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A Note from the President and Secretary of the USP Convention

This report highlights the progress USP has made in the second fiscal year of the 2020-2025 cycle.

Trust and confidence that people have a supply of the quality medicines they need when they need them – that's core to USP's mission. It is through that lens that the USP Convention adopted 15 Resolutions during the Convention Governance Meeting in 2020. The Resolutions help guide how USP delivers on that mission, where we focus, and what we prioritize.

Like the first year of the cycle, year two was shaped by external disruptions. Longstanding vulnerabilities of the medicines supply chain were thrown into sharp relief, as were USP's opportunities to continue fostering its resilience. COVID-19 remained an organizational priority as we worked with stakeholders around the world to help ensure the supply of safe, quality vaccines, treatments, and preventatives. This work, while resulting from remarkable circumstances, is core to USP's mission and reflected in the following FY 2022 Resolutions Progress Report to the Convention.

USP's accomplishments during our fiscal year ending June 30, 2022, represent significant progress toward the five-year cycle goals. Importantly, that progress reflects the contributions and collaboration of USP's many volunteers, Convention members, and stakeholders from around the world.

Select highlights from FY 2022 include:

- Advancing solutions to medicines supply chain vulnerabilities, including work to reduce technical, scientific, and knowledge barriers to the adoption of advanced manufacturing technologies; and 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 5, 12, and 15.
- Developing new standards, guidelines, best practices, and related programs on impurities, vaccines, complex generics, cell and gene therapies, medicines compounding, new analytical techniques, and other priorities, addressed in the updates to Resolutions 3, 4, 5, 9, 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.
- Continuing to advance 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 stakeholder collaboration and engagement through the convening of Convention Sectors and Regional Chapters; maintaining consistent dialogue with the U.S. FDA and other regulators; growing participation in the Nitrosamines Exchange online community; and other efforts to share knowledge, perspectives, and expertise, as addressed in the updates to Resolutions 1 and 13.

Additional details on USP's progress across each of the 15 Resolutions are summarized in this report, along with a preview of work planned for FY 2023. Looking ahead to year three, select highlights include plans for a joint webinar with FDA and other stakeholders on standards development (Resolution 3); work to expand the supply and manufacture of vaccines, including COVID-19 vaccines, to more geographies (Resolution 8); and collaboration with FDA and Asia-Pacific Economic Cooperation (APEC) forum partners to convene an in-person meeting on the medical product supply chain during the APEC USA 2023 host year (Resolution 15).

We invite USP Convention members and other stakeholders to provide input and share ideas about this progress report. Each Resolution update includes the name and email of a USP staff member close to that work.

Thank you for your continued support.

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 2 Update

Advancing patient safety and increasing access to quality medicines are as complex as they are critical. To maximize its impact in these efforts, USP 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:

FDA's Drug Competition Action Plan – USP continued its support of FDA's list of "Off-Patent, Off-Exclusivity Drug Products 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 monographs associated with five different drug products on the OPOE list that are in the *United States Pharmacopeia-National Formulary (USP-NF)*. Since 2017, USP has developed a total of 17 monographs associated with 16 drug products on the OPOE list and in the *USP-NF*. USP is continuing to prioritize development of monographs associated with drug products on the OPOE list to support patient access to quality medicines.

Compounding – USP continued to develop monographs to help ensure the quality of products on FDA's lists of bulk drug substances that can be used in compounding drug products. During the year, USP published five draft compounded preparation monographs (CPMs) in *Pharmacopeial Forum* for public comment, and six new CPMs in *USP-NF*. In addition, USP continued to collaborate with stakeholders on revisions to *USP* General Chapters <795> *Pharmaceutical Compounding – Nonsterile*



Preparations, and <797> Pharmaceutical Compounding – Sterile Preparations to help ensure the supply of quality compounded drugs. (See Compounding Resolution update.)

Asia-Pacific Economic Cooperation

Forum - In collaboration with the Asia-Pacific Economic Cooperation (APEC) forum and FDA, the USP-APEC Supply Chain Center of Excellence hosted an event on "Confronting Substandard and Falsified COVID-19 Vaccines and Treatments" in partnership with the Pharmaceutical Security Institute, Moderna, and Sanofi. The workshop was attended by 75+ regulators and other key stakeholders across Asia and the Americas. USP also led the APEC Task Force on Post-Market Surveillance and contributed to the APEC Task Force on Internet Pharmacies led by the Alliance for Safe Online Pharmacies to help support access to quality-assured medicines across the region. (See Impact Expansion Resolution update.)

FDA-India Engagement – USP built on prepandemic engagements with FDA's India office in Fiscal Year 2022, initiating further collaborations with them on priorities for the region aimed at strengthening medicines supply chain resilience. These include regulatory strengthening, addressing nitrosamine impurities and anti-microbial resistance, and lowering barriers to adoption of advanced manufacturing technologies.

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 initiated a pilot project on testing for nitrosamine impurities with the Vietnam National Institute of Drug Quality Control. The collaborative

- project assisted the country in strengthening post-marketing surveillance to detect nitrosamine impurities in 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 provided the lab with nitrosamine impurities Reference Standards as well as training on nitrosamine testing in line with USP standards.
- ▶ USP expanded stakeholder engagement with its Nitrosamines Exchange online community in year 2, more than doubling its user base to 1,600 across 60+ countries and 22 language capabilities. The Nitrosamines Exchange is a focused forum for global pharmaceutical stakeholders and experts to share upto-date information and facilitate realtime conversations on nitrosamine impurities.

U.S. Government Supply Chain

Engagement – USP continued to work with 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 sharing data and data-derived insights generated from USP's Medicine Supply Map to inform policy decisions in support of increasing supply chain resilience. (See Evidence Generation to Inform Policy Resolution update.)

Engagement on Legislation – USP worked to ensure that key recommendations from USP to improve medicines supply chain resilience, including those developed in collaboration with other stakeholders, were shared with legislators for inclusion in legislative proposals developed during the



year, including the PREVENTS Act and COMPETES Act. As part of a multi-faceted approach to inform and shape the ongoing dialogue on supply chain-related issues, USP remained an active participant with various public-private partnerships and continued to build and strengthen relationships with key committees and offices on Capitol Hill. During the year, USP made over a dozen submissions, including statements for the record, comments to proposed legislation, and letters of support for key supply chain resilience policies.

Planned for Year 3

- In collaboration with FDA, USP will release an infographic on biosimilars quality designed to help healthcare practitioners and patients have informed conversations about using biosimilars.
- ▶ USP will continue to identify the priorities of FDA and other stakeholders, and look for opportunities for collaboration to help advance patient safety, public health, innovation, and access to quality medicines.
- ▶ USP will identify opportunities for collaboration on responding to quality paradigm shifts in biopharmaceuticals, including potentially in the areas of new drug delivery systems, analytical

- technologies, and novel vaccine platforms and adjuvants.
- ▶ USP will bring together regulators from the 21 APEC economies at USP headquarters in Rockville for a seminal dialogue on supply chain resilience during the APEC USA 2023 host year.
- ▶ USP will publish a comprehensive supply chain report entitled "A Holistic View of the Global Medicines Supply Chain and Recommendations to Improve Resilience and Ensure Access to Quality Medicines." Based on dialogue and gathered evidence, the report will be positioned as a foundational resource to inform policy reforms, investments, and the utilization of standards to improve supply chain resilience and maintain global public health.
- ▶ USP will continue to expand regulatory engagement internationally including through formal memorandums of understanding to advance capability building and medicines supply chain resilience. Specific focus areas will include pharmaceutical impurities and dietary supplement quality.

Contact

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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 2 Update

USP standards support global medicines supply chain resilience, helping ensure access to safe, quality medicines people can trust. USP engaged with FDA, industry, healthcare practitioners, and other stakeholders to maintain a modernized *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 – Over the past several years, USP has continued to implement solutions, including its Adapt-Transform-Progress (ATP) initiative, to increase the efficiency and effectiveness of the standards-development process and

systems. Under ATP, multiple pilots for case-based staffing processes were implemented as the necessary foundational information was captured and applied. In addition, multiple software releases within the USP Business Process Management (BPM) application were deployed to support Reference Standards development. The discovery phase for the BPM application for documentary standards was also completed ahead of the initial release (known as "Minimum Viable Product 1") in fall 2022.

Standards Engagement Model – This cycle, USP is focused on advancing a more iterative and agile approach to standards development. This approach stimulates early discussion, allowing for more rapid development of standards, further ensuring the availability of quality-assured medicines based on engaging the right volunteers and stakeholders at the right time. During the year, this approach included exploration of health equity principles as a key



consideration for standards-setting activities and broadened efforts at inclusivity among independent volunteer experts through expansion of USP's Call for Candidates and the Scientific Expert Fellowship program. USP also continued to analyze and streamline approaches for direct stakeholder engagement in support of the Standards **Engagement Model and Science Quality** Framework (see below). To accomplish this, USP deployed new stakeholder engagement tools including open forums, round tables, webinars, and workshops, which have drawn 7,400+ stakeholders to events targeted at specific standards-setting areas and challenges. The majority of stakeholder registrations in Fiscal Year 2022 were for events focusing on revisions to USP General Chapters <795> and <797> on compounding, how USP handles public comments on proposed revisions to the USP-NF that are published in the Pharmacopeial Forum, and the USP Biologics Stakeholder Forum on analytical solutions to support advanced biomanufacturing.

Science Quality Framework – This framework establishes a consistent set of focus areas and principles that help guide our science priorities and the work of our expert bodies. Specific accomplishments included the introduction of new standards, revisions, and other deliverables with a focus on complex generic drugs, pharmaceutical continuous manufacturing, and improvement of performance testing for dissolution.

Government Liaison Program – USP increased the total number of FDA government liaisons that serve across USP's expert bodies to 249, further expanding involvement of this priority stakeholder in our standards-setting activities. As part of our commitment to continuous improvement, we also proposed a real-time reporting

mechanism to be utilized by FDA government liaisons to allow us to pinpoint issues and identify trends across expert bodies more rapidly. The proposal was approved by all FDA centers and is slated to launch by fall 2022.

Information Sharing – USP and FDA continued to collaborate on efforts to increase critical information exchange between USP, industry, and FDA for standards development, including the revision of compendial processes. USP and FDA continue to discuss the incorporation of language into FDA communications with industry during the application filing process, with the goal of educating industry about how to work with USP to develop standards.

Planned for Year 3

- ▶ USP will implement a BPM application for documentary standards, continue to pursue further development of BPM applications to support standards creation, and review and implement further case-based standards-development approaches.
- USP will continue to evaluate opportunities to engage USP volunteers and other stakeholders in new and more targeted ways, including through learnings from virtual engagements.
- By fall 2022, USP will launch a realtime mechanism for FDA government liaisons to report operational challenges and successes, allowing USP to identify trends and pinpoint issues across expert bodies more rapidly.
- USP will conduct a joint webinar on standards development with FDA and the Association for Accessible Medicines in the summer of 2023.



▶ USP will work with FDA to develop a memorandum of understanding to facilitate the timely sharing of information to support the efficient development of quality standards and build upon collaborative efforts.

Contact

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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 2 Update

USP has prioritized revision and development of new quality standards that can have a greater public health impact. Leveraging the standards engagement model implemented in year one of the five-year cycle, USP revised and created standards that are timely and fit for purpose. As USP worked on these standards, we also worked to advance stakeholder adoption. These efforts help to ensure a resilient medicines supply chain by enabling consistency and uniformity in the production of safe, quality medicines from raw materials through packaging, distribution, and delivery.

Key progress areas over the past fiscal year include:

Priority Standards – USP advanced revisions and development of multiple standards, guidelines, and best practices in areas where they are most needed:

► USP General Chapter <1469> Nitrosamine Impurities became official on December 1, 2021. This chapter

- provides information, tools, and recommendations to help users understand potential sources of nitrosamine impurities, assess risk, and establish strategies and suitable methods to control nitrosamines in pharmaceutical products. USP also expanded its education and training activities in this area.
- Proposed new USP General Chapter <477> User-Determined Reporting Thresholds, published in the Pharmacopeial Forum (PF), outlines an approach for determining the appropriate numeric reporting threshold value for impurities in chromatographic test procedures when referenced in individual monographs.
- USP announced a format change for presenting relative retention times for organic impurities in monographs.
- ► USP revised and published General Chapters <761> Nuclear Magnetic Resonance Spectroscopy and <1761> Applications of Nuclear Magnetic



- Resonance Spectroscopy to support the use of quantitative nuclear magnetic resonance (qNMR) technology to help ensure quality.
- ▶ A proposed revision to USP General Chapter <711> Dissolution published in PF would replace existing USP Reference Standard (RS) Prednisone Tablets with a new USP Dissolution Performance Verification Standard – Prednisone RS.
- ▶ USP continued to develop monographs to ensure the quality of products on FDA's lists of bulk drug substances that can be used in compounding drug products. During the year, USP published five draft compounded preparation monographs (CPMs) in PF for public comment, and six new CPMs in USP-NF. In addition. USP continued work with stakeholders on revisions to *USP* General Chapters <795> Pharmaceutical Compounding -Nonsterile Preparations, and <797> Pharmaceutical Compounding - Sterile *Preparations* to help ensure the supply of quality compounded drugs. (See Compounding Resolution update.)
- ➤ Technical guides on control strategy, as well as three proposed new standards for the physical properties of material used in pharmaceutical continuous manufacturing, have been identified for development. USP anticipates that these and future guides could be developed into documentary standards as they mature in industry, potentially positioning USP as the industry leader in control strategy development.
- ▶ USP released a series of draft guidelines, including "Analytical Procedures for mRNA Vaccines Quality" and "Analytical Procedures for Viral Vectored Vaccine Quality" that help build trust and confidence in innovative vaccine products.

▶ USP's U.S. COVID-19 Vaccine Handling Toolkit and International COVID-19 Vaccine Handling Guide, as well as the COVID-19 Vaccine Quality Assessment Toolkits, were updated to reflect new vaccine information and enhanced practitioner guidance. The vaccine handling toolkit and guide provide operational strategies to address potential efficiency gaps in vaccine delivery and to accelerate the pace of vaccinations while maintaining safety and quality. The quality assessment toolkits serve as a resource for laboratories that need to develop and validate assays for the assessment of quality attributes of vaccines.

Iterative Standards Approach - USP published a Stimuli article titled USP's Iterative Approach to Standards Development and the "Emerging Standards" Concept. The paper outlines USP's iterative approach, through which we aim to share our preliminary work on standards to build stakeholder communities, stimulate early discussion and contribution, and enable more rapid, dynamic development of standards. By accelerating the development of relevant, timely resources and public quality standards, the iterative approach can help USP fulfill its important role in ensuring availability of quality-assured medicines. The article also introduces the concept of an "emerging standard" as a standard under development that is made available at an earlier stage for stakeholder input and contributions. The first two examples of emerging standards (for acetaminophen injection and palbociclib) were published along with the article.

Standards Engagement Model – Additional progress was made on the new approach for engaging volunteers and stakeholders in standards development that helps ensure



that the right individuals are engaged at the right time to support a more iterative approach. (See Efficiency in Standards Development and Revision Resolution update).

Science Quality Framework – USP made significant progress developing standards and solutions guided by USP's Science Quality Framework, which comprises five strategic pillars that cover evolving and expanding standards, product and substance performance, emerging modalities, advanced technologies, and the quality environment. (See Efficiency in Standards Development and Revision Resolution update).

Health Equity Initiative – USP continued to advance this initiative, which aims to address long-standing public health challenges that have contributed to inequitable access to quality medicines. During the year, USP formed the Health Equity Advisory Group to provide ongoing counsel for the initiative and explore ways Expert Volunteers can incorporate health equity metrics into our standards development and prioritization work for enhanced public health impact.

Critical Resources – Information Sharing
Priorities – USP continued to make progress
on 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 agreed to develop a memorandum of understanding to facilitate the timely sharing of information on standards development. ▶ USP and FDA continued to discuss the incorporation of language into FDA communications with industry during the drug application process, with the goal of helping industry to understand how to work with USP to develop standards.

Planned for Year 3

- ▶ USP will continue to prioritize standards development and to advance initiatives to address key topics, including impurities, complex generics, and dissolution.
- ▶ USP will conduct outreach to stakeholders with additional information in preparation for the planned revision to *USP* General Chapter <711>.
- ▶ USP will continue to engage with FDA and other stakeholders to facilitate approaches that support efficiency through greater and earlier information sharing. This will include holding a joint webinar on information sharing and standards development with FDA and the Association for Accessible Medicines.
- USP will continue to address health equity principles in standards setting. This will include efforts to continue to broaden inclusion of independent Expert Volunteers by expanding USP's Call for Candidates and the Scientific Expert Fellowship program.

Contact

For additional information on this Resolution, contact Veronica Boone at vab@usp.org.



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 2 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 that includes recombinant therapeutic proteins, vaccines, blood components, tissues, and cell and gene therapies. During the year, USP expanded its focus on emerging modalities, including mRNA and viral vector-based vaccines and therapeutics, with advancement of new standards, tools, and educational offerings. These efforts are helping to build a common understanding of relevant quality attributes and test methods for biologics to support quality and consistency, as well as the integrity of the global supply chain for biologics. These tools provide greater efficiency to industry in the development process and support regulatory reviews. During the year, USP also continued to explore advanced manufacturing technologies with 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:

Advanced Manufacturing and Analytics -

New manufacturing and analytical technologies hold promise for enabling more efficient production and testing of qualityassured biotherapeutics. USP convened experts in advanced manufacturing to discuss related challenges and opportunities, help reduce barriers to adoption, and foster an environment that facilitates industry adoption of these technologies. Over 100 external experts attended USP's Biologics Stakeholder Forum on analytical solutions to support advanced biomanufacturing. In response to stakeholder requests, USP held a follow-up roundtable with subject matter experts, which led to creation of a new Expert Panel to develop a general chapter on the topic.

Vaccine Quality – USP expanded efforts to support an increased supply of new and existing vaccines through publication of new tools and educational offerings, and



continued engagement with global stakeholders. Our work focuses on quality, which is an imperative for the development of new vaccines and entry of new manufacturing capacity on the market.

- ▶ USP released quality assessment toolkits to support platforms for manufacturing of newly authorized and approved vaccines, e.g., subunit protein vaccines. Related educational webinars were also released.
- ➤ To further support a common understanding of quality attributes for mRNA and viral-vectored vaccines, USP developed and published draft guidelines on related analytical methods. USP received feedback and additional methods from a broad range of global stakeholders to support further evaluation and qualification of methods.

Advanced Therapies – USP expanded development of standards and tools to support the quality of cell and gene therapy products.

- ▶ USP hosted a roundtable on adenoassociated virus (AAV)-based gene therapies to discuss analytical approaches and challenges for these emerging treatments. The roundtable led to the formation of an Expert Panel, which has initiated work on a general chapter on AAV gene therapies.
- In collaboration with the National Institute for Innovation in Manufacturing Biopharmaceuticals and the National Institute of Standards and Technology, USP initiated a study in multiple industry labs to compare analytical techniques used for analysis of empty and full AAV capsids to assess the quality of gene therapy products.

Raw and Starting Materials – USP developed new standards for assessing the quality of raw and starting materials that ultimately impact the quality of finished biological medicines.

- USP published a proposed new general chapter in *Pharmacopeial* Forum on starting materials for synthetic peptides. Expert volunteers also completed a chapter on strategies for addressing trace elements in cell culture media and approved it for publication.
- USP released a new physical performance standard for quality assessment of raw materials used in manufacturing of pegylated proteins. USP also initiated development of physical standards to support quality assessments of raw materials used in manufacturing of oligonucleotide therapies.

Stakeholder Engagement – USP expanded biologics stakeholder engagement through workshops, webinars, and courses to build capability and a common understanding of biologics quality attributes.

- USP added 25 new biologics training courses and educational webinars. Over 5,000 stakeholders attended USP biologics educational offerings during the year.
- ▶ USP conducted an Asia-Pacific Economic Cooperation Center of Excellence for Advanced Therapies training workshop for regulators on best practices for development and validation of bioassays to support cell and gene therapy products. Attended by nearly 200 regulators, the talks were also posted for on-demand viewing to allow other stakeholders to benefit. A related white paper was published in *Cell & Gene* to further raise awareness.



▶ USP's workshop on therapeutic peptides and oligonucleotides drew 300+ attendees.

Planned for Year 3

- In collaboration with FDA, USP will release an infographic on biosimilars quality aimed at helping healthcare practitioners and patients have informed conversations about using biosimilars.
- ▶ USP will continue its commitment to vaccine quality through publication of related draft guidelines. This will include updating guidelines for mRNA and viral-vectored vaccines informed by public comments, and release of a new draft guideline for subunit vaccines.
- ▶ USP will expand the scope of its work in cell and gene therapy with a stakeholder forum on chimeric antigen receptor (CAR) T-cell therapies.
- ▶ USP will continue engagement in continuous manufacturing for biologics

- through the *USP/BioPhorum Joint Workshop on Continuous Manufacturing of Biologics*, to be held for industry leaders and regulators in the field.
- ▶ USP will expand its portfolio of standards for monoclonal antibodies, which remain the largest modality for biotherapeutics. The new standards will support functional testing as well as testing for impurities and critical quality attributes.
- ▶ 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.

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 2 Update

USP standards build trust and confidence in healthcare breakthroughs, support market access, and advance the quality of medical products to strengthen 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. In order 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:

Graph Database and Artificial Intelligence
Capabilities – USP expanded exploration of
graph database and artificial intelligence (AI)
capabilities such as natural language
processing and deep learning. The goal is to
use these capabilities to facilitate evaluations
of the impact that specific federal regulatory
changes may have on current and future

standards development, and improve understanding of the interconnectivity of standards to support stakeholder needs. To advance this goal, USP tested and demonstrated related capabilities through specific use cases. Examples included: 1) use of a "Regulatory Document Associator" tool to identify connections between USP standards, FDA guidance, and U.S. laws, and pinpoint areas impacted by changes in U.S. federal requirements, and 2) a dashboard to highlight connections between USP standards and related drug development information. The ongoing exploration, piloting, and implementation of capabilities such as graph database and Al will enable better linking, manipulation, and visualization of USP data assets to provide insights that drive decision-making and further optimize our ability to enhance our products and services for the benefit of stakeholders.

Pharmaceutical Continuous

Manufacturing – USP advanced work on multiple fronts to lower technical and knowledge barriers to adoption of pharmaceutical continuous manufacturing



(PCM) technology, which can facilitate medicines supply chain resilience through efficiencies that make it more practical to make more medicines in more places, alongside traditional batch manufacturing.

- ▶ Under a strategic alliance forged in Fiscal Year 2021 with Phlow, a public benefit corporation. USP continued to develop early scientific guidelines for high-quality PCM processes and construction of the USP Advanced Manufacturing Technology Lab. During the year, the alliance worked to facilitate creation of an active pharmaceutical ingredient (API) strategic reserve. leveraging PCM technology, to provide a national stockpile of key ingredients for the domestic manufacture of essential medicines and reduce U.S. dependence on foreign supplies concentrated in only limited geographies. The work progressed on five critical APIs with a hybrid approach utilizing elements of both PCM and traditional batch manufacturing technology.
- ▶ USP acquired Pharmatech Associates in July 2021. Pharmatech remains a separate entity providing consulting services independent from USP standards-setting activities that can help manufacturers through the decision-making process on PCM adoption, production line development, and related regulatory processes.
- ▶ USP signed an agreement with the National Institute for Pharmaceutical Technology and Education (NIPTE) to co-develop a Continuous Manufacturing Knowledge Center partially funded by FDA.

3-D Printing of Pharmaceuticals – USP launched a <u>webinar series</u> on 3-D printing of pharmaceuticals in partnership with Purdue University and sponsored by Aprecia

Pharmaceuticals, the "International 3DP Pharma Technology Forum." Attended by industry, academia, and regulatory bodies, the series included a focus on the benefits of 3-D printing of pharmaceuticals to patients, manufacturers, formulation scientists, and compounding pharmacists. Through collaboration with Purdue, USP also continued to make strides in research exploring and identifying quality considerations for 3-D printing of pharmaceuticals and related roles for quality standards. During the year, USP worked to develop a perspective paper and conducted qualitative interviews to outline the current landscape for 3-D printed pharmaceuticals and collect insights from external stakeholders on the role USP can play in advancing the quality of 3-D printing technology.

Drug Dissolution – USP conducted studies aimed at optimizing dissolution testing using a reduced volume of dissolution media. The change would reduce the environmental impact of dissolution testing while accelerating the process and expanding test applications. Particle-induced velocimetry studies were also initiated in collaboration with the New Jersey Institute of Technology to further characterize hydrodynamics in a reduced-volume dissolution system. These studies, along with computational fluid dynamics results, may provide further quidance for optimizing the use of lowvolume dissolution testing to improve analytical sensitivity while reducing the volume of solvents used.

Quantitative Nuclear Magnetic Resonance

 USP revised and published USP General Chapters <761> Nuclear Magnetic Resonance Spectroscopy and <1761>
 Applications of Nuclear Magnetic Resonance Spectroscopy to facilitate use of qNMR as an analytical technique for demonstrating quality. USP continued to expand evaluation



and integration of qNMR analytical procedures in reference standard operations. USP also expanded stakeholder outreach on adoption of qNMR, including through establishment of the qNMR-China discussion group. The group brings together Chinese pharmaceutical and academic experts, along with other global experts, to discuss advancement and applications of qNMR for quality control in the pharmaceutical industry.

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. During the year, USP advanced initiatives to identify related standards, physical materials, and services as well as gaps and opportunities for future standards development to support our stakeholders. This included efforts to engage stakeholders so USP could better understand pain points across various complex generic product classes. Through understanding and aligning with stakeholder needs, USP is positioned to provide documentary and reference standards, physical materials, educational tools, guidelines, and consultative services to support market entry of complex generic products.

Advanced Technology Evaluations – USP advanced efforts to identify and evaluate technologies for advanced polymer material characterization to help ensure quality and support product innovation. This included evaluation of benchtop NMR technology, matrix-assisted laser desorption/ionization-time of flight mass spectrometry, and optical imaging capabilities. USP also initiated projects focused on identification of spectroscopic technologies for

pharmaceutical assessments, including use of handheld instruments and other applications for use in advanced manufacturing technology applications.

Planned for Year 3

- ▶ USP will complete construction of the USP Advanced Manufacturing Technology Laboratory, accelerate its work with Phlow on the strategic API reserve, and continue to build USP capabilities to lower technical and knowledge barriers to adoption of advanced manufacturing technologies including PCM.
- ▶ USP will launch the Continuous Manufacturing Knowledge Center under an agreement with NIPTE.
- qNMR-China will host a joint symposium with the qNMR-Japan discussion group, comprising industry, academia, and governmental agencies in Japan, to expand the science and application of qNMR for pharmaceutical quality testing.
- USP will continue to evaluate technologies such as spectroscopy, optical image analysis, and predictive tools to expand our capabilities for pharmaceutical characterization and other applications.
- ▶ USP will continue to identity and evaluate emerging technologies and trends to help industry, regulators, and other stakeholders ensure consistency and quality in advancing promising healthcare innovations.

Contact

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101010

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 2 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 1) ensure that the standards-setting process can accommodate the rapidly evolving world of computational informatics, and 2) develop or otherwise support data services that meet stakeholder needs across USP nomenclature as well as pharmaceutical and healthcare informatics platforms that align with and complement USP standards.

Key areas of progress over the past fiscal year include:

Transition to Modern Platforms – USP implemented use of two technology platforms that are being leveraged to fundamentally change the way USP curates and disseminates scientific content as machine-readable, structured data. These platforms

were purchased in the prior fiscal year and went live with production data in Fiscal Year 2022.

- 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 used Symedical to maintain the USP Drug Classification (USP DC) and Medicare Model Guidelines for drug classification. USP DC 2022 was released on the Symedical platform. Symedical is also being used to model the work of the Exchange of Compounded Drug Preparation Information in Health IT Systems Expert Panel, the Pronunciation Expert Panel, and the Nomenclature and Labeling Expert Committee.
- ▶ USP continued to implement the Global Substance Registration System (GSRS) for curation and dissemination of high-quality sources of record for substance information. The platform



- was used to launch a redesigned USP Dictionary of United States Adopted Names and International Drug Names.
- USP also worked to integrate GSRS with USP's business process management system to improve information and data management throughout standards development. The GSRS platform also continued to support USP's exchange of structured data with FDA as part of a Collaborative Research and Development Agreement.

Transition to Structured Content – To integrate USP data into stakeholders' digital environments - thereby facilitating the ongoing industry modernization and digitization trend known as "Pharma 4.0" -USP has been working to shift to structured content. The effort will increase efficiency and decrease transcription errors through increased automation. To that end, USP created a data model for documentary standards content and began evaluating the use of natural language processing to extract assay methods from a subset of monographs. This will add granularity and structure to content through alignment with industry standards developed by the Allotrope Foundation. 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.

Digital Reference Standards – USP developed a software platform that allows quantitative nuclear magnetic resonance (qNMR) data to function as a digital reference to help ensure quality. By characterizing a physical Reference Standard using high-field qNMR, the resulting data can be compared with

experimental qNMR data through this process. Beta testing of the software, which uses smart algorithms to automate identity and purity analysis of molecules in complex mixtures, was completed with academic and industry partners. USP also formed a Council of Experts subgroup to examine potential compendial applications for digital reference standards. Separately, USP revised and published *USP* General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Applications of Nuclear Magnetic Resonance Spectroscopy* to facilitate use of qNMR.

Planned for Year 3

- ▶ USP will continue to expand application of the Symedical platform. This will include adding updated content from the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health related to the handling of hazardous drugs in healthcare settings, and modeling the work of the Allergies and Intolerances Expert Panel.
- ▶ USP will continue to expand use of GSRS. We will integrate it further with the business process management system for use in standards setting. USP will also integrate it with other internal systems (e.g., Oracle Commerce Cloud) to consolidate chemical information about reference standards, thereby establishing GSRS as the definitive source for all uses of chemical information at USP.
- USP will embark on a pilot with a major LIMS vendor focusing on the distribution and execution of machinereadable analytical methods found in USP monographs.
- USP will target benchtop R&D applications in launching its qNMRbased software platform.



- ▶ USP will continue to advance understanding of stakeholder needs for digital solutions through customer outreach, including through focus groups and surveys.
- USP will develop new direct and indirect distribution capabilities for getting USP content to external customers.
- ► USP will continue to monitor and prioritize upstream advances in

science where USP standards setting and solutions development may advance public health through digital implementations.

Contact

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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 2 Update

Education and training support adoption and implementation of USP quality standards. This includes 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, setting a new attendance record by surpassing 23,000 attendees in FY 2022. This represents a 7% gain over last year, aided by continued expansion of channels and online access.

- ▶ USP deepened its impact in new regions including Southeast Asia, Africa, and the Middle East by offering free-to-regulator access for online education. This included building on our relationship with the FDA Philippines by providing them with free access to online compounding courses.
- ▶ Licensing of USP courses to third parties which have included manufacturers, industry groups, and academia increased 31% during the year to make up 7% of our total program reach.
- Uptake was also bolstered by briefer course offerings on key topics like biologics and particulate matter.

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 showed that 88% of attendees would recommend a USP course to others, a



statistically significant increase from the previous 72%. Student ratings on whether USP courses will have a positive impact on the quality of their work also remained strong at 88% for new courses developed during the year.

Improved Timeliness – USP accelerated the availability of educational resources supporting key standards adoption using its Curriculum Roadmap process, initiated in Fiscal Year 2021. Through the process, we identify earlier the quality standards for which educational programming will be most impactful in support of stakeholder adoption and implementation, enabling work on educational materials to begin and be available earlier in the standards-publication cycle. During the year, the timeframe between when a USP standard is published and the availability of supporting educational courses decreased to a range of one to five months for projects identified through the Curriculum Roadmap process from a previous range of six to 12 months.

Planned for Year 3

- ▶ USP will continue to reduce the gap between the publication date of standards and the availability of new, related courses, consistently achieving gaps of one month or less for projects identified through the Curriculum Roadmap.
- ▶ USP will continue to ensure that courses are relevant to students' real-world practice and have an impact on 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, leveraging student evaluations.
- ▶ USP will continue to leverage strategic pricing, subscription, and licensing options to expand the reach of education and training offerings, including geographic expansion in markets such as Africa and Asia.

Contact

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NationResolution

Regulatory Systems Strengthening

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

Year 2 Update

From initial product reviews and inspections of manufacturing facilities, to preventing, detecting, and responding to substandard and falsified medical products, regulatory systems play an essential role in ensuring access to supplies of quality-assured medical products. USP works in 40+ countries with national regulatory authorities and other stakeholders to strengthen capabilities in these areas. Much of this work is supported by donors, including the U.S. Agency for International Development (USAID), the Australian Department of Foreign Affairs and Trade, the Global Fund, the World Bank, and the World Health Organization (WHO).

Key areas of progress over the past fiscal year include:

Promoting the Quality of Medicines Plus Program – This year, the Promoting the Quality of Medicines Plus (PQM+) program, funded by USAID, marked the completion of the first half of USP's current five-year agreement. PQM+ works to improve access to quality-assured medicines in low- and middle-income countries (LMICs). Highlights for the year include expansion of technical assistance to support regulators in the areas

of vaccines and medical device quality, as well as support for pharmacovigilance and lot release functions, particularly for COVID-19 vaccines. Building on earlier efforts, PQM+ also supported numerous countries (e.g., Bangladesh, Ethiopia, Kazakhstan, Nigeria, Pakistan, and Rwanda) on their journey to strengthen their regulatory systems.

COVID-19 Pandemic Response – Through PQM+, USP continued working with regulators in Africa and Asia to strengthen COVID-19 prevention and response efforts.

- Practical guidance documents on emergency use authorizations for vaccines and in vitro diagnostics were finalized and disseminated.
- ➤ To further support safe deployment of COVID-19 vaccines, PQM+ worked with several countries to strengthen systems for monitoring adverse events following immunization. During the year, we assisted Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan, and Uzbekistan in developing pharmacovigilance procedures and reporting systems.
- ▶ In Bangladesh, PQM+ collaborated with the National Control Laboratory to



develop guidelines for vaccine lot release.

Regional Harmonization and Coordination

 USP continued to promote efforts to advance mutual recognition, reliance, and regulatory convergence.

- ▶ In Uzbekistan, PQM+ successfully advocated for and guided the use of the WHO Collaborative Registration Procedure for accelerated registration of two WHO-prequalified tuberculosis (TB) medicines.
- USP worked in partnership with four technical committees of the African Medicines Regulatory Harmonization initiative to promote regional coordination and regulatory excellence.
- ▶ USP, via PQM+, is providing guidance and planning support toward the formation of the African Medicines Agency, a continent-wide regulatory body that is meant to complement existing regional initiatives and national regulatory authorities.

Partnerships and Thought Leadership – USP advanced key partnerships in Africa, Europe, South America, and Asia.

- ▶ USP signed a Memorandum of Understanding with the South African Health Products Regulatory Authority to advance risk-based inspections and post-marketing surveillance; strengthen quality control laboratories for medicines, biologics, and medical devices; and advance regional harmonization.
- ▶ USP is working with regulators in Europe, Brazil, China, Saudi Arabia, and elsewhere to improve detection and mitigation of nitrosamine impurities through workshops, access to the USP Nitrosamines Exchange, and preferential access to nitrosamine reference standards.

▶ PQM+ is supporting a multifaceted approach to developing Uzbekistan's pharmaceutical sector that includes economic incentives, strengthening regulatory systems, and building workforce capabilities. During the year, USP hosted the inaugural U.S.-Uzbek Pharmaceutical Summit, supported by PQM+, which aimed to catalyze partnership, collaboration, and investment opportunities.

Asia-Pacific Economic Cooperation - As part of the Asia-Pacific Economic Cooperation (APEC) Forum, USP convened two critical workshops under the auspices of the USP-APEC Center of Excellence (COE) on Securing Medical Product Quality through the Supply Chain and the COE on Advanced Therapies. The first workshop, on "Confronting Substandard and Falsified COVID-19 Vaccines and Treatments," drew 75+ regulators. The second workshop, on "Development and Validation of Bioassays for Advanced Therapies," was attended by 150+ regulators. USP also now leads the Task Force on Post-Market Surveillance and ioined the Task Force on Internet Pharmacies.

Planned for Year 3

- ▶ In August 2022, USP announced that \$7.1 million is being provided to the PQM+ program to help expand access to COVID-19 vaccines. The additional funding is part of the U.S. government's Global VAX initiative and will be used in FY23 to support the strengthening of regulatory systems in six African countries toward WHO maturity level three.
- ▶ USP and the PQM+ program will support an FDA webinar on "Regulatory Best Practices for Global Access to Medicines, Including Anti-TB Medicines" to share information with regulators in LMICs.



- ▶ USP will disseminate a paper entitled
 "A Holistic View of the Global
 Medicines Supply Chain and
 Recommendations to Improve
 Resilience and Ensure Access to
 Quality Medicines." The paper will be
 informed by broad perspectives based
 on dialogue and gathered evidence,
 and will include lessons learned during
 the pandemic as well as policy
 recommendations targeted at
 improving supply chain resilience and
 strengthening regulatory systems.
- ▶ USP is collaborating with FDA and other APEC partners to convene an inperson event on the medical product supply chain during the APEC USA 2023 host year.

Contact

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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 beyonduse dates, will be developed based on data, scientific evidence, and input from recognized healthcare professionals and state and federal regulators.

Year 2 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:

Updated COVID-19 Resources for Compounders – USP continued working with stakeholders to develop and provide operational strategies that enable compounders to respond more effectively to COVID-19 and potential future pandemics.

- ▶ USP updated its <u>Operational</u>
 <u>Considerations for Sterile</u>
 <u>Compounding During the COVID-19</u>
 <u>Pandemic</u> to ensure consistency with recent changes made to the packaging of conventionally manufactured COVID-19 treatments with emergency use authorization, including recommendations for minimizing waste.
- USP updated its recommendations for compounding alcohol-based hand sanitizers to provide specific information for incorporation of additional ingredients, such as denaturants.

Revised Compounding Chapters – USP continued work with stakeholders on revisions to *USP* General Chapters <795> Pharmaceutical Compounding – Nonsterile Preparations, and <797> Pharmaceutical Compounding – Sterile Preparations to help



ensure the supply of quality compounded drugs.

- Stakeholder engagement led by the Compounding Expert Committee on proposals to revise General Chapters <795> and <797> brought together diverse perspectives representing a broad range of practice settings in which USP compounding standards are implemented. Stakeholders provided feedback and reviewed public comments on earlier proposed revisions. As a result, USP published updated proposed revisions to the general chapters in *Pharmacopeial* Forum in November 2021 for further public comment. Virtual open forums in January 2022 were attended by 800+ participants.
- ▶ USP published supplementary resource documents summarizing the Compounding Expert Committee's responses to public stakeholder comments received during the revision process and the rationale for changes.

Monograph Development – USP continued to prioritize and develop compounded preparation monographs (CPMs), including key monographs to meet the needs of

pediatric and veterinary patients, to help ensure the quality of compounded drug preparations. USP published five draft CPMs in *Pharmacopeial Forum* for public comment, and six new CPMs in *USP-NF*.

Planned for Year 3

- ▶ Pending the anticipated publishing of General Chapters <795> and <797> in USP-NF, USP will host open forum webinars and workshops, and will update related educational resources to support stakeholders in implementation of the revised compounding chapters.
- ▶ USP will develop resources in response to topics raised by stakeholders during the revision of <795> and <797>, including stability studies, aseptic techniques, and quality assurance in compounding.
- ▶ USP will publish *Stimuli* articles on 3D printers and other automated devices used in compounding.

Contact

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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 2 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 – USP's Botanical Dietary Supplements and Herbal Medicines Expert Committee and Cannabis Expert Panel continued to develop quality specifications for cannabidiol (CBD) as a drug substance. The monograph proposal for CBD, which was published for public comment in *Pharmacopeial Forum (PF)*, includes analytical methods and acceptance criteria for CBD identification, quantitative estimation, and contaminant limits.

Quality of Cannabis and Cannabis-Derived Products – USP published a General Chapter Prospectus in May to solicit public comments on plans to develop informational General Chapter <1568> Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research for inclusion in the United States Pharmacopeia-National Formulary (USP-NF). The prospectus responds to active and growing interest in cannabis for medical purposes, where definition of quality attributes can help support sound and reproducible basic and clinical research.

Addressing Adulteration and Impurities -

In response to reports of products marketed as cannabis/hemp plant material being adulterated with an intoxicating cannabinoid (synthetic delta-8-tetrahydrocannabinol) or potentially containing high levels of other synthetic impurities with an unknown safety profile, USP published related perspectives on its website. USP's commentary highlighted the need for scientifically valid analytical methods to address potential adulteration and impurities, and the need for systematic clinical investigations using quality research materials and methods consistent with FDA draft guidance.



Outreach and Engagement – USP developed and shared comments and perspectives on cannabis quality-related issues with regulators and other stakeholders.

- ▶ USP submitted comments on a discussion draft of the Cannabis Administration and Opportunity Act, emphasizing the need for requirements for public quality standards for legally marketed cannabis-derived products.
- USP presented pharmacopeial perspectives on quality considerations for cannabis-derived compounds at a botanical science seminar held by FDA's Center for Drug Evaluation and Research.
- ▶ USP provided public comments on FDA's draft guidance on cannabis quality considerations for clinical research, and comments to state regulators in New York and California on a proposed rule and state bill, respectively, related to cannabis quality.
- ▶ USP submitted comments about cannabis quality attributes to Health Canada, the National Conference on Weights and Measures, and the American Council of Independent Laboratories.
- USP shared cannabis quality perspectives with the Cannabis Regulators Association and trade groups.

Planned for Year 3

► USP will continue to consider approaches to provide stakeholders with information on cannabis product

- consistency and quality, including development of the proposed informational General Chapter <1568>.
- ▶ USP will evaluate comments on a proposed monograph for cannabis inflorescence published in the non-official *Herbal Medicines Compendium*, building on its 2020 publication of quality considerations for cannabis inflorescence for medical use in the *Journal of Natural Products*.
- ▶ USP is in dialogue with quantitative nuclear magnetic resonance (qNMR) device manufacturers, and particularly benchtop NMR manufacturers, about the possibility of developing a digital toolkit for identification and quantitation of cannabis-derived and synthetic compounds.
- ▶ USP will evaluate public comments on proposed specifications for CBD, continue to work on providing appropriate methods and Reference Standards to limit impurities, and publish a revised monograph proposal for CBD in *PF* for further public comments.
- ▶ USP will continue to develop chromatographic methods to identify and quantify impurities and contaminants in cannabinoids to help regulators, industry, and public health professionals address related public health concerns.

Contact

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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 2 Update

Through collaboration with other global pharmacopeias, USP works to advance convergence around robust, science-based quality standards. Convergence helps build capabilities among emerging pharmacopeias and increase global alignment on the definition of quality to allow 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 of the ways the convergence of quality standards makes this possible is through increased availability of quality ingredients for medicines 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 includes USP, the European
Pharmacopoeia, and the Japanese
Pharmacopoeia, to increase the reach and
impact of PDG harmonization efforts.

- ➤ The PDG launched a pilot for expansion of group membership to include other prominent global pharmacopeias, with the Indian Pharmacopoeia Commission serving as the inaugural participant. This milestone marks the culmination of two years of discussions in the effort to initiate the pilot with objective criteria for new member participation and to help ensure its success.
- The PDG reached consensus on harmonization of standards for chromatography across related USP, European, and Japanese pharmacopeial chapters. Representing



a significant milestone in pharmacopeial convergence, the approved *United States Pharmacopeia–National Formulary* text for the harmonized chapter was posted on USP's website in November 2021 and will become official in December 2022.

China Engagement – USP engaged in significant technical collaborations with the Chinese Pharmacopoeia (ChP), launching initiatives on standards for biologics, metal packaging, and the use of quantitative nuclear magnetic resonance (qNMR) spectroscopy for quality assurance. These efforts, which built on a USP-ChP memorandum of understanding signed in Fiscal Year 2021, included formation of a USP-ChP working group on metal packaging that aims to outline a related pharmacopeial chapter by year-end.

Webinar with EDQM on Drug Substance Harmonization – USP and the European Directorate for the Quality of Medicines & Healthcare (EDQM) co-sponsored a joint webinar to advance their long-standing, mutual effort to prospectively harmonize drug substance monographs. The webinar increased project visibility and drew 150+ participants to discuss related opportunities, challenges, and proposed adjustments to the program based on lessons learned. The mutual convergence effort initially resulted in four prospectively harmonized monographs for active drug substances when it began in 2008 and continued with 19 additional prospectively harmonized drug substance and drug product monographs.

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 a

number of ICH Expert Working Groups, including those on pharmaceutical continuous manufacturing and analytical procedures. During the year, USP contributed to development of draft ICH guidelines in both areas and submitted related technical comments to help ensure alignment with USP standards and policies.

Interactive Dashboard for COVID-19

Treatments – Ten international pharmacopeias – including USP – collaborated to publish an interactive dashboard of active pharmaceutical ingredients and monographs for existing generic drugs being investigated as COVID-19 treatments. Over 700 monographs were listed on the dashboard.

Planned for Year 3

- USP will work with its PDG partners to evaluate lessons learned from the group's expansion pilot and consider potential next steps including continuation, conclusion, or further formalization of the pilot.
- USP will continue to work with its PDG partners on standards where convergence will have the most impact on global access to quality medicines, including a focus on potential harmonization of standards for elemental impurities.
- ▶ At a September 2022 event of the International Meetings of World Pharmacopoeias (IMWP), USP will lead a discussion with PDG on lessons learned from COVID-19 response efforts by the World Health Organization (WHO).
- USP will conduct hybrid bilateral meetings with WHO, the European Pharmacopoeia, British Pharmacopoeia, and Japanese Pharmacopoeia in fall 2022 to identify key technical areas for future work.



▶ USP will strengthen bilateral collaborative partnerships with global pharmacopeias in key technical and strategic areas, such as analytical quality by design, and qNMR technology.

Contact

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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 2 Update

Policymakers and stakeholders around the world recognize that the COVID-19 global public health emergency brought to the forefront long-standing vulnerabilities in the medicines supply chain. As the pandemic enters an endemic phase in some regions, factors including geopolitical dynamics, potential natural disasters, and disruptions due to factors yet unknown necessitate heightened efforts to build a more resilient global medicines supply chain to 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 qualityrelated research to build strong evidence and materials to advance 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 launched the three-part Convention Exchange series to bring together stakeholders with diverse perspectives and generate dialogue to inform policymakers' understanding of supply chain vulnerabilities, their potential impact on the availability of quality medicines, and USP solutions to bolster supply chain resilience. Topics included lowering barriers to the adoption of advanced manufacturing technologies, the requirements for establishing a cycle of preparedness to help withstand disruptions to the supply chain, and reducing antimicrobial resistance through a resilient supply of quality antimicrobials. Notably, the meeting on antimicrobial resistance included a briefing from a USP Quality Institute fellow on research into the link between poor-quality medicines and antimicrobial resistance, and discussion on related policy implications.



Quality Institute Research – The USP Quality Institute sponsors research to inform and enable evidence-based policy decisions that can help increase the availability of quality medicines. During the year, the Quality Institute sponsored several academic fellows who completed primary laboratory research, 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 continued to develop and improve its Medicine Supply Map (MSM) 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, MSM 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 to facilitate decisionmaking aimed at bolstering supply chain resilience.

Public-Private Partnerships – USP engaged with diverse stakeholders through public-private partnerships on supply chain issues to generate dialogue and evidence that 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 Asia-Pacific Economic Cooperation (APEC) forum.

 USP joined 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 MSM and Quality Institute, and provide insights into policy recommendations.
- ▶ USP continued to work with 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 MSM data and data-derived insights to inform policy decisions to reduce supply chain vulnerabilities.

Planned for Year 3

- ▶ USP will bring together regulators from the 21 APEC economies at USP headquarters in Rockville for a seminal dialogue on supply chain resilience during the APEC USA 2023 host year.
- ▶ USP will publish a comprehensive supply chain report entitled "A Holistic View of the Global Medicines Supply Chain and Recommendations to Improve Resilience and Ensure Access to Quality Medicines." Based on dialogue and gathered evidence, the report will be positioned as a foundational resource to inform policy reforms, investments, and the utilization of standards to improve supply chain resilience and global public health.
- USP will bolster the ability of its Quality Institute to generate evidence to inform policy that advances supply chain resilience. This will include promoting supply chain-focused work completed by past fellows. It will also include new



Quality Institute-sponsored independent research to assess stakeholders' perceptions of risk along the global supply chain.

Contact

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Coalition Building

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

Year 2 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 Regional Chapters – The USP Convention Regional Chapters continued to bring together Convention Members on shared priorities, thereby deepening connections and advancing critical dialogues. Through these engagements, Members received updates on USP's work and provided input and shared knowledge. Highlights include:

The Convention's Middle East and North Africa Regional Chapter launched with 60+ Member

- representatives in attendance. The meeting resulted in four areas of focus for the Chapter: biologics, capability building, technical assistance for lab accreditation, and implementation of risk-based post-marketing surveillance.
- ➤ The Latin America Regional Chapter convened 100+ Members and stakeholders to share strategies and best practices for regulating cannabis across the region.
- ► The Asia Pacific Regional Chapter convened with 100+ Member representatives in attendance. Presenters and attendees addressed supply chain resilience, impurities, and advanced therapies.

Supply Chain Resilience Dialogue and

Insights – USP hosted a three-part
Convention Exchange series on supporting a
resilient medicines supply chain, which
convened Members from across Sectors.
Diverse perspectives were shared to inform
policymakers' understanding of supply chain
vulnerabilities, their potential impact on the
availability of quality medicines, and USP
solutions to bolster supply chain resilience.
The series included the following events:



- "A Shared Imperative: Building a Resilient Pharmaceutical Supply Chain" explored ways to reduce barriers to adoption of advanced manufacturing technology. Focus areas included investments, policy reforms, and use of quality standards to foster efficient production of critical medicines using innovative manufacturing methods.
- "Preparedness: Bolstering Key Points Along the Medicines Supply Chain" provided a forum for attendees and USP experts to discuss requirements for establishing a continuous cycle of preparedness to ensure an effective crisis response. Topics included funding, training, staffing, data collection, and health equity.
- ▶ "Preserving a Quality Supply of Antimicrobials and Combatting Antimicrobial Resistance" addressed ensuring broad access to affordable medicines, proper stewardship of existing antimicrobial treatments, and investments in development of new treatments. The discussion also included a review of research describing the link between poorquality medicines and antimicrobial resistance.

Asia-Pacific Economic Cooperation
(APEC) Forum – The USP-APEC Supply
Chain Center of Excellence hosted an event
on "Confronting Substandard and Falsified
COVID-19 Vaccines and Treatments" in
partnership with the Pharmaceutical Security
Institute, Moderna, and Sanofi. The
workshop was attended by 75+ regulators
and key stakeholders from Asia and the
Americas. USP also assumed the lead for
the APEC Task Force on Post-Market
Surveillance and contributed to the APEC
Task Force on Internet Pharmacies, led by
the Alliance for Safe Online Pharmacies.

Coalitions for a Resilient Supply of Quality Medicines – In addition to leading coalitions, USP continued to participate in several coalitions formed by other organizations. This allowed us to combine our expertise, knowledge, and resources with that of others for greater impact.

- The Pharmaceutical Supply and Payment Coalition is led by the Pharmaceutical Care Management Association and consists of payers, industry, and pharmacy groups.
- ➤ The Critical Infrastructure Partnership
 Advisory Council, a coalition of both
 government and private sector public
 health groups, is a public/private
 partnership of key stakeholders
 created to facilitate information sharing
 on issues such as the supply of
 medicines, devices, and related
 healthcare equipment, e.g., personal
 protective equipment.
- ► The Fight the Fakes Alliance, a multisectoral initiative dedicated to eliminating substandard and falsified medicines from the supply chain, publicly distributed information on COVID-19 vaccine administration, and co-hosted the #StopFakeMeds Twitter Chat as part of World Antimicrobial Awareness Week.
- A coalition led by the American Society of Health-System Pharmacists on supply chain resilience developed several recommendations that were included in legislation, including the PREVENTS Act and COMPETES Act.

Planned for Year 3

▶ In collaboration with FDA, USP will release an infographic on biosimilars quality aimed at helping healthcare practitioners and patients have informed conversations about using biosimilars.



- ▶ USP will launch the Innovation Sector of the Convention through a three-part series that convenes Members to explore strategies for ensuring quality in healthcare innovations.
- ➤ Sectors and Chapters of the USP
 Convention will convene in conjunction
 with the development and release of a
 comprehensive USP supply chain
 report, tentatively titled "A Holistic View
 of the Global Medicines Supply Chain
 and Recommendations to Improve
- Resilience and Ensure Access to Quality Medicines."
- ▶ USP will collaborate with FDA and other APEC partners to convene an inperson event on the medical product supply chain during the APEC USA 2023 host year.

Contact

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Resolution

Culture of Excellence

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

Year 2 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. To continue to advance this goal, USP developed a custom KM tool called Oasis for USP staff to conduct curated searches of multiple information repositories and dynamic content types, and to facilitate access from core business applications and websites. The tool launched in June 2022 for use with over a dozen databases and repositories. These

included internal databases and network drives, as well as external websites.

Business Process Management – USP is implementing a Business Process
Management (BPM) application for standards development that facilitates automation of select processes with increased consistency and control. Progress this year on the BPM application for reference standards development included three enhancements to improve functionality. Development of processes for documentary standards began in January 2022.

User-Friendly Online Products and

Services – USP has continued to assess opportunities to improve users' experience with the organization's online products and services. During the fiscal year, work on a new, more user-friendly integrated platform for the *USP-NF/Pharmacopeial Forum* led to its debut in July 2022.

Digital Integration – USP continued progress on its Digital Integration Office (DIO), which was established to help drive development of digital products and services



built on quality data and standards. DIO was tasked with identifying, categorizing, and prioritizing digital products; planning and managing project data; and ensuring operational efficiency under the umbrella of USP's robust Quality Management System. During the year, a portfolio of 11 data projects was identified and launched. This included establishing the Global Substance Registration System platform as the definitive source for chemical substance information; creation of detailed process models for documentary standards development; and Salesforce account data cleanup.

Data Quality – USP integrated new data governance processes into its Quality Management System as part of its data quality governance program. New processes include establishment of a Data Governance Committee that meets monthly to oversee business data quality practices for customer account data, including removal of duplicate records and validation of client information, to help ensure effective use of data assets.

Quality Management System Software – USP implemented new Quality Management System software, called MasterControl, to centralize all quality processes in one system that includes document management, training, audits, deviations, corrective and preventive actions, lab investigations, risk management, and supplier quality management.

Employee Survey Initiative – USP launched a weekly pulse survey to gather employee feedback, measure progress, and inform leadership action to strengthen flexibility, inclusivity, and people

management. Metrics on collected data are made accessible to all employees.

Planned for Year 3

- ▶ USP will implement dashboards to track KM tool performance, utilization, and adoption; integrate additional systems with the tool; and review and address issues surfaced during the initial release.
- ▶ USP will build out the BPM system with multiple enhancements for reference and documentary standards to improve functionality. The initial release of BPM processes for documentary standards is slated for September.
- ➤ USP will develop a long-term, online product pipeline for rollout over the next several years, along with additional infrastructure to support it and an updated publication infrastructure to streamline processes and support additional languages.
- ▶ USP will develop initial data quality metrics and controls for key data elements on multiple data integration projects and expand data governance processes to multiple crossdepartmental projects.
- ▶ USP will develop a DIO quality policy and provide guidelines for data repositories and data cleaning initiatives to facilitate data integration and exchange across the organization and with external stakeholders.

Contact

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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 2 Update

USP continued to expand its impact internationally through a range of approaches and workstreams to increase the resilience of the global medicines supply chain, including through its efforts to support risk-based postmarketing surveillance; strengthen public procurement; develop standards for good distribution practices; lower barriers to adoption of pharmaceutical continuous manufacturing; and prevent, detect, and eliminate substandard and falsified medicines. USP's broader work to advance adoption of USP quality standards, guidelines, and best practices reached more people in more regions of the world, helping to strengthen the global medicines supply chain and improve patient safety and public health.

Key areas of progress over the past fiscal year include:

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

- ▶ USP initiated a pilot project on testing for nitrosamine impurities with the Vietnam National Institute of Drug Quality Control. The collaborative project assisted the country in strengthening postmarketing surveillance to detect nitrosamine impurities in 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 provided the lab with nitrosamine impurities Reference Standards as well as training on nitrosamine testing in line with USP standards.
- USP expanded stakeholder engagement with its Nitrosamines Exchange online community, more than doubling its user base to 1,600 across 60+ countries and 22 language capabilities. The Nitrosamines Exchange is a focused forum for global pharmaceutical stakeholders and experts to share up-to-date information and facilitate real-time conversations



on nitrosamine impurities. The site debuted in year one of the cycle with risk assessments as the primary focus, and evolved in year two to all things related to nitrosamines as community members deepened their engagement through activities including user-driven collaborative projects and publications. Examples include the co-development of specific nitrosamine impurity analytical methods leveraging external resources, and a peer-reviewed article on the complex nitrosamines landscape.

 USP's Promoting the Quality of Medicines Plus (PQM+) program to improve access to quality-assured medicines in low- and middle-income countries (LMICs), funded by the U.S. Agency for International Development, finalized a technical brief describing impurities in chlorhexidine and how manufacturers can address them during production. The brief will help local manufacturers increase the supply of quality-assured chlorhexidine gel to prevent umbilical cord infections in newborns.

Multi-Attribute Methods Exchange - USP launched a pilot Multi-Attribute Methods Exchange online community to facilitate knowledge sharing and real-time conversations globally on the emerging quality control analytical techniques. Since its debut in October 2021, the community has grown to 300+ users from 30+ countries, and includes scientists from industry, contract research organizations, and instrumentation companies, among other stakeholders.

Pharmaceutical Continuous Manufacturing in Asia - During the China Pharmaceutical Association of Plant Engineering Annual Meeting, USP collaborated with regulatory bodies and

industry to address challenges and opportunities in the adoption of pharmaceutical continuous manufacturing (PCM) as a means to bolster medicines supply chain resilience. The event was attended by key regulatory agencies from China and 200+ industry participants. Similarly, USP collaborated with the Indian Pharmaceutical Alliance on a PCM conference in India for global stakeholders in the field. Featuring speakers from industry, academia, and regulatory authorities including the U.S. FDA and European Directorate for the Quality of Medicines & HealthCare, the event drew 260+ participants.

Substandard and Falsified Medicines in Asia – USP worked with stakeholders across the region to advance efforts to prevent,

detect, and eliminate substandard and falsified medicines.

- ▶ In collaboration with the Asia-Pacific Economic Cooperation (APEC) forum, the USP-APEC Supply Chain Center of Excellence hosted an event on "Confronting Substandard and Falsified **COVID-19 Vaccines and Treatments**" in partnership with the Pharmaceutical Security Institute, Moderna, and Sanofi. The workshop was attended by 75+ regulators and other key stakeholders across Asia and the Americas, USP also led the APEC Task Force on Post-Market Surveillance and contributed to the APEC Task Force on Internet Pharmacies led by the Alliance for Safe Online Pharmacies to help support access to quality-assured medicines across the region.
- USP partnered with the Association of Southeast Asian Nations in an initiative led by Cambodia to combat substandard and falsified medicines in the region.



USP supported the Philippine FDA's National Consciousness Week on Anti-Counterfeiting campaign to increase awareness of the issue.

Strengthening Public Procurement in Asia and Africa – In collaboration with the World Health Organization's Southeast Asia regional office, USP provided technical support for self-assessments by public procurement agencies – including in the Indian states of Tamilnadu and Gujarat, and 10 other countries in Southeast Asia – to help strengthen public procurement practices in the region. Separately, PQM+ helped Rwanda and Nepal develop and implement procurement guidelines that incorporate medical product quality considerations.

China Engagement on Metal Packaging Standards – USP formed a joint working group on metal packaging standards with the Chinese Pharmacopoeia (ChP) that aims to outline a related pharmacopeial general chapter.

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

- ▶ USP's Preferential Access for Regulators program provided regulators in at least 38 countries with no-cost or subsidized access to USP educational courses, documentary standards, and reference standards to help those countries ensure access to quality medicines and support medicines supply chain resilience.
- ▶ PQM+ helped the regulatory authorities of several countries (e.g., Bangladesh, Ethiopia, Kazakhstan, Kenya, Mozambique, Pakistan, and Rwanda) on their journeys toward more advanced levels of regulatory maturity. More broadly, PQM+ efforts in 21 countries were focused on

- building the capacity of the regulatory authority and/or its quality control laboratory.
- USP facilitated efforts by the Egyptian Drug Authority to develop guidelines for risk-based postmarket surveillance by sharing related resources and organizing discussions to help guide the agency's work.
- ▶ USP collaborated with the Colombian regulatory agency INVIMA on an educational session on vaccine quality attributes to improve related regulatory capabilities, drawing 75+ regulatory officials.
- USP shared with the Peruvian Regulatory Authority and National Laboratory USP resources on ensuring the quality of cannabis for medical use to help improve their capabilities in the field.

Global Stakeholder Education and Engagement – USP engaged thousands of stakeholders globally around our standards and related solutions through educational courses, webinars, and workshops.

- ▶ USP co-led a workshop on good distribution practices for finished drug products with the trade association Sindusfarma in Brazil and the Brazilian Academy of Pharmaceutical Sciences. Over 800 participants, including regulators, trade associations, distributors, transporters, and regulatory affairs professionals, attended the event.
- ▶ USP co-led a workshop on dietary supplements with the Brazilian regulatory agency ANVISA and Sindusfarma. The event drew 1,400+ participants, including industry, academia, public laboratories, and regulators from across Latin America, for discussion on Brazil's regulatory framework and standards-setting process for supplements.



- ▶ USP organized the 6th Annual Workshop on Biologics and Peptides to facilitate knowledge-sharing on these rapidly growing product classes among 290+ global regulatory, industry, and academia stakeholder attendees.
- USP collaborated with the Centre of Regulatory Excellence at Duke-NUS Medical School in Singapore to provide training on postmarketing surveillance through a "good reliance practices" workshop.
- USP collaborated with South Korea's National Institute of Food and Drug Safety Evaluation on a joint workshop to identify challenges and provide solutions to expand development of advanced therapies.
- ▶ USP worked with the Indian Pharmacopoeia Commission to organize an industry training workshop on the fundamentals of drug dissolution, drawing 330+ participants from 149 companies.
- ► USP worked to strengthen pharmaceutical compounding in the Philippines by providing education and training to the Food and Drug Administration Philippines.
- ▶ USP organized a workshop on sterility testing in Indonesia in collaboration with the Indonesian FDA that provided hands-on training to provincial laboratories to help ensure drug safety in the country, drawing 400+ participants.
- ▶ USP delivered training courses and organized educational workshops to build regulatory capabilities in the Middle East. The effort included working with the Egyptian Drug Authority on data integrity and monograph-setting processes; the Saudi FDA on biologics; and the Jordanian FDA on biosimilars.

Collaboration with FDA Internationally -

USP worked with the U.S. FDA's office in India on activities related to regulatory strengthening, addressing nitrosamine impurities and anti-microbial resistance, and lowering barriers to adoption of advanced manufacturing technologies. Separately, PQM+ collaborated with the U.S. FDA to organize an online workshop for representatives of national medicines regulatory authorities from high-burden TB countries to share experiences with the regulatory review of new medicines, including TB medicines.

Planned for Year 3

- USP will continue to expand regulatory engagement internationally – including through formal memorandums of understanding – to advance capability building and medicines supply chain resilience. Specific focus areas will include pharmaceutical impurities and dietary supplement quality.
- ▶ 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.
- USP will continue to advance capability building solutions to ensure proper storage and transportation of finished drugs.
- ▶ USP will continue to engage global regulatory authorities to increase awareness of the opportunities and challenges of advanced manufacturing technologies, lower barriers to adoption, and explore options to provide related training.



▶ USP will collaborate with FDA and other APEC partners to convene an inperson event on the medical product supply chain during the APEC USA 2023 host year.

Contact

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