FISCAL YEAR 2023

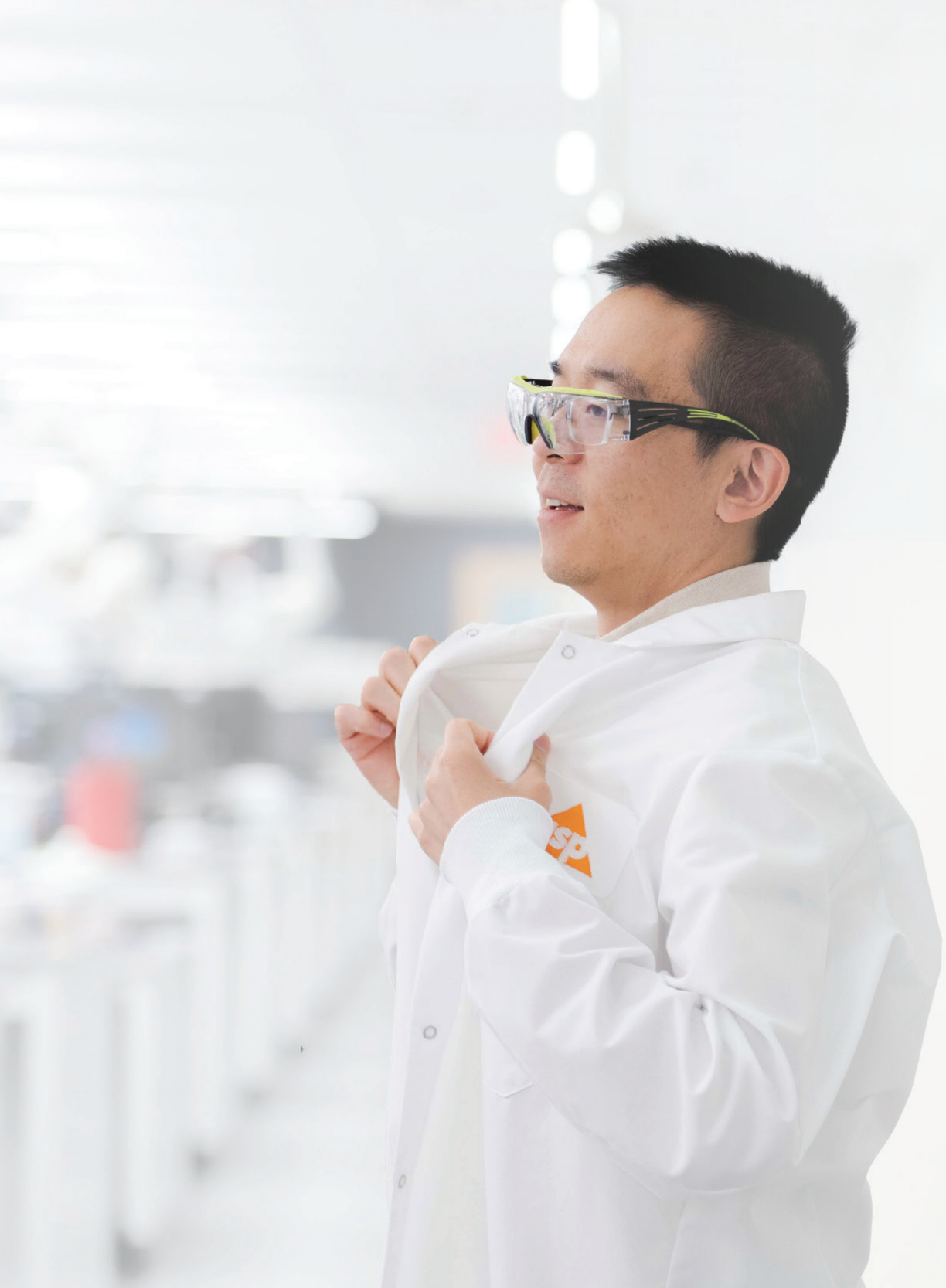
REPORT TO THE

Board of Trustees

ON

Council of Experts

ACTIVITIES



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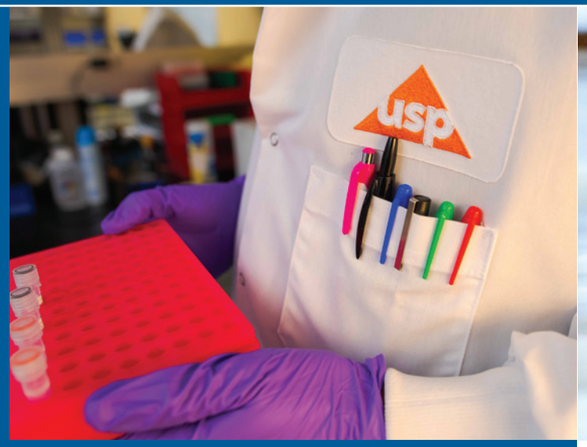
Letter FROM THE Chair



On behalf of the Council of Experts (CoE) and USP staff, I am pleased to present the fiscal year 2023 (FY23) CoE annual report. This is the third annual report of the 2020–2025 cycle, and it describes the activities and achievements of the CoE and its Expert Committees (ECs) and Expert Panels (EPs) in collaboration with the Global Science & Standards Divisional staff from July 2022 through June 2023.

Throughout FY23, USP has leveraged its resources to deliver impact through standards development, advocacy, and capability building, guided by the 2020–2025 Resolutions adopted by the USP Convention in May 2020. In particular, four areas are important in the context of our vision to be a definitive source of quality standards:

- **Supply Chain:** USP standards and quality-focused solutions help improve access to safe, quality medicines people can trust. This includes diverse activities such as addressing potential impurities like nitrosamines, working with stakeholders to modernize manufacturing to help produce medicines in more places, and using data to better understand and fix weaker links in the supply chain.
- **Innovation:** USP standards accelerate innovation, build trust and confidence in medical breakthroughs, and advance the quality of medical products, dietary supplements, and foods. Our standards and related programs promote common approaches to quality and adoption of new medicine modalities like biologics as well as advanced therapies and manufacturing technologies. Our focus on innovation includes continuing to advance the functionality of USP's standards in digital environments to help meet stakeholders' evolving needs.
- **Global Health:** USP is working with governments, industry, and other stakeholders around the world to build the capability to supply patients and consumers with quality medicines, dietary supplements, and foods. This includes addressing the potential for substandard and falsified medicines in low- and middle-income countries.
- **Science of Quality:** Our rigorous science informs the definition of quality and supports regulatory confidence. Through our work with independent scientific and healthcare experts from industry, government, and academia, our standards help to expand the availability of trusted, quality medicines, dietary supplements, and foods.

FY23 was a year of significant change and accomplishments. We emerged from the pandemic to evolve new ways of working together. I really enjoyed our first hybrid Volunteer Leadership Meeting as well as subsequent CoE meetings where we tested new ways to provide a satisfactory and effective meeting experience for in-person and remote participants. We also expanded our scientific solutions beyond our compendial standards, demonstrating agility where and when necessary. In parallel, several standards were finalized that were many years in the making. Overall, it has been a very good year with standards development meeting and, in several cases, exceeding the plans and targets we set for ourselves at the start of the year.

We have achieved all of this thanks to the dedication, commitment, and perseverance of our global network of thousands of USP staff and Expert Volunteers, our strong relationship with the U.S. Food and Drug Administration (FDA) and other regulatory agencies, and insights obtained from our industry stakeholders worldwide. In this context, it is critical to access the best expertise and talent, and USP is committed to creating a culture where everyone feels fully empowered and valued and can contribute their full potential to accomplish our mission to help build quality foundations for a healthier world. We embrace diversity, equity, inclusion, and belonging (DEIB) for our volunteers and staff as these are central to our public health mission and make USP stronger as an organization.

In this introduction, I want to highlight a few of our many FY23 activities and accomplishments and the key factors that have contributed to our successes.

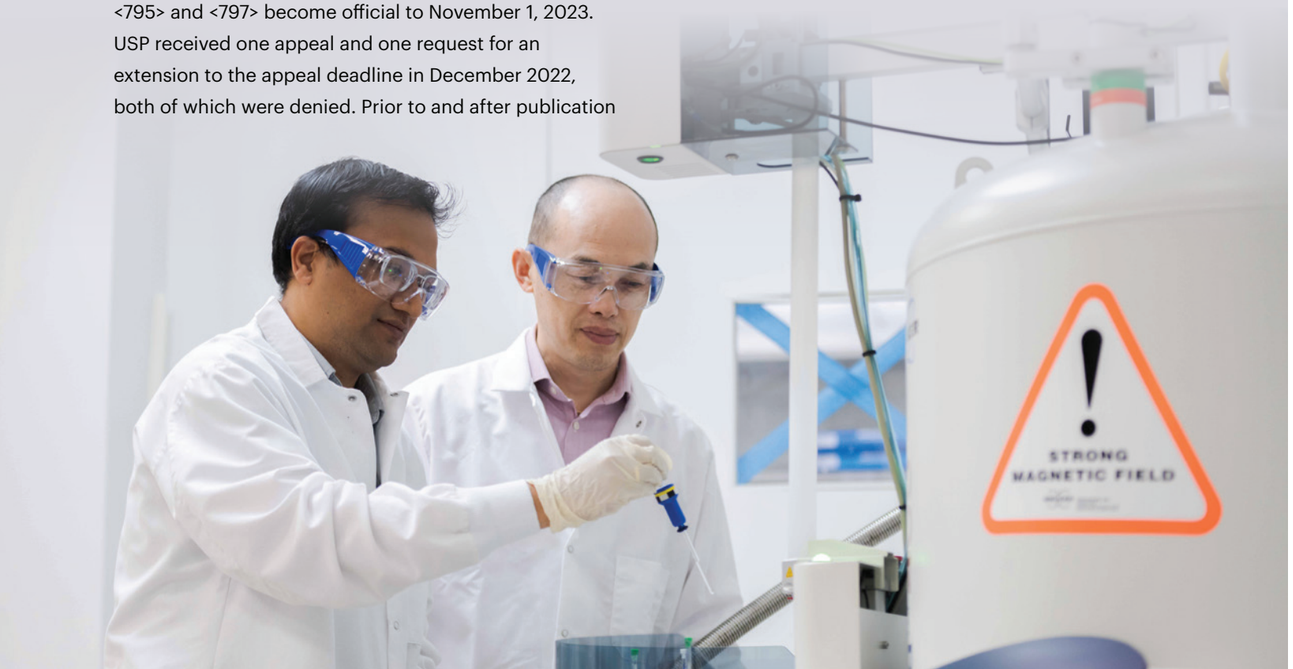
1. **We have developed agile responses to several emerging public health issues:**

   - **Toolkit for Identifying Deadly Contaminants in Allergy, Cold, and Cough Medicines:** In January 2023, USP made its virtual toolkit for measuring and controlling levels of diethylene glycol and ethylene glycol contamination associated with allergy, cold, and cough medicines available as a free resource to all stakeholders at https://www.usp.org/impurities/diethylene-glycol-resources. The USP toolkit includes information from relevant chapters, monographs, and other resources that can help manufacturers and regulators test the quality of these medicines.
   - **Infant Formula Guide:** The Foods team formed an internal task force to create a strategy for helping to address overall concerns about infant formula quality in the face of ongoing supply chain constraints and concerns over microbial contamination. In May 2023, the task force created the "Guide to Food Ingredient Standards and Solutions for the Infant Formula Industry," which outlines existing USP Documentary Standards (DSs), Reference Standards (RSs), and other materials that can be used to assess the purity and quality of ingredients used in the manufacture of infant formula.
   - **COVID-19 Toolkits:** USP previously created toolkits to support quality assessment as well as handling of COVID-19 vaccines. In October 2022, USP released an updated version of the COVID-19 Vaccine Handling Toolkit, which included considerations

for administering booster and pediatric doses and mitigation strategies to avoid medication errors in a multi-vaccine environment. The USP COVID-19 Vaccine Quality Assessment Toolkits were updated in March 2023, and USP Biologics added resources for assessing the quality attributes of multiple vaccine platforms, including inactivated, virus-like particle, and DNA vaccines. These toolkits can help reduce risks from substandard and falsified vaccines, and, ultimately, increase public trust.

These efforts helped to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution III, on quality standards; Resolution V, on innovation; and Resolution XV, on impact expansion.

2 **We have published final revised compounding chapters:** USP has passed important milestones by delivering the final revised *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* and supporting their early adoption by stakeholders. After over a decade of standards development and stakeholder engagement by multiple ECs, the Compounding EC voted in July 2022 to extend the date on which the final revised General Chapters <795> and <797> become official to November 1, 2023. USP received one appeal and one request for an extension to the appeal deadline in December 2022, both of which were denied. Prior to and after publication of the official standards, USP has engaged in extensive stakeholder communication to support stakeholders' early adoption of these General Chapters. This work aligns with Resolution II, on efficiency in standards development and revision; Resolution VII, on education and training; and Resolution IX, on compounding.



3 **We have developed priority standards and solutions.** USP's Science Quality Framework, which the CoE helped to develop, comprises five strategic topic areas: evolving and expanding standards, product and substance performance, emerging modalities, new analytical and manufacturing technologies, and quality environment. In each of these areas, we have made significant progress and major achievements:

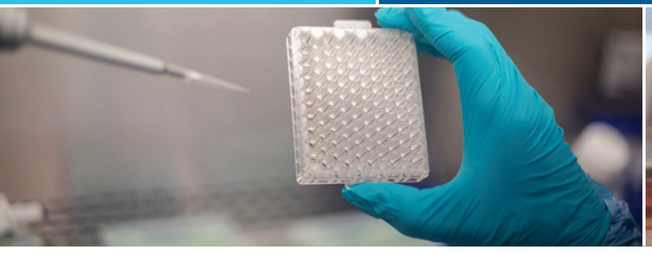
- **New Dissolution Performance Verification Standard (DPVS):** USP has achieved a major milestone by delivering the new and improved DPVS–Prednisone RS after years of development. Dissolution standards are one of the most impactful and frequently used USP standards. The DPVS has been shown to have lower tablet-to-tablet variability, more consistent performance, and a more stable shelf life than the previous RS used by laboratories that conduct performance verification testing using the USP Apparatus 1 (basket) or 2 (paddle). This was accompanied by the revision of *USP* General Chapter <711> *Dissolution*, which replaced the previous RS with the new DPVS and became official in May 2023.

- **Controlling Nitrosamine Impurities:** To safeguard patients from the adverse effects of nitrosamine impurities in medicines, USP offers *USP* General Chapter <1469> *Nitrosamine Impurities* and eight USP Nitrosamine RSs. In FY23, USP's Nitrosamines team has been working to bring additional solutions such as Pharmaceutical Analytical Impurities to market that include a variety of simple nitrosamine impurities and nitrosamine drug substance-related impurities.
- **Emerging Standards:** USP is proposing to take a more iterative approach to standards development, where an emerging standard—a potential standard not yet under development—is shared through our website to help stimulate early discussion and stakeholder input and contributions prior to formal notice and comment through publication in the *Pharmacopeial Forum* (*PF*). As part of this effort, USP has launched the Emerging Standards Concept website at https://go.usp.org/emerging-standards, which includes links to emerging standards.
- **New Flexible Approach for Reporting Thresholds of Unspecified Impurities:** The General Chapters–Chemical Analysis EC published the new *USP* General Chapter <477> *User-Determined Reporting Thresholds* in *PF* 48(5) [Sep.–Oct. 2022], which would provide a flexible approach for reporting unspecified impurities referenced in *United States Pharmacopeia–National Formulary* (*USP–NF*) monographs. This approach empowers manufacturers to apply product-specific knowledge in establishing reporting thresholds instead of using prescriptive numeric values and would enable accuracy and consistency concerning the control of organic impurities for the benefit of patients and public health.

These activities helped to fulfill multiple Resolutions, including Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution III, on quality standards; and Resolution V, on innovation.

4 **We have expanded our work on vaccines, antibodies, and cell-based therapies.** The following activities help to fulfill Resolution IV, on access to biologics, and Resolution V, on innovation:

- **mRNA Vaccine Quality Draft Guidelines:** USP Biologics released the second version of its draft guidelines on Analytical Procedures for mRNA Vaccine Quality, which has been updated to incorporate public comments and donated methods provided by stakeholders. These analytical procedures and best practices support quality assessments for mRNA vaccines and therapies and help build consensus on quality attributes and appropriate test methods for this new modality.
- **Quality Monoclonal Antibody (mAb)-Based Therapeutics:** Critical donations have been secured to expand our mAb pipeline of RSs and materials to support functional and physiochemical testing. In January 2023, USP released an mAb Analytical Guide that outlines testing needs at different phases of development and brings together USP resources to support mAb quality, including DSs, RSs, training, and educational resources.
- **Quality Biologic Medicines:** In February 2023, USP announced that it has entered a strategic collaboration with ATCC, a nonprofit global biological materials management and standards organization, to jointly provide co-branded analytical materials to support the development and characterization of quality biologic medicines and therapies. The initial set of products ATCC and USP will launch together include genomic DNA from top cell lines used in bioproduction.




- **Transitioning Insulin and Insulin Analog Products to *In Vitro*-Based Bio-Identity Methods:** The Biologics Monographs 2–Proteins EC's Insulin EP worked toward transitioning insulin and insulin analog products to *in vitro* cell-based testing for bio-identity. The goal is to omit the rabbit blood sugar method from *USP* General Chapter <121> *Insulin Assays*. Currently, the *in vitro* test is applied to only two insulin analogs, Insulin Glargine and Insulin Lispro. In FY23, the Insulin EP continued its work evaluating data for transitioning the remaining insulins.

5 **We have released new cannabis analytical tools.** The following work supports Resolution X, which encourages USP to leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions that help address quality-related concerns and support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds:

- **USP Cannabis Tool Kits:** USP's newly released four-volume Cannabis Tool Kits garnered more than 1,182 page views and 707 downloads in FY23 Q4. These tool kits provide scientists, manufacturers, and regulators with the resources needed to help protect public health by establishing a framework for the consistent characterization of cannabis for medical use.
- **Proposed *USP* General Chapter <1568> *Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research*:** This proposed general chapter would provide the specifications for quality attributes that are fundamental to characterizing the materials for clinical research. Proposed in *PF* 49(3) [May–Jun. 2023] for public comment, General Chapter <1568> is intended to complement the FDA Guidance on cannabis quality for clinical research with specific analytical methods and acceptance criteria.
- **USP Certified Reference Materials (CRMs) for Cannabinoids:** USP began developing CRMs for cannabinoids to provide ISO 17034 compliant reference materials for determination of cannabinoids in cannabis product samples in the ISO 17025 environment. These materials for non-compendial application include information about assigned values, uncertainty values, homogeneity, and stability.
- **Delta-8 THC Product Impurities:** Concerns about health hazards associated with the consumption of delta-8 THC products have been highlighted in public health advisories from the FDA and Centers for Disease Control and Prevention (CDC). USP has collaborated with an external laboratory to generate information on the identity of impurities in synthesized delta-8 THC products and develop analytical methods to separate these impurities using chromatographic methods.

6 **We are committed to diversity, equity, inclusion, and belonging. USP's strength lies in its people, staff and volunteers, and accessing and providing opportunities for everyone is essential.** The following are concrete examples of our work in this area in alignment with Resolution XIV, on culture of excellence:

- **New DEIB EP:** USP launched a Call for Candidates to invite qualified candidates to apply to serve on the newly formed DEIB EP, which reports to the CoE. This EP will advise Expert Volunteer leadership and USP staff on strategies and best practices to establish a diverse and inclusive environment that fosters strong collaboration.
- **Scientific Expert Fellowship (SEF):** USP staff has been reviewing and selecting candidates for the USP SEF Program for the upcoming fiscal year. The SEF Program provides opportunities for scientists, engineers, public health professionals, and clinicians from populations underrepresented in USP Expert Volunteer activities to participate on ECs or EPs for 1 year with flexible hours and develop drafts and final versions of white papers, trade articles, and other important documents.
- **Inclusive Volunteer Recruitment:** USP is focused on transparency and inclusivity in recruiting mission-committed people with diverse backgrounds, experiences, and talents. More than 260 applications were received in response to USP's Call for Candidates to form a new General Chapters–Microbiology (GCM) EC, indicating a high level of interest by the scientific community. The CoE elected a new GCM EC Chair in November 2022 and onboarded 20 GCM EC members—bridging 16 time zones and six countries—by January 2023.

7 **We have launched an Updated Standards of Conduct (SoC) program to help Expert Volunteers and USP staff adhere to SoC provisions and USP's culture of integrity in standards-setting activities.** The following core elements of this program have been implemented:

- New and revised training modules that cover SoC principles (i.e., representation, confidentiality, and conflicts of interest) and their application to standards-setting activities.
- USP's Compendial Integrity Manager, working across science and in consultation with legal and QA staff, has performed SoC evaluations when necessary and provided training to Expert Volunteers and USP staff. Additionally, the Compendial Integrity Manager has collaborated with the CoE during their meetings, reported on the outcomes of evaluations, held a listening session on Expert Volunteers' experience with SoC, and delivered confidentiality training.
- An SoC Program Manual for USP staff that references guiding principles and identifies policies, procedures, and newly updated controlled documents covering SoC provisions has been published on a new internal SoC SharePoint site.

Additionally, Code of Ethics refresher training, which was rolled out to all USP Volunteers in FY22, was completed by FY23. These activities helped to support Resolution XIV, on culture of excellence.

I am sincerely grateful to everyone who helped accomplish these impressive achievements. In particular, I would like to highlight the work of our Expert Volunteers, who tirelessly dedicate their own time to support USP's global mission to help build quality foundations for a healthier world. Indeed, our impact in FY23 was made possible by the numerous hours—estimated at 63,327—that were generously contributed by our Expert Volunteers and augmented by our dedicated staff. I warmly invite you to read the following pages, which tell the stories of how our collaborative activities in FY23 have benefited consumers, patients, and other global stakeholders by helping to improve and protect public health in the United States and around the world.

Jaap Venema, Ph.D.

USP Chief Science Officer & Chair, USP Council of Experts

Fostering Collaboration:

FY23 AT A GLANCE

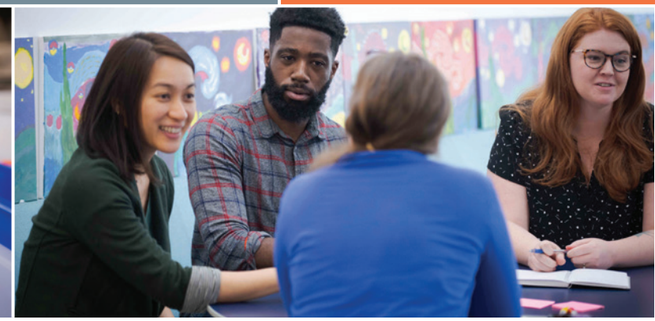
CoE Overview

The CoE, consisting of the 29 EC Chairs plus USP's Chief Science Officer, who serves as CoE Chair, is one of USP's three governing bodies. Its members direct the scientific standards-setting initiatives for the organization and ensure that these efforts align with USP's Resolutions, policies, and strategies. The CoE oversaw the activities of numerous global scientific experts who served on ECs, EPs, and Joint Standards-Setting Subcommittees (JS3s) in FY23.

USP Governing Bodies and Related Groups

Board of Trustees (BoT)	USP Convention Membership and Council of the Convention (CoC)	CoE	Expert Bodies Under the CoE
14 members, including 10 members elected by the USP Convention, three at-large members appointed by the BoT, and the USP CEO, responsible for USP's: · Policy oversight · Fiduciary obligations · Strategic direction · Sustainability	**461 organizations comprise the Convention Membership,** invited by the BoT based on recommendations of the CoC, responsible for: · Providing input to USP throughout each cycle, informing work, and advancing mission · Adoption of Resolutions that guide USP priorities and initiatives · Amendments to the USP *Bylaws* · Election of the BoT and CoE The CoC guides meaningful engagement of the Convention and represents the membership in important governance decisions.	**29 Chairs** of USP ECs, elected by the USP Convention, plus USP's Chief Science Officer, who serves as CoE Chair, responsible for: · USP scientific and standards-setting decisions · Standards-setting work of USP's Expert Bodies · Adherence to the direction set forth by the BoT and USP Convention	**ECs** Scientific experts who create, revise, review, and approve standards for a specific topic area. EC members are elected by the CoE and serve a 5-year term. **EPs** Advisory bodies formed to supplement EC expertise on specific topics. Each has a specific charge and is dissolved upon completion of its work. Members may include EC members and may serve on multiple EPs. **JS3s** Representatives from ECs who serve on subcommittees formed to address issues that affect multiple standards-setting areas.

USP Staff: Individuals who support and shepherd the work of all governing bodies and related groups



USP Standards Approved in FY23

Expert Volunteers play a vital role in approving DSs for publication and RSs for release. Expert Volunteers ballot on all regular DS revisions, new RSs (F Lots), and a sampling of Replacement and Continuation (R&C) Lots.

FY23 Balloted and Approved Standards, by the Numbers

107 DS Ballots	**347** DS Items Balloted
341 New or Revised DSs Approved	**96** Modernized DSs Approved

6 *USP–NF*, *Food Chemicals Codex* (*FCC*), and Supplements DSs Omitted	**503** RS R&C Lots Released	**123** RS F Lots Released

Pharmaceutical Analytical Impurities (PAIs)

Manufacturers can use USP PAIs in analytical testing to detect, identify, and measure impurities. USP PAIs are released through a quality process designed to ensure identity and quality for analytical applications. PAI products are different from official USP RSs, but together they can help to provide a comprehensive solution for research and analytical needs across the drug life cycle. Their use can help control impurities to consistently produce safe and effective products so patients have access to quality medicines.

PAIs

168 New Products in FY23	**39** Replacement Lots in FY23	**361** Total Products in the PAI Catalog

CoE Key Activities and Accomplishments

FY23 HIGHLIGHTS

The CoE met 11 times during FY23. In addition to leading and managing the work of ECs, CoE members drive USP's bold strategic direction for science, facilitate robust scientific dialogue, evaluate public input on USP standards, uphold and champion policies and practices that ensure the integrity of the standards-setting process, and help to identify and mentor the next generation of USP Expert Volunteers. The following are highlights of the CoE's key activities and accomplishments during FY23, guided by the organizational goals defined by the 2020–2025 Convention Resolutions.

Medicine Supply Chain Quality Activities: The CoE and USP staff deliberated on the standards-setting, advocacy, and stakeholder outreach activities aimed at strengthening supply chain resilience at its May 24–25, 2023, meeting. The CoE and USP staff discussed ways to increase stakeholder use of USP's Medicine Supply Map, a predictive analytics platform that identifies, characterizes, and quantifies risk in the upstream pharmaceutical supply chain so that stakeholders can prioritize investments in supply chain resilience and proactively prevent drug shortages. This work helped to fulfill Resolution III, on quality standards; Resolution VII, on education and training for industry and healthcare professionals; and Resolution XV, on impact expansion.

Strengthening the Expert Volunteer Experience: In breakout sessions during its May 24–25, 2023, meeting, the CoE collaborated on key elements of the value proposition for enhancing the ways Expert Volunteers experience their involvement with USP. The CoE, facilitated by USP staff, used the key themes from the Expert Volunteer value proposition to inspire and enrich engagement that contributes to quality standards and other solutions at USP. This work relates to Resolution XIV, on culture of excellence.

Operational Review of QA Conflict of Interest and Balloting Evaluation Reports: The CoE and USP staff reviewed routine QA evaluation reports on conflict-of-interest declarations during *USP–NF* standards balloting as regular agenda items at its May 24, 2023, January 23, 2023, and September 19, 2022, CoE meetings. These evaluations were initiated following the review of special targeted audits in FY21 Q4 through FY22 Q3. This work helped to support Resolution XIV, on culture of excellence.

Advanced Manufacturing Technology (AMT) and Pharmaceutical Continuous Manufacturing (PCM): The CoE deliberated on setting standards for—and reducing barriers to—AMT at its April 27, 2023, meeting. The CoE provided feedback to USP staff on efforts to develop non-compendial Technical Guides that provide industry with instructions and approaches for establishing quality using PCM. These activities help to fulfill Resolution III, on quality standards, and Resolution VII, on education and training.

Increasing USP's DS Pipeline: The CoE provided feedback to USP staff on the strategic priorities for increasing the number of new, modernized, and revised monographs and public standards at the March 20, 2023, CoE Meeting. The discussion emphasized the Small Molecules standards pipeline, which is driven by data, stakeholder needs, relevancy, and impact, and Biologics' approach, which focuses on quality attributes and analytic methods across a therapeutics category, such as mAbs. This work helps to fulfill Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; Resolution IV, on access to biologics; and Resolution V, on innovation.

Quantitative Nuclear Magnetic Resonance (qNMR) Applications: The CoE deliberated and provided feedback on qNMR applications in the pharmaceutical industry and standards/monograph development activities related to dietary supplements presented by USP staff at the February 27–28, 2023, CoE Meeting. USP staff noted that qNMR is scientifically ready for pharmacopeial analysis and fits well in USP's 2020–2025 top-level priorities due to its metrological acceptance, practical feasibility, and increasing applications. These activities are in accordance with Resolution III, on quality standards, and Resolution XV, on impact expansion.

National Urban Fellow Project for Broadening the Diversity of Expert Volunteers: The CoE provided feedback on the project proposals presented by Geniro Dingle, National Urban Fellow, at the January 23, 2023, CoE meeting. The key deliverables include updated recruitment materials, targeted engagement events, and onboarding activities support as per Resolution XIV on culture of excellence.

***USP–NF* and *Food Chemicals Codex* (*FCC*) RS Guideline Revisions:** The CoE approved revisions to the "Guideline for Review and Approval of Reference Standards for Use with *USP–NF* and *FCC* Monographs or General Chapters" at the January 23, 2023, CoE Meeting. The guideline revisions align with updates to the RSs Evaluation Operational Manual. These activities align with Resolution II, on efficiency in standards development and revision.

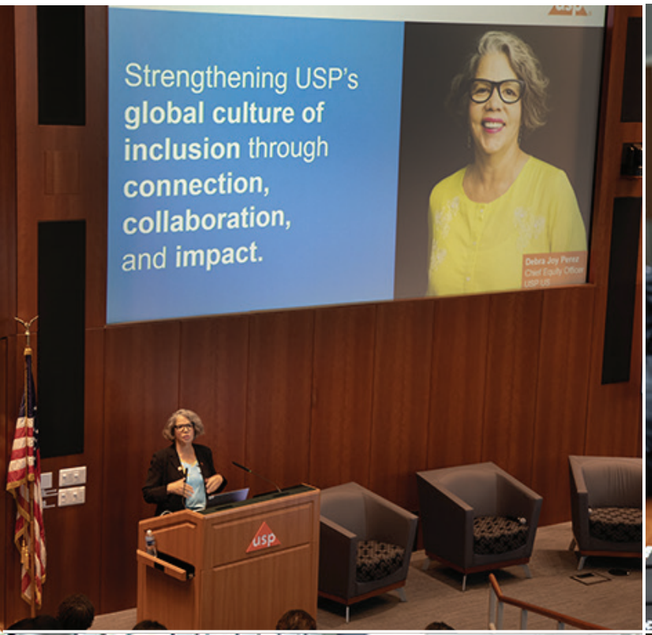
New DEIB Expert Panel (EP): USP launched a Call for Candidates to invite qualified candidates to apply to serve on the DEIB EP, which reports to the CoE, in December 2022. This EP will advise Expert Volunteer leadership and USP staff on strategies and best practices to establish a diverse and inclusive environment that fosters strong collaboration. These activities align with Resolution XIV, on culture of excellence.

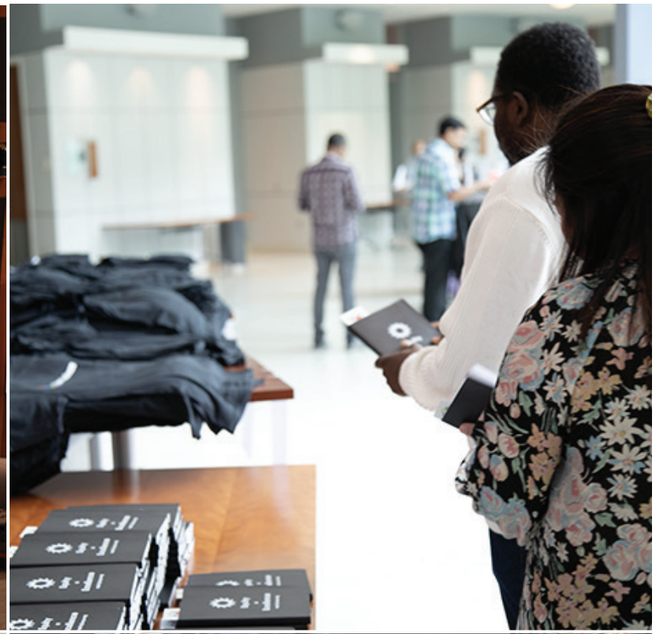
New General Chapters–Microbiology (GCM) EC: The CoE elected Mark Schweitzer, Ph.D., as the new GCM EC Chair on November 16, 2022, and the new GCM EC members were onboarded by January 2023. The GCM EC is responsible for critical quality areas, including sterility, bacterial endotoxins, and microbiological quality, and will be developing modern microbiological methods related to cell and gene therapy, rapid testing, and sterility testing to ensure that standards are relevant in an evolving global environment. These activities help to fulfill Resolution IV, on access to biologics; Resolution V, on innovation; and Resolution XIV, on culture of excellence.

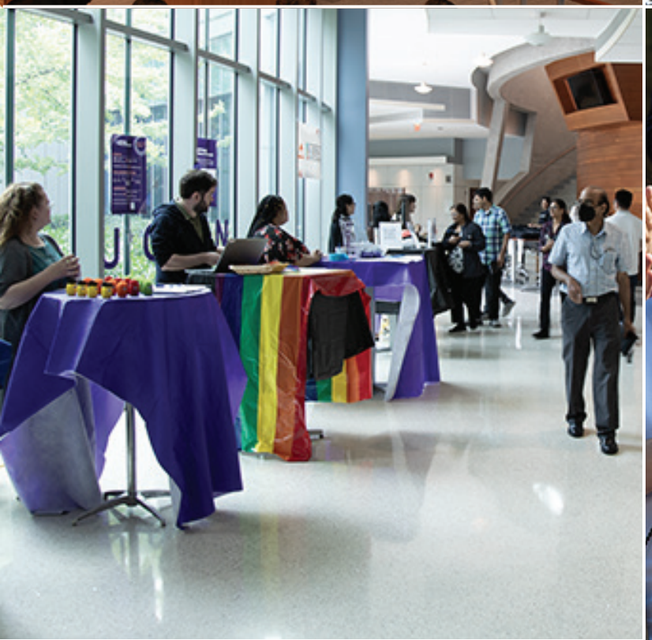
Driving Global Convergence of Pharmaceutical Quality Standards: The CoE provided feedback to USP staff on USP's engagement in the global pharmacopeial landscape at its October 12, 2022, meeting. USP, along with the *European Pharmacopoeia* and *Japanese Pharmacopoeia*, continued to lead efforts for the first major reforms of the Pharmacopeial Discussion Group (PDG) since its founding over 30 years ago. The most significant of these involves a pilot to expand the global membership of PDG. In November 2022, PDG invited the Indian Pharmacopoeia Commission to join the 1-year pilot. PDG will evaluate the effectiveness of the pilot when it meets in October 2023. This work supports Resolution XI, on pharmacopeial cooperation and convergence.

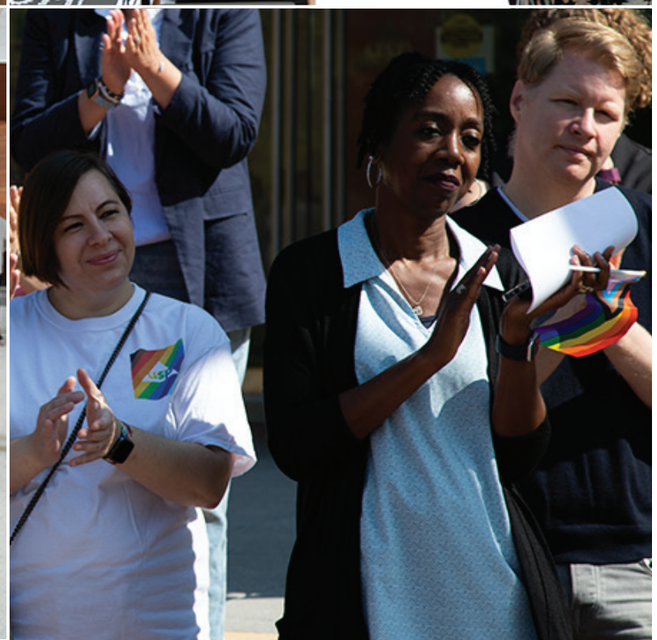
Diversity, Equity, Inclusion, and Belonging (DEIB)

FY23 HIGHLIGHTS









We continue to advocate for DEIB, which is central to our public health mission and makes USP stronger as an organization. Our science vision is steadfastly focused on driving global convergence of quality standards for a future with safe and equal access to quality medicines, foods, and dietary supplements and improved health regardless of race, gender, belief, geographic, economic, or socioeconomic factors. The following activities are in alignment with Resolution XIII, on coalition building; Resolution XIV, on culture of excellence; and Resolution XV, on impact expansion.

USP's Office of Organizational Culture, Equity and Inclusive Excellence (Equity Office), headed by Debra Joy Pérez, Ph.D., Chief Equity Officer and Senior Advisor to the CEO, helps shape and implement all DEIB programs and initiatives. Key DEIB activities in FY23 included the following:

New DEIB Expert Panel (EP): USP launched a Call for Candidates (C4C) to invite qualified candidates to apply to serve on the newly formed DEIB EP, which reports to the CoE. This EP will advise Expert Volunteer leadership and USP staff on strategies and best practices to establish a diverse and inclusive environment that fosters strong collaboration. Additionally, the EP will steward the implementation of the USP Health Equity Guiding Principles within the standards-development process to advance USP's public health impact. Visit callforcandidates.usp.org to learn more about volunteer opportunities within USP.

National Urban Fellows Initiative: The USP-sponsored National Urban Fellows Initiative is a leadership accelerator program for diverse mid-career professionals committed to equity, public service, and social impact. Two USP National Urban Fellows have been selected for FY23: one has been working with USP's Equity Office, and one has been supporting the Global Science and Standards Division.

Scientific Expert Fellowship (SEF): USP's C4C for the USP SEF Program closed on January 17, 2023, and delivered a robust pool of applicants. USP staff has been engaged in reviewing and selecting candidates for the upcoming fiscal year. The SEF Program provides opportunities for scientists, engineers, public health professionals, and clinicians from populations underrepresented in USP Expert Volunteer activities to participate on ECs or EPs for 1 year with flexible hours and develop drafts and final versions of white papers, trade articles, and other important documents. Each will have formal mentorships with EC leadership and USP staff.

New Ethics Liaisons Support Speak Up Culture Initiative: USP has added Ethics Liaisons in USP–U.S., Frederick and Rockville, MD, sites, USP–Ghana, and USP–India. USP staff volunteer to serve as Ethics Liaisons to expand awareness of the Compliance & Ethics Program and USP's commitment to the Speak Up culture initiative, an organization-wide effort to communicate the importance of reporting workplace concerns and fostering a psychologically safe work environment for open and honest communication.

Strategic Initiative for Women Thriving at USP: To address disparities in favorability and workplace experiences for women, women of color, and women scientists, USP launched a strategic initiative during FY23, built on previous efforts, to examine and address the adverse experiences of women at USP and determine how to ensure that all women have an equal opportunity to thrive. The strategic initiative is focused on developing an action plan for the next 1 to 3 years based on existing USP-specific data and scientific literature. The Strategic Initiative will conclude in July 2023, and recommendations will begin to be reviewed and rolled out beginning in FY24.

USP's Affinity Network: USP's Affinity Network helps drive inclusion and belonging at USP by creating a safe space for support, sharing, connection, and professional development while increasing staff engagement and retention. USP supports and sponsors nine affinity groups.

> "We were thrilled to launch a Peer Learning Network program that equipped 92 People Managers from 12 countries with inclusive management styles; the Strategic Initiative on Women Thriving at USP to address inequities and advance equal opportunities for women; and a pilot on Inclusive Hiring for the Small Molecules group."
>
> **Debra Joy Pérez, Ph.D., Chief Equity Officer and Senior Advisor to the CEO, USP Equity Office**

Global Science and Standards Division

FY23 HIGHLIGHTS

The Global Science and Standards Division (GSSD) comprises Documentary Standards and Compendial Policy, Global Laboratory and Technical Operations (GLTO), Global Biologics, Scientific Affairs, and associated groups. Its scientific vision is for USP to become more iterative in creating standards and disseminating knowledge, a thought leader in the science of quality, and the definitive source of quality standards. The GSSD's Scientific Affairs team serves as global impact amplifiers by engaging the scientific community and supporting key USP activities. FY23 highlights included the following:

USP Reached a Key Milestone in Delivering New Dissolution Performance Verification Standard (DPVS): USP has achieved a major milestone by delivering the new USP DPVS–Prednisone RS after years of development. The DPVS has been shown to have lower tablet-to-tablet variability, more consistent performance, and a more stable shelf life than the previous RS used by laboratories that conduct performance verification testing using the USP Apparatus 1 (basket) or 2 (paddle). The revision of *USP* General Chapter <711> *Dissolution*, which replaced the previous RS with the new DPVS, became official in May 2023. Go to the USP Store for more information on the new RS. These activities helped to fulfill Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; and Resolution V, on innovation.

FDA Grant to Create a Multi-Attribute Method (MAM) Knowledge Base: USP has obtained funding from the FDA to assess the performance of MAM through a research grant awarded under the Biosimilar User Fee Act Regulatory Research Pilot Program. This grant allows USP to study ways to enhance biosimilar and interchangeable biosimilar product development and regulatory science through use of MAM. The objective is to assess challenges associated with MAM implementation and to create a knowledge base that can enable wider use of MAM by biosimilar manufacturers. This work aligned with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution V, on innovation.

Materials Program Pipeline: USP's vision for the Materials Program is to help increase the global supply of quality medicines. This will involve expanding our portfolio of quality materials—including non-RS materials—and working with customers at key points of their product life cycle, including research and development, process method development, and formulation. Work on the Materials Program pipeline during FY23 has included the release of some 200 non-compendial solutions known as Pharmaceutical Analytical Impurities (PAIs). The most recent Q4 releases included several Nitrosamine PAIs and the first of our biological Analytical Reference Materials (characterized substances for use in pharmaceutical quality testing). These activities are in accordance with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution III, on quality standards; Resolution V, on innovation; and Resolution XI, on pharmacopeial cooperation and convergence.

Increasing Engagement in USP Knowledge Hub Online Community Pilots: The Scientific Affairs & Strategy team played a key role in increasing early scientific engagement in USP Knowledge Hubs' online community pilots. In FY23, membership, diversity, and page views have increased, with engagement in more than 80 countries. These online communities provide places for stakeholders to exchange knowledge and best practices in multiple languages. The Nitrosamine Exchange has rapidly expanded to include scientific collaborations, including the publication of a peer-reviewed article titled "The Landscape of Potential Small and Drug Substance-Related Nitrosamines in Pharmaceuticals" in the *Journal of Pharmaceutical Sciences* on November 16, 2022.

"In FY23, GLTO realized synergies from consolidating our global laboratories in Rockville and India. RS availability rate is the highest in a decade, and we released numerous new RSs and produced numerous PAI Lots. We launched a pilot CRM program and R&D Analytical Solutions laboratory services to advance continuous manufacturing technologies, while supporting nitrosamine, cannabinoid, and other emerging standards method development."

Bruk Alemayehu, M.B.A., Senior Vice President, GLTO

The Scientific Affairs & Strategy team also led the launch of the Nitrosamine Exchange's new Analytical Hub, an online repository containing downloadable non-compendial analytical procedures (i.e., analytical notes) for the testing of nitrosamine impurities and related substances. Two analytical methods, developed and validated in-house, were published in the Analytical Hub and made available to stakeholders through the non-compendial channel. These activities helped to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; Resolution XII, on evidence generation to inform policy; and Resolution XIII, on coalition building.

USP Advanced Manufacturing Technology Laboratory Grand Opening: USP held a grand opening and ribbon-cutting ceremony in December 2022 for the Advanced Manufacturing Technology (AMT) Laboratory in Richmond, VA, accelerating its work with Phlow Corp. on the strategic active pharmaceutical ingredient (API) reserve. The opening is an important milestone reflecting USP's commitment to support advanced manufacturing, including pharmaceutical continuous manufacturing, with education and training opportunities as well as public standards that facilitate AMT adoption across the innovator and generics sectors. This work relates to Resolution V, on innovation; Resolution VII, on education and training; and Resolution XV, on impact expansion.

New NMR Lab at USP–Rockville, MD: USP's new NMR lab contains a 500 MHz NMR spectrometer liquid state instrument equipped with state-of-the art technology. This advanced instrumentation will help advance the pipeline of qualitative and quantitative NMR testing for USP's business units and USP catalog offerings, including RSs, DSs, and PAIs, in accordance with Resolution II, on efficiency in standards development and revision; Resolution V, on innovation; and Resolution VI, on the digital transformation of standards.

Apheleia for RS and DS Development: USP's Apheleia team advanced its activities on RS and DS development in FY23. Work on the second minimally viable product for DSs has begun and defines the next major release of the DS value stages in the Business Process Management system. The Apheleia program aims to create an automated tool that adds transparency and centralized information accessibility to the DS and RSs development process. This work supports Resolution V, on innovation; Resolution VI, on the digital transformation of standards; and Resolution XIV, on culture of excellence.

FY23–24 Scientific Exchange Program: Scientists from the global regulatory and pharmacopeial communities participate in USP's Scientific Exchange Program, which is designed to advance the development of scientists committed to pharmacopeial work and foster international recognition and harmonization of USP standards that help ensure the quality, safety, and benefit of medicines and foods. The following individuals participated in the FY23–24 Scientific Exchange Program:

- Shaima Abdulilah Kutbi worked with the Novel Excipients EP to update *USP* General Chapter <1074> *Excipient Biological Safety Evaluation Guidelines* to align with FDA and International Pharmaceutical Excipients Council (IPEC) guidelines.
- Wala Turkistani worked with the Biologics Monographs 5–Advanced Therapies EC to write an article summarizing challenges in the field of genome editing.

This work supports Resolution XI, on pharmacopeial cooperation and convergence; Resolution XIV, on culture of excellence; and Resolution XV, on impact expansion.

USP Translation Team

The USP Translation team's mission is to translate USP DSs and other scientific content into Spanish. This work helped to fulfill Resolution III, on quality standards; Resolution VII, on education and training; Resolution XIV, on culture of excellence; and Resolution XV, on impact expansion. Highlights of the team's activities during FY23 included:

- Translated and provided scientific review of more than 370 documents related to *USP–NF 2022 Issue 3, USP–NF 2023 Issues 1* and *2* and Accelerated Revisions
- Provided translation support for the Spanish Translation EP's work related to 53 titles for new *USP–NF* chapters, monographs, and reagents, as well as glossaries for 14 monographs or general chapters
- Provided support to multiple stakeholder engagement activities, including four workshops
- Translated and reviewed more than 50 communication materials (e.g., web pages, USP Education course captions)
- Relaunched the Spanish *USP–NF/PF* Newsletter
- Responded to more than 1,000 customer and stakeholder queries in Spanish

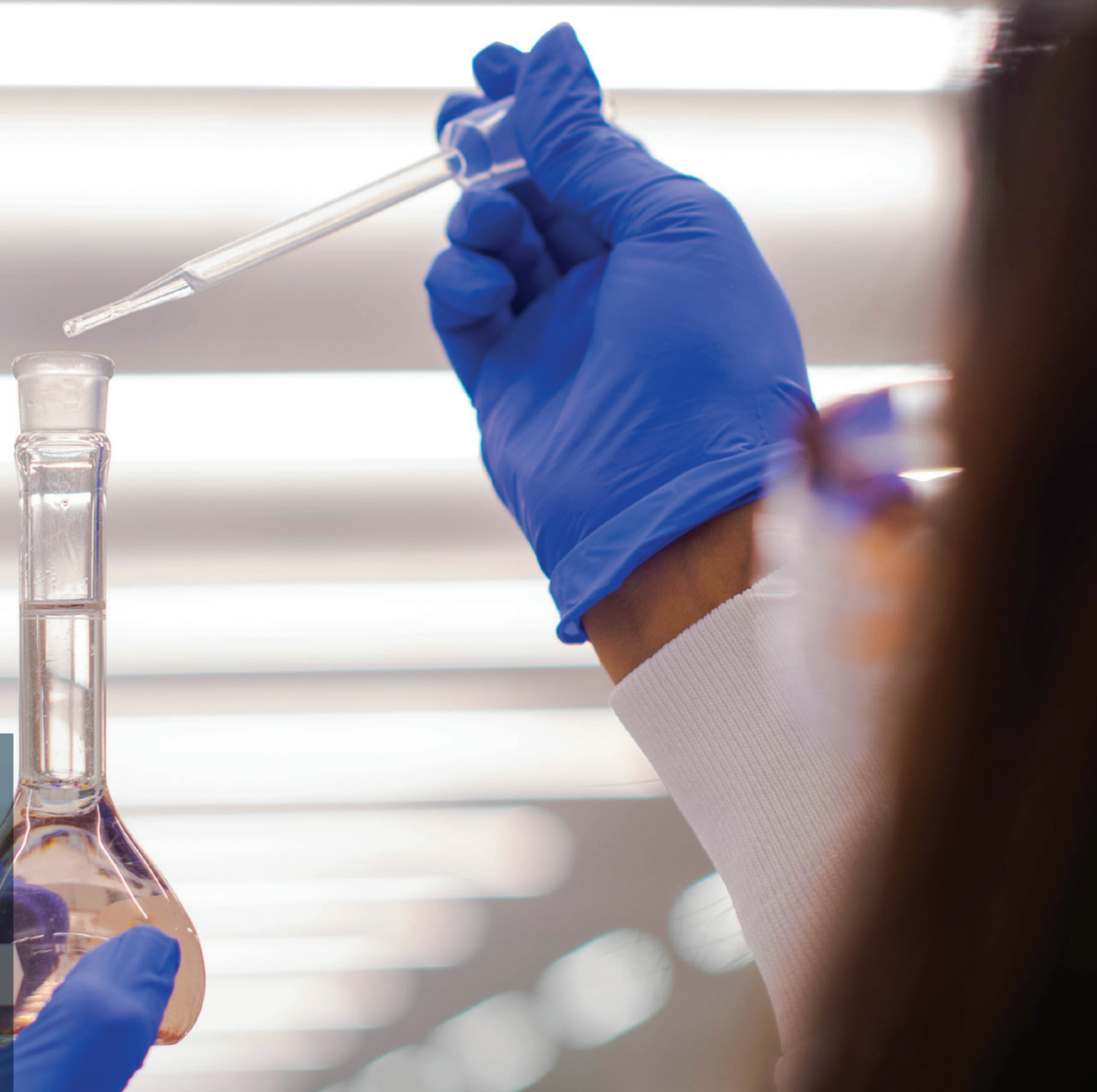
Scaling Scientific Engagement: The Scientific Affairs & Strategy team engaged more than 8,000 global stakeholders on key USP priorities in FY23. Outreach engagements included a symposium on qNMR in pharmaceutical analysis and multicity user forums and presentation support on nitrosamines, USP PAIs, *USP* General Chapter <621> *Chromatography* updates, dissolution performance verification testing, cannabis, advanced therapies, mAbs, and peptides. Additionally, the team worked to enhance Analytical Quality by Design capability across USP laboratories through two modernization projects in India. These stakeholder outreach events help fulfill Resolution VII, on education and training, and Resolution XV, on impact expansion.

Envisioning Engagement Capabilities: The Scientific Affairs & Strategy team launched the Regional Scientific Advisory Panel (RSAP), which includes seven key leaders from industry and academia, in Goa on February 1, 2023. RSAP's goal is to help USP understand and address the needs and concerns of regional stakeholders and help USP develop and promote standards that are relevant and beneficial to the biopharmaceutical industry. This work supported Resolution XV, on impact expansion.

qNMR Symposium: USP's Scientific Affairs & Strategy team, Digital & Innovation Division, General Chapters group, and USP–China sponsored "USP's Second qNMR Symposium" on January 8–10, 2023. More than 500 attendees from industry, academia, and regulatory authorities participated in the virtual stakeholder event, which explored qNMR applications, benchtop qNMR, advanced qNMR data analysis, and included a roundtable with the qNMR community in China. This work helped to fulfill Resolution V, on innovation; Resolution VII, on education and training; Resolution VIII, on regulatory systems strengthening; and Resolution XV, on impact expansion.

"Documentary Standards and Compendial Policy evolved the science by developing new, revised, and emerging standards, tool kits, and guides while connecting with stakeholders and implementing a business process management system ensuring the relevancy of USP public standards and solutions."

Jennifer Devine, J.D., Senior Vice President, Documentary Standards & Compendial Policy



"The Publications department received a high overall satisfaction rating from the Science division respondents to our FY23 Satisfaction Survey and reported overall improvement in quality of science submissions based on data in the Monitoring & Evaluation Report. The results reflect our continuous improvement in editorial services, production, scientific and technical writing, and training. In FY24, the Publications department will continue to work with our science colleagues to further enhance our services."

Caroline Martin, Senior Director, Publications

"Among the many notable Scientific Affairs team achievements, we launched the Analytical Hub for nitrosamines, created the Regional Scientific Advisory Panel in Goa, and improved our internal capability building. I take immense pride in their commitment as true ambassadors of science, strengthening USP's relevance and impact in the scientific community."

Annu Uppal, Ph.D., Director, Scientific Affairs & Strategy

USP–India, Hyderabad

FY23 HIGHLIGHTS

USP–India supports USP's global standards-setting efforts and pursues collaborative opportunities with policymakers, regulators, professional and manufacturing associations, and leaders in India's pharmaceutical and food sectors. USP–India staff supported key USP activities in FY23, including the following:

Developing Flow Chemistry Lab Capabilities at USP–India, Hyderabad: USP–India's Synthetics Laboratory has developed internal capabilities for flow chemistry setup and expertise in alignment with USP's advanced manufacturing initiative for lowering barriers to the adoption of pharmaceutical continuous manufacturing. The program's objective is to develop continuous flow processes for select APIs from a list of essential medicines and API impurities. To further enhance internal capabilities, USP–India has initiated work on peptide synthesis under USP's Digital & Innovation Microgrant program to evolve future platform technology. These activities help to fulfill Resolution III, on quality standards; Resolution VI, on the digital transformation of standards; and Resolution VII, on education and training.

Latest USP Tools for Understanding and Controlling Nitrosamine Impurities: USP advanced efforts to protect patients and strengthen the global medicines supply chain with new standards, tools, and solutions for testing, assessing risk, and understanding potential sources related to nitrosamine impurities. USP–India has successfully delivered more than 30 nitrosamine impurities reference materials as part of the material strategy and PAI program. This work addresses Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; and Resolution VII, on education and training.

USP–India Biologics: The India Biologics Lab continued to expand scientific capabilities and implement new technologies to support the development of new biologics standards, including expanding capabilities for functional testing for mAbs, adding mass spectrometry capabilities to support Multi-Attribute Methods, and establishing methods to support mRNA and viral vectored vaccines. This work helped to fulfill Resolution III, on quality standards; Resolution IV, on access to biologics; and Resolution V, on innovation.

Promoting the Quality of Medicines Plus (PQM+) Support: USP–India collaborated with USP's PQM+ Program for a 4-day visit on May 22–25, 2023, attended by 26 regulators from six African countries under the Global VAX program supported by the U.S. Agency for International Development. The visit served as a catalyst for achieving the PQM+ program's objectives, including empowering our partners in Africa through strategic planning assistance and knowledge exchange. These activities helped to fulfill Resolution XV, on impact expansion.

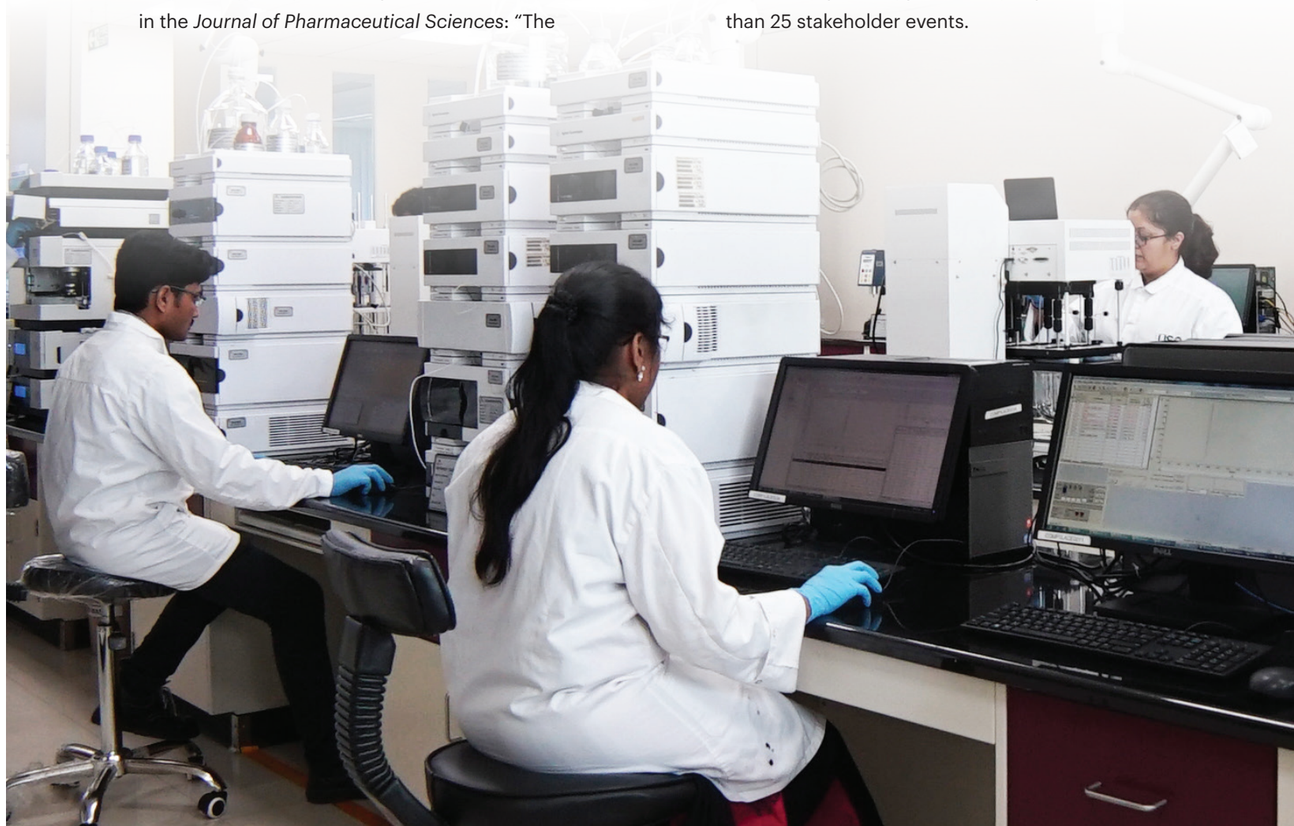
USP–India, Hyderabad, Stakeholder Events: USP–India staff engaged with stakeholders in the following activities that helped to fulfill Resolution III, on quality standards; Resolution VII, on education and training; and Resolution XV, on impact expansion:

- Cosponsored the "2023 USP Workshop on Nitrosamine Impurities" with the Indian Pharmaceutical Alliance in Hyderabad on February 16, 2023, attended in person by more than 250 individuals from industry and global regulators.
- Launched the Regional Scientific Advisory Panel (RSAP) in Goa on February 1, 2023. The RSAP met virtually on April 19, 2023, and identified two working areas: publishing a policy paper on alternatives to animal models and setting up a Center of Excellence for Workforce Training.

"FY23 was a phenomenal year with respect to scientific accomplishments, operational excellence, stakeholder engagement, and integrating DEIB in our work. FY24 holds promise and optimism for building upon our scientific work for monoclonal antibodies, expanding laboratory capacities and output, and hosting the PDG meeting from USP–India. We will also continue to focus on bringing in diverse talent and strengthening inclusive management styles for People Managers."

Girish Kapur, M.Pharm., M.B.A., Vice President, India Site Operations

- Held 38 in-person User Forums and webinars attended by some 2,400 stakeholders on priority topics (e.g., nitrosamines, insulin standards, dissolution performance verification testing).
- Conducted 15 in-person or virtual education programs for more than 400 participants from the pharmaceutical industry, including events for Micro, Small, and Medium Enterprises and webinars for universities and academic institutions.
- Published "Overcoming challenges to CAR-T cell therapies in India" in *Cell & Gene Therapy Insights* on March 8, 2023, and two peer-reviewed articles in the *Journal of Pharmaceutical Sciences*: "The Landscape of Potential Small and Drug Substance Related Nitrosamines in Pharmaceuticals" on November 16, 2022; and "A GC-MS/MS Method for Trace Level Quantification of Six Nitrosamine Impurities (NDMA, NDEA, NEIPA, NDIPA, NDPA, and NDBA) in Commercially Used Organic Solvents: Dichloromethane, Ethyl Acetate, Toluene, and O-xylene" on November 30, 2022.
- Contributed to "Empowering women in science: How can organizations bridge the gender gap," a blog published by *Springer Nature* on May 24, 2023.
- Served as speakers, presenters, or panelists at more than 25 stakeholder events.



Biologics

USP Biologics develops and modernizes standards for diverse therapeutic products, from peptides and proteins to vaccines and cell and gene therapies. The Biologics program is expanding standards development to cover quality testing throughout the overall biopharmaceutical product life cycle. Expert Volunteers serve on the following ECs: Biologics Monographs 1–Peptides & Oligonucleotides (BIO1), Biologics Monographs 2–Proteins (BIO2), Biologics Monographs 3–Complex Biologics and Vaccines (BIO3), Biologics Monographs 4–Antibiotics (BIO4), and Biologics Monographs 5–Advanced Therapies (BIO5). Throughout FY23, the Biologics program worked to fulfill Resolution IV, which calls for USP to 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. Work related to additional Resolutions is noted below.

Key Activities in Biologics

Supporting Quality Monoclonal Antibody (mAb)-Based Therapeutics: Critical donations have been secured to expand our mAb pipeline of RSs and materials to support functional and physiochemical testing. In January 2023, USP released an mAb Analytical Guide that outlines testing needs at different phases of development and brings together USP resources to support mAb quality, including DSs, RSs, training, and educational resources. These activities helped to fulfill Resolution V, on innovation, and Resolution VII, on education and training.

Lentivirus-Based Cell Therapies: USP Biologics is expanding the scope of its work in cell and gene therapies and has recruited a new Lentivirus Cell Therapy EP under the direction of the BIO5 EC. The EP will focus on developing a general chapter on best practices for lentivirus-based therapeutics such as chimeric antigen receptor (CAR)-T cell therapies. These activities help to fulfill Resolution V, on innovation.

Transitioning Insulin and Insulin Analog Products to *In Vitro*-Based Bio-Identity Methods: The BIO2 EC's Insulin EP worked toward transitioning insulin and insulin analog products to *in vitro* cell-based testing for bio-identity. The goal is to omit the rabbit blood sugar method from *USP* General Chapter <121> *Insulin Assays*. Currently, the *in vitro* test is applied to only two insulin analogs, Insulin Glargine and Insulin Lispro. The Insulin EP continued its work in FY23 evaluating data for transitioning the remaining insulins. This work helped to fulfill Resolution V, on innovation.

FDA Grant to Create a Multi-Attribute Method (MAM) Knowledge Base: USP has obtained funding from the FDA to assess the performance of MAM through a research grant awarded under the Biosimilar User Fee Act Regulatory Research Pilot Program. This grant allows USP to study ways to enhance biosimilar and interchangeable biosimilar product development and regulatory science through use of MAM. The objective is to assess challenges associated with MAM implementation and to create a knowledge base that can enable wider use of MAM by biosimilar manufacturers. This work aligns with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution V, on innovation.

Updated USP COVID-19 Vaccine Quality Assessment Toolkits: As part of its USP COVID-19 Vaccine Quality Assessment Toolkits March 2023 update, USP Biologics added resources for assessing the quality attributes of multiple vaccine platforms, including inactivated, virus-like particle, and DNA vaccines. These toolkits can help reduce risks from substandard and falsified vaccines, and, ultimately, increase public trust. These activities support Resolution V, on innovation, and Resolution XV, on impact expansion.

mRNA Vaccine Quality Draft Guidelines: USP Biologics released the second version of its draft guidelines on Analytical Procedures for mRNA Vaccine Quality, which incorporates public comments and methods donated by stakeholders. The analytical procedures and best practices support quality assessments for mRNA vaccines and therapies and build consensus on quality attributes and appropriate test methods. This work relates to Resolution I, on collaboration with FDA and other stakeholders on health priorities.

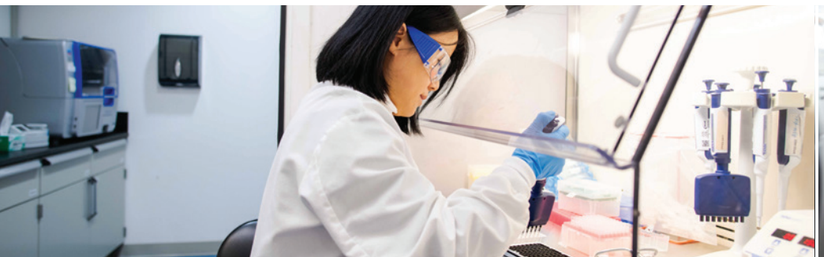
Strategic Collaboration to Support the Quality and Safety of Biologics: In February 2023, USP announced it has entered a strategic collaboration with ATCC, a nonprofit global biological materials management and standards organization, to jointly provide co-branded analytical materials to support the development and characterization of quality biologic medicines and therapies. The initial set of products ATCC and USP will launch together include genomic DNA from top cell lines used in bioproduction. These activities are in accordance with Resolution I, on collaboration with FDA and other stakeholders on health priorities.

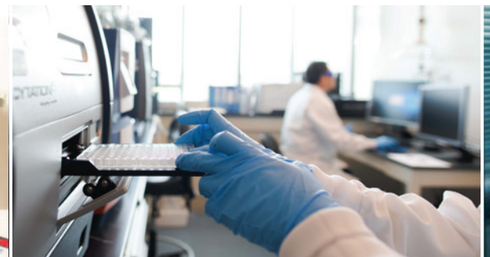
Advancing Work on Quality Considerations for Plasmid DNA: The Plasmid DNA EP of the BIO5 EC completed an initial draft of the proposed *USP* General Chapter <1040> *Quality Considerations of Plasmid DNA as a Starting Material for Advanced Therapies* in October 2022 and has been working with the BIO5 EC to finalize it for submission to *PF*. The EP is also working on analytical tools for detecting cross contamination. This work aligns with Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; and Resolution V, on innovation.

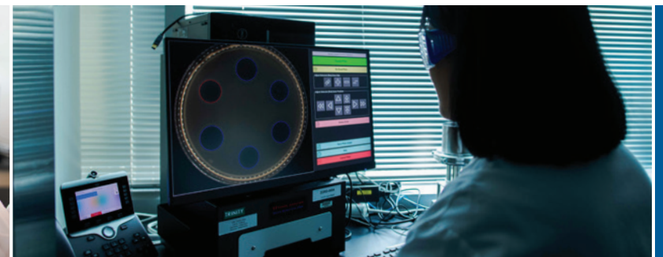
Progressing Adeno-Associated Virus (AAV) Gene Therapy Activities: An ongoing collaboration between the National Institute of Standards and Technology, National Institute for Innovation in Manufacturing Biopharmaceuticals, and USP on the measurement of AAV full-to-empty ratio has concluded its preliminary experiments. Separately, the AAV Gene Therapy EP of the BIO5 EC outlined a new general chapter with best practices for AAV vector design, manufacturing, quality control, and regulatory considerations. These activities are in accordance with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution V, on innovation.

Proposing Standards: The BIO2 EC continued its work on the quality of raw and starting materials, analysis of impurities, and emerging analytical techniques. USP Biologics is also working to expand its portfolio of standards for monoclonal antibodies, which remain the largest modality for biotherapeutics. Proposed new standards and analytical reference materials are anticipated to support functional testing as well as testing for impurities and raw materials. This work supports Resolution II, on efficiency in standards development and revision, and Resolution V, on innovation.

Launching the Biosimilars Infographic: Through the Biologics Sector of the USP Convention, USP and the FDA Center for Drug Evaluation and Research's Office of Therapeutic Biologics and Biosimilars collaborated on an infographic to inform dialogue between patients and healthcare providers about the quality attributes of biosimilars. The infographic, launched on September 15, 2022, was informed by multiple stakeholders, including those who represent patient advocacy organizations, healthcare professional societies, innovator and generic manufacturing trade associations, and payor and pharmacy benefit manager groups. This work aligned with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution XIII, on coalition building.







> "BIO5 EC has emphasized engaging stakeholders to raise awareness and explain USP's growing collection of standards for raw and ancillary materials."
>
> **Mehrshid Alai, Ph.D., Chair, BIO5 EC**

USP Biologics Supported Virtual Stakeholder Outreach Events: The following stakeholder outreach events align with Resolution II, on efficiency in standards development and revision, and Resolution VII, on education and training for industry and healthcare professionals:

- Stakeholder Forum on Collaborating to Solve Chemistry, Manufacturing, and Controls Challenges and Support Efficient Development of Lentiviral-Mediated CAR-T Cell Therapies on October 26, 2022. More than 30 industry and regulatory agency representatives attended in person, and more than 100 participated online.
- "Continuous Manufacturing of Biologics: Addressing Barriers to Adoption" cosponsored by USP and BioPhorum on December 7–8, 2022. More than 100 attendees from the biopharmaceutical industry, equipment vendors, academia, and regulatory agencies participated in the hybrid event.
- "AAV Analytical Characterization Workshop" cosponsored by USP and the Alliance for Regenerative Medicine on March 8–9, 2023. More than 675 industry, regulatory, and academia representatives attended this hybrid event, including 75 in person.

USP Biologics Supported Education/Training Courses: More than 3,500 professionals attended biologics education programs in FY23. More than 140 regulators from around the globe received insights into the development, manufacturing, and regulatory expectations of gene-modified cell therapies from the FDA and other experts. This work helped to fulfill Resolution VII, on education and training.

Published Papers: These activities align with Resolution II, on efficiency in standards development and revision:

- "Here's How USP mAb Standards Support Fast-Evolving Platform Approaches," published May 24, 2023, in *Bioprocess Online*
- "Reference Standards to Support Quality of Synthetic Peptide Therapeutics," published March 22, 2023, in *Pharmaceutical Research*
- "Overcoming challenges to CAR-T cell therapies in India," published March 8, 2023, in *Cell & Gene Therapy Insights*
- "Where Do We Stand On Adopting Continuous Manufacturing For Biologics," published December 5, 2022, in *Bioprocess Online*
- "Assessing Quality of Viral Vectored Vaccines," published November 11, 2022, in *Cell & Gene*
- "Assessing Quality of mRNA Vaccines: Key Considerations," published October 12, 2022, in *Bioprocess Online*
- "What's the Environmental Impact of Biopharma Continuous Manufacturing? Part II," published August 22, 2022, in *Bioprocess Online*
- "What's the Environmental Impact of Biopharma Continuous Manufacturing? Part I," published August 18, 2022, in *Bioprocess Online*
- "Impurity Control Strategies for Therapeutic Peptides," published August 12, 2022, in *Outsourced Pharma*
- "Solving Bioassay Challenges for Cell & Gene Therapies," published July 1, 2022, in *Cell & Gene*

FY23 Highlights: Biologics

2 New General Chapters in *USP–NF*

6 Monograph Revisions in *USP–NF*

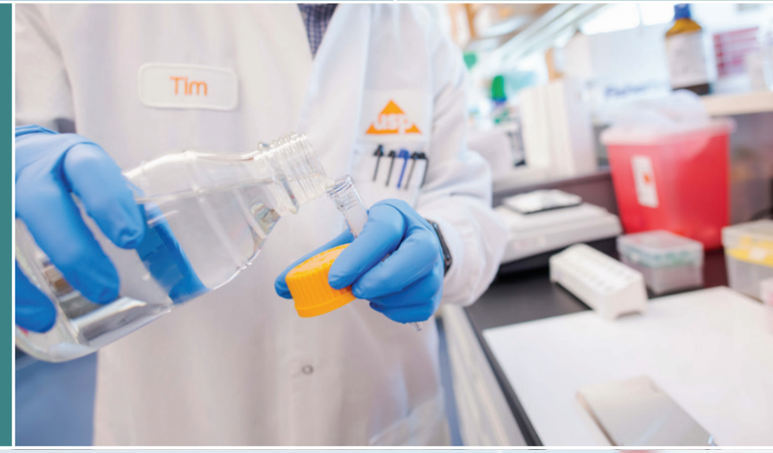
2 Monograph Modernizations in *USP–NF*

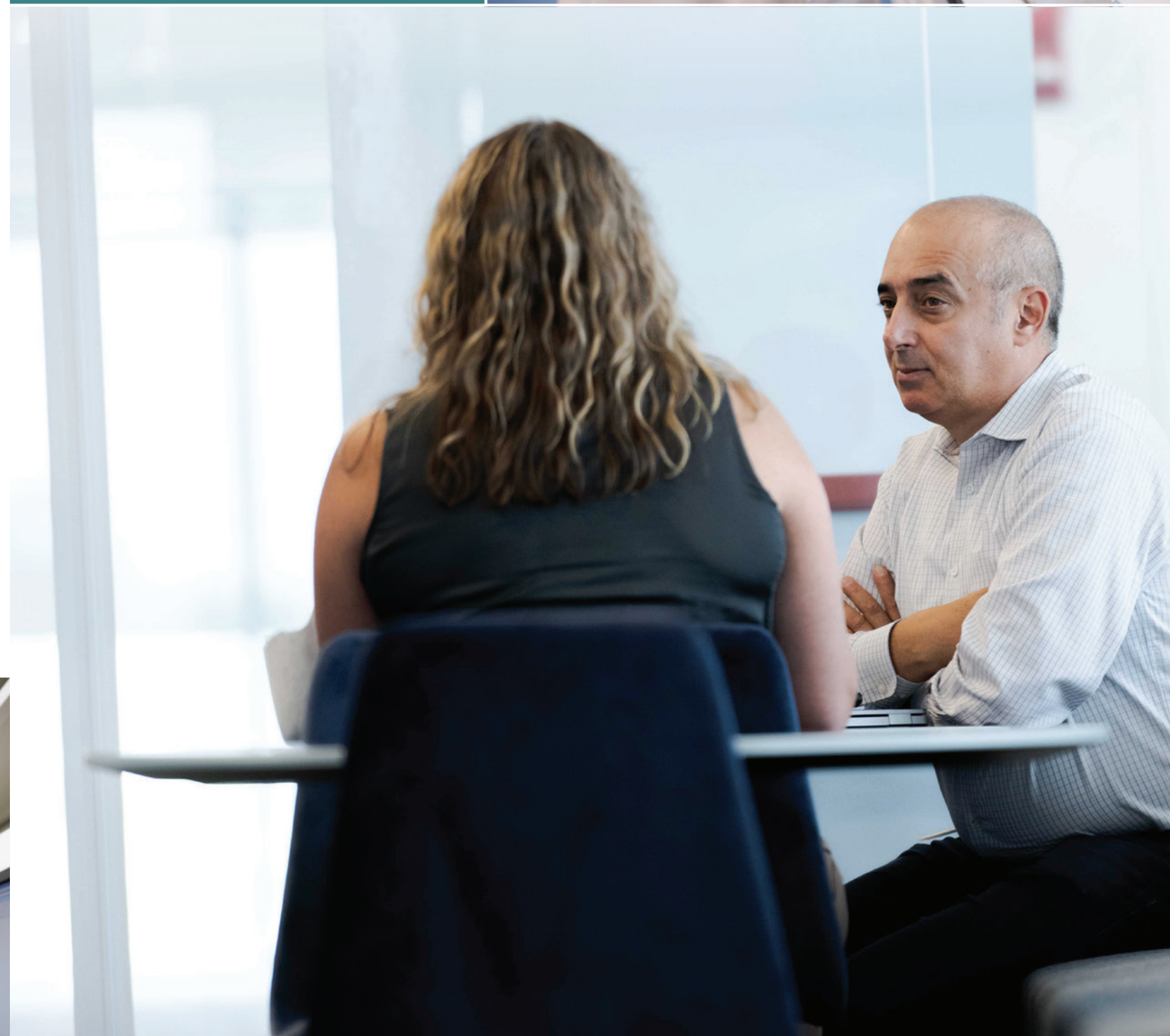
11 New RSs (F Lots) Released

3 New General Chapters Published in *PF*

2 New Monographs Published in *PF*

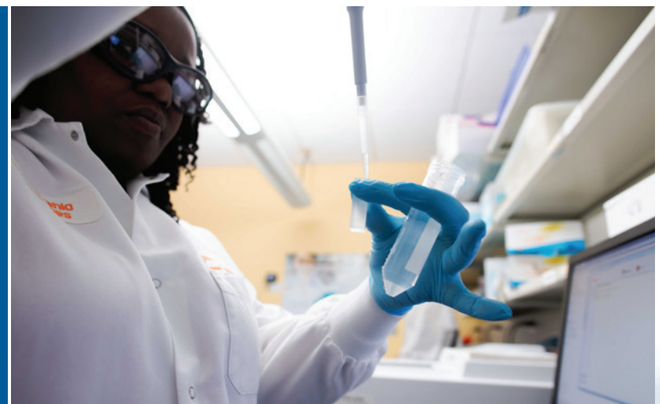
9 Monograph Revisions Published in *PF*





"BIO1 EC leveraged stakeholder engagement to identify critical needs for synthetic oligonucleotide therapeutics. This key input has guided the work plan for advancing documentary and reference standards to ensure quality of this rapidly growing novel pharmaceutical modality."

Michael R. De Felippis, Ph.D., Chair, BIO1 EC



Small Molecules

> "The upcoming opportunity for a hybrid meeting, which includes an option for on-site participation, has reinvigorated the SM5 EC's spirit of volunteerism. We look forward to interactions with our EC team members and Government Liaisons that will facilitate robust collaboration for the remainder of the cycle."
>
> **Amy Jo Karren, B.Sc., Chair, SM5 EC**

The Small Molecules group develops and revises monographs for drug substances and associated manufactured dosage forms for human and veterinary use. Monographs for diagnostic imaging agents are also included in this category. Expert Volunteers serve on the following ECs: Small Molecules 1, Small Molecules 2, Small Molecules 3, Small Molecules 4, Small Molecules 5 (SM5), and Over-the-Counter (OTC) Methods and Approaches. Together, the Small Molecules group is a champion for quality medicine by providing high-quality, up-to-date standards and unique services across the product development life cycle to small molecule manufacturers and regulatory agencies worldwide.

Key Activities in Small Molecules

Emerging Standards: USP is proposing to take a more iterative approach to standards development, where an emerging standard—a potential standard not yet under development—is shared through our website to help build stakeholder communities and stimulate early discussion and contribution. Emerging standards provide opportunities for stakeholders to provide input prior to formal notice and comment through publication in *PF*. Emerging standards also highlight other USP products such as Pharmaceutical Analytical Impurities (PAIs) and RSs. The Small Molecules group, Compendial Operations, and the Analytical Development Laboratory launched the Emerging Standards Concept website at https://go.usp.org/emerging-standards, which contains links to emerging standards published in FY23 (with more in progress), and related content. These efforts help to fulfill Resolution III, on quality standards, and Resolution V, on innovation.

Case-Based Standards-Development Approach: The Small Molecules team has operationalized the case-based standards-development approach by centralizing various standards-development activities within smaller dedicated teams and has moved away from artisanal approaches where all staff perform all standards-setting activities. Additionally, the team has collaborated with USP's Compendial Operations Department to designate EC Scientific Leads to provide centralized USP points of contact for EC scientific operations. These activities are in accordance with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution II, on efficiency in standards development and revision; and Resolution XIV, on culture of excellence.

USP Tools for Understanding and controlling Nitrosamine Impurities: To safeguard patients from the adverse effects of nitrosamine impurities in medicines, USP offers *USP* General Chapter <1469> *Nitrosamine Impurities* and eight USP Nitrosamine RSs. USP's Nitrosamines team has been working to bring non-compendial solutions such as PAIs to market that include simple nitrosamine impurities and nitrosamine drug substance-related impurities. The Small Molecules group is also exploring ways to link emerging standards to existing or in-process PAIs, which manufacturers can use in various analytical tests or applications to detect, identify, and measure impurities in APIs and drug products. The new Analytical Hub housed in USP's Nitrosamines Exchange will publish additional analytical procedures to support stakeholders. These activities helped to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution XII, on evidence generation to inform policy; and Resolution XIII, on coalition building.

OTC Pilot Study: To support USP's overall strategy on OTC drug product standards, USP Small Molecules, Analytical Development Laboratory staff, and external stakeholders are collaborating on a pilot study to evaluate the transferability of three organic impurities methods developed for Diphenhydramine Oral Solution drug product with complex formulations as the first step of the validation of the methods. This work has led to the development by the Diphenhydramine Joint Subcommittee of a *Stimuli* article titled "A Novel Approach Using Quality by Design to Develop and Implement Flexible Methods in Non-Application Over-the-Counter Monographs" published in *PF* 49(1) [Jan.–Feb. 2023]. This work addresses Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution II, on efficiency in standards development and revision.

Developing the Global Substance Registration System (G-SRS): The Small Molecules Chemical Information team, in collaboration with the Information Technology and RS Evaluation teams, worked to develop USP's G-SRS as the central repository of chemical information across all USP publications. Based on the G-SRS and front-end software, USP developed a new public-facing customized version of the *USP Dictionary of United States Adopted Names* (*USAN*) and *International Drug Names*. This work relates to Resolution V, on innovation; Resolution VI, on the digital transformation of standards; and Resolution XV, on impact expansion.

Small Molecules Group Supported Virtual Stakeholder Outreach Events: The following stakeholder outreach events align with Resolution II, on efficiency in standards development and revision; Resolution V, on innovation; and Resolution VII, on education and training:

- "Improving the Pharma Environmental Footprint," a virtual Open Forum on February 21, 2023, with some 100 attendees from nearly 20 countries. This notable event provided an opportunity for stakeholders to engage with USP and share information and perspectives on improving the environmental impact of pharmaceutical manufacturing and quality testing across the supply chain while ensuring quality medicines.
- Monograph Prioritization and Donor Engagements, a virtual roundtable on November 9, 2022, with some 25 compendial representatives from U.S. pharmaceutical companies.

FY23 Highlights: Small Molecules

46 Monograph Modernizations Published in *USP–NF*

20 New Monographs Published in *USP–NF*

82 Monograph Revisions Published in *USP–NF*

48 Monograph Modernizations Published in *PF*

49 New Monographs Published in *PF*

46 Monograph Revisions Published in *PF*

Dietary Supplements and Herbal Medicines

The Dietary Supplements and Herbal Medicines (DSHM) group helps protect and improve the health of millions of people who use DSHM. Expert Volunteers who serve on the Botanical Dietary Supplements and Herbal Medicines (BDSHM) and Non-Botanical Dietary Supplements (NBDS) ECs develop and revise monographs, general chapters, and USP RSs for the *USP–NF*, *Dietary Supplements Compendium* (*DSC*) *Online*, and *Herbal Medicines Compendium*. Expert Volunteers who serve on the Dietary Supplements Admission Evaluation and Labeling EC determine the admissibility of dietary supplement articles for monograph development, monitor the literature on the safety of dietary ingredients, and contribute to projects related to safety assessments of DSHM ingredients.

Key Activities in Dietary Supplements and Herbal Medicines

NMR/qNMR for Difficult-to-Quantify Materials: Significant progress has been made through an external grant on the development of NMR/qNMR methods for compendial use with difficult-to-quantify materials. The scope of work is expected to yield significant advancements in compendial analyses that are contextually new to the global pharmacopeia. These activities are in accordance with Resolution V, on innovation; Resolution XI, on pharmacopeial cooperation and convergence; and Resolution XV, on impact expansion.

Modern Analytical Methods Joint Subcommittee (JS) Activities: The Modern Analytical Methods JS is considering a liquid chromatography with tandem mass spectrometry methodology with chemometric analysis to support authentication of proanthocyanidins-containing products, which are prone to intentional adulteration. The JS has discussed deficiencies in current analytical practices for quantitation of certain pesticide residues and is considering recommendations for inclusion in the relevant general chapter. The JS is continuing to endorse the expanded use of flexible identification methods in compendial monographs as well as flexible assay/quantitative methods with the current focus on difficult-to-analyze amino acids. These efforts help to fulfill Resolution V, on innovation.

USP Cannabis Tool Kits: USP's newly released four-volume Cannabis Tool Kits provide scientists, manufacturers, and regulators with the resources needed to help protect public health by establishing a framework for the consistent characterization of cannabis for medical use. This work supports Resolution X, which encourages USP to leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions that help address quality-related concerns and support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

> "The NBDS EC builds capacity and fosters innovation for analytically challenging articles, coordinates the integration of modern scientific methods for monograph modernization via the Modern Analytical Methods Joint Subcommittee, and contributes to major renovations of *USP* General Chapters."
>
> **Guido F. Pauli, Ph.D., Pharm.D., Chair, NBDS EC**

> "During FY23, the BDSHM EC enhanced our collaboration and diversity of perspectives for developing documentary standards.... We obtained valuable input from our Botanical Pan-America, East Asia, South Asia, and Cannabis EPs. And we published a peer-reviewed article in *Frontiers in Pharmacology* to help stakeholders with well-documented confusion regarding botanical extract label declarations."
>
> **Robin Marles, Ph.D., Chair, BDSHM EC**

USP Certified Reference Materials (CRMs) for Cannabinoids: USP began developing CRMs for cannabinoids to provide ISO 17034 compliant reference materials for determination of cannabinoids in cannabis product samples in the ISO 17025 environment. These materials for non-compendial application include information about assigned values, uncertainty values, homogeneity, and stability. This work supports Resolution X, on cannabis.

Researching Delta-8 THC Product Impurities: Concerns about health hazards associated with the consumption of delta-8 THC products have been highlighted in public health advisories from the FDA and CDC. USP has collaborated with an external laboratory to generate information on the identity of impurities in synthesized delta-8 THC products and develop analytical methods to separate these impurities using chromatographic methods. These activities extend the Cannabis EP's commentary on public health concerns regarding delta-8 THC and facilitate public health measures supported by quality research materials and methods. This work supports Resolution X, on cannabis.

Proposed Monograph for Cannabis Inflorescence: USP proposed a monograph for cannabis inflorescence in the *Herbal Medicines Compendium*, building on its 2020 publication of quality considerations for cannabis inflorescence for medical use in the *Journal of Natural Products*. The Cannabis EP evaluated the public comments on the proposal and suggested changes that would require republication of the proposal for public comments. Separately, USP submitted comments to the European Directorate for the Quality of Medicines & HealthCare (EDQM) and shared information to help inform the EDQM's proposed Cannabis Flos monograph. This work supports Resolution X, on cannabis.

Proposed *USP* General Chapter <1568> *Quality Considerations for Cannabis and Cannabis-Derived Products for Clinical Research*: This proposed general chapter would provide the specifications for quality attributes that are fundamental to characterizing the materials for clinical research. Proposed in *PF* 49(3) for public comment, General Chapter <1568> is intended to complement the FDA Guidance on cannabis quality for clinical research with specific analytical methods and acceptance criteria. This work supports Resolution X, on cannabis.

Cannabis-Related Outreach: The following activities support Resolution X, on cannabis:

- "Global Workshop on Cannabis Quality: Part One—America and Europe" cosponsored by USP and ASTM International on December 7–8, 2022. Some 500 stakeholders who represented industry, testing laboratories, regulators, and academia from more than 20 countries attended the virtual event. Additionally, USP and ASTM organized a webinar to engage stakeholders from Africa and Asia held on June 22, 2023.
- Cannabis Quality Tools Presentation on the value of public standards to reduce harm to patients from contaminated or adulterated products held on March 6, 2023. USP continued to engage with the Cannabis Regulators Association (CANNRA) through this presentation. Some 100 regulators from more than 20 states attended this virtual presentation.

Dietary Supplements and Herbal Medicines Supported Stakeholder Events: The following stakeholder outreach events align with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution V, on innovation; and Resolution VII, on education and training:

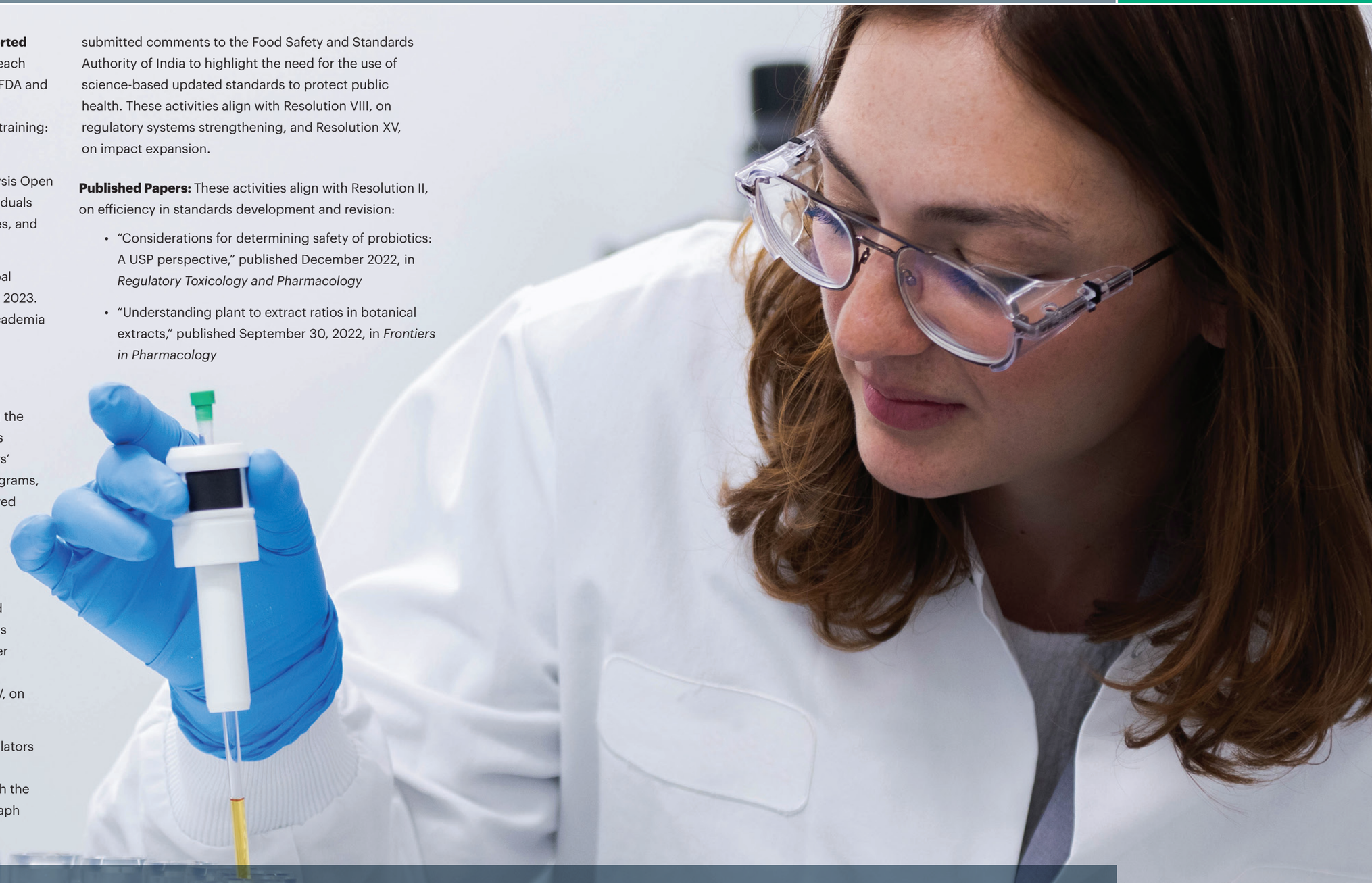
- "Emerging Technologies in Probiotic, Live Biotherapeutic Product, and Microbiome Analysis Open Forum" on October 6–7, 2022. Some 585 individuals from industry, associations, regulatory agencies, and academia attended this virtual event.
- "2023 Virtual USP Dietary Supplements & Herbal Medicines Stakeholder Forum" on February 16, 2023. More than 200 attendees from industry and academia participated in this event.

Dietary Supplement Regulatory Engagement: USP submitted public comments to the FDA emphasizing the importance of utilizing preferred methods of analysis in updated versions of the Office of Regulatory Affairs' Laboratory Procedures Manual, FDA compliance programs, and other resources. USP recommended that preferred methods of analysis in these documents include up-to-date public standards from USP and other trustworthy sources. USP also submitted comments to the Food Safety and Standards Authority of India highlighting the need to use updated, science-based standards to protect public health. This activity aligns with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution VIII, on regulatory systems strengthening; and Resolution XV, on impact expansion.

Korea and India: USP has engaged with Korean regulators and industry providing educational seminars to the Korean Functional Food Association and working with the Korean Ministry of Food and Drug Safety on monograph development and other activities. Additionally, USP submitted comments to the Food Safety and Standards Authority of India to highlight the need for the use of science-based updated standards to protect public health. These activities align with Resolution VIII, on regulatory systems strengthening, and Resolution XV, on impact expansion.

Published Papers: These activities align with Resolution II, on efficiency in standards development and revision:

- "Considerations for determining safety of probiotics: A USP perspective," published December 2022, in *Regulatory Toxicology and Pharmacology*
- "Understanding plant to extract ratios in botanical extracts," published September 30, 2022, in *Frontiers in Pharmacology*



FY23 Highlights: Dietary Supplements and Herbal Medicines

- 18 New Monographs Published in *PF*
- 68 Monograph Modernizations Published in *PF*
- 16 Monograph Revisions Published in *PF*
- 1 New General Chapter Published in *PF*
- 1 New General Chapter Published in *USP–NF*
- 12 New Monographs Published in *USP–NF*
- 8 Modernizations Published in *USP–NF*
- 7 Revisions Published in *USP–NF*
- 20 New RS (F Lot) Releases

The 2023 *DSC Online* included the following unique content:

- 6 New Admission Evaluation Summaries
- 6 New Illustration Sets (Photomicrographic and Chromatographic Data, Chemical Structures)
- 4 Revised Survey Tables of Dietary Reference Intake and Tolerable Upper Intakes for Vitamins and Minerals

Excipients

> The CE EC has continued to progress on our 2020–2025 work plan and priorities focusing on consequential/ mission priority monographs and working on hot topics like the limit of EG/DEG in PEG excipients. We have also had six monograph PDG harmonization sign-offs."
>
> **Otilia Koo, Ph.D., Chair, CE EC**

Excipients—considered "inactive" ingredients in medicine—play an essential role in delivering APIs to their targets and can comprise up to 90% of a medication. They are critically important to how well a drug functions in the body and can cause great harm to patients if their quality is poor. The Excipients group helps ensure that excipients are fit for purpose and addresses potential threats from the complexities of global supply chains and quality deficiencies that may arise in the absence of appropriate good manufacturing practices (GMPs). Expert Volunteers who serve on the Simple Excipients (SE) and Complex Excipients (CE) ECs develop new—and revise existing—monographs and their associated RSs for pharmaceutical excipients. Expert Volunteers on the Excipient Test Methods (ETM) EC are responsible for developing and updating excipient-related general chapters.

Key Activities in Excipients

Toolkit for Identifying Deadly Contaminants in Allergy, Cold, and Cough Medicines: In January 2023, USP made its virtual toolkit for measuring and controlling levels of diethylene glycol (DEG) and ethylene glycol (EG) contamination associated with allergy, cold, and cough medicines available as a free resource to all stakeholders at https://www.usp.org/impurities/diethylene-glycol-resources. The USP toolkit includes information from relevant chapters, monographs, and other resources that can help manufacturers and regulators test the quality of these medicines. USP is actively monitoring the evolving situation of contaminated medicines reported in multiple countries and will update this toolkit accordingly. This work aligns with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution V, on innovation; and Resolution XV, on impact expansion.

DEG and EG Testing in High-Risk Drug Components: On February 10, 2023, USP received a letter from FDA requesting that USP include the Limit of EG/DEG test in the *Identity* sections of excipient monographs for Polyethylene Glycol (PEG) and PEG 40 Castor Oil. Additionally, in May 2023, FDA published a final guidance for industry titled *Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol*. In response to the FDA's request, Excipients Program Unit Team (PUT) has been working with two PEG manufacturers on optimizing the gas-chromatography EG/DEG method for use as an identification test in the PEG monograph. Additionally, USP will collaborate with the FDA laboratory on this important task. This work aligns with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution II, on efficiency in standards development and revision.

Excipient Nomenclature Guidelines Released: The Excipients PUT achieved a major milestone with the publication of the Excipient Nomenclature Guidelines. Finalized by the Excipient Nomenclature and Labeling Joint Subcommittee on January 31, 2023, and released to the public in March 2023, the guidelines are intended to 1) provide a brief overview of the history of excipient nomenclature, 2) discuss the categorization of excipients based on composition, and 3) provide a clear process for naming new excipients. This work aligns with Resolution II, on efficiency in standards development and revision.

New Talc General Chapters and Monograph Approved: The SE and ETM ECs have balloted and approved *USP* General Chapter <901> *Detection of Asbestos in Pharmaceutical Talc*, *USP* General Chapter <1901> *Theory and Practice of Asbestos Detection in Pharmaceutical Talc*, and the updated Talc monograph. General Chapters <901> and <1901>, published in *USP–NF 2023*, *Issue 3*, are anticipated to become official on December 1, 2023. The Talc monograph, published in *USP–NF 2023, Issue 3*, will have an extended official date of December 1, 2025; the additional 2 years are intended to provide the time needed by manufacturers and users to implement the changes. Additionally, USP Education has launched a pharmacopeial education course titled "Test for Asbestos in USP Talc Chapters 901 and 1901" in June 2023. These efforts align with Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; and Resolution VII, on education and training.

Developing Standards for Polymeric Excipients: Pharmaceutical polymeric excipients made from lactide or lactic acid and/or glycolide or glycolic acid monomers (LG polymers) are used in many complex extended-release drug products and medical devices approved by the FDA. However, generic drug products that include LG polymers have yet to gain FDA approval due to the many complexities in formulation, characterization, and evaluation of test products. The Complex Excipients EC has developed the following new monographs for these excipients as well as a *Stimuli* article to help facilitate excipient selection and regulatory evaluation:

- DL-Lactide and Glycolide (50:50) Copolymer 12000 Ethyl Ester in *PF* 48(6) [Nov.–Dec. 2022]
- DL-Lactide and Glycolide (50:50) Copolymer 46000 Acid submitted for publication in *PF* 49(6) [Nov.–Dec. 2023]
- A *Stimuli* article titled "Responses to Comments on *Stimuli* Article: A Practical Approach to Compendial Nomenclature and Testing For Lactide and Glycolide Polymers and Related Polymeric Excipients," submitted for publication in *PF* 49(6)

Additionally, the ETM EC developed the proposed new *USP* General Chapter <312> *Molecular Weight Determination for Alginates*, which covers natural polymeric excipients. The General Chapter <312> proposal has been published in *PF* 48(6) and moved to the EC for balloting. These efforts help to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution II, on efficiency in standards development and revision; and Resolution V, on innovation.

Developing Standards for Lipid Nanoparticle (LNP) and Lipid-Based Formulations: With the increased complexity of generic drug product formulations (e.g., liposomes, LNP, lipid emulsions), the general approach used in the *National Formulary* (*NF*) for the Lecithin monograph, which covers vegetable sources, is no longer sufficient to adequately control the evolving expectations for the quality of these excipients. USP has therefore embarked on developing several new specific excipient public standards to support their use in FDA-approved drug products, including phospholipids that have been either submitted to PF for public comment, are in development, or are in acquisition. These efforts help to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution II, on efficiency in standards development and revision; and Resolution V, on innovation.

Novel Excipients Interlaboratory Studies: Novel excipients that have no prior use in a drug or food are not yet eligible for *NF* admission; however, some of these excipients are now used in LNP platform delivery systems (e.g., COVID vaccines). USP is engaging stakeholders to identify potential collaborative

opportunities, including development of general chapters and guidelines to meet evolving regulatory quality expectations for these lipid-type excipients. As part of this work, USP Laboratories will participate in an interlaboratory study of liposomal lipid quantitation using liquid chromatography with tandem mass spectrometry. These efforts help to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution V, on innovation.

USP Launches Novel Excipients Knowledge Hub Pilot: USP has created a Novel Excipients Knowledge Hub Pilot. The goal is to create an online community for stakeholders to exchange knowledge and best practices and to converse in multiple languages about challenges working with novel excipients. This activity helped to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution XII, on evidence generation to inform policy; and Resolution XIII, on coalition building.

Updating *USP* General Chapter <1074> *Excipient Biological Safety Evaluation Guidelines*: The Novel Excipients EP of the ETM EC began updating General Chapter <1074> in November 2022. The EP's work involves developing a mechanism for assessing the safety of novel excipients dependent on their intended use, duration, and dosing. The EP has tasked four subgroups with developing a *Stimuli* article on the proposed <1074> revisions and a survey to help identify features of the chapter that will be most helpful to stakeholders. This work relates to Resolution II, on efficiency in standards development and revision.

Revising *USP* General Chapter <1078> *Good Manufacturing Practices for Bulk Pharmaceutical Excipients*: The ETM EC has recommended a major revision proposal for General Chapter <1078> in *PF* 48(4) [Jul.–Aug. 2022] to provide a harmonized and comprehensive set of criteria for the quality management systems used in the manufacture of pharmaceutical excipients worldwide. Additionally, a risk management/risk assessment concept was introduced for excipient manufacturers making decisions regarding suitable applications of GMP based on the level of impact on the quality of the final excipient and drug product. This major revision was based on the results of a comprehensive gap analysis of the current <1078> that utilized several U.S. and international GMP standards. The ETM EC has been working to address public comments received on the chapter proposal. These activities support Resolution II, on efficiency in standards development and revision; Resolution III, on quality standards; and Resolution V, on innovation.

Revising *USP* General Chapter <1059> *Excipient Performance*: The ETM EC has proposed a major revision to General Chapter <1059> in *PF* 48(5). The revision combines the <1059> proposal published in *PF* 46(1) [Jan.–Feb. 2020] and responses to the comments reviewed and addressed by the <1059> Excipient Performance EP and approved by the ETM EC. This work helps to fulfill Resolution II, on efficiency in standards development and revision.

Excipients Group Supported Stakeholder Outreach Events: The following stakeholder outreach events align with Resolution II, on efficiency in standards development and revision, and Resolution VII, on education and training:

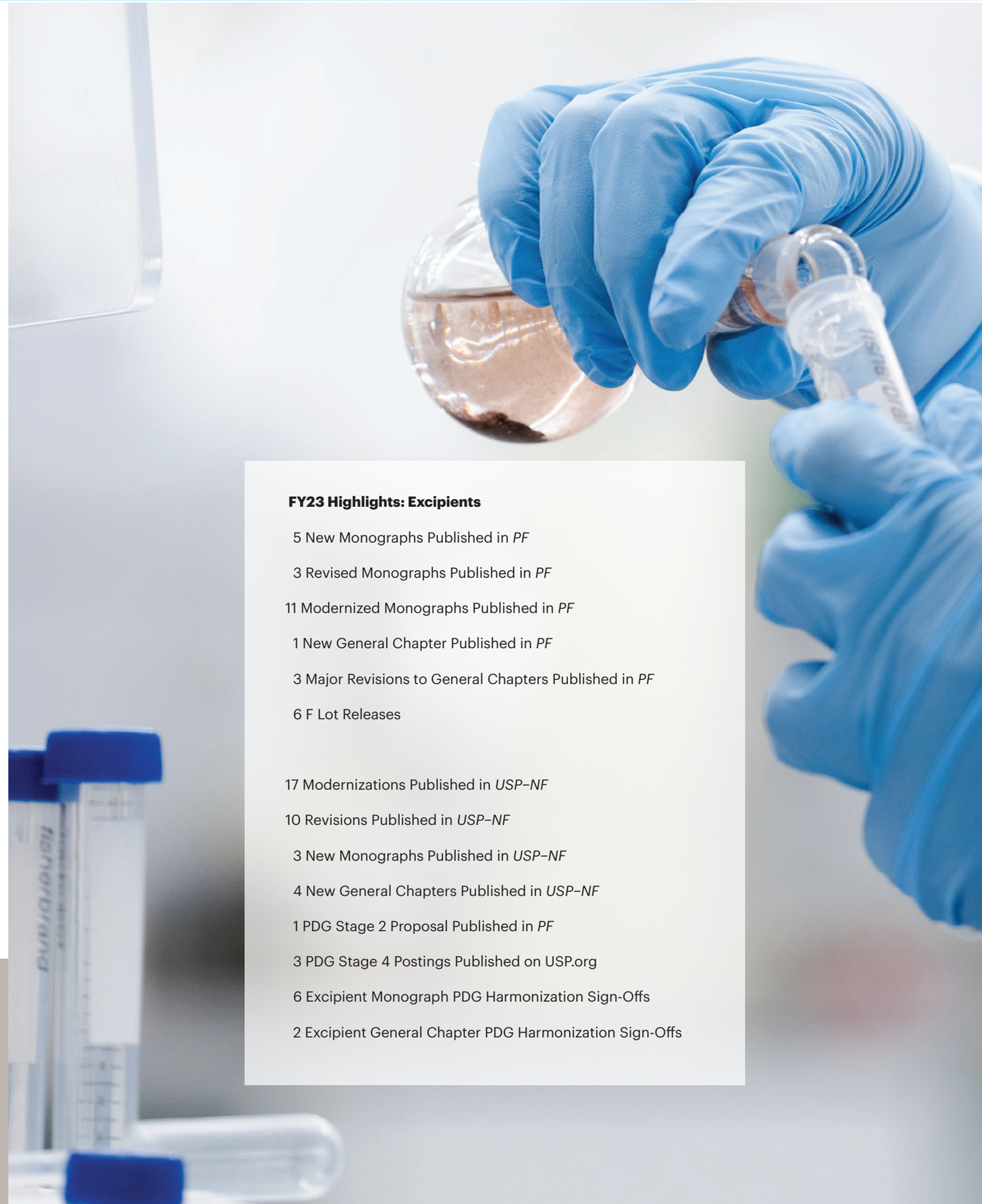
- USP's Europe, Middle East, and Africa office sponsored a virtual User Forum titled "Excipient Quality and Development for Use in Medicines" on February 15, 2023. More than 100 attendees from Europe and Southeast Asia representing industry, regulators, and academia participated in this virtual User Forum.
- USP staff delivered presentations at stakeholder engagement events, including the IPEC Americas Compendial Review Committee meeting on March 1, 2023; the IPEC Europe Excipient Forum on March 16, 2023; the Lipid Nanoparticle Summit in April 2023; and Excipient World in May 2023.

"The ETM EC works in collaboration with the other Excipients ECs and the General Chapters–Physical Analysis EC to develop general chapters and test methods to help improve and strengthen the characterization and understanding regarding excipients and to develop tools to improve and strengthen their supply chains."

Chris Moreton, Ph.D, Chair, ETM EC

"Maintaining the supply chain of excipients is critical to pharmaceutical manufacturing. The SE EC is working on ensuring that the tests are available to maintain USP quality excipients needed to deliver both brand name and generic drugs."

Eric Munson, Ph.D., Chair, SE EC



FY23 Highlights: Excipients

5 New Monographs Published in *PF*

3 Revised Monographs Published in *PF*

11 Modernized Monographs Published in *PF*

1 New General Chapter Published in *PF*

3 Major Revisions to General Chapters Published in *PF*

6 F Lot Releases

17 Modernizations Published in *USP–NF*

10 Revisions Published in *USP–NF*

3 New Monographs Published in *USP–NF*

4 New General Chapters Published in *USP–NF*

1 PDG Stage 2 Proposal Published in *PF*

3 PDG Stage 4 Postings Published on USP.org

6 Excipient Monograph PDG Harmonization Sign-Offs

2 Excipient General Chapter PDG Harmonization Sign-Offs

Food Ingredients

Expert Volunteers who serve on the Food Ingredients (FI) EC focus on developing standards for FIs to ensure the identity, quality, and purity of food additives, processing aids, flavors, colors, and other substances used to manufacture food products. These standards are published in the *Food Chemicals Codex* (*FCC*), which is used by product developers, ingredient suppliers, food manufacturers, testing laboratories, and regulators in the United States and internationally. The FI EC works closely with the Botanical Dietary Supplements and Herbal Medicines and the Non-Botanical Dietary Supplements ECs to coordinate the development of standards for substances that are used as both FIs and dietary ingredients.

Key Activities in Food Ingredients

Infant Formula Task Force and Guide: The Foods team formed an internal task force to create a strategy for helping to address overall concerns about infant formula quality in the face of ongoing supply chain constraints and concerns over microbial contamination. In May 2023, the task force created the "Guide to Food Ingredient Standards and Solutions for the Infant Formula Industry," which outlines existing USP DSs, RSs, and other materials that can be used to assess the purity and quality of ingredients used in the manufacture of infant formula. These efforts helped to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution III, on quality standards; and Resolution V, on innovation.

High-Value Standards: The following activities on high-value standards align with Resolution II, on efficiency in standards development and revision, and Resolution III, on quality standards:

- New monographs for Rice Protein and Pea Protein and a new identity standard for Moroccan Argan Oil were proposed in the December 2022 *FCC Forum* and balloted in June 2023.
- A new identity standard proposal for Sichuan Pepper Oil and a new monograph proposal for beta-Lactoglobulin will be proposed in the June 2023 *FCC Forum*.
- A document with guidelines aimed at mitigating the risk of honey fraud has been drafted and will be submitted for publication in the *FCC Forum* by the end of 2023.
- A new monograph for Lactoferrin, which will be supported by a new USP RS for this specialty dairy ingredient, is in development and will be submitted for publication in the *FCC Forum* by the end of 2023.

***FCC* Analytical Materials Program:** The Foods PUT released eight new *FCC* Analytical Materials (FAMs). Newly launched FAMs included validated methods and physical analytical materials to analyze whey protein ingredients using modern, specific technology and skim milk powder samples for the presence of melamine and undeclared starch. FAMs are validated, commercially representative samples of articles that are used as food ingredients that are fit for purpose for the food industry and food testing laboratories in areas that complement *FCC* standards. This work aligns with Resolution V, on innovation.

Elemental Impurities in Food Ingredients Open Forum: USP and *FCC* held a virtual Open Forum titled "Elemental Impurities in Food Ingredients: Pathways to Reducing Levels" on October 24–25, 2022, with some 170 individuals from industry, associations, regulatory agencies, and academia. The event was planned in conjunction with scientists and food safety experts from FDA's Center for Food Safety and Applied Nutrition and Health Canada, and it was intended, in part, to address FDA's Closer to Zero initiative from the perspective of public standards. This outreach activity aligns with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution II, on efficiency in standards development and revision; and Resolution VII, on education and training.

FY23 Highlights: Food Ingredients

2 New Appendixes Published in *FCC Forum*

4 New Monographs Published in *FCC Forum*

27 Monograph Revisions Published in *FCC Forum*

3 Monograph Modernizations Published in *FCC Forum*

4 Monograph Modernizations Published in *FCC*

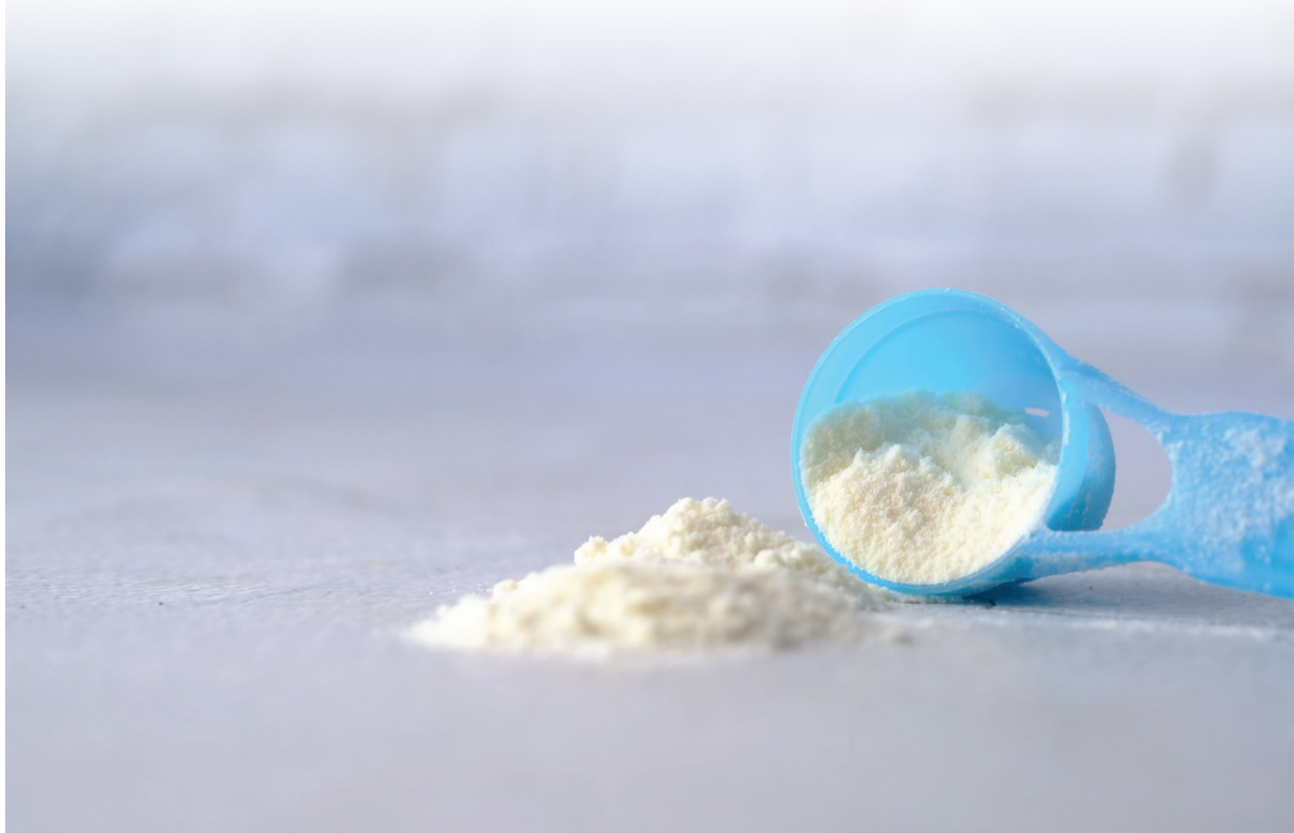
24 Monograph Revisions Published in *FCC*

4 New Appendix General Tests Published in *FCC*

7 New Monographs Published in *FCC*

"Following several years of being plagued with the shortcomings brought on by COVID, this past year saw major increases in excitement with the opportunity for in-person interactions for generating ideas, settling issues, and just plain better understanding among our colleagues on the FI EC."

Jonathan DeVries, Ph.D., Chair, FI EC



General Chapters

USP General Chapters provide specifications for tests, procedures, and other standards as well as general guidance for *USP–NF* monographs. Expert Volunteers serve on the following General Chapters Collaborative Group Expert Bodies: General Chapters–Chemical Analysis (GCCA), General Chapters–Dosage Forms (GCDF), General Chapters–Measurement & Data Quality (GCMDQ), General Chapters–Microbiology (GCM), General Chapters–Packaging and Distribution (GCPD), General Chapters–Physical Analysis, and General Chapters–Statistics ECs and their affiliated EPs and subcommittees. Their work impacts the quality control, packaging, and supply integrity of drugs and drug products as well as standards governing analytical procedure validation and verification.

Key Activities in General Chapters

New *USP* General Chapter <1083> *Supplier Qualification*: The GCPD EC developed General Chapter <1083> to support pharmaceutical supply chain resilience. This chapter emphasizes the importance of supplier qualification through a risk-based approach for selecting, assessing, approving, and monitoring suppliers of materials and services. Using the principles in <1083> to qualify suppliers of raw materials, ingredients, and services for foods and dietary supplement ingredients can help safeguard the integrity of those supply chains as well. This work aligns with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution III, on quality standards.

New Flexible Approach for Reporting Thresholds of Unspecified Impurities: The GCCA EC published the new *USP* General Chapter <477> *User-Determined Reporting Thresholds* in *PF* 48(5). This chapter would provide a flexible approach for reporting unspecified impurities referenced in *USP–NF* monographs. This approach would empower manufacturers to apply product-specific knowledge in establishing reporting thresholds instead of using prescriptive numeric values and would enable accuracy and consistency concerning the control of organic impurities for the benefit of patients and public health. Noncontroversial comments were received, and the chapter was balloted on June 23–July 5, 2023, and approved. These efforts help to fulfill Resolution III, on quality standards.

New Chapters on Microbial Methods: The Rapid Microbial Methods Subcommittee of the new GCM EC has been reviewing the comments received for *USP* General Chapters <72> *Respiration-Based Rapid Microbial Methods for the Release of Short Shelf Life Products* and <73> *ATP Bioluminescence-Based Rapid Microbial Methods for the Release of Short Shelf Life Products*, which were balloted in FY22. To align with the content in those chapters, the EC has proposed revising *USP* General Chapter <1071> *Rapid Microbial Tests for Release of Sterile Short-Life Products: A Risk-Based Approach*. All three chapters are anticipated to be published in *PF* 50(1) [Jan.–Feb. 2024]. Additionally, the GCM EC proposed the following new general chapters on rapid microbial methods in *PF* 48(5): *USP* General Chapter <74> *Solid Phase Cytometry-Based Rapid Microbial Methods for the Detection of Contamination in Short Shelf-Life Products* and *USP* General Chapter <77> *Mycoplasma Nucleic Acid Amplification Tests*.

Separately, the Endotoxins and Pyrogens Subcommittee of the GCM EC has been drafting a proposed new *USP* General Chapter <86> *Bacterial Endotoxins Test Using Recombinant Reagents* as an alternative to the *USP* General Chapter <85> *Bacterial Endotoxins Test*. The proposed new chapter is anticipated to be published in *PF* 49(6). These efforts align with Resolution II, on efficiency in standards development and revision, and Resolution III, on quality standards.

New GCM EC and Priority Areas: The new GCM EC chaired by Mark Schweitzer, Ph.D., with 20 members bridging 16 time zones and six countries, identified rapid microbial methods and endotoxins as top priority areas at its February 15–16, 2023, EC meeting. Four subcommittees and two joint subcommittees have been formed and started reviewing in-process documents, including eight proposed new general chapters, and began major revisions of five general chapters. These activities help to fulfill Resolution IV, on access to biologics; Resolution V, on innovation; and Resolution XIV, on culture of excellence.

Revision to *USP* General Chapter <660> *Containers—Glass*: The GCPD EC continued working to modernize the chapter posted in *PF* 49(2) [Mar.–Apr. 2023] to address public health concerns regarding global glass production and the potential for resulting drug shortages. On January 27, 2023, USP posted a General Announcement outlining USP's two-pronged approach to help address these concerns and posted a Notice of Intent to Revise that provides additional details and contact information. Comments received in FY23 Q4 were under review. These activities are in accordance with Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution II, on efficiency in standards development and revision.

Updating Nuclear Magnetic Resonance (NMR) Chapters: The quantitative NMR (qNMR) EP of the GCCA EC concluded its draft revisions to *USP* General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Nuclear Magnetic Resonance Spectroscopy—Theory and Practice* and initiated a draft of the new *USP* General Chapter <1762> *Solid-State Nuclear Magnetic Resonance Spectroscopy—Theory and Practice*. These were posted in *PF* 48(4) along with a *Stimuli* article titled "Consistent Terminology for Advancement of NMR Spectroscopy." General Chapters <761> and <1761> will be republished in *PF* 49(5) [Sep.–Oct. 2023] to reflect the updates and revisions based on the feedback received. These activities support Resolution II, on efficiency in standards development and revision, and Resolution V, on innovation.

> "Substantial changes to the GCM EC have been completed resulting in the establishment of a new highly diverse EC with members from six countries covering 16 time zones. The members have brought a new general chapter into the compendium and prepared several general chapters for *PF* publication."
>
> **Mark Schweitzer, Ph.D., Chair, GCM EC**

Complex Generics in Early Stages of Product Development: The Complex Generics team has identified more than 100 candidate materials—including extractables and leachables (E&Ls), dissolution materials, reagents, non-U.S. APIs, and injectable physical materials—for the material strategy team's market and business case evaluation and next steps. Of these, approximately 60 are individual E&Ls yielding four sets of physical standards. These activities helped to fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities, and Resolution V, on innovation.

Mutagenic and Potential Mutagenic Impurities: Recent concerns about the presence of mutagenic impurities in the commercial drug supply have focused USP's attention on the need to address this important category of impurities in general chapters and monographs. The GCCA EC and USP staff have developed a *Stimuli* article titled "Mutagenic Impurities and Potential Mutagenic Impurities in the *USP–NF*" to briefly describe some of the unique challenges posed by mutagenic and potentially mutagenic impurities and to solicit early input on how USP could best support manufacturers to ensure product quality. This article was published in *PF* 48(5), and a limited number of comments have been received. A cross-functional team of USP staff is developing a strategy for an interim solution as well as a long-term proposal. This work addresses Resolution II, on efficiency in standards development and revision, and Resolution V, on innovation.

New Advancements in the Product Performance Tests (NAPPT) EP: The NAPPT EP working groups of the GCDF EC have been responsible for the following *Stimuli* articles, as per Resolution II, on efficiency in standards development and revision:

- "*In Vitro* Performance Tests for Continuous Manufacturing: The Impact on the Current Compendial Framework from the Viewpoint of the USP New Advancements in Product Performance Testing Expert Panel" in *PF* 48(4)

> GCPA EC has assembled a wide range of Expert Advisors to support emerging and classic manufacturing and analytical technologies.... These are key areas that will help ensure that the *USP* will continue to be a relevant resource for the physical analysis of drug substances and pharmaceutical products into the future."
>
> **Kate Houck, Ph.D., Chair, GCPA EC**

- "*In-Vitro* Product Performance of Parenteral Drug Products: View of the USP Expert Panel" in *PF* 48(4)
- "Testing the *In Vitro* Product Performance of Inhalation and Nasal Drug Products: Views of the USP Expert Panel" in *PF* 48(5)

The General Chapters Group Supported Open Forums: The following stakeholder outreach activities align with Resolution II, on efficiency in standards development and revision; Resolution VII, on education and training; and Resolution XV, on impact expansion:

- Virtual Validation, Verification, Transfer: Current Situation and Evolution, held as a hybrid meeting on March 8, 2023, in collaboration with USP customers in Egypt, attended by 70 individuals from industry, regulatory agencies, and academia.
- Virtual Open Forum on *USP* General Chapter <1010> *Analytical Data—Interpretation and Treatment*, held on March 9, 2023, in collaboration with USP Customer Experience in Latin America, attended by some 80 individuals from industry.
- Virtual Open Forum on Technical and Regulatory Challenges for the Development of Complex Injectable Products, held on April 25–26, 2023, attended by 875 registrants from more than 30 countries, including representatives of FDA and other international regulatory authorities.

The General Chapters Group Supported Outreach: The following stakeholder outreach activities align with Resolution II, on efficiency in standards development and revision; Resolution VII, on education and training; and Resolution XV, on impact expansion:

- Dissolution Best Practices and International Harmonization held on August 16, 2022, at the American Association of Pharmaceutical Scientists attended by 60 participants.
- Application of General Chapter <1220> *Analytical Procedure Life Cycle* in the Development of Procedure for qNMR held on March 22, 2023, in Philadelphia, attended by 50 participants.
- *USP* General Chapter <1220> an Overview and Implementation Roadmap held on May 7–8, 2023, in San Diego, attended by 75 individuals from industry.
- Perspectives of Spectral Library at USP held on June 3, 2023, at IFPAC in Bethesda, MD, attended by 100 individuals from industry, regulatory agencies, and academia.

The General Chapters Group Supported USP Webinars: The following stakeholder outreach activities align with Resolution II, on efficiency in standards development and revision; Resolution VII, on education and training; and Resolution XV, on impact expansion:

- *USP* General Chapter <660> *Containers—Glass* on March 15, 2023
- qNMR Method Development and Validation on March 17, 2023
- Introduction to qNMR on March 27, 2023
- qNMR Method Development and Validation on April 24, 2023

The General Chapters Group Supported Trainings: The following activities help to fulfill Resolution VII, on education and training:

- "Impurities in Pharmaceutical Products: A USP Focus" held on August 5, 2022, at the Puerto Rico School of Chemistry in Puerto Rico

> "The GCCA EC addresses a wide variety of topics. In the current cycle several key improvements have been possible. Among them, after years of discussions, the harmonization of *USP* General Chapter <621> *Chromatography* has been finalized."
>
> **Nancy Lewen, B.Sc., Chair, GCCA EC**

> "Just as a small speck of solid can act as a seed crystal for crystallization, the publishing of *USP* General Chapter <1220> has been the seed for change and improvement in pharmaceutical analytical chemistry. The EC has published seven detailed articles to further explain how to implement the analytical procedure life cycle.... This helps ensure pharmaceuticals are safe, efficacious, and have the quality patients need."
>
> **Jane Weitzel, B.Sc., Chair, GCMDQ EC**

FY23 Highlights: General Chapters

- 3 New General Chapters Published in *PF*
- 1 New General Chapter Official in *USP–NF*
- 13 Major General Chapter Revisions Published in *PF*
- 8 Major General Chapter Revisions Official in *USP–NF*
- 16 Minor General Chapter Revisions Published in *PF*
- 8 Minor General Chapter Revisions Official in *USP–NF*
- 1 Omission
- 9 *Stimuli* Articles

- "Validation" held on August 30–31, 2022, for the Brazilian Health Regulatory Agency
- "*USP* General Chapter <1469> *Nitrosamine Impurities*" held on May 3–4, 2023, for USP Latin America

Published Papers: These activities align with Resolution II, on efficiency in standards development and revision:

- "Paradigm Shift in Drug Development: Analytical Quality by Design and Analytical Procedure Life Cycle," published May 17, 2023, in *Quality Matters*
- "Evolution of Analytical Procedure Validation Concepts: Part I," published March 15, 2023, in *BioPharm International*
- "Evolution of Analytical Procedure Validation Concepts: Part II," published March 15, 2023, in *BioPharm International*
- "Ongoing Analytical Procedure Performance Verification—Stage 3 of USP <1220>," published March 2, 2023, in *PharmTech*
- "Spectroscopy and Spectroscopic Analytical Techniques in the *United States Pharmacopeia–National Formulary* (*USP–NF*)," published March 1, 2023, in *Spectroscopy in Pharmaceutical Analysis*

The General Chapters Group Supported Presentations: General Chapters staff delivered 48 presentations as part of stakeholder outreach activities aligned with Resolution II, on efficiency in standards development and revision; Resolution VII, on education and training; and Resolution XV, on impact expansion.

Healthcare Quality and Safety

CENTER OF EXCELLENCE

The Healthcare Quality and Safety (HQS) group is a designated Center of Excellence that enables USP to deliver quality standards and solutions that meet the needs of healthcare professionals to help improve medicine quality, patient safety, and access. HQS provides:

- Standards and solutions that enhance quality, accessibility, and equity of medication practices
- Data and digital tools designed to improve the use of standards in knowledge sharing, decision-making, and reporting
- Standards and solutions for quality medication and treatment tailored to the individual characteristics of each patient

Expert Volunteers serve on the Compounding (CMP), Healthcare Information and Technology (HIT), Healthcare Safety and Quality (HSQ), and Nomenclature and Labeling ECs and related EPs and subcommittees. Together, these Expert Volunteers deliver quality standards and solutions that address the needs of patients, healthcare professionals, and overall public health, including standards and solutions for safe medication use, drug formulary classification, sterile and nonsterile compounded preparations, the handling of hazardous drugs, and the naming and labeling of drug products and ingredients.

Key Activities in Healthcare Quality and Safety

USP Achieves Major Milestones in Delivering Final Revised Compounding Chapters: USP has passed important milestones by delivering the final revised *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations* and supporting their early adoption by stakeholders. The USP CMP EC voted in July 2022 to extend the date on which the final revised General Chapters <795> and <797> become official to November 1, 2023, to allow for increased flexibility and engagement for adoption. One appeal and one request for an extension to the appeal deadline were received in December 2022 in response to the publication of these chapters. Both submissions were assessed by the Chair of the CoE, in consultation with the Chair of the CMP EC. After careful review, no process deficiencies were found, and the appeal to General Chapter <795> was denied in January 2023. The request for an extension of the appeal deadline for General Chapter <797> was not granted as the Rules and Procedures of the CoE Section 9.08(b) clearly states the timeline and requirements for submitting an appeal. Both appellants were encouraged to continue to engage with USP. The appeals process has concluded, and both General Chapters are now available in the *USP–NF* and online through the *USP Compounding Compendium*.

USP is hosting stakeholder events and updating educational resources to support stakeholders' early adoption of General Chapters <795> and <797>. USP sponsored "The USP Third Annual Compounding Implementation Workshop" on February 7–8, 2023, a hybrid stakeholder event that explored quality compounding improvements that enhance patient safety through the development of standards for compounded medicines. The workshop convened a wide range of stakeholders—more than 180 attendees from compounding member associations, hospital systems, regulatory authorities, the pharmaceutical industry, contract laboratories, and academia—and focused on topics that help compounders understand and implement General Chapters <795> and <797>.

USP staff has also provided presentations on the <795> and <797> revisions at the National Home Infusion Association Annual Conference, American Pharmacists Association Annual Meeting, Midland Health System Pharmacist Association Annual Meeting, and National Community Oncology Dispensers Association Spring Meeting. USP is developing additional resources in response to topics raised by stakeholders during the revision of <795> and <797>, including stability studies, aseptic techniques, automated compounding technologies, and quality assurance in compounding. Visit www.usp.org/compounding/updates for the latest updates. This work aligns with Resolution II, on efficiency in standards development and revision; Resolution VII, on education and training; and Resolution IX, on compounding.

COVID-19 Vaccine Handling Toolkit: In October 2022, the HSQ EC released an updated version of the COVID-19 Vaccine Handling Toolkit. This update includes considerations for administering booster and pediatric doses and mitigating strategies to avoid medication errors in a multi-vaccine environment. These activities support Resolution III, on quality standards; Resolution V, on innovation; and Resolution XV, on impact expansion.

Monkeypox Dose Maximization Studies: In September 2022, the HQS Center of Excellence conducted dose maximization studies validated through collaborative testing with local health systems. USP was able to identify optimal needle/syringe combinations that would extract the most doses per vaccine vial working within the syringe/needle supply parameters specified by regulators. These activities support Resolution III, on quality standards; Resolution V, on innovation; and Resolution XV, on impact expansion.

Excipient Nomenclature Guidelines Released: The Excipient Nomenclature Guidelines have been added to the suite of Nomenclature Guidelines for drug products and dietary supplements on the HQS Compendial Nomenclature web page. The guidelines, finalized on January 31, 2023, are intended to 1) provide a brief overview of the history of excipient nomenclature, 2) discuss the categorization of excipients based on composition, and 3) provide a clear process for naming new excipients. This work aligns with Resolution II, on efficiency in standards development and revision.

Setting Allergies and Intolerances Value: Although electronic tools have facilitated electronic prescribing, verifying accurate capture, confirmation, and exchange of drug allergy information within this electronic environment is challenging. The HIT EC has appointed its Allergies & Intolerance EP to develop value sets that will establish standardized coding, enhance clinical decision-making, and support safer care by ensuring allergy information travels with the patient. This work addresses Resolution V, on innovation; Resolution VI, on the digital transformation of standards; and Resolution XII, on evidence generation to inform policy.

Expanding the Symedical Platform: USP has continued to expand the application of the Symedical platform beyond

> "Improving medication safety for children who often require compounded medications has been an exciting endeavor this year.... Standards are being developed for the electronic transmission of these prescriptions that will include USP-validated formulations."
>
> **Jeanne Tuttle, B.S.Pharm., Chair, HIT EC**

> "The HSQ EC is proud to have adopted guiding principles for the MMG and the USP Drug Classification, which include explicit consideration of health equity and medication access."
>
> **Melody Ryan, Pharm.D., M.P.H., Chair, HSQ EC**

its current usage for the USP Drug Classification, Medicare Model Guidelines (MMG), *USP* General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*, and National Institute for Occupational Safety & Health Hazardous Medication List content. The Symedical platform provides a robust, scalable solution for USP to efficiently curate and publish standards and solutions as structured data directly into health IT systems used in healthcare delivery, including value sets and data models. This platform has been extended to include content from the National Institute for Occupational Safety and Health related to the handling of hazardous drugs in healthcare settings as well as USAN written and future audio pronunciation content. This work supports Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution VI, on the digital transformation of standards; and Resolution XII, on evidence generation to inform policy.

USP Drug Classification: The HSQ EC completed the USP Drug Classification 2023 (USP DC 2023), an independent drug classification system to assist with formulary support outside of Medicare Part D. USP DC 2023 was published on December 16, 2022, and is available for download. This work supports Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution XII, on evidence generation to inform policy; and Resolution XIV, on culture of excellence.

MMG Public Comment Period: The draft of the USP MMG v9.0 was posted for comment from June 1–30, 2023. This updated version of MMG will be revised to include drugs approved by the FDA from November 2019–June 2023 that are covered by Part D benefits. This work supports Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution II, on efficiency in standards development and revision; and Resolution XII, on evidence generation to inform policy.

Virtual Roundtable: The HIT EC hosted a roundtable meeting on the electronic exchange of compounded preparation information on August 23, 2022, with more than 60 stakeholders representing retail and hospital pharmacies as well as academia. The event enabled USP to gather input and perspectives on ways to improve the quality and safety of compounded nonsterile preparations (CNSPs) prescribed through a USP-designed data framework that standardizes information transmitted in e-prescriptions for pediatric CNSPs. The event aligns with Resolution II, on efficiency in standards development and revision; Resolution VI, on the digital transformation of standards; and Resolution IX, on compounding.

Selected Published Papers: USP staff collaborated on "Creating data standards to support the electronic transmission of compounded nonsterile preparations (CNSPs): Perspectives of a United States Pharmacopeia Expert Panel," published September 29, 2022, in *Children*. This work supports Resolution II, on efficiency in standards development and revision; Resolution VI, on the digital transformation of standards; and Resolution IX, on compounding.

USP Education: USP offered the following courses on revised compounding standards as webcasts in alignment with Resolution VII, on education and training:

- *USP* General Chapter <795> on April 4–6, 2023, attended by 202 participants
- *USP* General Chapter <797> on April 4, 2023, attended by 249 participants
- *USP* General Chapter <800> on April 4, 2023, attended by 228 participants

> "The highly productive NL EC approved numerous monograph titles and drafted extensive revisions to *USP* General Chapter <7> *Labeling*. Additionally, the Excipient Nomenclature Guidelines and Version 2 of the Guideline for Assigning Titles to USP Dietary Supplement Monographs were approved, and the USP/USAN Pronunciation work was extended with re-establishment and appointment of the Pronunciation Expert Panel and AI-enhanced digital audio pronunciations to augment written pronunciations."
>
> **Stephanie Crawford, Ph.D., Chair, NL EC**

FY23 Highlights: Healthcare Quality and Safety

1 New Monograph Published in *PF*

3 Monograph Revisions Published in *PF*

2 Minor General Chapter Revisions Published in *USP–NF*

5 New Monographs Published in *USP–NF*

43 Nomenclature Monograph Titles Approved

Expert Volunteers AND Government Liaisons

Among USP's greatest assets are the transparency and scientific rigor that 675 Expert Volunteers and 226 Government Liaisons helped bring to USP's standards-setting process in FY23. Through the contribution of their individual expertise, they have helped to ensure the identity, strength, quality, and purity of chemical and biological medicines, excipients, dietary supplements, and food ingredients and benefited consumers, patients, and other stakeholders in the United States and around the world.

The CoE—consisting of the 29 EC Chairs listed in the following table, plus Jaap Venema, Ph.D., USP's Chief Science Officer & CoE Chair—oversees the activities of numerous global scientific experts who serve on ECs, EPs, and JS3s. These Expert Volunteers play a vital role in providing expertise and in the development of standards by participating in Expert Body discussions and reviewing documents and information. EC members approve DSs for publication and RSs for release. They ballot on all regular DS revisions, new RSs, and a sampling of R and C Lots.

Government Liaisons—representatives from the FDA, other federal or state government agencies in the United States, and government agencies in other countries—contribute to discussions at Expert Body meetings to which they are assigned. Government Liaisons do not vote on standards that are up for ballot. They offer opinions on all facets of standards development from the perspective, and on behalf of, the government agency they represent, and may be tasked with seeking further information or soliciting opinions from the agency they represent.

Visit usp.org/get-involved/volunteer to learn more about how volunteers contribute to USP's more than 200-year-old mission to improve global health through public standards and related programs that help ensure quality medicines, foods, and dietary supplements. Find out how you can start the application process to become a member of our ECs or EPs by clicking on callforcandidates.usp.org.

Collaborative Groups

Biologics

Biologics Monographs 1–Peptides & Oligonucleotides EC
Michael De Felippis, Ph.D., Chair

Biologics Monographs 2–Proteins EC
Wendy Saffell-Clemmer, M.S., Chair

Biologics Monographs 3–Complex Biologics & Vaccines EC
Earl Zablackis, Ph.D., Chair

Biologics Monographs 4–Antibiotics EC
Matthew Borer, Ph.D., Chair

Biologics Monographs 5–Advanced Therapies EC
Mehrshid Alai, Ph.D., Chair

Small Molecules

Small Molecules 1 EC
Mary Seibel, B.Sc., Chair

Small Molecules 2 EC
Justin Pennington, Ph.D., Chair

Small Molecules 3 EC
Eric Kesslen, Ph.D., Chair

Small Molecules 4 EC
Kim Huynh-Ba, M.S., Chair

Small Molecules 5 EC
Amy Jo Karren, B.Sc., Chair

Over-the-Counter Methods & Approaches EC
Raphael Ornaf, Ph.D., Chair

Excipients

Simple Excipients EC
Eric Munson, Ph.D., Chair

Complex Excipients EC
Otilia Koo, Ph.D., Chair

Excipients Test Methods EC
Chris Moreton, Ph.D., Chair

General Chapters

General Chapters–Dosage Forms EC
Martin Coffey, Ph.D., Chair

General Chapters–Chemical Analysis EC
Nancy Lewen, B.Sc., Chair

General Chapters–Microbiology EC
Mark Schweitzer, Ph.D., Chair

General Chapters–Packaging & Distribution EC
Renaud Janssen, Ph.D., Chair

General Chapters–Measurement & Data Quality EC
Jane Weitzel, B.Sc., Chair

General Chapters–Statistics EC
Charles Tan, Ph.D., Chair

General Chapters–Physical Analysis EC
Kate Houck, Ph.D., Chair

Healthcare Quality & Safety

Nomenclature & Labeling EC
Stephanie Crawford, Ph.D., Chair

Healthcare Safety & Quality EC
Melody Ryan, Pharm.D., M.P.H., Chair

Compounding EC
Brenda Jensen, M.A., Chair

Healthcare Information & Technology EC
Jeanne Tuttle, B.S.Pharm., Chair

Dietary Supplements & Herbal Medicines, Food Ingredients

Botanical Dietary Supplements & Herbal Medicines EC
Robin Marles, Ph.D., Chair

Non-Botanical Dietary Supplements EC
Guido F. Pauli, Ph.D., Pharm.D., Chair

Dietary Supplements Admission Evaluation & Labeling EC
Tieraona Low Dog, M.D., Chair

Food Ingredients EC
Jonathan DeVries, Ph.D., Chair

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