



2020-2025 Resolutions Progress Report

FY 2021



Table of Contents

Introduction

USP's COVID-19 Response

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

Resolution 2: Efficiency in Standards Development and Revision

Resolution 3: Quality Standards

Resolution 4: Access to Biologics

Resolution 5: Innovations

Resolution 6: Digital Transformation of Standards

Resolution 7: Education and Training for Industry and Healthcare Practitioners

Resolution 8: Regulatory Systems Strengthening

Resolution 9: Compounding

Resolution 10: Cannabis

Resolution 11: Pharmacopeial Cooperation and Convergence

Resolution 12: Evidence Generation to Inform Policy

Resolution 13: Coalition Building

Resolution 14: Culture of Excellence

Resolution 15: Impact Expansion

A Note from the President and Secretary of the USP Convention

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

In May 2020, the USP Convention adopted 15 Resolutions to help guide USP's work and impact over the next five years. At that time the world didn't fully know how devastating COVID-19 would become or how vast the worldwide response would be. But as USP began its new cycle, it was clear that responding to the pandemic must be an organizational priority—one that aligned with our mission to improve global health by helping to build trust in medicines.

At the same time, USP's core obligations still required our focus. Staff and volunteers continued to advance that work while also urgently mobilizing to address the global public health crisis. We are proud to share this report on progress that USP has made in the first fiscal year of the 2020–2025 cycle for each of the 15 Resolutions.

In this report, you will find updates on progress made during FY 2021 toward each Resolution as well as work planned for FY 2022. And because our COVID-19 response was and remains a priority for USP, we have included an update on those efforts and how they will evolve in FY 2022. We strategically leveraged our expertise, Expert Bodies, and global footprint in our COVID-19 response,

so you will also see that work reflected in many of the Resolution updates.

USP's efforts throughout the fiscal year that closed on June 30, 2021, have helped advance our mission and activate our strategy to deliver impact through standards development, advocacy, and capacity-building efforts to help ensure global access to quality-assured medicines, dietary supplements, and foods.

Select highlights from Year 1 include:

- ▶ Advancing solutions to medicine supply chain risks exposed by the COVID-19 pandemic, including development of the USP Medicine Supply Map, which you can read more about in Resolutions 6 and 12
- ▶ Launching the remodel of the Convention through Sectors and Regional Chapters that bring members together more consistently to share knowledge, perspectives, and input on USP's work, helping to support Resolution 13
- ▶ Improving access to quality-assured medicines in low- and middle-income countries through USP's Promoting the Quality of Medicines Plus program, addressed in Resolution 8
- ▶ Forging a strategic alliance with Phlow to develop early scientific and regulatory guidelines for continuous manufacturing processes, as part of



Resolution 5; and acquiring Pharmatech Associates to provide consulting services that help manufacturers meet quality standards, as part of Resolution 15

- ▶ Making more of USP's standards content available through digital processes to help maximize our impact, included under Resolutions 6 and 14

Additional details on USP's progress across each of the 15 Resolutions and our response to COVID-19 are included in the pages that follow. We invite USP Convention Members

and other stakeholders to provide input, ask questions, and share ideas about these updates. Each Resolution update includes the name and email for a USP staff member familiar with that work. Thank you for your continued support.

Sincerely,

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

Anthony Lakavage, J.D.
Secretary, USP Convention





COVID-19

Year 1 Update: Strengthening the Supply of Vaccines, Treatments, and Preventatives

Just ahead of the 2020–2025 USP Convention Governance Meeting in May 2020, the global healthcare landscape changed considerably. Responding to the COVID-19 pandemic became a critical USP priority. We rapidly mobilized to leverage the expertise of staff and Expert Volunteers to help strengthen the supply of trusted, quality-assured COVID-19 vaccines, treatments, and preventatives.

Year 1 Update

USP developed a suite of tools and resources to address quality challenges and potential efficiency gaps in the delivery of COVID-19 vaccines, treatments, and preventatives. Today, they are helping to build capacity, support trust, get more shots in arms, and save lives. These resources include:

Vaccine Handling Toolkit – USP’s COVID-19 Vaccine Handling Toolkit outlines operational considerations for vaccine administrators and other stakeholders to address potential efficiency gaps in vaccine handling. Toolkit strategies are designed to help maximize shots in arms and minimize waste while maintaining safety and quality.

The toolkit includes vaccine-specific guides and a video on maximizing doses per vial, a factsheet on beyond-use dates, guides on vaccine transportation and visual inspections, and FAQs. An international version of the toolkit was created for use outside the U.S. and has been translated into multiple languages.

Substandard & Falsified Product Tools –

USP’s resources for preventing, detecting, and responding to the threat of substandard and falsified (SF) vaccines, particularly in low- and middle-income countries, include a white paper with practical guidance on quality assurance, toolkits for vaccine quality assessments, and a visual inspection guide to help ensure trust in quality-assured vaccines. Additional USP resources addressing the potential for SF COVID-19 treatments include 1) a toolkit for determining the identity and purity of remdesivir and 2) a white paper on responding to SF health products.

Hand Sanitizer Toolkit – USP’s Hand Sanitizer Toolkit addresses quality challenges for production and use of alcohol-based hand sanitizers intended to reduce the risk of COVID-19 transmission. The toolkit includes free access to standards, information, and education on producing quality hand sanitizers and addressing the potential for potency issues and methanol contamination.

Training & Education – USP held a webinar in conjunction with the World Health Organization and Sabin Vaccine Institute that offered a forum for immunization expert dialog on delivering COVID-19 vaccines globally. Additional trainings held include:

- ▶ Webinars on USP’s toolkits for vaccine quality assessments targeting regulators in low- and middle-income countries in collaboration with USP’s Promoting the Quality of Medicines Plus (PQM+) program.
- ▶ A USP seminar focused on helping stakeholders ensure quality alcohol-based hand sanitizer production and supporting safe use of the products.
- ▶ A separate forum addressed regulatory and quality issues for the manufacturing of alcohol used in drug products more broadly, including hand sanitizers used to combat the public health emergency.

Awareness & Outreach Efforts –

Throughout the year, USP worked in concert with allied organizations, including Convention Members, to promote awareness of our COVID-19 resources among healthcare practitioners, manufacturers, regulators, educators, government officials, immunization professionals, and other key stakeholders. These efforts have had a quantifiable impact. Over 50 million additional COVID-19 vaccine doses were made available in the U.S. as of July 2021 with the help of strategies outlined in the USP COVID-19 Vaccine Handling Toolkit, which was received by over 76,000 U.S. vaccine network providers. The international version of the toolkit has reached over 50 countries. Meanwhile, we reached 4 million people globally with our Hand Sanitizer Toolkit to

increase the world’s supply of safe, effective hand sanitizer.

Planned for Year 2

- ▶ USP will update toolkits and resources as new vaccines and treatments achieve regulatory approval and new information becomes available.
- ▶ USP will continue to translate select resources to further facilitate dissemination around the globe and help end the pandemic.
- ▶ USP will continue to promote stakeholder awareness of our COVID-19 resources and related training and educational outreach. This includes plans for 1) a webinar series supporting responses to COVID-19 and future health crises in low- and middle-income countries, in collaboration with PQM+, with a focus on the international version of the Vaccine Handling Toolkit and 2) a shorter webinar on USP toolkits for vaccine quality assessments.
- ▶ USP will continue capability building efforts with a particular focus on low- and middle-income countries to 1) help diversify manufacturing and regulatory quality capabilities across geographies and manufacturers and 2) support a more resilient global pharmaceutical supply chain.
- ▶ USP will continue to collaborate with other public health leaders and influencers to advance best practices to shorten the pandemic and help prepare for future public health emergencies.

Contact

For additional information on this topic, contact Lindsey Clawson at LYC@usp.org.





Resolution

Year 1 Resolution Update: Collaboration with FDA and Other Stakeholders on Health Priorities

Resolution

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.

Alignment with USP's Mission

Over the course of USP's history, standards, training, and advocacy have been deployed by USP to help address the health priorities of the U.S. government and other governments around the world. As the medicines supply chain and economy further globalize and biomedical advances create new challenges and health priorities, USP can increase its impact by partnering with governments to support their objectives when they are aligned with USP's mission.

Year 1 Update

Key areas of collaboration on public health priorities over the past fiscal year include:

Methanol Contamination – Consistent with a request from FDA, USP worked quickly to

issue Revision Bulletins requiring the "Limit of Methanol" identification test in monographs for alcohol and dehydrated alcohol. The revisions address public health risks associated with methanol contamination of alcohol-based hand sanitizers. Since alcohols are widely used as pharmaceutical ingredients, the revisions also address contamination risks to the supply chain beyond hand sanitizers. USP and FDA held joint stakeholder calls with manufacturers and compounders to address the changes and answer questions.

FDA's Drug Competition Action Plan –

USP is committed to continuing to support FDA's list of "Off-Patent, Off-Exclusivity Drug Products without an Approved Generic" (the OPOE list) under the agency's Drug Competition Action Plan to help increase access to important generic drug therapies. Since 2017, USP has developed 12 monographs associated with 11 drug products on the OPOE list that are in the *USP-NF*. USP is prioritizing monographs associated with drug products on the OPOE list.

Compounding – USP is working on the development of monographs for drugs on FDA's lists of bulk drug substances that can be used in compounding drug products.

COVID-19 – USP's COVID-19 Vaccine Handling Toolkit and related international

version, which focus on operational considerations for maximizing doses and minimizing waste while maintaining safety and quality, were developed through collaborations with U.S. and international government agencies as well as USP Expert Committees.

Standards Engagement Model – USP is increasing engagement in support of standards through new engagement tools and expanded use of existing tools. For example, to stimulate early scientific discussion around nitrosamine risk assessment, USP launched its first online community Nitrosamines Exchange. The community now has over 400 members. USP has also launched the first Stakeholder Engagement Planning Committee for this cycle, focusing on the Prescription/Non-prescription Stakeholder Forum. Committee members—40% of whom are new this cycle—include stakeholders from FDA,

industry, and academia. Open Forums, another new engagement tool this cycle, have drawn hundreds of stakeholders to events targeted at specific standards-setting areas and challenges.

Planned for Year 2

- ▶ USP will continue to identify FDA and other stakeholder priorities and look for opportunities to collaborate to help advance patient safety, public health, innovation, and access to quality medicines.
- ▶ USP will seek to identify opportunities for collaboration on responding to quality paradigm shifts in biopharmaceuticals.

Contact

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Resolution

Year 1 Resolution Update: Efficiency in Standards Development and Revision

Resolution

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.

Alignment with USP's Mission

As science and technology advance and approvals of medicines increase, it will be important for USP to engage more effectively with FDA, industry, practitioners, and other stakeholders, and recognize the limited resources and other constraints impacting each organization and key constituents. This Resolution reaffirms USP's commitment to work collaboratively with FDA, industry, practitioners, and other stakeholders to maintain a modernized *USP-NF* compendia through efficient processes for continually

developing and revising standards. It also urges USP to work with FDA and industry on new approaches for sharing the information needed for efficient standards setting. Implementing new and better ways to share information among USP, FDA, and industry will enable a continually modernized *USP-NF* that advances access to quality medicines and helps ensure patient safety.

Year 1 Update

Key progress areas over the past fiscal year include:

Adapt-Transform-Progress – USP began implementing the Adapt-Transform-Progress initiative, designed to increase the efficiency and effectiveness of the standards-development process and systems. Multiple pilots for case-based staffing processes were completed this year and are being implemented, with additional pilots planned for the coming year. In addition, a Business Process Management System (BPMS) product to support reference standards production has been developed and is being progressively implemented. The discovery phase for development of a BPMS product to support documentary standards creation is slated to wrap up in the first quarter of year two.

Standards Engagement Model – A new approach for engaging volunteers and stakeholders in standards development has

been implemented. This model helps ensure that the right individuals are engaged at the right time to support a more iterative approach to standards development. The implementation began with more streamlined Expert Committees that have access to an expanding pool of Expert Advisors. The Expert Committees developed more targeted workplans that prioritize key challenges. To address those, the model leverages increased stakeholder engagement and better use of technology to obtain comprehensive input throughout the process. The result is intended to be a more agile and iterative approach to standards development. USP also has worked to analyze and streamline approaches for direct stakeholder engagement in support of the Standards Engagement Model and Science Quality Framework (see below). This has included employing new stakeholder engagement tools, including Open Forums, which have drawn hundreds of stakeholders to events targeted at specific standards-setting areas and challenges. It has also included changes to how USP solicits input through Stakeholder Forums and Project Teams.

Science Quality Framework – The framework forms the foundation for everything our Expert Bodies will accomplish during this cycle and comprises the following five strategic pillar topic areas: Evolving and Expanding Standards, Product and Substance Performance, Emerging Modalities, Technologies, and Quality Environment.

Government Liaison Program – A total of 208 government liaisons (GL) have been assigned for this cycle, of which 200 are from FDA; they serve in 254 GL program appointments across USP’s Expert Bodies.

To improve program collaboration between USP and FDA, USP has established a USP-FDA file sharing site for coordination and reporting.

Information Sharing – USP and FDA collaborated on approaches for specifying “disregard limits” in USP monographs and the control of nitrosamine impurities reported to be present in certain widely-used medications. USP also launched an online “knowledge hub” on nitrosamines to facilitate information exchange among a broad set of interested parties. USP continued to engage FDA on the need for a long-term and sustainable mechanism for general information exchange between FDA, USP, and industry.

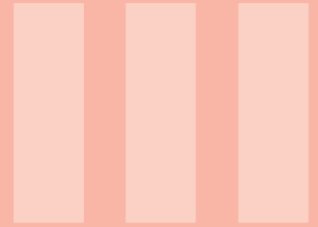
Planned for Year 2

- ▶ USP will continue to pursue development of a BPMS-based product to support documentary standards creation and review and implement further case-based standards-development processes.
- ▶ USP will continue to evaluate opportunities to engage USP volunteers and other stakeholders in new and more targeted ways, especially based on learnings from recent virtual engagements, and for earlier engagement in the standards-development process.
- ▶ USP will continue to engage with FDA to facilitate greater information sharing to support the efficient development of product quality standards.

Contact

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Resolution

Year 1 Resolution Update: Quality Standards

Resolution

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.

Alignment with USP's Mission

As standards are revised or created, USP must build stakeholders' resolve to adopt those standards and support their capabilities to use them. USP has a strong foundation—200 years of deep expertise—that makes us uniquely qualified to create relevant and impactful quality standards. USP's enhanced focus to prioritize standards that are most needed, and its reimagined standards engagement model, will help create the right standards at the right time, and ensure that they are high quality, timely, and fit for purpose.

Year 1 Update

Key progress areas over the past fiscal year include:

Priority Standards – USP worked to advance priority standards. This included development of vaccine and complex carbohydrate standards, as well as tools and solutions to address nitrosamine impurities and the COVID-19 pandemic, among other priorities.

- ▶ USP developed an outline for a new informational general chapter on messenger RNA (mRNA) vaccines. This included best practices for establishing critical quality attributes such as identity, molecular size, purity, potency, capping efficiency, and impurities. Physical standards to support vaccines were also a priority, including to support quality assessment of CRM-197, a carrier protein found in many polysaccharide-protein conjugate vaccines.
- ▶ USP provided tools and solutions that address the hazards of unacceptable levels of nitrosamine impurities, the presence of which has been reported in widely used prescription and over-the-counter medications. We developed a new general chapter on nitrosamine impurities (*USP General Chapter <1469> Nitrosamine Impurities*), and we created associated reference standards and educational

webcasts to help drug manufacturers and regulators analyze, monitor, and control for nitrosamine impurities.

- ▶ USP developed a range of tools and resources to respond to the COVID-19 pandemic. To address public health risks associated with potential methanol contamination of alcohol-based hand sanitizers used to help protect against disease transmission, and in response to a request from FDA, USP worked quickly to issue Revision Bulletins requiring the “Limit of Methanol” identification test in monographs for alcohol. Since alcohols are widely used as pharmaceutical ingredients, the revisions also address contamination risks to the supply chain beyond hand sanitizers. USP also posted a *Food Chemicals Codex* Ethyl Alcohol Immediate Standard revision to address FDA concern about hand sanitizers labeled to contain ethanol but that tested positive for methanol. In addition, USP collaborated with other international pharmacopeias on an interactive dashboard of monographs mapped to medicines investigated as COVID-19 treatments.

Standards Engagement Model – USP implemented a new approach for engaging volunteers and stakeholders in standards development. We transitioned to Expert Committees (ECs) that are smaller, more agile, and that hold more frequent and shorter meetings, with leaner work plans focused on key issues. We encouraged ECs to leverage Expert Advisors who can share their expertise as needed, without having to commit to a five-year cycle or participate in balloting activities. Our aspiration is that our new flexible model will help USP attract broader, more diverse participation, and increase volunteer engagement.

Science Quality Framework – USP’s Council of Experts helped to develop the Science Quality Framework, which comprises five strategic pillars covering the following areas: Evolving and Expanding Standards, Product and Substance Performance, Emerging Modalities, Advanced Technologies, and the Quality Environment. These focal points form the foundation for USP’s Global Science and Standards Division work during this cycle to advance our vision, become more iterative in creating standards and disseminating knowledge of quality, and to be a definitive source of quality standards.

Iterative Standards Approach – Under USP’s “iterative standards” approach, 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. Iterative approaches were employed, for instance, in developing USP’s “Methods to Assist in Detecting Falsified Remdesivir.” By accelerating the development of such relevant, timely resources and public quality standards, this model can help USP fulfill its important role in ensuring availability of quality-assured medicines.

Critical Resources - Information Sharing Priorities – We completed our 2021 Critical Resources - Information Sharing Priorities (CRISP) reanalysis showing the impact of the original CRISP roadmap, demonstrated by improved deferral rates. We built an overall narrative of CRISP into various USP and FDA engagements, including senior FDA-USP leadership discussions, to drive improved information sharing through the agency’s Center for Drug Evaluation and Research.

FDA’s Drug Competition Action Plan – We successfully mapped new USP monographs



to FDA's list of "Off-Patent, Off-Exclusivity Drugs without an Approved Generic" (the OPOE list) under FDA's Drug Competition Action Plan (DCAP) to help support development of new generic drug products and demonstrate USP's commitment to FDA's DCAP initiative. We also prioritized drug monographs associated with drug products on the OPOE list.

Health Equity Initiative – In alignment with our commitment to support global public health and access to quality medicines, USP continued its work developing a Health Equity Initiative and exploring ways Expert Volunteers can incorporate health equity into standards for enhanced public health impact. USP's Council of Experts has supported a phased approach, starting with formation of a Health Equity Advisory Group to provide ongoing counsel for the initiative.

Planned for Year 2

- ▶ USP will continue to prioritize standards development and engage with FDA on approaches that support efficiency through greater and earlier information sharing.
- ▶ USP will continue to advance initiatives to address key topics, including dissolution, impurities, and complex generics.
- ▶ USP will continue to evolve and implement the standards engagement model.
- ▶ USP will conduct a virtual workshop in fall 2021 to address the causes of health disparities and help identify potential solutions that can be applied to USP standards.

Contact

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IV

Resolution

Year 1 Resolution Update: Access to Biologics

Resolution

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.

Alignment with USP's Mission

USP continues to prioritize its portfolio of standards based on impact, technology, and regulatory considerations, providing a pathway for quality-assured medicines, including biologics. The best practices and requirements delineated in the *USP* General Chapters, as well as the existing monographs, provide the expectations for quality peptides, therapeutic proteins, and vaccines, thereby allowing manufacturers, regulators, and other interested parties to test for quality at any point in the biologics product lifecycle. Furthermore, USP performance standards are intended to support the development of analytical methods and new manufacturing processes, with a goal of facilitating the development of biologics and biosimilars. The evolution and availability of public and transparent quality standards, and adherence to those standards, will build patient and healthcare practitioner confidence in biologics.

Year 1 Update

Key progress areas over the past fiscal year include:

Standards – USP's Biologics program includes development of standards to support analytical testing of peptides, proteins, advanced therapies, and raw materials.

- ▶ USP launched the first set of monoclonal antibody performance standards to support assessment of multiple analytical methods used to evaluate product quality attributes, including identity, post-translational modifications, and aggregation.
- ▶ USP announced a collaboration with the National Institute of Standards and Technology, and the National Institute for Innovation in Manufacturing Biopharmaceuticals to design and implement a multi-laboratory study to assess analytical tools applicable to gene therapies, which will support the development of standards.
- ▶ USP developed a new standard for methoxypolyethylene glycol aldehyde, a raw material used in the production of pegylated protein therapeutics. In addition to the physical standard, a method is provided to assess the quality of the material when used with the recently approved standard.

COVID-19 Vaccines – To respond to the pandemic, USP formed a Vaccine Advisory Group comprised of external subject matter experts who advise USP on matters related to COVID-19 vaccines. We developed and released four toolkits for assessing the quality of COVID-19 vaccines, covering general/compendial tests and quality tests for mRNA, viral vectored, and inactivated vaccines. The toolkits link quality attributes for vaccines with possible methods and supporting chapters in the *USP–NF*.

Asia-Pacific Economic Cooperation – To help advance patient access to innovative therapies, including biologics, the 21 economies in the Asia-Pacific Economic Cooperation (APEC) organization endorsed USP to become an APEC Center of Excellence for Advanced Therapies. As a Center of Excellence, USP will work with regulators across the region in trainings and other forums to build capacity.

Convenings – USP launched the cycle’s Biologics Stakeholders’ Forum and delivered a series of roundtables to gather insight on key biologics topics. These included genomics and precision medicine, and the quality of insulins. USP is also engaging with the biologics continuous manufacturing (CM) community to understand where there is need and opportunity to develop standards to

support CM for biologics. This engagement includes a recently completed roundtable and stakeholders’ forum.

Planned for Year 2

- ▶ USP is engaging with Expert Volunteers and global stakeholders to identify areas where new standards are needed. Current efforts include development of standards to support new therapeutic modalities, such as gene therapy and oligonucleotides, and emerging analytical techniques, such as the multi-attribute method.
- ▶ We are developing additional performance standards for monoclonal antibodies and vaccines, including standards for raw materials and impurities testing.
- ▶ Additional toolkits for other vaccine platforms relevant to COVID-19 are under development.
- ▶ We are continuing to modernize existing standards with a particular focus on replacing animal-based assays with in vitro assays.

Contact

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Resolution

Year 1 Resolution Update: Innovations

Resolution

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.

Alignment with USP's Mission

For two centuries, USP has leveraged its capabilities and standards-setting across many areas of biomedical innovation. Given the abundance of new medicine modalities and manufacturing advances, the opportunity to support product development, quality assurance, and market and patient access through standards and other guidance is enormous, as is its potential to impact patient care and public health.

Year 1 Update

Key progress areas over the past fiscal year include:

3-D Printing of Pharmaceuticals – USP held a virtual workshop with over 600 participants on three-dimensional printing (3DP) and is cohosting a 10-part seminar series on the topic with Purdue University and Aprexia, known as the “International 3DP Pharma Technology Forum.” We are also conducting research on 3-D printing of

dosage forms using ZipDose technology in collaboration with Purdue University.

Drug Dissolution – We published a proposed revision to *USP General Chapter <711> Dissolution* in the *Pharmacopeial Forum*. We also worked to develop a major proposed revision to *USP General Chapter <1724> Semisolid Drug Products—Performance Tests* slated for publication in 2022. In addition, we published research on evaluation of dissolution performance using particle image velocimetry—an innovative application of the technology for fluid velocity measurement within a dissolution vessel—to help understand the mechanical dynamics of drug release.

Quantitative Nuclear Magnetic Resonance – qNMR provides the ability to identify and quantitate molecules in a solution to help ensure quality. USP continues to expand internal evaluation and integration of qNMR analytical procedures in our reference standard operations. We are working to revise *USP General Chapters <761> Nuclear Magnetic Resonance Spectroscopy* and *<1761> Applications of Nuclear Magnetic Resonance Spectroscopy*, with the proposed revisions slated for publication in 2022.

- ▶ qNMR methods for determining the strength of remdesivir, a medicine used to treat COVID-19, were included in USP's toolkit for addressing the potential for substandard and falsified

remdesivir. The toolkit was part of USP's broader suite of resources created to respond to the pandemic and related medicines quality challenges.

Knowledge Graphs and Natural Language

Processing – USP's work to adopt and integrate advanced technologies includes knowledge graph applications such as: Skill Seeker, which is used to identify staff and volunteers with specific skill sets; Regulatory Document Associator, which is used to identify links between USP documents and FDA guidance and laws; and a Nitrosamine Landscaping Tool that evaluates USP's impact on work to address the impurities. In addition, SciBite, a natural language processing offering, is being applied to each of these efforts to automate data extraction, taxonomy development, and knowledge graph creation. We also developed a drug pronunciation tool using artificial intelligence technology.

Emerging Technologies for Manufacturing

– USP sponsored research into understanding and developing predictive algorithms to help ensure product quality with the utilization of current and emerging manufacturing technologies, including process monitoring using residence time distribution and applications for real time release testing. We are also exploring advancements in spectroscopy, data evaluation, and inter-comparability for quality control and assessment in current and future manufacturing technologies.

Phlow Strategic Alliance – USP forged a strategic alliance with Phlow, a public benefit corporation, to develop early scientific guidelines for high-quality pharmaceutical continuous manufacturing (PCM) processes. The alliance will support certification and validation of PCM processes supporting high-

quality, U.S.-manufactured essential medicines.

Complex Generics – Complex generics—defined as drug products that have a complex active ingredient, formulation, route of delivery, or are part of a drug/device combination—are becoming increasingly predominant. Accordingly, USP launched an initiative to identify related standards, physical materials, and services as well as gaps and opportunities for future standards to support our stakeholders.

Polymers – USP initiated an incubation project to identify and evaluate technologies that address material characterization requirements for polymers, which is expected to contribute to the development of related documentary and physical reference standards.

Early Technology Identification – USP launched the “Radar” program to bolster our ability to identify and evaluate early technologies and prioritize emerging ideas and trends in pharmaceutical development to help anticipate and support stakeholder needs. We identified and researched over 20 ideas and trends during the year.

Planned for Year 2

- ▶ USP will continue to evaluate mechanisms to help industry, regulators, and other stakeholders ensure consistency and quality in advancing promising healthcare innovations.
- ▶ USP will complete ongoing lab work on 3-D printing to evaluate the need for documentary and reference standards as well as a small-vessel incubation project related to drug dissolution. USP will continue to engage with stakeholders and regulators as this work progresses.



- ▶ USP–China will host a symposium in November 2021 to promote acceptance of qNMR in China following USP’s 6th International qNMR Summit in October.
- ▶ USP will identify priority polymers with pharmaceutical applications and begin lab work on related quality assessments.

- ▶ USP will expand our ability to identify and evaluate early technologies and collect and prioritize trends around emerging science.

Contact

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Resolution

Year 1 Resolution Update: Digital Transformation of Standards

Resolution

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

Alignment with USP's Mission

Enhanced commitment to the rapidly evolving and increasingly meaningful digital realm is an essential step for USP. Transforming standards into interoperable digital components of the healthcare ecosystem is critical to delivering quality medicine and patient safety. USP must 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.

Year 1 Update

Key progress areas over the past fiscal year include:

Transition to Modern Platforms – USP launched the Digital & Innovation Division to accelerate and amplify our digitally enabled

public health initiatives and digital fluency for long-term public health impact and to help make more of USP's content available through digital processes. As part of this work, USP has started the transition to a more modern set of platforms to create, manage, and disseminate clinical, chemical, and laboratory informatics content. To date, two technology platforms are being leveraged to fundamentally change the way USP curates and disseminates scientific content as machine-readable structured data.

- ▶ Clinical Architecture's Symedical platform provides a robust and scalable solution for USP to efficiently curate and publish standards and solutions as structured data directly into health IT systems used in healthcare delivery. The software also has simplified editorial interfaces that are being used today by USP Expert Volunteers, including for creation of the USP Drug Classification, which is published each year as a standard to build, map, and evaluate outpatient formularies.
- ▶ The Global Substance Registration System (G-SRS) has been implemented at USP for curation and dissemination of high-quality sources of record for substance information. To date, the platform contains records for USP Reference Standards and is used as the content source for the USP dictionary of drug names. A USP-



branded version of the G-SRS software will serve as the newly redesigned USP dictionary product for the upcoming publication in early 2022. The platform is also being used as the foundation to exchange structured data with FDA as part of a Collaborative Research and Development Agreement between FDA and USP.

Transition to Structured Content – USP is establishing key pilots and partnerships to advance our transition from unstructured to structured standards content, building on USP’s previous licensing of the HazRx Drug Classification data asset. To date, this solution has been deployed to major retail pharmacies, pharmacy benefit managers, and distributors to increase the impact of USP standards through embedded content at the fingertips of healthcare providers. In addition, a project is underway to create a data model for our documentary standards content. This will give USP the blueprint and, eventually, the turnkey tooling and processes to publish our 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. A pilot with a major LIMS vendor scheduled for early 2022

focuses on the distribution and execution of machine-readable analytical methods found in USP monographs.

Medicine Supply Map – USP is creating the Medicine Supply Map to identify, characterize, and quantify vulnerabilities in the upstream medicine supply chain. The map will help strengthen the supply chain through data and insights that can guide risk mitigation and investment in supply chain resilience.

Planned for Year 2

- ▶ USP will continue to advance understanding of stakeholder needs in digital spaces through customer outreach, including through focus groups and surveys.
- ▶ USP will develop direct and indirect distribution capabilities for USP content to external customers.
- ▶ USP will continue to monitor and prioritize upstream advances in science where USP standards-setting and solution development may advance public health in digital implementations.

Contact

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VIII

Resolution

Year 1 Resolution Update: Education and Training for Industry and Healthcare Professionals

Resolution

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.

Alignment with USP's Mission

USP is striving to become the world leader by 2025 in education and training delivery related to the quality of medicines, dietary supplements, and foods. By offering a wide range of education and training options in a variety of settings, USP aims to reach at least 60,000 trainees annually by the end of the 2020–2025 cycle through a scalable and sustainable model that is applicable around the globe. Through the use of state-of-the-art technology USP can deliver each training opportunity to a far wider audience. By helping enable the correct adoption of USP's quality standards, this Resolution supports USP's mission to improve public health. The curricula expansion, content licensing/university curricula integration, and global expansion strategic imperatives all align with USP's strategy to build capability among stakeholders.

Year 1 Update

Key progress areas over the past fiscal year include:

Education Program – USP completed an education program refresh and refocused resources where they could have the most impact, supporting those who are implementing USP quality standards.

Attendance & Impact – USP hosted industry, regulatory, and healthcare professional education and training for 20,000+ attendees. Of those completing surveys, 88% reported that the course would have a positive impact on the quality of their work.

Training Channels and Access – USP continues to expand channels and access to our training materials to ensure that they reach all who require them. USP entered into an agreement with Chinese pharmaceutical company GenSci to deliver a full suite of training to their technical staff, and we licensed courses to a Korean pharmaceutical manufacturers' association for delivery of content to their members. USP entered long-term agreements to license its courses through two universities in the U.S. and two in India to directly impact the capabilities of students as they prepare to enter industry. In addition, we implemented subscription models that will allow organizations to provide full access to USP online courses to

their staff as part of their learning and development programs.

Technology – USP has embedded links to relevant training materials throughout the *USP–NF*, so that users can more readily access materials that support appropriate application of our standards. In addition, we added more sophisticated online course technologies, increasing engagement with students and effectiveness of the programming.

Planned for Year 2

- ▶ USP will continue to monitor high-impact/consequential standards activities, ensuring that courses are available during the implementation periods.

- ▶ USP will focus on real-world applicability when updating and creating courses to increase their effectiveness.
- ▶ Subscription offerings will be integrated into the USP store so that existing customers are aware of the offerings and that they can be purchased directly.
- ▶ USP will launch marketing campaigns targeting key customer segments to raise awareness about USP’s offerings.

Contact

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VIII Resolution

Year 1 Resolution Update: Regulatory Systems Strengthening

Resolution

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

Alignment with USP's Mission

USP will continue to work with key stakeholders, including national medicines regulatory authorities (NMRAs), national quality control laboratories, academic institutions, regional regulatory systems, and international organizations to strengthen regulatory systems. By promoting collaboration and engagement across key sectors, USP will build capabilities among NMRAs to help ensure medicine quality while expanding patient access to essential medicines in countries around the world.

Year 1 Update

Key progress on regulatory systems strengthening efforts over the past fiscal year include:

Promoting the Quality of Medicines Plus Program Expansion – This year, USP's flagship "Promoting the Quality of Medicines Plus" (PQM+) program to improve access to quality-assured medicines in low- and middle-income countries, funded by the U.S.

Agency for International Development, added Guinea, Mozambique, the Democratic Republic of the Congo, Madagascar, and Tajikistan. The Mozambique project includes the first PQM+ funding under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Funding for USP regulatory system strengthening efforts also comes from the World Bank to support the strengthening of lab capacity in Chad, Mali, Niger, and the Democratic Republic of the Congo, as well as from the Australian Department of Foreign Affairs and Trade, and World Health Organization (WHO).

PQM+ Partner Engagement – USP engaged 13 PQM+ consortium partners to amplify our reach and strengthen our offerings under the program. We are continuing to expand our circle of donors and partners to further amplify our ability to strengthen regulatory systems in low- and middle-income countries.

Risk-Based Post-Marketing Surveillance – USP deployed risk-based post-market surveillance implementation guidelines and associated Medicines Risk-based Surveillance (MedRS) tools to 20 countries.

Regional Harmonization and Coordination – USP provided the following support to key stakeholders for regional harmonization and coordination efforts:

- ▶ USP provided support to regional technical groups and economic development bodies to strengthen coordination across key geographies and facilitate mutual reliance in regulatory efforts. These organizations included: the Intergovernmental Authority on Development secretariat, the African Union Development Agency-New Partnership for Africa's Development, the Regional Development Mission for Asia regional program, and the Economic Community of West African States.
- ▶ USP collaborated with the Pan American Health Organization on efforts to strengthen regulatory capacity of the Caribbean Public Health Agency, which implemented key regulatory functions in the Caribbean Regulatory System. This resulted in development of guidance, policies, and documents on regulatory inspections and post-market surveillance.
- ▶ USP supported key Asia-Pacific Economic Cooperation (APEC) forum-related events, and the group endorsed USP as a Center of Excellence in Advanced Therapies. We led an APEC workshop on raw materials used in manufacturing cell and gene therapies attended by 125+ regulators from 21 countries. USP also co-led a workshop and webinar series on good distribution practices and track-and-trace with the Malaysia Ministry of Health and Taylor's University, attended by 400+ government regulators and industry representatives from 31 countries.

Brazilian Dietary Supplement Standards –

USP co-led a workshop on Dietary Supplements with the Brazilian regulatory agency ANVISA and local trade association Sindusfarma with 1,000+ participants from

industry, academia, public laboratories, and regulators who discussed the country's regulatory framework and standards-setting process for supplements.

COVID-19 Response – USP regulatory system strengthening activities included the following global efforts responding to the pandemic.

- ▶ PQM+ is providing critical support for safety and quality surveillance of vaccines, treatments, and preventatives, and for emergency use authorization pathways for vaccines and treatments. PQM+ is implementing COVID-19 programs in seven countries: Bangladesh, Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan, and Uzbekistan.
- ▶ USP webinars supporting access to quality-assured COVID-19 vaccines, treatments, and preventatives attracted large numbers of regulators and public health officials from low- and middle-income countries. These webinars included: "Safeguarding Populations from Poor Quality COVID-19 Vaccine Products: Toolkits for the Assessment of Quality Attributes," and "Storage and Distribution of Vaccines."
- ▶ To address potential methanol contamination of alcohol-based hand sanitizers, USP supported revision of methanol testing requirements for medical products by China's National Medical Products Administration. China is implementing method verification and sample testing using the "Limit of Methanol" test from the USP monograph.

Planned for Year 2

- ▶ USP will continue to support regulatory system strengthening interventions, including through our collaboration with the WHO as an independent, non-state actor in official relations with WHO.



- ▶ USP will continue to provide support for COVID-19 response through the PQM+ approved work plan activities to strengthen product quality and safety surveillance, immunization readiness and implementation, as well as to support laboratory systems.

- ▶ USP will continue to support global expansion of COVID-19 vaccine manufacturing capacity.

Contact

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IX

Resolution

Year 1 Resolution Update: Compounding

Resolution

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

Alignment with USP's Mission

USP engages with stakeholders to advance compounding quality, promote patient safety, and respond to evolving public health needs. Through its education and training programs as well as stakeholder engagement, USP helps strengthen practitioner awareness of appropriate circumstances and settings for compounded drug preparations, including how to consistently follow procedures that promote patient safety. USP informs the development and revision of standards by monitoring relevant advancements in science and patient safety issues related to compounding.

Year 1 Update

Key progress areas over the past fiscal year include:

Stakeholder Collaboration – USP has continued to collaborate with stakeholders on standards development, including on recently proposed revisions to *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations*, to help ensure the quality of compounded drugs.

- ▶ Related stakeholder engagement activities brought together groups with diverse perspectives representing a broad range of practice settings in which USP compounding standards are implemented. The groups provided feedback and reviewed public comments on earlier proposals to revise compounding general chapters (<795> and <797>).
- ▶ USP interviewed certain stakeholders to gain further understanding and clarification on the feedback received.
- ▶ To further determine the scope and breadth of new and revised compounding standards, USP held roundtable discussions and Open Forum meetings with healthcare practitioners, state and federal regulators, veterinarians, and others, attracting a total of 800+ participants.

Planned for Year 2

- ▶ USP's Compounding Expert Committee will continue to consider

- stakeholder input on the need for new/revised compounding standards.
- ▶ USP will review anticipated public comments on new proposed revisions to compounding general chapters (<795> and <797>). The proposed revisions were pre-posted on USP's website in September 2021, ahead of their planned publication in the *Pharmacopeial Forum*.
 - ▶ USP plans additional Open Forum sessions in January 2022 to continue to gather feedback on the proposed

compounding standards revisions. This follows two initial Open Forum sessions in September 2021 where Compounding Expert Committee members discussed the proposed revisions with stakeholders and took questions.

Contact

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Resolution

Year 1 Resolution Update: Cannabis

Resolution

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

Alignment with USP's Mission

This Resolution encourages USP to continue its history of providing scientific and technical guidance for products used by consumers to help protect patient safety and public health. This is relevant for cannabis and related products due to their widespread use and the uneven regulatory environment across the U.S.

Year 1 Update

Key progress areas over the past fiscal year include:

Collaborating on Cannabis Quality – USP is driving conversation as a thought leader on quality through the following collaborative efforts:

- ▶ USP participated in meetings with industry, other standards development organizations, and stakeholders on the

importance of cannabis quality standards for public health, as well as on the appropriate quality attributes. In addition, USP engaged U.S. state and international regulators following our publication of quality attributes for cannabis inflorescence in the *Journal of Natural Products* with the goal that these attributes will be utilized by regulatory bodies.

- ▶ Voluntary consensus standard organization ASTM International (formerly known as the American Society for Testing and Materials) subsequently adopted USP Cannabis Expert Panel recommendations for cannabis inflorescence quality attributes as a part of industry guidelines. Beyond use for cannabis inflorescence, the quality attributes are also fit for use in analysis of hemp extract oil matrix, as was determined through USP's participation in a National Institute of Standards and Technology proficiency test program.
- ▶ USP provided comments on FDA's draft guidance on cannabis quality for clinical research applications, and to multiple state regulators on proposed quality controls. USP also provided comments in response to the Cannabis Administration and Opportunity Act discussion draft, including the recommendation that legally marketed products containing cannabis and

hemp-derived substances like cannabidiol (CBD) should adhere to science-based public quality standards.

Quality Specifications for CBD – USP’s Botanical Dietary and Herbal Medicine Expert Committee and its Cannabis Expert Panel developed quality specifications for CBD as a drug substance. These include analytical methods and acceptance criteria for identification, quantitative estimation supported by suitable reference standards, and limits on CBD contaminants. Because CBD may be purified from the cannabis or hemp plant, or chemically produced, suitable methods were provided to analyze related compounds and impurities derived from hemp as well as synthetic processes.

Quality Specifications for Food Chemicals Codex Monographs – The USP Food Ingredients Expert Committee has published proposed monographs for hemp seed oil and hemp seed proteins. FDA had no questions about the conclusion that the substances are “generally recognized as safe” (GRAS) food ingredients under the conditions identified as part of the FDA GRAS notification process. Both proposed monographs contain specifications and test methods for identification, purity, and limits on impurities including tetrahydrocannabinol and CBD. If finalized, the monographs will be the first

public compendial standards for cannabis-derived food ingredients in the world.

Planned for Year 2

- ▶ USP will continue to work on standards development. This will include working through the Cannabis Expert Panel on specifications for cannabis and hemp extracts, suitable nomenclature, definitions, and quality specifications. USP will also evaluate the need for Expert Panel or other work processes to address synthetic CBD health hazards.
- ▶ USP will continue to monitor the evolving regulatory landscape, engage on development of general draft comments for discussions with U.S. federal and state regulators, and seek interactions with global regulators and industry to advance adoption of USP informational resources.
- ▶ USP will continue its work on capability building in concert with other standards-setting organizations, advance education and training, and proficiency testing based on public standards.

Contact

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XI

Resolution

Year 1 Resolution Update: Pharmacopeial Cooperation and Convergence

Resolution

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.

Alignment with USP's Mission

Through scientific exchange, training programs, and engagement in critical collaborative venues, USP remains committed to pursuing convergence with other national and regional pharmacopeias to build capabilities among emerging pharmacopeias while advocating for robust, science-based standards to improve patient safety and public health. For this work to be successful, it will be important for industry and regulators to continue their support by working with USP to identify and advance more efficient mechanisms and approaches for convergence.

Year 1 Update

Key progress areas over the past fiscal year include:

COVID-19 Response – USP led efforts to trigger the pharmacopeial alert system through the World Health Organization International Meetings of World Pharmacopoeias (IMWP) to help provide a platform for global pharmacopeias to convene and collaborate around COVID-19 response efforts. The alert system facilitated creation of a COVID-19 alert team and related activities, including monthly meetings and global cooperation on the role of global pharmacopeias in the development of COVID-19 vaccines and therapeutics. Outcomes included an interactive dashboard listing standards from IMWP for COVID-19 treatments, and development of a first-of-its-kind IMWP monograph for favipiravir antiviral treatment that could serve as a model for other potential treatments.

Workshops – USP co-hosted the following workshops dedicated to pharmacopeial convergence:

- ▶ A virtual workshop with the Parenteral Drug Association in September 2020 on the role of pharmacopeias in responding to public health crises, which included over 200 participants from industry, global regulatory bodies, and pharmacopeias.
- ▶ A virtual workshop with Japan's Pharmaceuticals & Medical Devices Agency in June 2021 on the "Role of Quality in Pharmaceuticals," which included over 800 participants,

primarily scientists and regulators from Japan and Southeast Asia, and showcased the role of pharmacopeias alongside industry and regulators in responding to public health crises.

Pharmacopeial Discussion Group – PDG partners, which include USP, the *European Pharmacopoeia*, and *Japanese Pharmacopoeia*, initiated strategic workstreams to reform how PDG engages regulators, industry, and other pharmacopeias. The most significant of these reforms—which collectively represent the first major changes to PDG since its inception in 1989—is creation of a pilot for global expansion of the PDG with specific criteria that would need to be met for other pharmacopeias to participate.

China Engagement – USP signed a memorandum of understanding with the *Chinese Pharmacopoeia* for technical collaboration in areas including packaging components, biologics, and botanicals/dietary supplements/herbal medicines.

Planned for Year 2

- ▶ The IMWP will evaluate lessons learned at the end of 2021, after publication of the favipiravir pilot monograph, to determine if it would be valuable to continue this activity for other collaboratively developed standards.
- ▶ The PDG will finalize criteria for other pharmacopeias to join the group and evaluate applications seeking inclusion, with the goal of beginning the expansion pilot by fall 2022.
- ▶ USP will begin development of glass packaging standards through a newly formed working group with experts from the *Chinese Pharmacopoeia*. Additional working groups are in development for collaboration in the areas of biologics and botanical/dietary supplements/herbal medicines.

Contact

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XIII

Resolution

Year 1 Resolution Update: Evidence Generation to Inform Policy

Resolution

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

Alignment with USP's Mission

USP supports the expansion of medicine quality-related research to build strong evidence and materials to advance policy advocacy, capability building, and public awareness.

Year 1 Update

Key progress areas over the past fiscal year include creation of a range of papers and articles in the following areas to inform policy advocacy, capability building, and public awareness:

Supply Chain Resilience – To support the work of the USP Pharmaceutical Supply Chain Center and the Medicines Supply Map, USP published policy papers outlining proposals for strengthening the medicines supply chain. The papers noted critical elements of a resilient supply chain and

included recommendations to help harness the potential of pharmaceutical continuous manufacturing as part of the solution. The papers also addressed challenges posed by information gaps across the supply chain and ways to expand information availability, such as through data sharing.

COVID-19 Vaccines – In addition to other tools and resources USP created in response to COVID-19, we developed a white paper with practical strategies and tools to address substandard and falsified COVID-19 vaccines. USP also prepared a brief highlighting the importance of USP quality standards and resources in ensuring access to quality-assured COVID-19 vaccines in the U.S. A USP blog article highlighted policy recommendations to foster broader access to quality-assured COVID-19 vaccines, as informed by a roundtable co-hosted by USP, the World Health Organization, and the Sabin Vaccine Institute.

Antimicrobial Resistance – USP Quality Institute fellows wrote two peer-reviewed journal articles demonstrating how substandard medicines accelerate drug resistance in *Escherichia coli* bacteria and malaria disease treatment. Additionally, USP developed a paper with policy recommendations more broadly examining how substandard medicines can lead to antimicrobial resistance, particularly in the context of the COVID-19 pandemic.

Pharmacopeial Principles – USP developed a paper describing seven principles as a framework to govern a core function of pharmacopeias, which is to establish public quality standards that foster trust in medicines.

Planned for Year 2

- ▶ USP will continue to advance policies to build a more resilient global supply chain.

- ▶ USP will further develop a policy agenda that actively supports biomedical innovation.
- ▶ USP will continue to engage stakeholders to highlight the negative impact of substandard and falsified medicines around the world and make recommendations to mitigate issues raised by such products.

Contact

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XIII Resolution

Year 1 Resolution Update: Coalition Building

Resolution

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

Alignment with USP's Mission

To optimize our impact and increase access to quality medicines globally, USP will activate partners in medicines quality with broad geographic and political reach, including members of the USP Convention. Either as a leader or participant in coalitions, USP can elevate national and global health policy discussions to inform debate around key issues and influence policy outcomes. Engagement of the Convention Membership and coalitions will also position USP and its allies to take on new issues as they arise and create a balanced public narrative. This multifaceted approach will allow USP to provide scientific input on relevant policy issues and deepen its role in the public conversation around medicines safety and quality.

Year 1 Update

Key progress areas over the past fiscal year include:

USP Convention Sectors and Regional Chapters – The USP Convention launched

Sectors and Regional Chapters to connect with Convention Members on shared priorities. Sectors launched are: Biologics, Generic Medicines, Healthcare Practice, and Dietary Supplements. Regional Chapters launched are: South Asia, Latin America, and Greater China. Through these convenings, Convention Members share knowledge, experiences, and perspectives around critical issues impacting quality. They also provide valuable input to USP, informing our work to advance public health and patient safety.

Call for Collaboration – The USP-led coalition, “Call for Collaboration,” has advanced shared priorities, including monograph development and modernization to facilitate patient access to medicines. In August 2020, FDA announced support for the coalition’s work to advance expanded access to medicines. The American Cancer Society signed on in September 2020. Targeted outreach to additional patient advocacy and trade groups is continuing.

Supply Chain Coalitions – USP continued to collaborate with the American Society of Health-System Pharmacists, American Medical Association, American Hospital Association, American Society of Anesthesiologists, and American Society of Clinical Oncology, to identify advocacy opportunities and policy recommendations to strengthen the healthcare supply chain. Related activities included the July 2020

“Virtual Summit on Safe, Effective, and Accessible High-Quality Medicines as a Matter of National Security.” USP participates in additional supply chain related initiatives, including the: 1) HHS Office of the Assistant Secretary for Preparedness and Response (ASPR); 2) Healthcare and Public Health Sector Coordinating Councils; 3) Federal Emergency Management Agency’s Committee for the Distribution of Medical Resources Necessary to Respond to a Pandemic Plan, Action #2 – Drug Products & Drug Substances; and 4) to-be-developed ASPR Healthcare and Public Health Sector’s Supply Chain Working Group.

Dietary Supplements Quality

Collaborative – DSQC developed new resources and began stakeholder outreach for consumer protection legislation, gaining coverage in *Morning Consult*, *Nutra-Ingredients USA*, *WholeFoods Magazine*, *Drug Store News*, *Nutritional Outlook*, and *Natural Products Insider*. In September 2020, DSQC hosted a webinar for congressional staffers on ways to advance the quality and safety of dietary supplements.

Planned for Year 2

- ▶ USP will expand on the foundation established in FY 2020 for increased engagement with Convention Members via Sectors and Regional Chapters, as well as related opportunities for

Member dialogue and input, and co-creation of content. We will launch additional Sectors and Chapters, including the Middle East and North Africa Regional Chapter, and the Innovation Sector.

- ▶ USP will continue to seek opportunities for coordinated engagement with Convention Members and other stakeholders to identify and prioritize monograph development for greatest impact on public health and patient access, such as working with patient advocacy communities on their needs for products such as complex generics.
- ▶ USP will continue to identify opportunities to gain insights and for collaboration in areas where USP and stakeholders can work together to strengthen the resiliency of the medicines supply chain.
- ▶ USP will continue to develop spaces for Convention Members and other stakeholders to leverage and amplify collective expertise and networks to help promote safety, advance transparency, and embrace quality in dietary supplements.

Contact

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XIV

Resolution

Year 1 Resolution Update: Culture of Excellence

Resolution

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

Alignment with USP's Mission

A culture of excellence at USP means people, processes, and systems are aligned and working optimally in pursuit of the organization's mission. An effective foundation of rigorous process and data management with continuous improvement will enhance decision making as well as how USP interacts and shares information with stakeholders. By focusing on improving effective and reliable procedures and systems, USP will be better positioned to expand access to quality medicines, facilitate innovation for quality medicines, and improve public health.

Year 1 Update

Key progress areas over the past fiscal year include:

Strategic Plan and Knowledge

Management – USP has established a strategic plan to model a culture of excellence and tools to solidify effective knowledge management (KM). The tools are designed to help USP effectively identify,

receive, share, and store content, and enhance internal and external transparency. Elements of a strong foundation for the planned KM platform have been established. An evaluation was conducted to ensure the platform can help create an ecosystem that cultivates critical institutional knowledge.

Business Process Management – USP is designing and beginning to implement a Business Process Management (BPM) application for standards development that will facilitate automation of processes with increased consistency and control. Progress was made during the year on the BPM application for reference standards development, which will yield a more streamlined process with built-in quality parameters once fully implemented. Evaluation of processes for documentary standards began at the end of the fiscal year and will expand in Fiscal Year 2022 (see below).

Data Quality – USP established a formal data quality governance program to help ensure effective decision making and use of assets, enhanced support of digital processes, and mitigation of potential risks to USP's organizational reputation and sustainability.

Digital Integration Office – The DIO was established to help transform the business of USP by driving development of digital

products and services built on quality data and standards. DIO is tasked with identifying, categorizing, and prioritizing digital products as well as planning and managing project data and outcomes with operational efficiency under the umbrella of USP's robust Quality Management System.

Online Products & Services – USP is improving capabilities, access, controls, and support for its online products and services. A risk assessment led to the following:

- ▶ An enhanced disaster recovery plan for the *USP-NF* online platform
- ▶ Increased customer support, including expanded hours of operation and geographic coverage

Planned for Year 2

- ▶ USP will roll out the KM tool and plan for its expansion to additional knowledge sources (internal and

external) that will provide the most value to USP staff and stakeholders.

- ▶ USP will advance build-out of the BPM system for documentary standards development with a focus on streamlining the process and building in quality metrics, which will effectively manage key risks and provide more transparency to stakeholders.
- ▶ USP will fully develop the DIO to include key subject matter experts who will evaluate and make recommendations on digital projects and data quality as well as execute a formal launch of that function.
- ▶ USP will continue to assess opportunities to improve users' experience with online products and services.

Contact

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XV

Resolution

Year 1 Resolution Update: Impact Expansion

Resolution

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

Alignment with USP's Mission

The complexities of our interconnected world impact patient safety and public health globally. This is especially true for the medicine supply chain, which is global for all countries, making adherence to science-based standards more important than ever. Globalization has also brought shared societal public health risks that can accompany medicine quality challenges. By cultivating critical success factors that focus on people, continuous improvement, digital optimization, and investment and sustainability, USP advances its mission and expands its impact, reaching more people in more areas around the world.

Year 1 Update

Key progress areas over the past fiscal year include:

Nitrosamines Initiative – USP engaged thousands of stakeholders globally around our solutions to help control the risk of nitrosamine impurities in medicines through

USP standards, educational courses, webinars, and workshops. Piloting a new online community approach to sharing knowledge on risk assessments, USP launched the Nitrosamine Exchange and engaged 400+ members to date from 63 countries. We also engaged numerous regulatory agencies and pharmacopeias on the topic.

China Methanol Standards – To address potential methanol contamination of alcohol-based hand sanitizers, USP supported revision of methanol testing requirements for medical products by China's National Medical Products Administration. China is implementing method verification and sample testing using the "Limit of Methanol" test from the *USP* monograph.

South Asia Engagement – USP collaborated with the Centre of Regulatory Excellence at Duke-NUS Medical School in Singapore on "good reliance practices" and to address risk-based post-market surveillance as a key regulatory function through a session attended by 43 regulators from 15 countries across the South Asia and other global regions.

Asia-Pacific Economic Cooperation – USP worked to develop resources to support post-market surveillance and monitoring as components of the Asia-Pacific Economic



Cooperation (APEC) Supply Chain Security Toolkit.

Promoting the Quality of Medicines Plus Program – USP’s flagship Promoting the Quality of Medicines Plus (PQM+) program to improve access to quality-assured medicines in low- and middle-income countries, funded by the U.S. Agency for International Development (USAID), this year added Guinea, Mozambique, the Democratic Republic of the Congo, Madagascar, and Tajikistan. USP also engaged 13 PQM+ consortium partners to amplify our reach and strengthen our offerings under the program.

Convention Regional Chapters – The USP Convention launched regional chapters for convention members. They provide a consistent and structured way for regional members to share their perspectives, expertise, and input on USP’s work. We launched regional chapters in Latin America, South Asia, Greater China, and the Asia Pacific. To further expand our reach, USP actively engaged with regulatory agencies across the Middle East and North Africa (MENA) region to renew collaborations with Turkey, the United Arab Emirates, Saudi Arabia, Oman, Pakistan, Egypt, Kenya, Ethiopia, Sudan, Jordan, Tunisia, and Morocco, and worked toward an anticipated launch of USP’s MENA regional chapter.

Virtual Stakeholder Engagement – The COVID-19 pandemic’s requirement for social distancing ushered in changes to the way USP interacts with customers and stakeholders globally, including new ways to work virtually. As a result, we more than doubled the number of global attendees for USP events, including workshops, forums, roundtables, and webinars. We estimate attendance at USP events by those outside of North America almost tripled.

Education – USP hosted industry, regulatory, and healthcare professional education and training for over 20,000 attendees during the year, with significant participation by those outside the U.S. Attendees shared high marks (88%) when asked if the course they took would have a positive impact on the quality of their work.

Pharmatech Acquisition – USP acquired Pharmatech Associates, creating a foundation for increasing our global impact through consulting services that will assist manufacturers in meeting quality standards across the product lifecycle.

Planned for Year 2

- ▶ USP will apply learnings from its work on nitrosamines to strengthen global engagement on other initiatives.
- ▶ USP will continue to expand regulatory engagement with authorities in Brazil, South Korea, India, and Russia through formal memorandums of understanding on capability building, pharmaceutical impurities, cell and gene therapies, vaccines, and dietary supplement quality.
- ▶ USP will continue to engage regulatory authorities in Asia, Egypt, and Latin America to advocate for risk-based post-market surveillance programs and explore opportunities to provide related trainings.
- ▶ USP will launch the MENA regional chapter for convention members and continue to build engagement through all the regional chapters.
- ▶ USP will continue to translate our scientific materials and content into more languages, including Spanish, Mandarin, Portuguese, Russian, and Korean, to facilitate global stakeholder engagement.
- ▶ USP will continue to learn how best to leverage virtual tools to strengthen global engagement.

- ▶ USP will work to expand Pharmatech's geographic reach to increase global impact.

Contact

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