scientific and technical guidance for the evaluation of the quality of cannabis and cannabis-derived products intended for medical use, including for purposes of conducting reproducible scientific research. Related efforts included USP's development of proposed monographs, general chapters, reference standards, and other scientific resources for regulators and other stakeholders, supported by collaborative stakeholder engagement.

Key outcomes during the cycle include:

Quality Specifications for CBD – USP developed proposed quality specifications for naturally derived cannabidiol (CBD) as a drug substance. Related analytical methods and acceptance criteria for CBD identification, quantitative estimation, and contaminant limits, as well as methods to separate impurities to help ensure CBD quality, were included in a proposed monograph standard published in *Pharmacopeial Forum* (*PF*). USP is incorporating input from stakeholder comments and anticipates publishing a revised proposal in *PF* in 2025.

Quality Considerations for Cannabis Research – USP developed and published in *PF* proposed General Chapter <1568> *Cannabis Inflorescence Quality Attributes for Clinical Investigations*. The proposal provided specifications for quality attributes and analytical methods fundamental to characterizing cannabis for clinical research that are intended to complement FDA guidance. The effort responded to active and growing interest in cannabis for medical purposes, where definition of quality attributes can help support sound and reproducible research. USP is incorporating input from stakeholder comments and anticipates publishing a revised proposal in *PF*.

Proposed Monograph for Cannabis Inflorescence – USP proposed a monograph for cannabis inflorescence in the non-official *Herbal Medicines Compendium*, building on its 2020 publication of quality considerations for cannabis inflorescence for medical use in the *Journal of Natural Products*. USP will consider stakeholder comments for inclusion as part of any revised proposal.

Cannabinoid Reference Standards – USP developed reference standards to help ensure the quality of cannabis – including CBD and cannabis inflorescence – when used in conjunction with related analytical methods. These reference standards and analytical methods were also found suitable for National Institute of Standards and Technology (NIST) proficiency testing of hemp extract in an oil matrix.

Reference Materials for Cannabinoids – USP participated in a collaborative study that demonstrated the need for scientifically validated analytical methods and well-characterized USP reference standards to help ensure the accuracy of cannabis product labels. Organized by the American Council of Independent Laboratories, the study evaluated the potential role of existing Certified Reference Materials (CRMs) to ensure cannabis product label accuracy, observing a ±5% variability in the content of CRMs from multiple vendors. While this variability may be acceptable for products based on cannabis inflorescence, CRMs with this level of variability are not suitable for ensuring the quality of pure cannabinoid active pharmaceutical ingredients in the proposed CBD monograph under development.

Quality Specifications for Food Ingredients – USP developed monographs for hemp seed oil and hemp seed proteins, which were deemed "generally recognized as safe (GRAS)" food ingredients under the FDA GRAS notification process. The monographs, which include specifications and test methods for identification and purity as well as limits on impurities like tetrahydrocannabinol and CBD, will help ensure the quality of related food ingredients.

Addressing Impurities – In response to concerns about health hazards associated with certain products containing delta-8-tetrahydrocannabinol (D8-THC) or related impurities

as highlighted in public health advisories, USP collaborated with an external lab to identify impurities in synthesized D8-THC products and develop analytical methods to separate the impurities using chromatographic methods. The methods were subsequently used to analyze commercial D8-THC samples and published in *Planta Medica*.

Outreach and Engagement – USP engaged with regulators and other stakeholders on a range of cannabis quality-related issues.

- USP organized and hosted a cannabis regulator forum in 2024 with representation from 17 states, FDA, NIST, the Cannabis Regulators Association, and Health Canada to discuss regulator needs and science-based resources to help support cannabis quality.
- USP and ASTM International cosponsored the Global Workshop on Cannabis Quality in 2022, gathering 500+ stakeholders from industry, testing laboratories, regulatory bodies, and academia across the Americas and Europe. The virtual event facilitated the sharing of perspectives on regulatory issues, standards development, potential harmonization among standards-setting bodies, and needs for future research. A similar 2023 USP-ASTM webinar focused on Africa and Asia, while a related 2024 event in Philadelphia helped sustain stakeholder engagement with a focus on identifying existing gaps and priority topics for standards development.
- USP created cannabis toolkits in four volumes to facilitate stakeholder engagement and education. The toolkits provide scientists, manufacturers, and regulators with the resources needed to establish a framework for the consistent characterization of cannabis for medical use.
- USP submitted comments on cannabis quality-related issues to Congress, FDA, and state regulators. USP emphasized the need for public quality standards for cannabis-derived products in response to proposed federal legislation and responded to a separate Congressional request for information about regulation of cannabidiol products. USP also provided public comments on FDA's draft guidance on cannabis quality considerations for clinical research, and comments to state regulators in New York and California on a proposed rule and state bill, respectively, related to cannabis quality.
- The value of USP cannabis-related quality standards was recognized in a report from the National Academies of Science, Engineering and Medicine that recommended state cannabis regulators adopt and enforce such standards to ensure the safety and quality of legal cannabis products. The report, titled *Cannabis Policy Impacts Public Health and Health Equity*, specifically cited USP's establishment of standards for cannabis inflorescence and development of standards for cannabis extracts.

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.

2020 – 2025 Cycle Update

Through collaboration with other pharmacopeias, USP worked to advance convergence around robust, science-based quality standards. This work increased global alignment on drug quality as defined in the compendia and best practices to develop and update compendial standards. Convergence can reduce or eliminate redundant or even conflicting quality standards in local areas and allow governments, manufacturers, and healthcare professionals to expand access to safe, quality medicines, thereby improving patient safety and public health. One way convergence of quality standards makes this possible is through increased availability of quality ingredients for medicines made locally in regions of the world where they are needed most. USP supports convergence through scientific exchange, training programs, and other stakeholder engagement activities.

Key outcomes during the cycle include:

Pharmacopeial Discussion Group Collaboration – USP worked with fellow Pharmacopeial Discussion Group (PDG) members to increase the reach and impact of PDG harmonization efforts. This was accomplished by expanding PDG membership and strengthening PDG engagement with regulators, industry, and other pharmacopeias around the world.

- The PDG, which originally included USP, the European Pharmacopoeia (EP), and the Japanese Pharmacopoeia (JP), officially added the Indian Pharmacopeial Commission (IPC) as a member in 2023. The addition represents the PDG's first expansion of membership in its 34 years of existence and followed IPC's year as the inaugural participant in a pilot for expansion of the PDG membership to include other prominent pharmacopeias. The move represents a critical step in the PDG's commitment to increase recognition of harmonized pharmacopeial standards and global convergence, reduce redundant regulations, and improve access to quality medicines worldwide.
- The PDG harmonized a number of high-impact quality standards, including chapters on chromatography and elemental impurities, to ensure alignment across regions. With completion of a new harmonized general chapter on elemental impurities in 2024, all 31 chapters in the PDG's previously defined workplan were harmonized.
- The PDG added to its harmonization workplan three excipients including polysorbate 20, purified water, and water for injection in response to stakeholder requests. The polysorbate 20 effort leveraged an early engagement model with industry stakeholders who provided input into the harmonization of this critical excipient.

ICH Engagement – USP has been an observer of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly since 2016. During the cycle, USP contributed to the development of several ICH quality guidelines that allow regulators to better align and harmonize their regulatory approaches. This helps to increase regulatory efficiency and support the availability of quality medicines.

- USP provided input into the development and completion of ICH Q13, which provides scientific and regulatory guidelines for continuous manufacturing processes for drug substances and products; ICH Q2, which provides updated guidelines for analytical method validation; and ICH Q14, which outlines scientific principles and risk-based approaches for developing analytical procedures.
- USP also contributed to the development of several earlier-stage ICH guidelines – including ICH Q6 on specifications, ICH Q3E on extractables and leachables, and an addendum to ICH M7 on nitrosamines. In addition, USP participated in an informal ICH discussion group on cell and gene therapies.
- USP and its PDG partners led efforts to develop a maintenance procedure for ICH technical guidelines on pharmacopeial interchangeability. A process allowing for parallel implementation of the PDG text along with local text was developed to give ICH members with active pharmacopeias time to revise and update their respective pharmacopeias to fully align with the PDG text. This approach was formally approved by the ICH Assembly in 2024.

Prospective Harmonization with Europe and Japan – USP advanced prospective harmonization efforts with other individual pharmacopeias to align development

of new quality standards for select active substances and medicinal products that do not yet have established pharmacopeial standards. USP worked with the European Directorate for the Quality of Medicines & Healthcare (EDQM), the parent organization of the European Pharmacopoeia, to harmonize prospectively a total of 13 monographs this cycle. In addition, USP and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), the parent organization of the Japanese Pharmacopoeia, started a pilot for their first prospective bilateral harmonization of a drug product monograph.

China Engagement – USP engaged in significant technical collaborations with the Chinese Pharmacopoeia (ChP), which built on a USP-ChP memorandum of understanding signed in Fiscal Year 2021 and formation of a USP-ChP working group on metal packaging in Fiscal Year 2022. These efforts culminated in successful development of new draft General Chapters <662> *Metallic Packaging Systems and Their Materials and Components of Construction* and <1662> *Materials and Manufacturing Processes for Metallic Packaging Systems*.

Egypt Engagement – USP engagement led to inclusion in the 5th Edition of the Egyptian Pharmacopeia of 3,360 monographs and 500 general chapters adopted from USP standards. This achievement resulted from more than two years of close collaboration and coordination between USP scientific teams, the Egyptian Drug Authority, and industry stakeholders to facilitate standards alignment and implementation that will enhance medicines quality.

Convergence and Harmonization Policy – USP published its first policy position on pharmacopeial convergence and harmonization as one strategy for supporting an efficient and effective response to medicines supply chain vulnerabilities. The policy paper aims to advance opportunities to address regulatory variation across borders to improve resiliency of the global supply chain.

WHO International Meeting of World Pharmacopeias – USP was an active participant throughout the cycle in the annual International Meeting of World Pharmacopeias (IMWP), organized by the World Health Organization (WHO). Bringing together representatives from national, regional, and international pharmacopoeias to collaborate on pharmacopeial convergence, the IMWP provides a forum for participants to share experiences, collaborate on joint projects, and work towards aligning their standards to facilitate global access to quality medicine. Key IMWP outcomes supported by USP during the cycle included creation of a Pharmacopeial Alert System during the COVID-19 pandemic for pharmacopoeias around the world to share related knowledge and experience, development of a white paper on the value of pharmacopeial standards, and establishment of a working group on principles of environmental sustainability in standards setting.

Collaborative Workshops – USP engaged in a number of joint workshops with pharmacopeial partners to promote collaboration and public health. Highlights included workshops held in conjunction with Japan's PMDA on harmonization, the role of pharmaceutical quality standards, and responding to emerging quality issues and public health emergencies. USP also held key workshops with Europe's EDQM on prospective quality standard harmonization, the role of pharmacopeial reference standards across the product lifecycle, and compendial testing methods and requirements for detecting ethylene glycol and diethylene glycol in pharmaceutical products and excipients.

Evidence Generation to Inform Policy

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Resolution

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.

2020 – 2025 Cycle Update

Policymakers and stakeholders continued to grapple with long-standing vulnerabilities in the medicines supply chain throughout the cycle. Factors including geopolitical dynamics, increasingly frequent natural disasters, and disruptions due to other factors necessitated heightened efforts to build a more resilient global medicines supply chain and thereby help protect and improve public health. To address the growing need, USP engaged directly with stakeholders from around the world to understand related challenges and opportunities, and to inform policy recommendations, informational resources, and advocacy. At the same time, USP expanded medicines quality-related research to build strong evidence and materials in support of global policy advocacy and capability-building efforts needed to help prevent drug shortages and further bolster supply chain resilience.

Key outcomes during the cycle include:

Medicine Supply Map – USP developed the Medicine Supply Map surveillance system to assist stakeholders, including U.S. federal agencies, Congress, and pharmaceutical manufacturers, in their efforts to identify, characterize, and quantify vulnerabilities in the upstream pharmaceutical supply chain, deliver insights that can guide risk mitigation strategies and investments, and help inform policy changes that advance supply chain resilience. Key focus areas included insights into the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines such as antimicrobials and cancer medicines. USP shared related insights with stakeholders to facilitate decision-making and inform policy and legislation aimed at bolstering supply chain resilience.

- USP published its first Annual Drug Shortage Report, which leveraged data-driven Medicine Supply Map insights to analyze the economic factors of drug shortages in the U.S. and better equip policymakers and industry leaders to shape policies and investments to prevent and mitigate future shortages.
- Through collaboration with stakeholders including the End Drug Shortages Alliance, the Medicine Supply Map contributed to analyses of the impact of recent supply chain disruptions, including those stemming from damage to pharmaceutical production facilities during hurricanes Helene and Milton.

Supply Chain Resilience Dialogue and Insights – USP engaged with stakeholders from across the globe to understand the diverse challenges in strengthening supply chain resilience. This effort generated dialogue to inform policymakers' understanding of global supply chain vulnerabilities and their potential impact on the availability of quality medicines and raised awareness of USP solutions.

- USP and FDA co-hosted the Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue in 2023 as part of the U.S.'s APEC forum host year. Over 45 economies were represented at the two-day meeting centered on knowledge sharing and dialogue to advance supply chain resilience. Key topics included upstream supply chain vulnerabilities, mitigating and managing risks in excipient quality, manufacturing solutions to bolster resilience, strengthening quality assurance, regulatory reforms to strengthen preparedness efforts, good distribution practices, post-marketing surveillance, and online pharmacy risks and safety solutions.
- USP established a Drug Shortage Task Force to prevent and mitigate drug shortages through policy advocacy and related educational activities. In 2024, the 22-organization Task Force hosted a briefing on Capitol Hill to help policymakers better understand the root causes, complexities, and pervasiveness of drug shortages and the urgent need for a comprehensive solution. (See *Coalition Building* Resolution update.)

Research to Advance Medicine Quality – USP sponsored research to inform and enable evidence-based policy decisions that can help increase the availability of quality medicines.

- USP-sponsored academic fellows published several peer-reviewed articles and presented their work at national and international scientific and public health conferences. Topics included substandard and falsified

medications, antimicrobial resistance, excipients, and procurement of materials used for medicines manufacturing.

- USP worked with organizations, including the Center for Analytics & Business Insights at Washington University in St. Louis, to research and report on vulnerabilities and risks associated with the medicines supply chain.

Collaboration and Engagement – USP engaged with a range of stakeholders through collaborations and conference participation to generate dialogue and evidence to inform policymaking on key topics including the medicines supply chain, biologics, and regulatory reform. Key contributors to this progress included:

- USP's service as a Center of Excellence in global medical product quality and pharmaceutical supply chain security, as designated by the APEC forum, through which USP hosts the web-based APEC Supply Chain Security Toolkit.
- USP's membership in the Healthcare and Public Health Sector Coordinating Council, which together with the Government Coordinating Council forms a public-private partnership to protect national healthcare infrastructure.
- USP's collaboration with various U.S. agencies on supply chain-related issues, including the FDA, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, and Federal Emergency Management Agency.
- USP's membership in the Duke-Margolis ReVAMP Drug Supply Chain Consortium, through which USP participated in a panel on policy to prevent drug shortages.

Vimala Raghavendran

Vice President, Informatics Product Development

"From the outset, the USP Medicine Supply Map has been relentlessly stakeholder focused. Drug shortages are a top priority for stakeholders and for public health. Through regular debriefs, we learn how they're using the Medicine Supply Map, what it has enabled for them, and how it might better inform their decision making in the face of shortages or their potential.

We know the Medicine Supply Map is just one piece of the solution, but we will continue to make it more powerful and impactful."

Coalition Building

Resolution 13

USP will lead and power a stakeholder movement for quality to advance public health and patient safety.

2020 – 2025 Cycle Update

The medicines supply chain is complex, thereby requiring many perspectives, broad expertise, and holistic approaches to strengthen its resilience and ensure patients have access to the quality medicines they need. Through strategic engagement with the USP Convention Membership and by building and participating in coalitions, USP elevated and advanced critical conversations that shaped strategies, fueled action, and informed policies, helping build a stronger and more resilient medicines supply chain.

Key outcomes during the cycle include:

Reinvigorated USP Convention – At the start of this cycle, USP launched a new approach to engaging with the Convention Membership that resulted in more insights and input, and deeper connections with leading stakeholders around the world and across the science and healthcare ecosystem. Through meetings of the Convention Sectors, Convention Regional Chapters, and Council of the Convention (CoC), USP connected with members on shared priorities, updated them on USP activities, and engaged in dialogue that helped advance quality issues.

USP Convention Sectors – The sectors convene member representatives around common areas of focus. In the first two years of the cycle, USP launched the following sectors: Generic Medicines, Biologics, Healthcare Practice, Dietary Supplements, Excipients, and Innovation. Meetings included guest speakers and panel discussions featuring perspectives from industry, FDA, patient groups, and others, as well as member dialogue, which surfaced insights on challenges, best practices, and available resources. Select sector engagement highlights from the cycle include:

- USP hosted a three-part Convention Exchange series on supply chain resilience, which convened members from across sectors to share diverse perspectives to inform policymakers' understanding of supply chain vulnerabilities and solutions.
- Resulting from a dialogue during a Biologics Sector meeting, the USP Convention and FDA collaborated on an infographic titled "Biosimilars: Are they the same quality?" to help practitioners and patients have informed conversations about biosimilars. The resource was subsequently updated in Fiscal Year 2025 to reflect stakeholder input.
- A resource titled "Choosing Quality: Dietary Supplements – Information for Pharmacists Advising Consumers on Quality Considerations" was developed and distributed by the Dietary Supplements Sector with input and distribution support from the Healthcare Practice Sector.
- The Innovation Sector hosted a three-part Innovation Series that addressed advancing quality in breakthrough treatments, novel pharmaceutical production and delivery, and digital transformations in healthcare.

USP Convention Regional Chapters – Regional chapters convene member representatives from a geographic region to discuss ongoing and emerging issues, share knowledge and experience, and collaborate to advance common priorities. During the cycle, USP launched the following chapters: Asia Pacific, South Asia, Greater China, Latin America, Middle East and North Africa, Europe, and Africa. Select chapter highlights include:

- The Asia Pacific Regional Chapter hosted several notable meetings, including the first meeting to exceed 100 attendees – which was a hybrid meeting hosted at USP headquarters as part of the Asia Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue – and a meeting in Tokyo in Fiscal Year 2025. This chapter's priority topics have included supply chain resilience, impurities, and advanced therapies.
- The Latin America Regional Chapter hosted a well-attended collaborative meeting to share strategies and best practices for regulating medical cannabis across the region. Six countries attended and shared their perspectives, insights, and challenges.

- The South Asia Regional Chapter hosted a dynamic meeting in New Delhi and welcomed the drug controller general of India and the country director for the U.S. FDA India Office. The dialogue addressed a range of priorities including biosimilars, regulatory convergence, and pharmaceutical continuous manufacturing.
- The Middle East and North Africa Regional Chapter focused one of its meetings during the cycle on regulatory systems strengthening. Members shared their challenges, strategic priorities, and best practices, learning from each other and highlighting available resources.
- The Greater China Regional Chapter launched in 2021 with a meeting focused on discussion of USP's COVID-19 response, post-market surveillance, and impurities.
- The Europe Regional Chapter convened a robust discussion for its launch meeting. Members shared their organizational priorities and covered topics ranging from mitigating risks posed by nitrosamines and other impurities to rapid microbiological testing.
- USP launched the Africa Regional Chapter in Johannesburg in June 2024, focused on partnership and commitment to advance Africa's new Public Health Order. The chapter hosted member representatives from 20 countries who participated in a dialogue on local manufacturing and progressing towards Africa self-reliance; the role of standards in quality and regulatory compliance; and fostering an effective medicines regulatory environment in Africa.

Council of the Convention – The new USP Convention engagement structure was extended to the CoC, the volunteer leadership body that represents Convention Membership throughout the cycle. At the start of the cycle, the Convention president appointed members to the CoC, forming a diverse leadership body that includes a variety of perspectives, experiences, and knowledge. CoC membership includes the chairs of both the Convention Sectors and Regional Chapters, who bring Convention Member perspectives to governance discussions and decisions; Council of Experts (CoE) representatives, who help maintain open communication with the CoE and its standards-setting activities; and at-large members. The diverse perspectives and expertise represented on the CoC resulted in strong strategic leadership that increased Convention Member engagement throughout the cycle and helped position USP for the coming cycle.

Drug Shortages Task Force – In response to rising and pervasive drug shortages in the U.S., USP and the American Cancer Society Cancer Action Network convened a Drug Shortage Task Force. The Task Force is a 22-organization, multi-stakeholder collaborative of patient, provider, and public health organizations advocating for comprehensive reforms to prevent and mitigate drug shortages in the U.S. In March 2024, the Task Force hosted a briefing on Capitol Hill to help policy makers better understand the root causes, complexities, and pervasiveness of drug shortages and why a comprehensive solution is urgently needed. The briefing included panel discussions and dialogue with key thought leaders about the pharmaceutical supply chain, surfacing insights to help prevent future shortages and improve access to critical medicines for all patients.

Coalitions for a Resilient Supply of Quality Medicines – Throughout the cycle, USP participated in multiple coalitions formed to strengthen the global supply of quality medicines. By combining USP's scientific expertise, capabilities, and global network with those of other leading institutions, the coalitions helped advance critical understanding of challenges and solutions, and combined voices and influence to raise awareness of and investment in a resilient supply chain. Some of the coalitions USP participated in during this cycle included:

- The End Drug Shortages Alliance, comprising health systems, manufacturers, distributors, and other supply chain stakeholders. As part of the coalition, USP hosted a roundtable addressing communication before, during, and after a drug shortage.
- The Healthcare Industry Resilience Collaborative, founded by Mayo Clinic and Banner Health and developed to champion and lead standards and best practices in healthcare supply chain resiliency.

- The Duke-Margolis ReVAMP Drug Supply Chain Consortium, developed to identify effective policy solutions that support supply chain resiliency.
- The Alliance for Building Better Medicine, formed with a mission to reduce the cost of manufacturing pharmaceuticals by using chemical and engineering innovations.

Asia Pacific Economic Cooperation Dialogues – Throughout the cycle, USP continued its relationship with APEC, serving as an APEC Center of Excellence and disseminating best practices, standards, and guidance that improve the quality and security of the global pharmaceutical supply chain.

- In partnership with the Pharmaceutical Security Institute, Moderna, and Sanofi, the USP-APEC Supply Chain Center of Excellence hosted an event titled "Confronting Substandard and Falsified COVID-19 Vaccines and Treatments," attended by 75+ regulators and other key stakeholders.
- USP and FDA cohosted the APEC Medical Product Supply Chain Dialogue in 2023 as part of the U.S.'s APEC forum host year. Over 45 economies were represented at the two-day meeting that featured knowledge-sharing and dialogue to advance supply chain resilience. (See *Evidence Generation to Inform Policy* Resolution update.)

Amy Sonderman
Senior Director, U.S. Advocacy and Stakeholder Engagement

"USP recognizes that supply chain resiliency requires a cross-sector, coordinated effort. As a result of a robust dialogue during a Convention Sector meeting, USP partnered with the American Cancer Society Cancer Action Network to build the Drug Shortage Task Force. **Twenty-two organizations have joined forces, starting with a meeting on Capitol Hill, urging policymakers to help advance a holistic and coordinated response to a systemic drug shortage crisis.** This work is one way that USP is collaborating with stakeholders around the world to ensure supplies of quality medicines."


Africa
Regional Chapter

Culture of Excellence

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Resolution

USP will model operational excellence, continuous improvement, stakeholder responsiveness, and transparency.


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2020 – 2025 Cycle Update

A culture of excellence at USP means that people, processes, and systems are aligned and working optimally in pursuit of the organization's mission. Building on a foundation of rigorous process and data management that was continually improved, including through increased standardization of our systems, USP strengthened its decision making, stakeholder engagement, and information sharing. By focusing on improving effective and reliable procedures and systems through increased integration of quality considerations, USP bolstered its ability to expand access to quality medicines, facilitate innovation, and improve public health.

Key outcomes during the cycle include:

Enhanced Business Process Management – USP launched a Business Process Management application to enhance development of both reference standards and documentary standards. The platform facilitates automation and management of select, complex business processes to allow increased consistency, efficiency, and control. USP launched three major releases of the platform, each further enhancing applications and functionality.

User-Friendly Online Products and Services – USP developed and began executing a long-term plan to provide user support and improve the user experience for the online *U.S. Pharmacopeia-National Formulary* (*USP-NF*) publication. USP also updated the content-hosting platform infrastructure to support up to five additional languages, starting with French, and reduced the time users wait for search results by up to 90%. In addition, the amount of time it takes USP to publish new content was decreased from 2-3 weeks before the update to just 3-4 days post-update in most cases. The three-year plan will further optimize processes and expand features, supported by additional infrastructure and enhanced software applications, to benefit *USP-NF* users.

Digital Integration – USP advanced its vision for machine-readable digital standards that will facilitate stakeholders' ability to ensure availability of quality medicines. A key milestone was USP's launch of the USP-ID nuclear magnetic resonance analysis software platform, which automates identity, strength, and purity analysis of molecules in complex mixtures. (See *Digital Transformation of Standards* Resolution update.)

Data Quality – To maintain and foster the quality of data essential to excellence in outcomes, USP worked to improve data management and monitoring. This included development of data governance structures for USP's Salesforce/Master Data Hub application and the Global Substance Registration System. These data governance structures incorporate data quality metrics and reports for key data elements, which allow for continuous monitoring and improvement of data accuracy. In addition, USP developed enterprise-wide data governance, quality, and management policies; a data dictionary; and databases to store monograph/reference standard relationships and comments submitted to the *Pharmacopeial Forum*.

Quality Management System – USP implemented a new Quality Management System software program, MasterControl, which reduced costs by providing a single, centralized platform for multiple functions – including managing documents, training, audits, and corrective/preventive actions – that previously required multiple separate systems. USP also enhanced its Supplier Quality Management program by developing supplier performance indicators. The indicators facilitate enhanced quality control, risk mitigation, cost management, and improved supplier performance while helping to ensure the quality, reliability, and efficiency of the supply chain.

Employee Survey Initiative – USP administered a weekly pulse survey, Employee Voice, to gather employee feedback, measure progress, and inform leadership action aimed at strengthening six key areas: talent recruitment and retention, people management, elevation of the employee experience, inclusivity, USP's "speak up culture," and employee empowerment for individual growth. Data was collected, evaluated, and made available to all employees to provide real-time visibility into the organization's progress against key metrics. Team leaders were encouraged to use the data to better identify strengths and inform decisions on how to continuously improve USP's support of its employees.

Knowledge Management – USP developed a customized knowledge management tool, Oasis, to strengthen USP's ability to manage knowledge repositories and facilitate access to core business databases. The tool, which is used with internal databases and network drives as well as external websites, helps USP staff conduct curated searches of multiple information repositories and dynamic content types.

Impact Expansion

Resolution 15

USP will expand its public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.


APEC 2023
USP
FDA
APEC Medical Product Supply

2020 – 2025 Cycle Update

USP identified opportunities to expand its impact around the world through a range of strategies that helped increase the resilience of the global medicines supply chain. This included efforts to strengthen stakeholder capabilities to address potential challenges of pharmaceutical impurities and contaminants, facilitate innovation, support good distribution practices, and ensure supplies of quality vaccines and essential medicines around the globe. USP's broader work to advance adoption of USP quality standards, guidelines, and best practices reached more people in multiple regions of the world, helping to strengthen the medicines supply chain and improve patient safety and public health.

Key outcomes during the cycle include:

Increasing Medicines Supply Chain Resilience – USP engaged stakeholders in Asia, Latin America, Africa, and elsewhere to address medicines supply chain vulnerabilities, advance regulatory convergence, enhance quality testing capabilities, and raise awareness and understanding of how USP quality standards help strengthen supply chain resilience. Key highlights include:

- USP collaborations with the Asia Pacific Economic Cooperation (APEC) forum drove significant impact during the cycle. As an APEC Center of Excellence (CoE) in global medical product quality and pharmaceutical supply chain security, USP produced updates to good distribution practices and launched a web-based version of the APEC Supply Chain Security Toolkit. Available on the USP website, these resources facilitated capacity building for regulators worldwide. USP also cohosted with FDA the APEC Medical Product Supply Chain Dialogue in 2023 as part of the U.S.'s APEC forum host year. Over 45 economies were represented at the two-day meeting centered on knowledge sharing and dialogue to advance supply chain resilience.
- USP convened a summit in São Paulo, Brazil in 2023 on improving supply chain resilience, which included regulators, industry, academia, and other stakeholders from the region. Attendees discussed lessons learned from the handling of the COVID-19 pandemic, good distribution practices, strategies to address potential medicines shortages, and preparation for future public health emergencies.
- USP contributed to the development and launch of the Americas RISE for Health (RISE) forum, a public-private initiative focused on health issues across the Americas. USP provided thought leadership on the importance of regulatory convergence as part of the group's policy agenda and to strengthen the resilience and security of the medical product supply chain.
- USP served as a technical partner on eight technical committees of the African Medicines Regulatory Harmonization (AMRH) initiative, which is serving as the foundation for the African Medicines Agency (AMA) – a continent-wide regulatory body designed to complement existing regional initiatives and national regulatory authorities. (See *Regulatory Systems Strengthening* Resolution update).

Strengthening Regional Government Relationships – USP collaborative agreements with overseas government agencies played a pivotal role in enhancing the supply of quality medicines around the world. These relationships focused on supporting development and implementation of quality standards, increasing harmonization and convergence of quality testing practices across borders, and advocating for medicines quality to protect public health. Key highlights include:

- **India:** USP signed a memorandum of understanding (MoU) with the Indian Pharmacopoeia Commission (IPC) during a high-level government delegation to USP's Rockville facility, underscoring our joint commitment to ensuring the availability of quality pharmaceuticals. Additionally, IPC became a member of the Pharmacopeial Discussion Group to support increased recognition of harmonized pharmacopeial standards and improved access to quality medicines worldwide. (See *Pharmacopeial Cooperation and Convergence* Resolution update.)
- **China:** USP collaborated with the China Chamber of Commerce for Import & Export of Medicines and

Health Products to share updates with over 300 regulatory and industry stakeholders on quality considerations for complex generics during the CPHI (convention on pharmaceutical ingredients) China event in Shanghai in 2024. USP also conducted a workshop in Suzhou, China in 2024, attended by over 100 stakeholders, on advances in packaging material standards and collaborated with the Chinese Pharmacopoeia to develop new draft general chapters on metal packaging.

- **Turkey:** USP signed an MoU and broader agreement with the Turkish Medicines and Medical Devices Agency to align Turkish pharmaceutical standards with USP standards, focusing on biologics testing, post-market surveillance, and nitrosamine impurity analysis.
- **Ukraine:** USP hosted a delegation from the Ministry of Health of Ukraine in Rockville, Maryland, to discuss challenges facing Ukraine's health system and how USP standards can help support medicines quality in that country.
- **Republic of Korea:** USP conducted a scientific exchange with the Republic of Korea's National Institute of Food and Drug Safety Evaluation (NIFDS) as part of USP's ongoing MoU with the agency. Several senior scientists from NIFDS visited Rockville for discussions on the rigorous process of monograph development, evolution of digital standards, pharmacopeial collaboration, and other topics.
- **Republic of Korea/Japan:** USP conducted a joint workshop in Asia with NIFDS and Japan's Pharmaceuticals and Medical Devices Agency on advanced therapies covering aspects of regulatory convergence, biologics approval processes, quality control methods, and preclinical safety studies.
- **Egypt:** USP collaborated with the Egyptian Drug Authority and Egyptian Chamber of Pharmaceutical Industry leaders to foster collaboration and knowledge exchange on critical issues of pharmaceutical quality and safety.

Collaboration with FDA Internationally – USP expanded collaboration with FDA offices around the world to strengthen supply chain resilience and support global public health. USP worked with FDA's India office to conduct workshops and training to address nitrosamine impurities and support adoption of advanced manufacturing technologies. USP also partnered with FDA's China office and the agency's Office of Dietary Supplement Programs at the FDA Human Foods Program to co-host workshops to increase regional awareness of U.S. dietary supplement regulations and critical supply chain considerations for quality and security. (See *Collaboration with FDA & Other Stakeholders on Health Priorities* Resolution update.)

Regulatory Capability Building in LMICs – Through USP's Promoting the Quality of Medicines Plus (PQM+) program, which aimed to improve access to quality-assured medicines in low- and middle-income countries (LMICs), and USP regulatory affairs outreach, USP supported the advancement of 40+ national regulatory authorities in strengthening their regulatory functions and regulatory maturity levels, as defined by the World Health Organization Global Benchmarking Tool. In addition, USP established free access to all self-paced educational courses for national regulatory bodies, which helped equip them with resources to ensure the quality of medicines. (See *Regulatory Systems Strengthening* Resolution update).

Impurities and Substandard Medicines – USP supported stakeholders around the world through solutions to help control the risk of impurities in medicines and to help prevent, detect, and eliminate substandard and falsified medicines. USP developed global tools like the *Nitrosamine Exchange* online community for stakeholders to share up-to-date information, and a toolkit to address the potential for diethylene glycol (DEG) and ethylene glycol (EG) contamination. In addition, USP worked with regulators and other stakeholders around the world to develop mitigation strategies and address related challenges. Key highlights include:

- **Vietnam:** USP's India lab conducted a five-day course for Vietnamese regulators from the country's National Institute of Drug Quality Control covering regulatory guidelines and hands-on lab demonstrations addressing the potential for nitrosamine impurities in medicines.
- **Latin America:** USP hosted a summit in Mexico City for Latin American regulatory bodies to address regional progress and challenges in nitrosamine control.
- **China:** USP staff met with China's National Institutes for Food and Drug Control for a regulatory roundtable to discuss strategies for nitrosamine control and shared updates from the European Directorate for the Quality of Medicines & HealthCare.
- **Indonesia:** USP co-hosted a workshop with Indonesia's Ministry of Health on testing for high-risk impurities like DEG and EG in pharmaceutical excipients.

USP Convention Regional Chapters – During the cycle, USP strengthened its international engagement by establishing the following Regional Chapters of the USP Convention: Asia Pacific, South Asia, Greater China, Latin America, Middle East and North Africa, Europe, and Africa. The chapters convened member representatives from their respective geographic regions to discuss ongoing and emerging regional issues, share knowledge and experience, collaborate to advance common priorities, and bring critical global insights to inform USP's strategies and tactics. Key topics addressed included responding to the COVID-19 pandemic, supply chain resiliency, regulatory convergence, post-market surveillance, local manufacturing, nitrosamines, and substandard and falsified medicines. (See *Coalition Building* Resolution update.)





P.T.
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SPEAKER

Convention Meeting

2025

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