

A woman with long dark hair, wearing safety glasses and a white lab coat, is working in a laboratory. She is holding a pipette and looking down at it. In the background, there is a microscope and other laboratory equipment. A blue semi-transparent box is overlaid on the right side of the image, containing the title and year.

# 2020-2025 Resolutions Progress Report

FY 2023





# Table of Contents

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## **Introduction**

**Resolution 1:** Collaboration with FDA & Other Stakeholders on Health Priorities

**Resolution 2:** Efficiency in Standards Development and Revision

**Resolution 3:** Quality Standards

**Resolution 4:** Access to Biologics

**Resolution 5:** Innovations

**Resolution 6:** Digital Transformation of Standards

**Resolution 7:** Education and Training for Industry and Healthcare Professionals

**Resolution 8:** Regulatory Systems Strengthening

**Resolution 9:** Compounding

**Resolution 10:** Cannabis

**Resolution 11:** Pharmacopeial Cooperation and Convergence

**Resolution 12:** Evidence Generation to Inform Policy

**Resolution 13:** Coalition Building

**Resolution 14:** Culture of Excellence

**Resolution 15:** Impact Expansion



# A Note from the President and Secretary of the USP Convention

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This report highlights the progress USP made in the third fiscal year of the 2020-2025 cycle in addressing the objectives set by the USP Convention Membership. These strategies, collaborations, advancements, and solutions continue to help bolster the supply of quality-assured medical products so that more people around the world can access – and trust – the medicines they need.

USP's mission hasn't changed much since its founding in 1820 – improve public health through quality standards for medicines. But how, where, and with whom USP delivers on that mission has changed drastically. The 15 Resolutions that the Convention adopted in 2020 give a sense of the expanded scope, scale, and potential for USP's impact. An evolving global landscape continues to transform and disrupt the biopharmaceutical supply chain; digitalization is revolutionizing all drug stages, from development to delivery; and pharmaceutical advanced manufacturing is redefining long-standing fields of work and demanding new skills from the workforce. Wherever the biopharmaceutical industry goes, USP must also chart a path, positioning quality at the core of each transformation, innovation, and disruption. And this year's Resolutions progress report tells that story.

From supporting innovation in biologics to transforming USP standards for Pharma 4.0 to forming public and private partnerships that help build a more resilient pharmaceutical supply chain, USP continues to evolve, as it has for two centuries. We're proud to share this report that summarizes work completed during the fiscal year ending June 30, 2023.

## Select Highlights from Fiscal Year 2023

- ▶ Advancing solutions to medicines supply chain vulnerabilities, including efforts to reduce barriers to the adoption of advanced manufacturing technologies and continue ongoing development of the USP Medicine Supply Map, which enhances visibility into the upstream medicines supply chain. More information about this work can be found in the updates to Resolutions 1, 5, and 12.
- ▶ Developing new standards, guidelines, best practices, and related programs on impurities (including nitrosamines), vaccines, complex generics, cell and gene therapies, medicines compounding, new analytical techniques, and other priorities, addressed in the updates to Resolutions 1, 3, 4, 5, 9, and 15.
- ▶ Convening the Asia-Pacific Economic Cooperation (APEC) forum Medical Product Supply Chain Dialogue with the U.S. Food and Drug Administration (FDA) as part of the U.S.'s 2023 APEC host year activities. Gathering stakeholders from 45 nations, the event featured knowledge-sharing and discussion aimed at advancing global supply chain resilience. Information about this work can be found in the updates to Resolutions 1, 8, 13, and 15.

- ▶ Continuing to expand the supply of quality-assured medicines in low- and middle-income countries through USP's Promoting the Quality of Medicines Plus program, addressed in the update on Resolution 8.
- ▶ Advancing the functionality of USP's standards in digital environments to help meet stakeholders' evolving needs, described within the updates to Resolutions 6 and 14.
- ▶ Expanding and deepening stakeholder collaboration and engagement by maintaining consistent dialogue with the FDA and other regulators and convening the Convention's six Sectors and six Regional Chapters through which Convention Members share knowledge, perspectives, and expertise. Additional information is shared in the updates to Resolutions 1 and 13.

### **An Inspiring USP Community**

As always, USP's progress and impact are optimized by the critical contributions of its many Expert Volunteers, Convention Member Organizations, and stakeholders around the world. Your expertise, knowledge, informed perspectives, and deep commitment to quality amplify USP's impact and inspire USP staff to continue striving, innovating, and evolving to achieve our mission.

### **Progressing with Urgency and Resolve**

Each of the following Resolution updates includes plans for the remainder of this five-year cycle – how USP intends to deliver on its Resolutions and fulfill the responsibilities set by the Convention. We invite you to reach out to the staff contacts provided if you have questions or recommendations on how USP can strengthen this work through knowledge sharing, partnerships, and other strategies.

At this time, we're also looking ahead to the 2025-2030 cycle and considering how our work will evolve. What Resolutions will guide USP's work starting in July 2025? As the challenges and opportunities to strengthen the global supply of quality medicines, dietary supplements, and foods expand, USP accelerates its response. Our commitment to our mission will persist, especially with the powerful network of the USP Convention, the expertise of the volunteers who deliver our science, and our global community of stakeholders helping to fuel USP's impact.

Sincerely,

Dennis E. Doherty, M.D.

President, USP Convention

Anthony Lakavage, J.D.

Secretary, USP Convention



# Resolution

## 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.

### Year 3 Update

Advancing patient safety and increasing access to quality medicines is as complex as it is critical. To maximize USP's impact in these efforts, the organization continues to prioritize collaboration with diverse stakeholders – including FDA and other global regulators, industry, and healthcare providers – as it works to identify, seek alignment on, and address top priorities. As the global medicines supply chain has grown more complex, and biomedical advancements arrive with greater frequency, USP encounters new challenges and opportunities that benefit from collaboration. Through new and longstanding collaborations, USP has advanced quality and supported a more resilient global medicines supply chain.

Key areas of progress over the past fiscal year include:

#### **Asia-Pacific Economic Cooperation**

**Forum** – USP's collaborations with the Asia-Pacific Economic Cooperation (APEC) forum

and FDA resulted in two key stakeholder events during the year.

- ▶ As part of the U.S.'s 2023 host year activities for the APEC forum, USP and FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened over 500 stakeholders from 45 countries representing regulatory agencies, industry, academia, nonprofits, and multilateral organizations. The two-day meeting featured knowledge-sharing and discussion of topics aimed at advancing global supply chain resilience, including public health priorities, the impact of the COVID-19 pandemic, impurities, and resources available to help ensure supply chain security. The event stemmed from ongoing work of the USP-APEC Center of Excellence for the Medical Product Supply Chain, and USP's service on the Steering Committee of the Global Medical Product Quality and Supply Chain Integrity Priority Work Area,

chaired by FDA. Through the latter efforts, USP was announced in April 2023 as the new host of the APEC Supply Chain Security Toolkit, which now resides permanently on the USP website.

- ▶ In May 2023, the USP-APEC Center of Excellence for Advanced Therapies held a two-day virtual training on chemistry, manufacturing, and control challenges involved in chimeric antigen receptor (CAR) T-cell therapy. FDA and key industry leaders provided insights into the development and manufacturing of CAR T-cell therapy to address knowledge gaps between academia and real-life applications. More than 150 regulators involved in product assessment and registration from APEC economies and other regulatory bodies participated in the webinar and dialogue. The event stemmed from USP's ongoing service on the Steering Committee for the Advanced Therapies Priority Work Area, which is co-led by FDA and the Singapore Health Sciences Authority.

#### **FDA's Drug Competition Action Plan –**

USP continued its work supporting FDA's list of Off-Patent, Off-Exclusivity Drugs without an Approved Generic (the OPOE list) under FDA's Drug Competition Action Plan to help increase patient access to important generic drug therapies. Over the past year, USP published five new official monographs associated with five different drug products on the OPOE list in the *U.S. Pharmacopeia-National Formulary (USP–NF)*. Since 2017, USP has developed a total of 19 monographs associated with 18 drug products on the OPOE list.

- ▶ USP established a program to identify and prioritize development of monographs associated with complex generics on the OPOE list and pursued related collaboration with stakeholders.

- ▶ USP's Generics Access Plan website content was expanded to include links to draft monographs proposed in *Pharmacopeial Forum* to further promote development of monographs that would support access to OPOE items.
- ▶ Relationship-building efforts between USP and FDA communications teams led to dissemination of key USP messaging across FDA communications channels, including the agency's Generic Drugs Updates email listserv, which goes to 97,000+ subscribers.

**Compounding** – USP continued to develop monographs to help ensure the quality of products on FDA's list of bulk drug substances that can be used in compounding drug products. (See *Compounding* Resolution update.)

**Partnering for Education** – FDA and USP collaborated on several educational efforts to advance key health priorities:

- ▶ Agency subject matter experts participated in multiple USP-organized events during the year – including those focused on cell and gene therapies, and nitrosamine impurities – and addressed queries from industry and other stakeholders.
- ▶ The Biologics Sector of the USP Convention collaborated with FDA's Center for Drug Evaluation and Research (CDER) to develop an infographic that can inform dialogue between patients and healthcare providers on the quality of biosimilars. The infographic, launched in September 2022, was developed with input from multiple stakeholders, including patient advocacy organizations, innovator and generic manufacturing trade organizations,



healthcare societies, and payor and pharmacy benefit manager groups.

### **FDA Engagement in USP Convention**

**Sector Meetings** – FDA staff from CDER's Office of Therapeutic Biologics and Biosimilars spoke at several USP Convention Sector meetings, including discussions on mitigating vaccine hesitancy and misinformation, and provided updates on the agency's Biosimilar User Fee Amendments (BsUFA) III Regulatory Research Pilot Program.

**FDA-India Engagement** – USP built on pre-pandemic engagements with FDA's India office, initiating further collaborations with the agency on priorities for the region aimed at strengthening medicines supply chain resilience. These priorities include regulatory strengthening, addressing nitrosamine impurities, and lowering barriers to adoption of advanced manufacturing technologies.

- ▶ FDA's India office participated in the USP Convention's regional chapter meeting, which provided a venue to connect with regional regulators and understand their priorities. This further facilitated FDA's visits to respective Southeast Asian countries and meetings with regional regulators. Key priorities for continued engagement include scientific areas prioritized for extensive advocacy and capacity building (e.g., nitrosamines and quality compliance), identification and support of emerging pharmaceutical manufacturers, and continuous manufacturing.
- ▶ USP held a workshop on nitrosamines in February 2023 in India, convening 270 participants from industry and regulatory agencies.

### **Global Engagement to Address Impurities**

– USP engaged stakeholders globally around solutions to help control the risk of impurities

in medicines, including through related USP standards and training. (See *Impact Expansion* Resolution update.)

- ▶ USP collaborated with FDA and global regulators to develop mitigation strategies to address diethylene glycol-contaminated medicines. USP also worked with the Vietnam National Institute of Drug Quality Control to initiate a pilot on testing for nitrosamine impurities to strengthen post-marketing surveillance of angiotensin receptor antagonists (sartans).
- ▶ USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority.
- ▶ USP deepened its engagement with regulators in Latin America, the Asia-Pacific, and the Middle East and North Africa regions to address challenges posed by the potential for nitrosamine impurities in medicines and to build awareness of compendial and non-compendial solutions.
- ▶ USP continued to expand and diversify its Nitrosamine Exchange online community, adding about 2,000 new members, including members from 30 new countries.
- ▶ USP worked with the Indian Pharmaceutical Alliance (IPA) to cosponsor the 2023 USP Workshop on Nitrosamine Impurities in Hyderabad, India.

### **U.S. Government Supply Chain**

**Engagement** – USP continued to share data and data-derived insights from USP's Medicine Supply Map with the White House, FDA, and other federal agencies to inform policy decisions in support of increasing supply chain resilience. (See *Evidence Generation to Inform Policy* Resolution update.) USP is also working with the Administration for Strategic Preparedness and Response to analyze key starting



materials for a set of critical medicines to address potential supply chain vulnerabilities.

**Engagement with Policymakers** – USP worked to address pharmaceutical supply chain challenges by engaging with Congress and through related policy development. In March 2023, USP staff testified before the Senate Homeland Security and Governmental Affairs Committee on the capabilities of the USP Medicine Supply Map and ways that related insights can help prevent or mitigate supply chain disruptions. USP also submitted a statement to the House Energy and Commerce Committee regarding drug shortages. USP has also submitted several responses to general requests for information from policymakers on issues relating to drug shortages and supply chain issues.

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

- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit for Medical Products, and will collaborate with partners such as the Alliance for Safe Online Pharmacies to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ USP will continue to expand its work in support of FDA's Drug Competition Action Plan to prioritize standards that

support specific complex generics and aim for more publicly facing deliverables co-authored with FDA to address key public health issues.

- ▶ USP will continue dialogue with FDA to encourage technical and science policy interactions outside of USP on topics like impurities, nitrosamines, complex generics, and excipient quality.
- ▶ USP will continue to strengthen its collaboration with FDA's India office on key scientific priorities as well as advocacy and capability building activities.
- ▶ USP will convene global conversations to bring together FDA subject matter experts and industry on key quality-related topics.
- ▶ USP will seek additional opportunities for FDA to engage USP Convention Members to inform, share solutions, and promote trust around shared priorities.
- ▶ USP will continue to engage with FDA and other stakeholders at various levels to demonstrate our portfolio of resources under development to strengthen supply chain resilience.

#### **Contact**

For additional information on this Resolution, contact Sohail Mosaddegh at [sohail.mosaddegh@usp.org](mailto:sohail.mosaddegh@usp.org).





# Resolution

## Efficiency in Standards Development and Revision

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.

### Year 3 Update

USP standards support global medicines supply chain resilience, helping to increase access to safe, quality medicines people can trust. USP continued to engage with FDA, industry, healthcare practitioners, and other stakeholders to maintain a modernized *U.S. Pharmacopeia-National Formulary (USP–NF)* compendia through collaboration and implementation of efficient processes for continually developing and revising quality standards. This included working with FDA and industry on new approaches for sharing the information needed for efficient standards setting, advancing access to quality medicines, and helping protect patients.

Key areas of progress over the past fiscal year include:

**Adapt-Transform-Progress –** USP continued to operationalize solutions through its Adapt-Transform-Progress (ATP) initiative, advancing the standards development process for greater efficiency

and effectiveness. For example, USP marked significant progress in its implementation of a Business Process Management (BPM) application that facilitates automation of select processes within standards development, resulting in increased consistency and control. USP launched the first release of the BPM platform for documentary standards in February 2023 and continued to develop enhancements – including for its existing BPM platform for reference standards – to improve functionality of the system. By leveraging the BPM platform for documentary standards, USP operationalized various case-based methods to bolster its strategic approach to standards development.

**Standards Engagement Model –** This cycle, USP is focused on advancing a more iterative and agile approach to standards development. During the fiscal year, USP developed an agile framework for engagement throughout and before the

standards lifecycle begins, delivering on its commitment to efficient and effective standards development. Collaborating with stakeholders, USP focused on early and appropriate stakeholder involvement, early insights, and input for "fit-for-purpose" standards, all while ensuring transparency and accessibility. This approach included alignment with USP's principles for diversity, equity, inclusion, and belonging (DEIB), in partnership with the USP Equity Office. USP continues to further integrate DEIB principles across the Council of Experts (CoE) through adoption of a DEIB-centric approach for CoE candidate selection and implementation of USP's health equity principles. The following are key points of progress:

- ▶ Review of lessons learned and best practices to enhance USP stakeholder engagement approaches, and rollout of a stakeholder engagement model identifying four phases – early, pre-compendial, compendial, and post-publication – to drive a more consistent approach to stakeholder engagement.
- ▶ Revamping how Expert Committee chairs are identified, to include a more rigorous and transparent process and diverse pool of candidates.
- ▶ Expanding the Call for Candidates to be more inclusive to promote and support diversity, and broadening the Scientific Expert Fellowship Program with incremental increases in the cohort of fellows each fiscal year.
- ▶ Development and execution of a robust Expert Volunteer Experience strategy that will strengthen the experience for volunteers, growing their commitment to USP and attracting the next generation of volunteers.
- ▶ Providing support for a participant in the National Urban Fellows program throughout the year.

**Science Quality Framework** – The Science Quality Framework (SQF) establishes a

consistent set of focus areas and principles that help guide our science priorities and the work of our expert bodies. Related accomplishments during the fiscal year included:

- ▶ Advancements in the detection of impurities, including new *USP General Chapter <477> User-Determined Reporting Thresholds*, which provides an approach for determining the appropriate numeric reporting threshold value for organic impurities test procedures in monographs within the *USP-NF*. In addition, USP has prioritized its focus on detection of nitrosamines and how best to mitigate the risk of these impurities being above acceptable levels. This includes a physical analytical impurities (PAIs) catalog for nitrosamines as well as other PAIs.
- ▶ Increased prioritization of complex generics, including documentary standards and physical materials needed by manufacturers and vendors for products with complex active pharmaceutical ingredients (APIs), formulations, routes of delivery, dosage forms, and drug-device combination products. To date, USP has identified more than 100 candidate materials, including extractables and leachables, dissolution materials, reagents, non-U.S. APIs, and injectable physical materials.
- ▶ Greater attention to supply chain resiliency with the development of *USP General Chapter <1083> Supplier Qualification* to help assist in qualifying suppliers of raw materials, ingredients, and services for medicines, foods, and dietary supplement ingredients. This can help safeguard the integrity of supply chains globally.
- ▶ Addressing advanced manufacturing techniques – including development of a technical guide on control strategy as

well as three proposed new standards for the physical properties of material used in pharmaceutical continuous manufacturing (PCM) – to help reduce potential industry barriers to widespread PCM adoption.

- ▶ Preparing for anticipated demand for the digital evolution of standards through a pilot initiated for USP's nuclear magnetic resonance (NMR) analysis software platform USP-ID, which allows NMR spectral data to function as digital references by combining high-quality chemical reference databases with smart algorithms that automate identity, strength, and purity analysis of molecules in complex mixtures. (See Digital Transformation of Standards Resolution update.) In addition, USP revised General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Applications of Nuclear Magnetic Resonance Spectroscopy* in response to comments received from stakeholders, facilitating the use of NMR as an analytical technique for demonstrating quality. USP also initiated General Chapter <1762> on solid-state NMR to incorporate modern technologies and contemporary practices of NMR spectroscopy, and published a *Stimuli* article on "Consistent Terminology for Advancement of NMR Spectroscopy."

**Government Liaison Program** – USP collaborated with FDA on the Government Liaison Program across several key areas during the year, including:

- ▶ Enhancing stakeholder involvement in standards-setting activities by increasing the number of FDA government liaison appointments within USP's expert bodies to 316, thus further integrating FDA's perspective

while ensuring better alignment with stakeholder needs and expectations.

- ▶ Drafting a USP-FDA memorandum of understanding (MOU) aimed at streamlining information exchange, fostering efficient quality standards development, and bolstering collaborative efforts, demonstrating USP's commitment to facilitating collaboration and promoting quality standards.

**Information Sharing** – USP, in collaboration with the FDA and industry, continued to advance standards development by enhancing information exchange and revising compendial processes. This progress, which included incorporation of key language in FDA communications to industry, aimed to inform industry on how to collaborate with USP to develop standards.

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

- ▶ USP will continue to advance initiatives to develop standards and other informational resources that respond to key trends in science and technology, and will leverage opportunities to assist stakeholders in enhancing the quality of drug products, excipients, and foods across the global supply chain.
- ▶ USP will complete the second major BPM release focused on documentary standards, while simultaneously advancing BPM development to support both documentary and reference standards, further demonstrating our commitment to enhance case-based standards development.
- ▶ The draft FDA-USP MOU will be finalized and submitted for agency and USP approval.
- ▶ USP will implement a refined, real-time reporting mechanism enabling FDA liaisons, USP staff, and volunteers to swiftly highlight operational successes

and challenges, which will also facilitate prompt identification of trends and issues across expert bodies by USP.

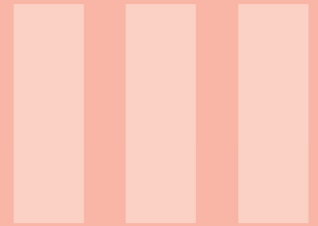
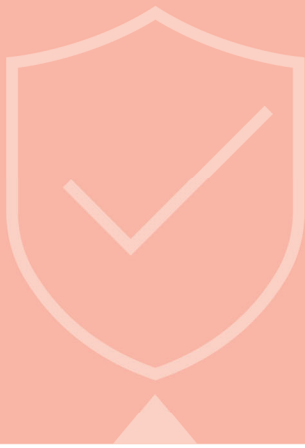
- ▶ USP will aim to expand its engagement across FDA by coordinating training in agency centers that are less familiar with USP-NF.
- ▶ USP will advance its collaborative efforts with the FDA and the Association for Accessible Medicines, focusing on a joint webinar on standards development targeted for launch in autumn 2024 (Fiscal Year 2025).
- ▶ USP will continue to streamline efforts to leverage the four-phase stakeholder engagement model by improving the

ability to receive feedback across the different phases, increasing ease of access to information as well as ways to deliver scientific content.

- ▶ USP will continue to integrate USP's health equity principles, and principles for diversity, equity, inclusion, and belonging, into the USP Expert Volunteer experience and across the CoE to broaden its composition.

### **Contact**

For additional information on this Resolution, contact Jeff Johnson at [JJ@usp.org](mailto:JJ@usp.org).



# Resolution

## Quality Standards

USP will be a definitive source and a recognized scientific leader in public quality standards to help protect patient and consumer safety, and to meet the needs of regulators, policy makers, healthcare practitioners, and industry working in evolving global regulatory environments. In doing so, USP will work to identify emerging trends; align with analytical, manufacturing and other technological advances; and develop innovative and agile approaches to address current and future needs of industry, regulators, practitioners, consumers, and patients.

## Year 3 Update

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

Key progress areas over the past fiscal year include:

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

manage the related risks to the supply chain.

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

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

### **Contact**

For additional information on this Resolution, contact Gabriel Giancaspro at [gig@usp.org](mailto:gig@usp.org).



# IV Resolution

## Access to Biologics

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

### Year 3 Update

USP continues to expand its portfolio of standards, best practices, and tools to support the quality and consistency of biologics, a fast-growing segment of medicine such as recombinant therapeutic proteins including monoclonal antibodies, vaccines, peptides, oligonucleotides, tissues, and cell and gene therapies. This year, USP continued to develop tools and solutions to support emerging modalities, including mRNA and viral vector-based vaccines as well as cell and gene therapies. These efforts help build a common understanding of relevant quality attributes and test methods for biologics to support quality and consistency, thereby strengthening the integrity of the global supply chain for biologics. In addition, these tools offer greater efficiency to industry in the development process and support regulatory reviews. USP also continued to explore 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 areas of progress over the past fiscal year include:

**Monoclonal Antibodies** – USP expanded its portfolio of solutions to support quality assessment of monoclonal antibodies (mAbs) and collaborated with FDA to evaluate new analytical tools that can accelerate biosimilars development.

- ▶ USP was awarded a two-year, \$1.5 million grant under the FDA Biosimilars User Fee Act Research Program to enhance biosimilars development and regulatory science. The research focuses on assessment of the multi-attribute method (MAM), an emerging analytical method that has the potential to provide more detailed information on product quality, thereby increasing the efficiency of biosimilars development.
- ▶ The MAM Expert Panel completed a draft of *USP General Chapter <1060> Best Practices for Mass Spectrometry-Based Multi-Attribute Method for Therapeutic Proteins*, which will be published in

*Pharmacopeial Forum (PF)* in September for public comment.

- ▶ USP published the “Monoclonal Antibody (mAb) Analytical Guide,” which outlines mAb testing needs at various phases of development and provides links to USP resources to support mAb quality.
- ▶ USP expanded its standards and tools for assessment of host cell protein impurities in biologics. Activities included publication in *PF* of new *USP* General Chapter <1132.1> *Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry*, and release of a new reference material.

#### **Advanced Manufacturing and Analytics –**

USP responded to stakeholder feedback on challenges implementing pharmaceutical continuous manufacturing and in-line/at-line analytics for biologics.

- ▶ 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, vendors, academia, and regulators. A publication summarizing the key themes from the workshop was published in *Pharmaceutical Engineering* (July/August 2023 issue).
- ▶ USP initiated a new Expert Panel on the topic of in-line/at-line monitoring and real-time release testing to develop a new general chapter that will provide guidance on the application of process analytical technology (PAT) and provide a summary of related technologies, including their strengths and weaknesses.

**Vaccine Quality –** USP continued its efforts to support quality and consistency of

vaccines through publication of new tools and educational offerings and continued its engagement with global stakeholders.

- ▶ USP expanded its vaccine quality toolkits to include DNA, virus-like particle, and attenuated virus vaccines.
- ▶ USP published a second edition of the Analytical Procedures for mRNA Vaccine Quality: Draft Guidelines, which incorporates feedback and more than 15 new methods received from stakeholders.
- ▶ USP expanded engagement efforts, developing new educational materials and trade articles, and presenting over 15 talks on vaccine quality.

**Advanced Therapies –** USP continued to advance development of standards and tools to support the quality of advanced therapies, with particular focus on adeno-associated virus (AAV)-based gene therapies and lentivirus-based cell therapies.

- ▶ USP, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), and the National Institute of Standards and Technology completed a multi-laboratory study comparing analytical techniques for analysis of empty and full AAV capsid gene therapy. Preliminary results were presented at the NIIMBL national meeting and prepared for publication.
- ▶ The AAV Expert Panel continues to advance a new chapter on best practices for manufacturing and quality control of AAV-based gene therapies.
- ▶ USP initiated a new Expert Panel on lentiviral cell therapy. The panel is drafting a new general chapter on best practices for the design, manufacturing, and quality control of lentivirus-based cell therapies.

**Analytical Reference Materials** – USP worked to introduce a new class of products called analytical reference materials (ARMs). These products complement USP's reference standard portfolio by providing materials for use during development and characterization of biotherapeutics. The first ARM, which launched in June 2023, consists of a common host cell protein impurity found in biological products derived from a common bioproduction cell line. ARMs in development aim to support other modalities, including peptides, vaccines, and cell and gene therapies.

**Raw and Starting Materials** – USP advanced both documentary and physical reference standards and materials to support quality assessments of raw and starting materials.

- ▶ The Plasmid DNA Expert Panel completed a draft of *USP General Chapter <1040> Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies*, which will be published in *PF* in November 2023 for public comment.
- ▶ USP released five new reference standards for DNA phosphoramidites, which are critical raw materials for oligonucleotide therapeutics. Additional raw material standards are in development to support other types of oligonucleotides.
- ▶ To provide guidance on quality starting materials in the production of oligonucleotide drug products, USP's BIO 1 Expert Committee (EC) recruited expert advisors to draft a white paper in this area as an initial step toward developing a related general chapter.

**Stakeholder Engagement** – Throughout the year, USP convened stakeholders to help identify and inform solutions that support trust in supplies of quality biologics and to

raise awareness of USP solutions that can accelerate quality assessments of biologics. Some highlights in FY23 were:

- ▶ The Biologics Sector of the USP Convention collaborated with the FDA Center for Drug Evaluation and Research to develop an infographic to inform dialogue between patients and healthcare providers on the quality of biosimilars. The infographic was launched in September 2022 and was informed by multiple stakeholders, including patient advocacy organizations, innovator and generic manufacturing trade organizations, healthcare societies, and payor and pharmacy benefit manager groups.
- ▶ USP held its Asia-Pacific Economic Cooperation (APEC) forum Center of Excellence training in May 2023 for approximately 150 regulators from the APEC region and beyond to address knowledge gaps about quality considerations for chimeric antigen receptor (CAR) T-cell therapies.
- ▶ The Fiscal Year 2023 Biologics Stakeholder Forum focused on CAR T-cell chemistry, manufacturing, and control considerations. Based on feedback from attendees, it's clear that additional guidance is needed in this area and input from the event will help the new Lentiviral Expert Panel as they begin their work.
- ▶ USP staff delivered approximately 60 presentations at industry conferences and other stakeholder events focused on biologics.
- ▶ USP Biologics staff published eight trade journal articles and one peer-reviewed article to raise awareness of solutions supporting the quality of proteins, cell and gene therapies, vaccines, and peptides.

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

- ▶ USP will expand its portfolio of standards and materials for mAbs, with a particular focus on common impurities, functional assessment, and new analytical techniques such as MAM.
- ▶ USP will continue to advance draft guidelines for mRNA and viral vectored vaccines based on stakeholder feedback, including evaluating and validating methods. Relevant reference standards and materials will also be identified and developed to support platform methods for these new vaccine modalities.
- ▶ USP will continue to expand its portfolio of standards and tools to support cell and gene therapies, including new general chapters on plasmid starting material, AAV-based gene therapies, and lentivirus-based products and reference standards and materials to support common test methods.
- ▶ USP will continue to advance work on standards for protein biomarkers used in drug development to support consistent measurement of biomarkers across different immunoassay platforms and kits, with a particular focus on biomarkers used in cell therapy and oncology.
- ▶ USP will investigate opportunities to develop microbiology testing reference materials for in-process and release testing of pharmaceuticals in support of existing USP documentary standards. The objective is to facilitate implementation of rapid microbiology testing methods that support industry efforts to make more affordable high-quality drugs for larger patient populations through innovative technologies.

## **Contact**

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# Resolution

## 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.

### Year 3 Update

USP standards build trust and confidence in healthcare breakthroughs, support market access, and advance the quality of medical products, strengthening the medicines supply chain. Given the abundance of new medicine modalities and manufacturing advances, the opportunity is enormous 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 areas of progress over the past fiscal year include:

#### **Pharmaceutical Continuous**

**Manufacturing** – USP's approach to identifying and addressing industry barriers to adoption of pharmaceutical continuous manufacturing (PCM) shifted gears from planning to executing on long-term initiatives across all three pillars of the strategy, including consulting, science, and standards.

The goal is to help companies interested in pursuing PCM unlock its potential efficiencies, which can facilitate increased geographic diversity in manufacturing and bolster medicines supply chain resilience.

- ▶ USP opened its Advanced Manufacturing Technology laboratory in Richmond, VA, and launched its analytical lab services offerings (also known as R&D analytical solutions) in December 2022. The analytical lab services provided in Richmond and at USP's facilities in Rockville, MD, will be used to characterize materials and develop and qualify methods to help ensure the quality of medicines made with PCM. At the same time, the services will help industry contain production costs and optimize efficiencies in staffing and resources.
- ▶ USP collaborated through a strategic alliance to develop new methods for three active pharmaceutical ingredients (APIs), which will be included in the Biomedical Advanced Research and Development Authority (BARDA) Strategic API Reserve for essential medicines.



- ▶ Pharmatech Associates (a USP company) executed three projects to facilitate adoption of PCM by providing organizations with targeted business strategy development support and upskilling staff through customized education and training.
- ▶ USP launched the Continuous Manufacturing Knowledge Center (CMKC) in collaboration with the National Institute for Pharmaceutical Technology and Education (NIPTE), supported in part by funding awarded to NIPTE by FDA. The online platform is intended to help address potential knowledge gaps by providing stakeholders with rapid access to the latest, updated information to help identify and address barriers to adoption of PCM.
- ▶ USP joined the Alliance for Building Better Medicines – a central Virginia regional coalition of municipal and state government, industry, academia, and not-for-profits with the goal of leveraging PCM and other advanced manufacturing technologies (AMTs) to help build medicines supply chain resilience.
- ▶ To ensure that USP's AMT work remains nimble, this year we made two strategic adjustments. First, USP shifted the strategic focus of laboratory services offerings from commercially-focused to a donor and government focus. This allowed USP to develop and advance projects specifically related to strengthening the supply chain through the application of AMTs like PCM. Second, USP launched the U.S. Government Federal Practice. This new department within USP's Global Health and Manufacturing Services division is designed to build relationships across the U.S. government sector to expand USP's

solutions within and beyond our two main partners, FDA and the U.S. Agency for International Development (USAID).

- ▶ USP launched a flow chemistry laboratory in Hyderabad, India, to support industry, governments, and USAID- and other donor-funded projects, including development of new, economically and sustainably viable routes of synthesis for APIs and key starting materials.
- ▶ USP developed the first in a planned series of technical guides for PCM, covering development of control strategies for continuous manufacturing of solid oral dosage form drug products.
- ▶ USP organized a July 2023 workshop on identifying and addressing barriers to continuous manufacturing adoption, convening 150 stakeholders from industry, academia, and FDA, in Rockville, MD.

**3-D Printing of Pharmaceuticals – 3-D printing (3DP) initiatives at USP graduated from early evaluation to the formal programming and standards development phase. These initiatives aim to help unlock the potential for 3DP technology to enable production of smaller batches of medicines with tailored dosages, shapes, sizes, and release characteristics to facilitate personalized medicine.**

**Advanced Technology Evaluations – USP continued to identify, explore, and support advancement of new production and distribution methods, new medicine modalities, emerging analytical technologies, and informatics trends and applications.**

- ▶ USP launched new research projects to inform its understanding of imaging analytical technologies and to explore green chemistry and other tools to



improve pharmaceutical environmental impact (such as with per- and polyfluoroalkyl substances).

- ▶ In February 2023, USP hosted its first open forum to engage stakeholders on their needs for improving the pharmaceutical environmental footprint.
- ▶ USP initiated studies to evaluate the potential substitution of solvents to reduce environmental impact.
- ▶ USP initiated a pilot evaluation of algorithmic modeling for data comparability of handheld instruments.
- ▶ USP continued to advance polymer material characterization through applications of light scattering technologies.

**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 increasingly challenging. This year, through robust engagement strategies, USP advanced initiatives to develop a deeper understanding of gaps and opportunities to meet stakeholder needs, identifying appropriate standards, materials, and solutions. Notable accomplishments include:

- ▶ Development of a plan to introduce new extractable and leachable standards, published as a *Stimuli* article in *Pharmacopeial Forum* in July 2023.
- ▶ Convening a two-day complex injectables roundtable that welcomed over 800 global registrants, including those from industry, regulators, and other stakeholders. As a result, USP is developing a needs-based scientific strategy to support stakeholders in the development of complex injectables. Examples

include creating a general chapter for microsphere complex products and developing application notes or methods for molecular weight determination of complex polymers.

- ▶ USP conducted a global regulatory landscape assessment, charting global regulations impacting complex products, documenting global regulatory pathways, and identifying key opportunities for engagement on complex products.
- ▶ USP further engaged with FDA and the Center for Research on Complex Generics (CRCG) through USP-FDA quarterly meetings and discussions with CRCG on nitrosamines and other topics.

### **Nuclear Magnetic Resonance**

**Spectroscopy** – USP advanced multiple initiatives leveraging nuclear magnetic resonance (NMR) spectroscopy technology for use in quality assurance.

- ▶ USP revised General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Applications of Nuclear Magnetic Resonance Spectroscopy* in response to public comments received and to facilitate use of NMR as an analytical technique for demonstrating quality.
- ▶ USP initiated General Chapter <1762> on solid-state NMR to incorporate modern technologies and contemporary practices of NMR spectroscopy and published a *Stimuli* article on “Consistent Terminology for Advancement of NMR Spectroscopy.”
- ▶ USP sponsored its second quantitative NMR (qNMR) symposium in January 2023 with over 500 global attendees, concluding with a roundtable with the qNMR community in China.

- ▶ USP advanced work on the qNMR Knowledge Hub, which is expected to launch in Fiscal Year 2024.
- ▶ In collaboration with a third-party vendor, USP completed the first Good Manufacturing Practice (GMP)-validated method for NMR-based digital references.
- ▶ USP completed feasibility studies for potential use of NMR to identify diethylene glycol (DEG) in cough syrup and create a digital reference for cannabidiol (CBD) suitable for identity and assay testing.
- ▶ In collaboration with the University of British Columbia Department of Chemistry, USP demonstrated proof of concept for a benchtop NMR process analytical technology (PAT) setup for reaction monitoring leveraging USP's USP-ID NMR analysis software. (*See Digital Transformation of Standards Resolution* update.)

**Drug Dissolution** – In collaboration with the New Jersey Institute of Technology, USP completed studies focusing on the hydrodynamics of reduced-volume dissolution systems using particle image velocimetry (PIV) technologies. As a result of these studies, USP is preparing a scientific paper addressing the findings for publication in a peer-reviewed journal.

**Graph Database and Artificial Intelligence Capabilities** – USP continued to accelerate its understanding of graph databases and artificial intelligence (AI) capabilities to uncover hidden connections and anomalies across complex data assets and create data-driven predictions and personalized recommendations to meet stakeholder needs. 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 and create an “ecosystem” view, potentially enabling increased utilization of a range of USP products and services. By leveraging graph databases and AI capabilities, USP has the potential to innovate and transform our business operations, customer experiences, and strategic insight generation as a more digitally-enabled organization.

- ▶ USP matured its understanding of the operational and business impact of graph databases by developing use cases and proofs of concept to understand requirements for scaling graph databases into an enterprise capability.
- ▶ USP developed an early understanding of AI capability and the current market landscape, specifically around large language models (LLMs). Through collaboration with business owners, USP built several use cases to gain additional insight into the capability.
- ▶ In a cross-functional effort, an AI strategy workshop was conducted in January 2023 to understand the potential benefits and impact of AI tools and capabilities on USP's business and operations. Input gathered at the workshop has been incorporated into the development of an AI strategy that will recommend an enterprise approach to AI.

### Planned for Remainder of the Cycle

- ▶ USP will develop a mechanism for gathering earlier stakeholder feedback on its portfolio of new solutions to facilitate industry adoption of innovations.
- ▶ USP will continue to identify, evaluate, and incubate emerging technologies for potential integration into the organization's quality-focused solutions.

- ▶ USP plans to leverage PAT to support expanded adoption of PCM through formation of a PAT Expert Panel and expanded laboratory capabilities for PAT research in live manufacturing systems.
- ▶ USP will develop additional technical guides for PCM best practices.
- ▶ USP will publish data evaluating the hydrodynamics of reduced-volume dissolution systems and determine potential applications for monograph inclusion. USP will also conduct computational fluid dynamics studies to understand hydrodynamics across multiple volumes of dissolution media.
- ▶ USP will consolidate learnings on knowledge graph prototyping, propose a roadmap for enterprise

implementation, and continue to identify use cases for AI to enhance USP's current products and ways of working.

- ▶ USP will strengthen our business case for scaling graph databases enterprise wide and will continue to build our understanding for adoption of AI capabilities, such as LLMs and natural language processing.
- ▶ USP aims to launch the qNMR Knowledge Hub in Fiscal Year 2024.
- ▶ USP will launch the USP-ID NMR software. (*See Digital Transformation of Standards Resolution update.*)

### **Contact**

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# Resolution

## Digital Transformation of Standards

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

### Year 3 Update

In a rapidly evolving, increasingly digital and interconnected world, USP is working to transform quality standards into interoperable digital components of the healthcare ecosystem to facilitate the ability of regulators, manufacturers, healthcare professionals, and other stakeholders to deliver quality medicines and help ensure a resilient medicines supply chain. To achieve this goal, USP has worked to structure our content for enhanced machine readability, transitioned to a more modern clinical informatics platform, advanced the development of digital reference standards, and leveraged data through advanced analytics to enhance visibility into the upstream medicines supply chain.

Key areas of progress over the past fiscal year include:

**Transition to Structured Content** – To integrate USP data into stakeholders' digital environments – thereby facilitating the ongoing industry modernization and digitization evolution known as "Pharma 4.0" – USP has been working to shift to machine-readable, structured documentary content. The effort will increase efficiency and decrease transcription errors through increased

automation. Building upon the data model created for documentary standards content, USP developed a mechanism to extract assay methods from raw substance monographs and used natural language processing to add granularity and structure to content through alignment with industry standards developed by the Allotrope Foundation. The scope was further expanded to include assay methods for identification of substances, and for impurities, as well as finished dosage form monographs. These efforts are foundational in establishing the capability to publish documentary standards content directly into Laboratory Information Management System (LIMS) vendors' software platforms, which are used in research and development and quality assurance/quality control labs.

**Transition to Modern Platforms** – USP continues to utilize two technology platforms to curate and disseminate scientific content as machine-readable, structured data.

- ▶ Clinical Architecture's Symedical platform provides a robust and scalable solution for USP to efficiently curate and publish standards and solutions as structured data directly into health IT systems used in healthcare delivery. During the year, USP staff and Expert Volunteers applied Symedical for a range of applications, including to





maintain the USP Drug Classification (USP DC), Medicare Model Guidelines, and *HazRx* <800> database for drug classification. Symedical also facilitated creation of a new audio pronunciation product with an artificial intelligence (AI) voice avatar, based on the work of the Pronunciation Expert Panel. In addition, Symedical was utilized to develop content for the Compounded Prescription Information Exchange, and initial data modeling was completed to maintain content developed by the Allergies and Intolerances Expert Panel.

- ▶ USP continued to utilize the Global Substance Registration System (GSRS) for curation and dissemination of chemical substance information, which serves as the source of record for chemical information. USP identified related quality metrics and a data governance framework and continued to refine integration of GSRS with USP's business process management system to improve information and data management throughout standards development. GSRS also continues to support the exchange of structured data with FDA as part of a Collaborative Research and Development Agreement.

**Digital Reference Standards** – USP made progress on efforts to advance digital reference standards during the year.

- ▶ USP's nuclear magnetic resonance (NMR) analysis software platform USP-ID received initial approval to launch from USP's Digital Impact Committee. USP elected to delay the launch of USP-ID when a late-breaking opportunity arose to integrate USP-ID into an industry-leading NMR analysis software package, which would facilitate access to a broader market. USP-ID allows NMR spectral data to function as digital references by combining high-quality chemical reference databases with smart algorithms that automate identity, strength, and

purity analysis of molecules in complex mixtures.

- ▶ A Council of Experts (CoE) subgroup, the Digital Standards Working Group, was formed, bringing together subject matter experts from across USP and the CoE to define the process by which digital standards become compendial. The working group defined digital standards at USP and began the process of drafting a monograph that references an NMR-based digital reference standard. Gaps in the existing compendial process for digital standards development were identified to inform gap-closing activities planned for Fiscal Year 2024.
- ▶ The first good manufacturing practices-validated method to use USP-ID and digital references for identity and assay testing was developed for ascorbic acid in collaboration with Steelyard Analytics.
- ▶ Collaboration with the University of British Columbia yielded a draft manuscript for automated reaction monitoring with benchtop NMR and USP-ID.

**Medicine Supply Map** – Embodying USP's desire to make better use of data through advanced analytics, USP continued to develop and improve its Medicine Supply Map surveillance system 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. During the year, Medicine Supply Map focus areas included insights into the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines, including antimicrobials. USP shared related insights with stakeholders, including U.S. federal agencies and the U.S. Congress, to facilitate decision-making aimed at bolstering supply chain resilience. (See *Evidence Generation to Inform Policy* Resolution update.)

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

- ▶ USP will integrate its USP-ID software into an industry-leading NMR analysis software package and plans to launch the joint product in the second quarter of Fiscal Year 2024.
- ▶ The Digital Standards Working Group aims to have the first monograph with a digital reference standard submitted to *Pharmacopeial Forum* by the end of the fourth quarter of Fiscal Year 2024.
- ▶ USP will implement and monitor data quality metrics and a data governance framework for GSRS.
- ▶ USP will further integrate GSRS as the source of record for chemical information with other internal systems, such as the USP Store.
- ▶ USP will establish an Executable Methods Advisory Group of key external stakeholders to evaluate sample data from *USP-NF* monographs and provide feedback to USP on the level of granularity of the data model and mapping to external ontologies, acceptable delivery formats and methods, and customer insights on how the data can be used within their workflows.
- ▶ USP will further expand its natural language processing engine to cover all types of methods (e.g., spectroscopy).
- ▶ USP will define a roadmap to incorporate structured monographs back into the editorial process.

## **Contact**

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# VII Resolution

## 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.

### Year 3 Update

USP provides education and training that support adoption and implementation of USP quality standards. These efforts address both new and revised standards that accelerate innovation, build trust and confidence in medical breakthroughs, advance the quality of medical products, and help ensure a resilient medicines supply chain. USP offers a wide range of education and training programs to diverse audiences in a variety of settings using state-of-the-art technologies and continues to identify and develop new courses to further support standards utilization.

Key areas of progress over the past fiscal year include:

**Expanded Program Reach** – USP continues to expand participation in education and training, exceeding our attendance target for Fiscal Year 2023 by more than 15% and achieving a new attendance record of more than 29,000, a 26% increase over last year. Factors driving growth include an expanded catalog and use

of on-demand offerings (representing 64% of total program attendance); a post-pandemic return to classrooms with nearly 2,000 attending courses in person; the licensing of USP courses to third parties; and strong geographic growth in China, Latin America, and the U.S. Expanded course offerings included those on revised compounding standards and the addition of several short, free webinars.

**Impact and Real-World Practice** – USP's continued focus on ensuring the impact of its courses on real-world practice is being measurably recognized by course attendees. Results of USP's Perception Monitor survey continue to show that 88% of attendees indicate USP courses and materials will have a positive impact on their quality of work. The potential for impact was demonstrated by high marks from students for new courses in particular, including those on storage and distribution, and compounding. For example, revised courses on *USP* General Chapters <795> and <797> on compounding showed significant increases in student-reported

impact on their work, scoring 92% and 94%, respectively.

**Improved Timelines** – During the year, USP continued to reduce the timeframe between when USP publishes a new or updated standard and when USP makes available the supporting educational course, by leveraging USP’s Curriculum Roadmap process, initiated in Fiscal Year 2021. Eleven out of 13 new or updated courses tied to consequential standards revisions were launched within a month of the standard publishing. During the year, the average time between a standard publishing and educational materials being available was exactly one month.

- ▶ The Curriculum Roadmap process was executed quarterly as planned, generating most of the new course development and update activity. This process reviews the portfolio of consequential and high-impact standards to identify when in their revision cycle course development should begin.
- ▶ During the year, USP made great strides in its cycle goal to establish a new mindset across the organization that will allow course materials to be available to stakeholders at the time of official publication of the related standards, with USP Education and Science partnering to begin work during the *Pharmacopeial Forum* comment period on related standards to ensure timely delivery of related course materials.

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

- ▶ USP will work to drive continued expansion of education and training attendance by making available on-demand courses in the South Asia region and leveraging subscription capabilities to offer ongoing learning opportunities for regulatory and manufacturing organizations.
- ▶ USP will continue to ensure that courses are relevant to students’ real-world practice and improve the quality of their work by engaging learners through interactive tools and applying appropriate instruction design principles. We will also continue to train and provide guidance to USP instructors to further develop their course facilitation skills.
- ▶ USP will leverage its growing commitment to providing educational materials at the time a new or revised standard is published to ensure stakeholders have the tools needed to implement standards effectively.

### **Contact**

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# VIII Resolution

## Regulatory Systems Strengthening

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

### Year 3 Update

Scientific and technological innovations continue to push the boundaries of what's possible for preventing, treating, and curing medical conditions, and for saving and improving patients' lives. These innovations, combined with an increasingly complex global supply chain, present challenges for national and regional regulators tasked with ensuring the safety, efficacy, and quality of medical products. At the same time, many regulatory authorities, particularly those in low- and middle-income countries (LMICs), still lack the basic regulatory functions to ensure the quality of essential medical products. This year, USP worked with regulatory authorities and other stakeholders in 25 countries, and at the regional and global levels with groups such as the World Health Organization (WHO), to strengthen regulatory systems. Much of this work is supported by government agencies, including the U.S. Agency for International Development (USAID), the Australian Department of Foreign Affairs and Trade, and others.

Key areas of progress over the past fiscal year include:

**Asia-Pacific Economic Cooperation Forum** – USP engages in the Asia-Pacific Economic Cooperation (APEC) Regulatory Harmonization Steering Committee and currently hosts two APEC Regulatory Centers of Excellence – one for the Medical Product Supply Chain and the other for Advanced Therapies. This work resulted in key developments during the year.

- ▶ As part of the U.S.'s 2023 host year activities for the APEC forum, USP and FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened over 500 stakeholders from 45 countries representing international regulatory agencies, industry, academia, nonprofits, and multilateral organizations. The two-day meeting featured knowledge sharing and dialogue aimed at advancing global supply chain resilience. This included discussion of the impact of the COVID-19 pandemic, impurities, resources available to help ensure supply chain security, and other public health priorities. (See *Collaboration with FDA and Other*

*Stakeholders on Health Priorities Resolution update.)*

- ▶ In May 2023, the USP-APEC Center of Excellence for Advanced Therapies held a two-day virtual training with more than 150 regulators from APEC and beyond on chemistry, manufacturing, and control challenges in chimeric antigen receptor (CAR) T-cell therapy to address knowledge gaps in real-world applications. (See *Collaboration with FDA and Other Stakeholders on Health Priorities Resolution update.*)
- ▶ USP serves on the Steering Committee of the Global Medical Product Quality and Supply Chain Integrity Priority Work Area, chaired by FDA. In this capacity, in April 2023 USP was announced as the new host of the APEC Supply Chain Security Toolkit, which now permanently resides on the USP website.

**Promoting the Quality of Medicines Plus Program** – This year, USAID’s funding of the Promoting the Quality of Medicines Plus (PQM+) program supported advancement of 25 national regulatory authorities in their maturity levels, as defined by the WHO Global Benchmarking Tool (GBT).

- ▶ PQM+ continued to support operationalization of the African Medicines Agency – an agency of the African Union and continent-wide regulatory body that is designed to complement existing regional initiatives and national regulatory authorities, and which will build on the efforts of the African Medicines Regulatory Harmonization (AMRH) initiative. This included PQM+ support for development of a continental vaccine lot release laboratory framework, an active pharmaceutical ingredient database,

and a concept note for the Bioequivalence Subcommittee of the Evaluation of Medical Products Committee.

- ▶ Nearly all national regulators supported by PQM+ are engaged in the implementation of the WHO’s GBT and working to improve their capacity to regulate medical products. The GBT enables objective evaluation of a country’s regulatory capacity and facilitates formation of institutional development plans to advance regulatory maturity.
- ▶ Collaboration with another USAID-funded program – the Medicines, Technologies, and Pharmaceutical Systems Program (MTaPS) – resulted in a joint MTaPS/PQM+ guidance document that guides LMICs in digitizing regulatory information and defines minimum common data standards to support LMICs in modernizing their regulatory information systems to improve oversight, efficiency, and data sharing.
- ▶ PQM+ provided expert feedback on multiple WHO guidelines and normative frameworks including the Global Model Regulatory Framework for Medical Devices, antimalarial drug resistance guidelines, and the Global Competency Framework for Regulators of Medical Products.
- ▶ As part of USAID’s Global VAX initiative, and recognizing the common interest and need for biomanufacturing competency development in LMICs, PQM+ conducted a workshop in South Africa in collaboration with AMRH, the South African Health Products Regulatory Authority, Afrigen Biologics and Vaccines, and the WHO mRNA Technology Transfer Hub. The December 2022 hybrid



workshop aimed to increase the vaccine manufacturing competency of industry, regulators, and academia, and provide a forum for advocacy. Also, as part of Global VAX, PQM+ supported six African regulatory authorities in visiting three vaccine manufacturing sites in India to help build a bridge between regulators and industry by fostering mutual support, harmonization, and collaboration.

- ▶ PQM+ teamed up with the U.S. FDA to develop and host a three-day online conference titled “Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines” in August 2022. The virtual conference provided an important opportunity for regulators, industry, and USAID staff to learn directly from FDA about drug approval pathways and application reviews; the role of the FDA in international regulatory harmonization; and collaboration among FDA, WHO, and national medicines regulatory authorities.

### **Diethylene Glycol and Ethylene Glycol –**

The WHO urged a call to action after substandard medicines identified in The Gambia, Indonesia and Uzbekistan, and several other countries, were found to contain unsafe amounts of diethylene glycol (DEG) and ethylene glycol (EG) as contaminants. In response, USP developed a toolkit for manufacturers, regulators, and other pharmacopeias to address DEG and EG contamination associated with allergy, cold, and cough medicines.

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

- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit, and will work with partners such as the Alliance for Safe Online Pharmacies to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ Through donor-funded programs, USP will continue to support national-level regulators in building capacity for essential regulatory functions, strengthening oversight of expanding local manufacturing sectors, and achieving advanced levels of regulatory maturity. PQM+ will also support efforts to strengthen regional harmonization through ongoing support to regional bodies.
- ▶ USP’s work through the PQM+ program will support AMRH with the issuance of a reliance framework for laboratory lot release in Fiscal Year 2024.
- ▶ Through technical expertise, guidance documents and toolkits, and technical assistance, USP will work to advance regulation of complex generics, impurities, and contaminants to protect patients and ensure access to quality-assured medical products.

### **Contact**

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# IX Resolution

## Compounding

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

### Year 3 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 right concentration or dosage. This includes cases where patient needs can't be met with conventionally manufactured medicines during times of shortage. USP develops standards, guidelines, and best practices for medicines that frequently need to be compounded to help ensure equitable access to a supply of quality medicines and public trust in quality compounded drug preparations.

Key areas of progress over the past fiscal year include:

**Revised Compounding Chapters** – USP published final versions of revised compounding chapters in the *U.S. Pharmacopeia–National Formulary (USP–NF)* in November 2022 to help ensure the supply of quality compounded medicines. Representing the culmination of 12 years of work by the USP Compounding Expert Committee (CMP EC) and related stakeholder engagement, the revised

chapters included *USP General Chapters <795> Pharmaceutical Compounding – Nonsterile Preparations* and *<797> Pharmaceutical Compounding – Sterile Preparations*.

- ▶ The final versions reflect extensive feedback from 15,000+ comments received over three public comment periods from a diverse group of stakeholders such as healthcare practitioners, state and federal regulators, academicians, and industry.
- ▶ As USP continues to encourage early implementation, the CMP EC also voted to extend the date on which the chapters become official to November 1, 2023, to facilitate adoption.
- ▶ To support understanding and implementation of the revised chapters, USP published several supplementary documents with details on the scientific considerations and rationale for the changes. USP also hosted four open forums for stakeholders to pose

questions to, and hear directly from, CMP EC members. In February 2023, USP held a hybrid workshop to explore various aspects of implementation. In addition, USP updated its related education courses on compounding and gave presentations on the revised chapters at 14 stakeholder conferences, workshops, and annual meetings.

- ▶ USP migrated the *Compounding Compendium* to the online platform for the *USP–NF* and *Pharmaceutical Forum (PF)* to enable compounders to have more timely access to the most updated USP compounding standards.

**Monograph Development** – USP continued to prioritize and develop compounded preparation monographs (CPMs) to help ensure the quality of compounded medicines.

- ▶ In close consultation with stakeholders, USP updated the list of CPMs prioritized for development, including several compounded injectable medicines frequently on shortage, and medicines for key populations such as pediatric and veterinary patients.
- ▶ During the year, USP published five new CPMs in the *USP–NF* and six draft CPMs in the *PF* for public comment.

### **Updated COVID-19 Resources for Compounders**

– USP worked with stakeholders to review and update resources created to support compounders in responding effectively to the COVID-19 pandemic and future pandemics.

- ▶ Updates were made to recommendations for compounding alcohol-based hand sanitizers to respond to frequently asked questions from stakeholders and to reflect changes by regulatory bodies.

- ▶ Following the end of the U.S. public health emergency declaration in May 2023, plans were made to carefully collate and archive pandemic-related resources for potential future use. The documents will also form the basis for a future pipeline of standards to be used by compounders to respond rapidly to supply chain challenges during public health emergencies and environmental or humanitarian disasters.

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

- ▶ USP will develop resources to address topics raised by stakeholders during the revision process of <795> and <797>. Intended for publication as *Stimuli* articles in *PF* for public comment, the resources will cover topics such as development of stability studies for compounded preparations, application of technologies in pharmaceutical compounding, enhancing quality assurance and quality control, and application of aseptic techniques in pharmaceutical compounding.

### **Contact**

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# Resolution

## Cannabis

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

### Year 3 Update

To help protect patient safety and public health, USP provides scientific and technical guidance for the evaluation of the quality of cannabis and cannabis-derived products, including for research purposes.

Key areas of progress over the past fiscal year include:

**Quality Specifications for CBD** – The Cannabis Expert Panel of USP’s Botanical Dietary Supplements and Herbal Medicines (BDSHM) Expert Committee reviewed public comments on proposed quality specifications for cannabidiol (CBD) as a drug substance that were previously published for comment in *Pharmacopeial Forum (PF)*. USP verified new analytical methods to ensure quality and safety that were received after publication of the proposal in *PF*. A revised proposal for the monograph is planned for publication after incorporation of the inputs from public comments. The intent is for the proposal to include analytical methods and acceptance criteria for CBD identification, quantitative estimation, and contaminant limits.

### **Quality Considerations for Cannabis**

**Research** – USP published for public comment in *PF* its proposed General Chapter <1568> *Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research*. The proposal provides specifications for quality attributes fundamental to characterizing the materials for clinical research. It is intended to complement related FDA guidance and includes analytical methods, acceptance criteria, and reference standards for assessing quality.

### **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*. The Cannabis Expert Panel evaluated public comments on the proposal and suggested changes that would require republication of the proposal for additional public comment.

**Addressing Impurities** – In response to concerns about health hazards associated with consumption of delta-8-tetrahydrocannabinol (D8-THC) products 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 then used to analyze commercial D8-THC samples. In May 2023, an article on the topic was submitted for publication in *Cannabis and Cannabinoid Research*.

**Certified Reference Materials for Cannabinoids** – USP began developing certified reference materials for cannabinoids. The goal is to provide ISO 17034:2016 compliant reference materials for determination of cannabinoids in cannabis product samples in the ISO/IEC 17025:2017 environment, which is expected by regulators. The materials for non-compendial application include information about assigned values, uncertainty values, homogeneity, and stability.

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

- ▶ USP and ASTM International cosponsored the Global Workshop on Cannabis Quality in December 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 June 2023 USP-ASTM webinar focused on Africa and Asia.
- ▶ USP continued to engage with the Cannabis Regulators Association

through a presentation about USP cannabis quality tools that gathered nearly 100 regulatory officials from over 30 states. USP also engaged FDA's Cannabis Product Council to update the agency on USP's scientific work related to cannabis and cannabis-derived compounds.

- ▶ USP submitted comments to the European Directorate for the Quality of Medicines & HealthCare (EDQM) and shared information to help inform the EDQM's proposed Cannabis flos monograph.
- ▶ USP created cannabis toolkits in four volumes that provide scientists, manufacturers, and regulators with the resources needed to help protect public health by establishing a framework for the consistent characterization of cannabis for medical use. Though not standards, they are intended to facilitate stakeholder engagement and education.

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

- ▶ USP will incorporate changes to its proposed specifications for CBD based on public comments and plans to publish a revised monograph proposal for CBD in *PF* for further public comment.
- ▶ Based on public comments received on proposed specifications for cannabis inflorescence outlined in General Chapter <1568> and the *Herbal Medicines Compendium*, USP plans to incorporate changes and repropose the standards.
- ▶ USP will continue to work with collaborating labs to study the phenomenon of "potency inflation/standards creep" related to the expression of cannabinoid content on a dry weight basis and will publish the findings.

- ▶ USP will continue to engage stakeholders to increase awareness about available cannabis quality resources.

### **Contact**

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# XI Resolution

## 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.

### Year 3 Update

Through collaboration with other global pharmacopeias, USP works to advance convergence around robust, science-based quality standards. Pharmacopeial convergence helps increase global alignment on the definition of quality as well as the best practices used to measure quality to build capabilities among emerging pharmacopeias. Convergence also allows for reduction and/or elimination of redundant or even conflicting quality standards in local regions, which otherwise can create barriers to global access to quality medicines. In this way, convergence allows governments, manufacturers, and healthcare professionals to expand access to safe, quality medicines, improve patient safety and public health, and create a more resilient global medicines supply chain. 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 and capability building among emerging pharmacopeias through scientific exchange, training programs, and other stakeholder engagement activities.

Key areas of progress over the past fiscal year include:

#### **Pharmacopeial Discussion Group**

**Collaboration** – USP worked with the Pharmacopeial Discussion Group (PDG), which originally included USP, the European Pharmacopoeia (EP), and the Japanese Pharmacopoeia (JP), to increase the reach and impact of PDG harmonization efforts.

- ▶ The Indian Pharmacopoeia Commission (IPC) joined the PDG in October 2022 as the inaugural participant in a pilot for expansion of group membership to include other prominent global pharmacopeias. IPC participated in PDG meetings and submitted implementation timelines for PDG standards. The one-year pilot is a critical step in the PDG's commitment to expand recognition of harmonized pharmacopeial standards and global convergence.
- ▶ The PDG drafted a commitment to confidentiality to emphasize that information required to support the PDG's efforts to harmonize excipients

monographs and general chapters would be handled confidentially by all involved parties. The commitments were signed by each participating pharmacopeia.

- ▶ The PDG reached consensus on harmonization of pharmacopeial standards for particle size analysis by dynamic light scattering. Particle size distribution is an important characteristic of dispersed systems such as emulsions, suspensions, and liposomal formulations. The harmonized language can be used to determine the average hydrodynamic particle size and the broadness of the size distribution of submicron particles dispersed in a liquid.
- ▶ The PDG added standards for three excipients – polysorbate 20, purified water, and water for injection – to its work program in response to stakeholder requests and will work towards their harmonization.

**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. The working group met monthly to determine key quality attributes for metal packaging systems and to incorporate feedback from colleagues at USP and ChP. By the end of the fiscal year, the group began developing an initial draft pharmacopeial chapter for further discussion.

**ICH Engagement** – USP has been an observer to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly since 2016 and participates in several ICH Expert Working Groups, including those on pharmaceutical

continuous manufacturing, analytical procedures, viral clearance, and impurity assessment for control of extractables and leachables.

- ▶ USP contributed to the development of draft ICH guidelines in these areas and submitted related technical comments to help ensure alignment with USP standards and policies. A significant milestone in November 2022 was the completion of the ICH guideline Q13 on continuous manufacturing of drug substances and drug products.
- ▶ USP and its PDG partners led efforts to develop a maintenance procedure for the ICH technical guidelines on pharmacopeial interchangeability. A process allowing for parallel implementation of PDG text along with local text was developed to give ICH member 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 June 2023.

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

- ▶ USP will work with PDG partners to evaluate lessons learned from the PDG expansion pilot and consider potential next steps. USP will lead efforts to enhance the efficiency of the PDG structure based on learnings from other models.
- ▶ USP will host the PDG's autumn 2023 meeting in Hyderabad, India. Afterwards, PDG and USP will convene India stakeholders to discuss harmonization-related topics.
- ▶ As USP, with its PDG partners, continues to focus on standards that will have the most impact on global convergence, emphasis will be placed on finalizing a harmonized standard for elemental impurities.

- ▶ USP will work with ChP to finalize a pharmacopeial chapter for metal packaging components.
- ▶ USP will continue to work toward harmonization of standards for excipients including polysorbate 20, purified water, and water for injection.
- ▶ USP will participate in the International Meeting of World Pharmacopoeias (IMWP) in November 2023 in Mexico City as part of IMWP's focus on identification of key topics that affect global pharmacopeias as well as developing principles for pharmacopeias in the area of environmental sustainability.

USP will conduct bilateral meetings with the EP, JP, and British Pharmacopoeia to identify key technical areas for future work. USP and the EP will continue to explore opportunities for joint webinars, including one on nitrosamines. USP and the JP will plan a joint workshop in 2024 focused on the value of pharmacopeias in enhancing the quality of medicines and strengthening the medicines supply chain.

### **Contact**

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# XIII Resolution

## Evidence Generation to Inform Policy

USP will generate and disseminate evidence upon which informed choices can be made for investment in regulatory and quality systems, and reforms to regulatory paradigms that advance quality, patient safety, and public health.

### Year 3 Update

Policymakers and stakeholders continue to grapple with long-standing vulnerabilities in the medicines supply chain. Factors including geopolitical dynamics, increasingly common natural disasters, and disruptions due to factors yet unknown necessitate the continuation of heightened efforts to build a more resilient global medicines supply chain and thereby help protect and improve public health. USP has devoted considerable effort to advancing medicines supply chain resilience by engaging directly with global stakeholders to understand related challenges and opportunities, and to inform policy recommendations, informational materials, and advocacy. USP has also continued to expand medicines quality-related research to build strong evidence and materials that can advance the policy advocacy and capability-building essential to medicines supply chain resilience.

Key areas of progress over the past fiscal year include:

**Supply Chain Resilience Dialogue and Insights** – USP engaged with stakeholders from across the globe with diverse perspectives to understand their challenges in strengthening supply chain resilience, generate dialogue to inform policymakers' understanding of global supply chain vulnerabilities and their potential impact on the availability of quality medicines, and advance USP solutions to bolster supply chain resilience.

- ▶ As part of the U.S.'s 2023 host year activities for the Asia-Pacific Economic Cooperation (APEC) forum, USP and FDA co-hosted the APEC Medical Product Supply Chain Dialogue in April 2023. This two-day meeting featured knowledge sharing and discussion of many topics important to advancing supply chain resilience. These 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 completed one-on-one interviews with more than 40 global supply chain experts to inform regulatory policy reform opportunities and engaged in roundtable discussions with stakeholders to better understand challenges and opportunities to advance policy.

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

- ▶ USP worked with the Center for Analytics & Business Insights (CABI) at Washington University in St. Louis to sponsor and help shape a research study to assess the perception of risk along the global medicines supply chain. The work was led by Anthony Sardella, Senior Research Advisor at CABI and a recognized leader in analytics and policy issues associated with the pharmaceutical supply chain.
- ▶ During the year, 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, procurement of materials used for medicines manufacturing, and antimicrobial resistance.

**Medicine Supply Map** – USP actively utilized its Medicine Supply Map surveillance system to assist stakeholders, including U.S. federal agencies and the U.S. Congress, 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. During the year, Medicine Supply Map 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.

- ▶ Five analyses that used Medicine Supply Map data were published during the year.
- ▶ Medicine Supply Map analyses contributed to myriad media stories highlighting challenges related to drug shortages. The analyses also were leveraged in several comment letters to U.S. federal agencies, informed testimony that USP provided to the Senate Homeland Security and Governmental Affairs Committee (HSGAC), and were utilized in an HSGAC report on drug shortages and national security.
- ▶ Through partnership with stakeholders such as the End Drug Shortages Alliance, the Medicine Supply Map contributed to analyses of the impact of recent supply chain disruptions, such as the closure of Akorn Pharmaceuticals.

**Public-Private Partnerships** – USP engaged with diverse stakeholders through public-private partnerships on supply chain issues to generate dialogue and evidence that can inform policy. This included work in USP's capacity as a Center of Excellence in global medical product quality and pharmaceutical supply chain security, as designated by the APEC forum.

- ▶ USP continues to be a member of 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 will continue to be an active participant in conversations, share learnings generated from the Medicine Supply Map and quality-related research, and provide insights into policy recommendations.

- ▶ USP continues to work with the U.S. FDA, the Administration for Strategic Preparedness and Response, the Biomedical Advanced Research and Development Authority, and the Federal Emergency Management Agency on supply chain-related issues. This included providing Medicine Supply Map data and data-derived insights to inform policy decisions to reduce supply chain vulnerabilities.

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

- ▶ USP will continue to refine and leverage information gathered from stakeholder interviews to influence global regulatory reform.
- ▶ USP will continue to seek opportunities to fund work that will generate new evidence to support access to quality medicines.
- ▶ USP will continue to leverage insights from the Medicine Supply Map to inform policy decisions and provide valuable, actionable insights to help identify, prevent, and mitigate future disruptions to the supply of medicines.

### **Contact**

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# XIII Resolution

## Coalition Building

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

## Year 3 Update

The medicines supply chain is complex, so strengthening its resilience to help ensure patients have the quality medicine they need when they need it requires many perspectives, broad expertise, and holistic approaches. Through engagements with the USP Convention, and building and participating in coalitions, USP connects with other leaders around the world to elevate and advance critical conversations that inform strategies, action, and policies to help build a stronger and more resilient medicines supply chain.

Key areas of progress over the past fiscal year include:

**USP Convention Sectors** – The USP Convention hosted 11 sector meetings during the year, convening members to share updates, receive input, and discuss issues of shared priority. Chaired by leaders in their respective fields and members of the Council of the Convention, sector engagements inform USP's work and expand its impact. Highlights include:

- ▶ The Convention's Innovation Sector launched with a four-part series addressing learnings from COVID-19,

3D printing, digital interoperability, and sustainability in pharmaceutical manufacturing.

- ▶ The Convention's Excipients Sector launched with a joint meeting held with the Generic Medicines Sector. The sectors discussed the risk of nitrosamines and mitigation strategies.
- ▶ The Dietary Supplements Sector developed a resource – "Choosing Quality: Dietary Supplements – Information for Pharmacists Advising Consumers on Quality Considerations." The sector continues to collaborate with the Healthcare Practice Sector to distribute the resource to pharmacists and pharmacy students.
- ▶ The USP Convention and FDA released an infographic to help practitioners and patients have informed conversations about the quality of biosimilars. Conceived from dialogue during a Biologics Sector meeting, the resource continues to be distributed widely via Convention Member organization networks and FDA forums.

**USP Convention Regional Chapters** – The Regional Chapters continued to bring together Convention Members, deepening valuable relationships, sharing best practices, and advancing critical dialogues. Each Chapter is chaired by a member of the Council of the Convention who is a respected leader in medicine quality. Highlights include:

- ▶ The European Regional Chapter launched with 14 Member Organizations representing diverse perspectives, including regulatory authorities, pharmacopeias, practitioners, and manufacturers. The inaugural hybrid meeting addressed supply chain resilience, pharmaceutical environmental sustainability, convergence, managing the reduction of nitrosamines, and opportunities to contribute as an Expert Volunteer.
- ▶ The Asia Pacific Regional Chapter hosted a hybrid meeting in connection with the Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue. The chapter meeting, which convened 20 organizations from 10 countries, addressed nitrosamines, excipients quality, post-marketing surveillance, substandard and falsified medicines, and pharmaceutical continuous manufacturing around the region.

#### **Asia-Pacific Economic Cooperation**

**Forum** – As part of the U.S.'s 2023 host year activities for the APEC forum, USP and FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened more than 500 stakeholders from 45 countries representing regulatory agencies, industry, academia, nonprofits, and multilateral organizations. The two-day meeting featured knowledge-sharing and dialogue aimed at advancing global supply chain resilience. This included discussion of

public health priorities, the impact of the COVID-19 pandemic, impurities, and resources available to help ensure supply chain security. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)

#### **Coalitions for a Resilient Supply of**

**Quality Medicines** – USP continues to merge its knowledge, expertise, and capabilities with those of other leading organizations to maximize impact. USP enhanced its role in some coalitions and joined others this year, as follows:

- ▶ For the End Drug Shortages Alliance, comprised of health systems, manufacturers, distributors, and other supply chain stakeholders, USP's Vimala Raghavendran, Vice President of Informatics Product Development, serves as Vice Chair of the Transparency and Redundancy Committee. As part of the alliance, USP hosted a roundtable focused on communications before, during, and after a drug shortage. USP also participated in various rapid response actions, including after the closure of Akorn Pharmaceuticals.
- ▶ The Healthcare Industry Resilience Collaborative, founded by Mayo Clinic and Banner Health, was developed to champion and lead standards and best practices in healthcare supply chain resiliency. Member activities include supply chain mapping and monitoring, resiliency risk assessments, resiliency score carding, and application of resiliency key performance indicators.
- ▶ The Duke-Margolis Supply Chain Consortium was developed to identify effective policy solutions that promote a resilient medicines supply chain with advanced manufacturing capabilities and, ultimately, reduce the frequency and severity of drug shortages.

- ▶ The Alliance for Safe Online Pharmacies (ASOP) is dedicated to addressing the growing public health threat of illegal online drug sellers through strategic efforts around the globe. USP's Carrie Harney, Vice President, U.S. Government and Regulatory Affairs, serves as President of the ASOP Board of Directors.
- ▶ The Alliance for Building Better Medicine is a consortium of U.S.-based advanced pharmaceutical manufacturers and researchers with a mission to reduce the cost of manufacturing pharmaceuticals by using novel chemical and engineering innovations to improve the way critical medicines are made in the U.S.
- ▶ The USP Convention Dietary Supplements Sector and Healthcare Practice Sector will partner with additional organizations to distribute the dietary supplements resource to pharmacists and pharmacy students.
- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit for Medical Products, hosted on USP.org. USP will also work with partners such as ASOP to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ USP will engage Convention Membership in activities for the 2025 – 2030 cycle, including proposed Resolutions and amendments to the Bylaws.

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

- ▶ The USP Convention will launch its seventh regional chapter, the Sub-Saharan Africa Chapter.

### **Contact**

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# XIV

## Resolution

### Culture of Excellence

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

### Year 3 Update

A culture of excellence at USP means people, processes, and systems are aligned and working optimally in pursuit of the organization's mission. With a foundation of rigorous process and data management that is continually improved, USP strengthens its decision making, stakeholder engagement, and information sharing. By focusing on improving effective and reliable procedures and systems, USP is better positioned to expand access to quality medicines, facilitate innovation, and improve public health.

Key areas of progress over the past fiscal year include:

**Knowledge Management** – USP knowledge management (KM) tools help identify, receive, share, and store content, and enhance internal and external transparency. This year, USP continued to enhance its Oasis KM tool following its launch in Fiscal Year 2022. Oasis helps USP staff conduct curated searches of information repositories and dynamic content types, and it facilitates access from core business applications and websites. Work this year included integrating Oasis with additional systems; creating dashboards for tracking performance,

utilization, and user adoption; and development of reports for technical monitoring.

**Business Process Management** – USP marked significant progress in its ongoing implementation of a Business Process Management (BPM) application for standards development that facilitates automation of select processes with increased consistency and control. USP launched the first release of the platform for documentary standards in February 2023. Additionally, USP continued to develop enhancements for its existing BPM platform for reference standards to improve functionality of the system.

**User-Friendly Online Products and Services** – USP has developed a long-term plan to provide support for the online *United States Pharmacopeia–National Formulary (USP–NF)* publication; this includes additional infrastructure, enhanced software applications, and optimization of processes. USP commenced development of a new integrated platform called OneUSP to support three-to-five additional languages and reduce the amount of time it takes USP to prepare regular updates by 20-40%.

**Digital Integration** – USP developed a roadmap and vision for machine-readable digital standards. USP's nuclear magnetic resonance (NMR) analysis software platform, USP-ID, also received initial approval to launch from USP's Digital Impact Committee, although USP elected to delay the launch when a late-breaking opportunity arose to integrate USP-ID into an industry-leading NMR analysis software package, which would facilitate access to a broader market. USP-ID is a software application that allows NMR spectral data to function as digital references to help ensure quality. The application combines high-quality chemical reference databases with smart algorithms to automate identity, strength, and purity analysis of molecules in complex mixtures. In the future, digital delivery of both reference standards and documentary standards will allow machines to perform automated data analysis that facilitates stakeholders' ability to deliver quality medicines. (See *Digital Transformation of Standards* Resolution update.)

**Data Quality** – USP developed a data governance structure for its Salesforce/Master Data Hub application. It includes data quality metrics and reports for the key data elements, which allows for continuous monitoring and improvement of data accuracy. In addition, USP enlisted a leading expert in data quality to conduct an organization-wide data quality audit. Based on the resulting recommendations, USP is developing a roadmap to improve data quality across the organization.

**Quality Management System** – USP continues to centralize quality processes into one system, MasterControl, a Quality Management System (QMS) software program. It includes document management, training, audits, deviations, corrective and preventive actions, lab investigations, risk management, and supplier quality

management. A Supplier Management module was developed in MasterControl to track supplier metrics, risk, and performance.

**Employee Survey Initiative** – USP continued administering a weekly pulse survey, Employee Voice, committed to gathering employee feedback, measuring progress, and informing leadership action to strengthen five areas of focus: employee recruitment and retention, workplace flexibility, inclusivity, people management, and USP's "speak-up" culture. Data is collected, evaluated, and distributed to all employees to provide real-time visibility into the organization's progress against key metrics. In addition, team leaders are encouraged to use the data to better identify strengths and inform decisions on how to continuously improve USP's support of its employees.

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

- ▶ USP will continue to add additional data sources to the Oasis KM tool to enhance the sharing of knowledge across the organization.
- ▶ USP will continue to build out the BPM system with multiple enhancements for reference standards and documentary standards to improve functionality.
- ▶ USP will launch the first version of the OneUSP integrated platform in Fiscal Year 2024.
- ▶ USP is aiming for a formal launch of USP-ID in Fiscal Year 2024.
- ▶ USP will continue to expand data quality activities to the Global Substance Registration System (GSRS) and other applications.
- ▶ USP will collect and track QMS data on supplier metrics and performance.
- ▶ USP will review and roll out recommendations of the Strategic Initiative for Women Thriving at USP. This initiative, built on previous

efforts, aims to examine and learn from past adverse experiences of women at USP and determine how best to ensure that all women have equal opportunity to thrive.

### **Contact**

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# XV Resolution

## Impact Expansion

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

### Year 3 Update

USP continued to expand its impact internationally through a range of strategies and initiatives to increase the resilience of the global medicines supply chain. This included efforts to support development of standards for good distribution practices, strengthen capabilities to address pharmaceutical impurities, facilitate innovation, 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 areas of progress over the past fiscal year include:

#### **Increasing Medicines Supply Chain**

**Resilience** – USP engaged stakeholders in Asia, Latin America, and elsewhere to address medicines supply chain vulnerabilities that became even more evident during the COVID-19 pandemic, to help strengthen regulations, and to raise awareness and understanding of how USP

quality standards help strengthen supply chain resilience.

- ▶ As part of the U.S.'s 2023 host year activities for the Asia-Pacific Economic Cooperation (APEC) forum, USP and the U.S. FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened over 500 stakeholders from 45 countries – representing international regulatory agencies, industry, academia, nonprofits, and multilateral organizations – to discuss public health priorities, the impact of the COVID-19 pandemic on supply chains, and valuable tools available to help ensure supply chain security. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)
- ▶ The USP Brazil Summit 2023 on Improving Supply Chain Resilience of Quality Medicines was held in Sao Paulo, Brazil, in March. The event convened regulators, industry, academia, and other stakeholders from the region to discuss lessons

learned from the pandemic and strategies to address potential medicines shortages and to prepare for the next public health emergency.

- In Kyrgyzstan, USP advanced efforts to ensure quality at different stages of the supply chain through the Cure TB program, funded by the U.S. Agency for International Development (USAID) and managed by the JSI Research & Training Institute. USP developed procurement guidelines and technical specifications for procurement; warehouse management guidelines recently approved by the ministry of health; and standard operating procedures to support testing the quality of tuberculosis medicines (and all essential medicines) procured by the state. USP also supported the National Reference Laboratory in Kyrgyzstan to obtain ISO 15189 accreditation, a hallmark for standard quality management systems, by helping them to meet biotechnology technical requirements for microbiological safety cabinets. USP also provided training on equipment maintenance for TB diagnostic labs at national and regional levels.

### **Strengthening Good Distribution**

**Practices** – USP continues to support regulators and stakeholders in the implementation of Brazilian good distribution practice (GDP) regulations by providing solutions and standards for capacity building. USP proposed updating a related general chapter with temperature excursion limits for climate zone IVb, which comprises several countries in Latin America, Africa, and Southeast Asia. In addition, a virtual workshop on GDPs – organized by USP in partnership with Brazilian regulator ANVISA and industry and academic stakeholders – convened over 2,400 participants and

included USP's guidance on standards and solutions to implement local regulations. The organizing stakeholders from industry and academia included Brazilian drug trade association Sindusfarma, the national academy of pharmaceutical sciences (ACFB/ANF), the Brazilian association of pharmacy and drugstore networks (ABRAFARMA), the Brazilian association of pharmaceutical wholesalers (ABAFARMA), and the Brazilian association of distribution and logistics of pharmaceutical products (ABRADILAN).

### **Diethylene Glycol and Ethylene Glycol Contamination**

– The World Health Organization (WHO) urged a call to action after substandard and falsified medicines identified in The Gambia, Indonesia, Uzbekistan, and several other countries were found to contain unsafe amounts of diethylene glycol (DEG) and ethylene glycol (EG) as contaminants. In response, USP developed a toolkit for manufacturers, regulators, and other pharmacopeias to assist in addressing DEG and EG contamination associated with allergy, cold, and cough medicines. USP also participated in a workshop organized by the WHO South-East Asia regional office in Indonesia in May 2023 to help build the capacity of regional regulatory agencies in South Asia to strengthen the upstream supply chain and address the potential for contaminated raw materials.

**Controlling the Risk of Impurities** – USP supported stakeholders around the world through its solutions to help control the risk of impurities in medicines, including through related USP standards and training.

- USP and the Vietnam National Institute of Drug Quality Control (NIDQC) completed the first part of a joint pilot project, begun in 2021, for post-market testing for nitrosamine impurities in targeted drug products.

USP provided related capability-building efforts through technical assistance, training, and expert guidance to NIDQC laboratory personnel for part one of the pilot, which involves validation of testing methodologies. Part two of the pilot, which is ongoing and involves testing of targeted sartan products, began in early 2023.

- ▶ USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority. USP provided the lab with nitrosamine impurities reference standards as well as training on nitrosamine testing in line with USP standards.
- ▶ USP supported various regulatory authorities in the implementation of impurity testing, including through a USP webinar on impurities in drug substances and drug products presented to regulatory authorities from Kazakhstan, Uzbekistan, Senegal, and Ethiopia.
- ▶ USP and the Indian Pharmaceutical Alliance hosted in February a nitrosamine impurities workshop in Hyderabad, India, titled “Nitrosamines Impurities: Analysis, Industry Needs and Regulatory Perspectives.” The event convened 270 participants including representatives from industry, academia, the European Directorate for the Quality of Medicines and HealthCare, and regulators from India, Japan, and the U.S. FDA.

**Strengthening Regional Relationships and Partnerships** – USP continued to strengthen regional partnerships through USP Convention Regional Chapter meetings, strategic additions to USP Convention Membership, and memorandums of

understanding (MOUs) in regions around the globe.

- ▶ The USP Convention European Regional Chapter launched with over a dozen Member Organizations representing diverse perspectives, including regulatory authorities, pharmacopeias, practitioners, and manufacturers. The inaugural hybrid meeting addressed supply chain resilience, pharmaceutical environmental sustainability, convergence, managing the reduction of nitrosamines, and opportunities to contribute as a USP Expert Volunteer.
- ▶ USP conducted meetings of Regional Chapters for Asia Pacific, South Asia, China, Latin America, and Middle East and North Africa.
- ▶ USP signed eight new MOUs and renewed two previous MOUs to strengthen regional relationships aimed at fostering collaboration and knowledge sharing, education and training, standards setting, advancing regional manufacturing, strengthening regulatory and laboratory systems, and supporting medicines quality and public health around the world. These included MOUs with regulatory bodies, industry groups, professional associations, and others in regions including Latin America, Asia, and Africa.

**Vaccines Quality** – USP worked to ensure supplies of quality vaccines in regions around the world.

- ▶ In support of the USAID Global Vax Initiative, USP facilitated a four-day visit to vaccine manufacturing sites in Hyderabad, India, accompanied by over a dozen regulators from six African countries – including Ghana, Kenya, Nigeria, Rwanda, Senegal,

and South Africa – as part of our ongoing commitment to strengthening regulatory systems and enhancing quality control capacities in low- and middle-income countries (LMICs).

- ▶ USP's Promoting the Quality of Medicines Plus (PQM+) program, supported by USAID, helped national medicines regulatory authorities (NMRAs) put into practice USP's proposed model to build capacity for emergency use authorization for vaccines.
- ▶ At the request of the African Union Development Agency (AUDA-NEPAD), PQM+ and the USP Global Health Technical Program developed a framework and five-year strategic plan to advance establishment of an African vaccine lot release laboratory network.
- ▶ USP engaged with Kazakhstan's State Center of Expertise and facilitated a webinar on quality assessments of vaccines as the country's pharmacopeia works to include general chapters covering vaccine quality assessment.

### **Supporting Advanced Therapies in Asia –**

In May, the USP-APEC Center of Excellence for Advanced Therapies held a two-day virtual training with more than 150 regulators from APEC and beyond on chemistry, manufacturing, and control challenges in chimeric antigen receptor (CAR) T-cell therapy to address knowledge gaps in real world applications. (See *Collaboration with FDA and Other Stakeholders on Health Priorities* Resolution update.)

### **Regulatory Capability Building in LMICs –**

USP continued to advance regulatory capability building in LMICs through a range of initiatives during the year.

- ▶ USP's PQM+ program helped increase the number of countries that can reliably test medical products, helping four national quality control laboratories (NQCLs) in Pakistan achieve World Health Organization (WHO) prequalification, helping two new NQCLs in Laos and Mali achieve ISO 17025 accreditation, and expanding the scope of testing in three NQCLs (one in Ethiopia and two in Nigeria). The effort also helped two Pakistan diagnostic labs achieve ISO 15189 accreditation.
- ▶ PQM+ began supporting the national regulatory authorities (NRAs) of Lesotho, Malawi, and Panama. In Lesotho, USP supported establishment of their NRA and implementation of related regulatory procedures, regional regulatory harmonization strategy, and protocols. In Malawi, USP conducted an analysis of the NRA and helped revise its strategic plan. In Panama, USP supported lab testing efforts and helped revise the curricula for the University of Panama to institutionalize and standardize information and requirements for a regulatory workforce.
- ▶ Through PQM+, USP provided technical assistance to manufacturers in Africa and Pakistan to achieve WHO prequalification, regulatory approval, and availability of quality-assured zinc sulphate treatments to treat childhood diarrhea, a leading cause of death among children under age five.
- ▶ USP supported two Ghana regional hospitals in obtaining ISO 15189 accreditation. USP also helped the Chad National Laboratory for Quality Control of Drugs strengthen its quality management system by 50% through hands-on capacity building

efforts in quality management systems, internal auditing, and quality control techniques in physical chemistry and microbiology. In the Solomon Islands, USP built capacity of the Ministry of Health and Medical Service and the National Pharmacy Services Division in the use of minilab equipment.

- ▶ With support from the World Bank, USP provided the Democratic Republic of the Congo with lab concept designs for new microbiology and medical devices laboratories and facilitated expansion of national control laboratory testing capabilities.
- ▶ USP held a workshop with Bangladesh regulators and industry to strengthen the country's regulatory capacity. The workshop addressed creation of a quality culture and raised awareness of the importance of pharmaceutical reference standards.
- ▶ USP presented at a conference organized by the Philippines Food & Drug Administration (PFDA) on "Empowered Regulators Gearing Up for Global Recognition." Convening over 500 staff of the PFDA, the event focused on raising awareness of international regulatory commitments.
- ▶ USP's Preferential Access for Regulators (PAR) program continued to provide regulators in LMICs with no-cost or subsidized access to USP educational courses, documentary standards, and reference standards to help ensure access to quality medicines and support medicines supply chain resilience. USP signed 11 PAR agreements and one renewal during the year, covering geographies in the Asia-Pacific, South Asia, Europe, the Middle East, Africa, and Latin America.

- ▶ USP conducted a comprehensive analysis of supply and demand for postpartum hemorrhage (PPH) products in sub-Saharan Africa with support from the Reproductive Health Supplies Coalition (RHSC), funded by the Bill & Melinda Gates Foundation. The study pinpointed gaps in access to quality-assured maternal health products. The findings are helping to shape RHSC stakeholder efforts to bolster regional manufacturing of PPH products.
- ▶ USP conducted ongoing discussions with the Health Division of the Association of Southeast Asian Nations (ASEAN) Secretariat to combat substandard and falsified medicines in the region.

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

- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit, and will work with partners, such as the Alliance for Safe Online Pharmacies, to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ USP will continue to expand regulatory engagement globally – including through formal MOUs – to advance capability building and medicines supply chain resilience. Specific focus areas will include pharmaceutical impurities and complex generics.
- ▶ USP will continue to deliver training courses and organized educational workshops to build regulatory capabilities in regions around the world.
- ▶ USP will continue to advance stakeholder engagement – including through Convention Regional Chapters – to share knowledge and

expertise and to learn from diverse perspectives around shared priorities on topics ranging from pharmaceutical impurities to adoption of advanced manufacturing technologies. The Sub-Saharan Africa Regional Chapter will launch.

- ▶ USP will continue to expand its PAR program to increase access to USP's standards and education programs.

### **Contact**

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