



FISCAL YEAR **2021**
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 this first annual report of the 2020–2025 cycle on the activities and achievements of the CoE, including its Expert Committees (ECs) and Expert Panels, for fiscal year 2021 (FY21).

As I reflect on the unique challenges and successes of this past year, our present endeavors, and the hard work ahead of us, I am filled with optimism and purpose that is firmly rooted in our science. USP’s compendia have grown dramatically, providing thousands of science-based public standards that serve as global quality benchmarks for medicines, food ingredients, dietary supplements, and healthcare. USP staff, scientists, and Expert Bodies are employing cutting-edge approaches to keep our portfolio up to date and developing new methods, materials, and technologies for compendial applications. We continue to advocate for diversity, equity, inclusion, and belonging (DEIB), which are central to our public health mission. Looking ahead, our Global Science and Standards (GSS) Division has a bold, long-term vision to address the COVID-19 pandemic and transform the way we develop and communicate our science-based public standards. I want to highlight six of our many FY21 activities and accomplishments, which are explained in detail in the pages that follow, and the key factors that have contributed to our successes.

We created the GSS Division and established the Science Quality Framework (SQF). The GSS Division comprises five scientific, technical, and operational units with major hubs in Rockville and Frederick (Maryland, United States) and Hyderabad (India). This merger united accomplished scientists across multiple disciplines to develop and revise our science-based public standards, expanding our ability to support important training and advocacy to strengthen USP’s scientific voice around the world.

We consolidated our laboratories to improve efficiencies. The transfer of projects and equipment from the China and Brazil laboratories to USP–India has been completed, expanding USP–India’s synthetic, analytical, and compendial development laboratories. With this transition,

the new synthetic laboratory became operational in October 2020. We closed the Hyderabad labs for several weeks in May 2021 in response to the rapidly changing COVID-19 pandemic. Operations have since resumed, and we will continue to monitor the situation. Construction has also been completed on the laboratory space at USP–U.S., Rockville, enabling the consolidation of all labs into one building. The move increases laboratory efficiencies, reduces capital building costs, and provides resources for USP’s expanding portfolio of critical public health standards.



The SQF comprises the following five strategic pillars that form the foundation for everything the GSS Division will accomplish during this cycle:

- 1) Evolving and Expanding Standards
- 2) Product and Substance Performance
- 3) Emerging Modalities
- 4) Technologies
- 5) Quality Environment

These focal points converge to form USP’s vision for the GSS Division 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.

We launched the 2020–2025 CoE and transformed our operating model. We have transitioned to 29 ECs that are smaller and more agile, with leaner work plans focused on the highest-priority problems. The new CoE and its ECs operate under a more flexible standards engagement model that includes our pilot for a reimagined Expert Volunteer experience. We encouraged ECs participating in the pilot to leverage Expert Advisors who can share their expertise as needed, without having to commit to a five-year cycle or participate in mandatory balloting activities. Our aspiration is that our new flexible model will help USP attract a broader, more diverse audience and increase volunteer engagement.



Since the beginning of the COVID-19 pandemic, USP's three-part response has centered on:

- 1) Ensuring the safety and security of staff and volunteers,
- 2) Adapting our operations, and
- 3) Delivering on our public health mission.



Much of our work during FY21 supported USP's COVID-19 mission priority. We have adopted new approaches to our work, resulting in more agile responses to the current public health crisis and other immediate health needs. The new and updated resources that we launched have helped support trust in COVID-19 vaccines, preventatives, and medicines. These resources include our ["COVID-19 Vaccine Handling Toolkit"](#) and ancillary guides for maximizing doses of the Pfizer-BioNTech and Moderna COVID-19 vaccines. Our work helped increase the supply of the Pfizer and Moderna vaccines by more than 53 million doses.

The USP Compounding EC developed ["Operational Considerations for Sterile Compounding During the COVID-19 Pandemic"](#) based on its scientific and professional expertise, with input from stakeholders and federal and state regulatory agencies. We also updated our ["Hand Sanitizer Toolkit"](#) to include information on methanol contamination in alcohol-based hand sanitizers.

Supply-and-demand imbalances during the pandemic created a surge in substandard and falsified treatments in some regions of the world. To help safeguard patients and build trust in COVID-19 treatments, USP released ["USP Methods to Assist in Detecting Falsified Remdesivir."](#) We rapidly developed this resource, providing timely information to help stakeholders determine the identity and strength of authentic remdesivir, a drug approved and/or authorized for COVID-19 treatment in approximately 50 countries. It was the latest in a [suite of resources](#) created in collaboration with our partners to help

manufacturers, regulators, and quality control laboratories ensure quality and trust in COVID-19 medicines. USP has also collaborated with other international pharmacopeias on an [interactive dashboard](#) of monographs mapped to medicines being investigated as COVID-19 treatments. More information about these resources and our broader efforts can be found at [USP's COVID-19 response hub](#).

USP scientists and Expert Volunteers helped safeguard patients from nitrosamine impurities in medicines. We provided tools and solutions that address the hazards of unacceptable levels of [nitrosamine impurities](#), probable or known human carcinogens whose presence has been reported in widely used prescription and over-the-counter medications. USP developed a proposed new informational general chapter on nitrosamine impurities, associated Reference Standards, and on-demand educational webcasts to help drug manufacturers and regulators worldwide analyze, monitor, and control for nitrosamine impurities, thereby strengthening the global supply chain for medicines and safeguarding patients.

USP Biologics delivered new biologics performance standards. The Biologics Monographs 2-Proteins EC approved three monoclonal antibody (mAb) performance standards that are applicable to a broad range of therapeutic mAb drugs. These new Reference Standards were the latest in USP's growing portfolio of standards focused on biological product classes and families. Scientists, developers, and manufacturers can use them to help ensure the consistency and reproducibility of analytical methods and, potentially, bring quality therapies to market faster. This work has led to more stakeholder engagement around biologics performance standards and promising future opportunities for USP Biologics.

We have continued to advocate for DEIB. USP is committed to creating a culture where everyone feels fully empowered and valued and

can contribute their full potential to accomplish our public health mission. Our focus on this is intentional and designed to build a sense of true belonging. In alignment with its commitment to support global public health and access to quality medicines, the CoE has continued its work developing a Health Equity Initiative.

Our activities and accomplishments have been supported by the strengthening relationship we have with the U.S. Food and Drug Administration and collaboration with scientists and stakeholders around the world. Indeed, our impact in FY21 was made possible by the numerous hours—estimated at 77,620—that were generously contributed by our Expert Volunteers and augmented by our dedicated staff. Thank you for your commitment to USP's mission.

In our 2021 scientific relevance framework survey, more U.S. stakeholders recognized USP as collaborative, science based, mission driven, impacting public health, and a thought leader around the science of quality. We use these findings to monitor changes in USP's perceived scientific relevance over time. It is very rewarding and satisfying to see these results. I'm especially proud that our stakeholders recognize USP as science based because this is directly linked to the ongoing work by the many individuals who create, present, and educate stakeholders about our science.

To support these activities, we have created a new type of stakeholder event, USP Open Forums, for discussing and receiving input on key topics so that we better understand the issues and impact on industry and regulators. We have launched [Our Science](#), a website that showcases the innovative work by USP scientists and volunteers as well as opportunities for emerging leaders in science, such as student fellowships and programs. We also held our third annual USP Science Week event, our virtual global celebration of USP science that showcases cutting-edge research and innovation from USP scientists to help position USP as a thought leader in the science of quality standards.

We are looking to work in an iterative and agile way in the future. Our organization-wide programs and initiatives to transform USP aim to develop new science-based activities and enhance our business value. We anticipate implementing a new case-based approach to standards development and reaching new milestones in ATP, our organization-wide effort to Adapt, Transform, and Progress our approach to standards development in a sustainable and consistent way. USP is working to augment and transform our existing compendia of standards with digital, interoperable components. In an increasingly digital world, these and other approaches to transformation aim to increase USP's data utilization, enhance staff capabilities to leverage data, and accelerate our generation of science-based public standards.

In these extraordinary times, I send my thanks and well wishes to all of our Expert Volunteers for everything you do to support USP's global mission to help build quality foundations for a healthier world. I warmly invite you to read the following pages, which tell the story of how our collaborative activities in FY21—guided by the organizational goals defined by USP's Success Sharing Plan and the [2020-2025 Convention Resolutions](#)—have benefited consumers, patients, and other global stakeholders by helping to improve and protect public health in the U.S. and around the world.

Jaap Venema, Ph.D.
USP Chief Science Officer & Chair,
USP Council of Experts



FOSTERING COLLABORATION

FY21 AT A GLANCE



CoE Overview

The Council of Experts (CoE), consisting of the 29 Expert Committee (EC) Chairs, 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, Expert Panels (EPs), and Joint Standards-Setting Subcommittees (JS3s) in fiscal year 2021 (FY21).

USP Standards Approved in FY21

Expert Volunteers play a vital role in approving standards, both documentary standards for publication and Reference Standards for release. Expert Volunteers ballot on all regular documentary standard revisions, new Reference Standards (F Lots), and a sampling of Replacement and Continuation (R&C) Lots.

USP Governing Bodies and Related Groups

Board of Trustees (BoT)	USP Convention	CoE	Volunteer Groups Under CoE
<p>10 members elected by USP Convention, plus the Past Convention President, three at-large members appointed by the BoT, and the USP CEO, responsible for:</p> <ul style="list-style-type: none"> • USP's policies • USP's finances • USP's strategic direction 	<p>502 organizations invited by Council of the Convention and BoT, responsible for:</p> <ul style="list-style-type: none"> • Resolutions that guide USP policies and initiatives • Adoption of <i>USP Bylaws</i> • Election of the BoT and CoE 	<p>29 Chairs of USP ECs, elected by the USP Convention, plus USP's Chief Science Officer who serves as CoE Chair, responsible for:</p> <ul style="list-style-type: none"> • USP scientific and standards-setting decisions • Standards-setting work of USP's volunteer scientific expert groups • Adherence to direction set forth by the BoT and USP Convention 	<p>ECs Scientific experts who create, revise, review, and approve standards for a specific topic area. EC members are elected by CoE and serve a five-year term.</p> <p>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 be EC members or serve on multiple EPs.</p> <p>JS3s Representatives from ECs who serve on subcommittees formed to address issues that affect multiple standards-setting areas.</p>

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

FY21 Balloted and Approved Standards by the Numbers*

97 Documentary Standards Ballots	539 Documentary Standards Items Balloted
398 New or Revised Documentary Standards Approved	157 Modernized Documentary Standards Approved
91 <i>United States Pharmacopeia-National Formulary (USP-NF), Food Chemicals Codex (FCC), and Supplements Documentary Standards Omitted</i>	476 Reference Standard R&C Lots Released
	129 Reference Standard F Lots Released

*July 1, 2020, through June 30, 2021

FISCAL YEAR 2021 CoE KEY ACTIVITIES AND ACCOMPLISHMENTS

The CoE met 11 times during FY21. In addition to leading and managing the work of ECs, CoE members continued to drive a 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 volunteers. The following are highlights of the CoE's key activities and accomplishments during FY21, guided by the organizational goals defined by the 2020–2025 Convention Resolutions.



Launched the 2020–2025 CoE: The CoE focused on ensuring that USP included underrepresented scientific and industry groups in the selection process and that the Expert Volunteer population reflected the communities USP serves. USP staff onboarded CoE members, and the CoE transitioned to 29 smaller, more agile ECs, with leaner work plans focused on the highest-priority problems in alignment with Resolution XIV, which relates to modeling a culture of excellence.

Continued to Advocate for Diversity, Equity, Inclusion, and Belonging (DEIB): The CoE continued working on DEIB objectives and developed a Health Equity Initiative to explore ways USP Expert Volunteers can incorporate health equity into standards to enhance public health impact. The CoE has supported a phased approach as part of USP DEIB efforts, starting with the formation of a Health Equity Advisory Group to provide ongoing counsel for the initiative. This will include their guidance and input for a workshop planned for the fall to address the underlying causes of health disparities and identify potential solutions that can be applied to USP standards. The outcome of the workshop and the recommendations from the Health Equity Advisory Group will be captured in a paper that will be provided to the CoE to determine the best path toward implementation. This work helped to fulfill Resolution I, on collaboration to help advance access to quality medicines; Resolution XII, on evidence generation to inform policy; and Resolution XV, on impact expansion.

Operated Under a More Flexible Standards Engagement Model: This included a pilot for a reimagined Expert Volunteer experience. We encouraged ECs participating in the pilot to leverage Expert Advisors who can share their expertise as needed without having to commit to a five-year cycle or participate in mandatory balloting activities. We designed the new flexible model to help USP attract a broader, more diverse audience and increase volunteer engagement, aligning with Resolution XIV, on culture of excellence.

Helped to Develop the Science Quality Framework (SQF): The SQF provides the foundation for the way USP staff and Expert Volunteers will work together during the 2020–2025 cycle. SQF comprises the following five strategic pillars:

- 1) Evolving and Expanding Standards
- 2) Product and Substance Performance
- 3) Emerging Modalities
- 4) Technologies
- 5) Quality Environment

Participated in the Development of Principles for Managing Conflicts of Interest: Conflicts of interest are managed through disclosure, transparency, and recusal from voting. All Expert Volunteers are required to proactively disclose to USP and fellow Expert Volunteers any actual or potential conflicts-of-interest issues that may arise during the course of their standards-setting activities. This work related to Resolution XIV, on culture of excellence.

Approved the Rules and Procedures (R&P) of the 2020–2025 CoE: For Expert Volunteers, one noteworthy change in the R&P was removing the requirement for final discussion before moving items to ballot. This change helps maintain transparency throughout the entire standards-setting process. Under the final R&P, all Expert Volunteers can remain engaged in the standards-setting process before voting. Conflicted members must abstain during the vote. This work related to Resolution XIV, on culture of excellence.

Approved Revisions to the Following Two Guidelines on the Processes and Types of Work That the CoE May Delegate to USP Staff and/or JS3s:

- The *Guideline for USP Staff Approval of Limited Documentary Standard Revisions and Omissions*, which details the process and specific types of revisions that may be delegated to USP staff without EC balloting. Delegation of such revisions will help reduce the EC workload while permitting more expeditious approval and publication of 1) clear-cut, necessary U.S. Food and Drug Administration (FDA) compliance-related revisions and 2) revisions consistent with codified decision-making processes for postponements and appeals.
- The revised *Guideline for Review and Approval of Reference Standards for Use With USP–NF and FCC Monographs or*

These focal points converge to form USP's vision for the Global Science and Standards Division 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. This work aligned with Resolution III, on quality standards; and Resolution XIV, on culture of excellence.

General Chapters, which details the process for the CoE to delegate to JS3s and USP staff the authority to approve the suitability and use of R&C Lots. This work aligned with Resolution XIV, on culture of excellence.

Continued to Develop the CoE 2020–2025 Work Plan: CoE members organized the plan based on the following three topic areas:

- Operations including the new standards engagement model and related aspects of DEIB and health equity initiatives
- Strategy including the evolution of Reference Standards testing and digital standards
- Substance (i.e., standards and other key topics) including General Notices revisions and development of a model for communication/implementation of crosscutting topics

For the FY 2022 portion of the Work Plan, CoE members added the following six SQF priority areas: impurities, analytical lifecycle, biorelevant dissolution performance verification tests, continuous manufacturing, complex generics, and supply chain. This work aligned with Resolution I, on collaboration with FDA and other stakeholders on health priorities; Resolution VI, on the digital transformation of standards; and Resolution XIV, on culture of excellence.

Piloted Virtual Visiting Scientists Projects: These were designed to develop scientists committed to pharmacopeial work and foster international recognition and harmonization of USP standards. This pilot helps fulfill Resolution XIV, on culture of excellence; and Resolution XV, on impact expansion.

THE GLOBAL SCIENCE AND STANDARDS DIVISION'S SCIENTIFIC AFFAIRS TEAM FY21 HIGHLIGHTS

The Scientific Affairs and Strategy Team served as global impact amplifiers. They engaged the scientific community and supported key USP activities in FY21, including the following:



New and updated COVID-19 resources that have helped support trust in COVID-19 vaccines, preventatives, and medicines. These resources included the [“COVID-19 Vaccine Handling Toolkit”](#) and ancillary guides for maximizing doses of the Pfizer-BioNTech and Moderna COVID-19 vaccines; the [“Hand Sanitizer Toolkit”](#) to include updated information on methanol contamination in alcohol-based hand sanitizers; and [“USP Methods to Assist in Detecting Falsified Remdesivir,”](#) which provides timely information to help stakeholders determine the identity and strength of authentic remdesivir, a drug approved and/or authorized for COVID-19 treatment in approximately 50 countries. More information about these resources and our broader efforts can be found at USP’s [COVID-19 response hub](#). These efforts align with Resolution III, on quality standards; Resolution V, on innovation; Resolution VIII, on regulatory systems strengthening; Resolution IX, on compounding; and Resolution XV, on impact expansion.



Key concepts used for the validation of analytical procedures based on quantitative nuclear magnetic resonance measurements. This work aligns with Resolution II, on efficiency in standards development and revision, by helping develop and update standards to maintain and continuously optimize their impact and share information that is critical to standards development.



New monoclonal antibody (mAb) performance standards. This work helps to fulfill Resolution IV, on access to biologics, by supporting innovation in the efficient development and manufacturing of quality biologics and Resolution V, on innovation, by developing standards that help stakeholders safeguard the quality of promising healthcare innovations.



A roadmap of activities to guide the development of the analytical quality by design approach and explore its application to pharmacopeial standards. This work aligned with Resolution II, on efficiency in standards development; and Resolution XII, on evidence generation to inform policy.



A new dialogue with the *Japanese Pharmacopoeia* and *European Pharmacopoeia* on strategic reforms of the pharmacopeial discussion group to increase the engagement of other pharmacopoeias, stakeholders, and regulators. The team also signed a new memorandum of understanding with the *Chinese Pharmacopoeia* with scientific collaborations planned in the areas of biologics, metal packaging components and systems, supplements, and information exchange. This work supports Resolution XI, on pharmacopeial cooperation and convergence.



Tools and solutions that help safeguard patients from the hazards posed by unacceptable levels of [nitrosamine impurities](#), probable or known human carcinogens whose presence has been reported in widely used prescription and over-the-counter medications. This work helped fulfill Resolution I, on collaboration with FDA and other stakeholders on health priorities; and Resolution III, on quality standards.



Research and activities on cannabis and related compounds by the Dietary Supplements and Herbal Medicines group. 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 will help address quality-related concerns and support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

USP–INDIA, HYDERABAD FY21 HIGHLIGHTS

USP–India supports USP’s global standards-setting efforts and pursues collaborative opportunities with policy makers, regulators, professional and manufacturing associations, and leaders in India’s pharmaceutical and food sectors. USP–India staff supported key USP activities in FY21, including the following:



Collaborating with internal and external stakeholders to develop USP General Chapter <1469> *Nitrosamine Impurities* and eight Reference Standards. Staff conducted training and educational courses, including a workshop on nitrosamine regulatory requirements for pharmaceutical professionals and regulators. Advocacy efforts featured roundtable discussions and webinars. This work helped to fulfill Resolution III, on being a scientific leader in quality standards; Resolution VII, on education and training; and Resolution XV, on expanding USP’s public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.



Prioritizing the synthesis of COVID-related Reference Standards via the Synthetic Laboratory and Analytical Research and Development teams. The Biologics Laboratory explored mAb treatments as potential COVID-19 treatments. The Scientific Affairs Team on September 17, 2020, published a *Quality Matters* article titled “Glycosylation in Monoclonal Antibody Treatments for COVID-19.” USP–India’s June 3, 2021, virtual workshop, “Combating Substandard and Falsified Medicines During the COVID-19 Pandemic,” convened approximately 150 attendees and speakers from the World Health Organization, Global Pharma Health Fund, and USP leadership. This work helped to fulfill Resolution V, on developing quality standards; and Resolution VII, on education and training.



Helping to create [“USP Methods to Assist in Detecting Falsified Remdesivir”](#) via the Compendial Development Laboratory. Staff also developed educational content for the remdesivir resource. These efforts aligned with Resolution III, on quality standards; Resolution VII, on education and training; Resolution VIII, on collaborating with global regulators and other partners to strengthen regulatory systems; and Resolution XV, on impact expansion.



Organizing 28 paid education programs with approximately 1,500 participants and introducing two new courses on vaccine manufacturing and sterile manufacturing through the Education Team, which also organized 15 free webinars on USP’s hot topics and general chapters with nearly 2,200 attendees and speakers that included USP EC members. This work helped to fulfill Resolution VII, on education and training.



Participating in global and regional meetings as a member of USP’s DEIB Council and launching a survey with DEIB-specific questions to help identify needs and inform DEIB planning activities. This work helped to fulfill Resolution XIV, on culture of excellence.

BIOLOGICS

FY21 Highlights: Biologics

- 2 New General Chapters
- 3 Major General Chapter Revisions
- 2 Minor General Chapter Revisions
- 8 Monograph Revisions
- 17 Omissions
- 1 Errata
- 10 New Reference Standards (F Lots) Released
- 2 New General Chapters Published in *PF*
- 1 Major General Chapter Revision Published in *PF*
- 2 Minor General Chapter Revisions Published in *PF*
- 1 Monograph Modernization Published in *PF*
- 7 Monograph Revisions Published in *PF*
- 6 Omissions Published in *PF*

USP Biologics develops and modernizes standards for peptides, proteins, blood products, vaccines, antibiotics, carbohydrates, tissues, and raw materials for manufacturing. The Biologics program is expanding standards development to cover quality testing throughout the overall biopharmaceutical product lifecycle. 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, and Biologics Monographs 5–Advanced Therapies (BIO5). Throughout FY21, 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 are noted below.

Key Activities in Biologics

Vaccine and Complex Carbohydrate Standards:

The BIO3 EC prioritized vaccine standards that can be applicable across a product class, such as messenger RNA (mRNA) vaccines. The EC developed an outline for a new informational general chapter on mRNA vaccines, including best practices regarding critical quality attributes such as establishing identity, molecular size, purity, potency, capping efficiency, and impurities. The EC also prioritized physical performance standards to support vaccines. This includes, for example, a physical standard to support the quality assessment of CRM-197, a carrier protein found in many polysaccharide-protein conjugate vaccines. In addition, developing methods for quality assessments with appropriate system suitability has been ongoing, including molecular sizing of polysaccharides and glycoconjugates. This work supports Resolution III, on quality standards that provide innovative and agile approaches to address stakeholders' current and future needs.

Cell and Gene Therapy Product Standards:

The BIO5 EC is a new Expert Body that began in the 2020–2025 cycle. It was formed to explore standards for gene therapies, gene-modified cell therapies, non-oligonucleotide-based gene editing, tissue engineering, and mRNA and cell therapies. The EC prioritized standards and formed subcommittees (SCs) for product potency, comparability, and rapid sterility assessment. These are critical elements for stakeholders involved in developing and producing cell and gene therapy products. Additionally, an SC was formed to revise *USP General Chapter <1047> Gene Therapy Products*, published in *Pharmacopeial Forum (PF) 44(6)* [Nov.–Dec. 2018]. This chapter summarizes the issues and best practices related to manufacturing, testing, and administering gene therapy products, and the revision will address the current state of this therapeutic modality. This work addresses Resolution II, on efficiency in standards development and revisions to maintain current standards and continuously optimize their impact.

Trace Metals in Cell Culture Media Analysis:

The Trace Metals in Cell Culture Media EP of the BIO2 EC was developing a proposed general chapter that describes best practices for analyzing trace metals in cell culture media. A key element of the Biologics strategy is to develop programs that support the qualification of raw materials (e.g., cell culture media) used in biological product manufacturing. Media components and trace levels of these components may have implications for the quality of biotech products. The EP also participated in developing a performance standard to support stakeholder needs in trace metal analysis. This work supports Resolution II, on standards development for the evaluation of fit-for-purpose analytical methods and specifications; and Resolution III, on quality standards that address stakeholders' current and future needs.

Multi-Attribute Methods (MAM): This work responded to stakeholder needs identified by roundtable and stakeholder forum discussions and a survey. Through these engagements, stakeholders relayed current practices for MAM and peptide mapping and identified the need for standards to support analyzing post-translational modifications such as deamidation and oxidation as part of a MAM workflow. Additionally, USP Biologics explored MAM as a method to provide more efficient and comprehensive protein characterization of USP Reference Standards and a means to select an appropriate material for a predigested mAb standard. The MAM EP of the BIO2 EC initiated work drafting a new informational general chapter on MAM in September 2020. This work supports Resolution III, on quality standards that address stakeholders' current and future needs.

New mAb Performance Standards: The BIO2 EC approved three mAb performance standards that are applicable to a broad range of therapeutic mAb drugs. These new non-compendial Reference Standards ([USP mAb 001-003](#)) were the latest in USP's growing portfolio of standards focused on biological product classes and families. Scientists, developers, and manufacturers can use them as independent control materials for analytical method development, training, method transfer, internal assay control support, and physicochemical testing standardization. Their use helps ensure consistency and reproducibility of analytical methods and, potentially, helps to bring quality therapies to market faster. This work helps to fulfill Resolution V, on the development of quality standards and solutions to help stakeholders safeguard the quality of promising healthcare innovations that address patient and public health needs.

USP donated samples from its suite of mAb Reference Standards to researchers developing mAb-based treatments for COVID-19. The donation was part of USP's new [Trust Accelerated program](#) to support scientists, developers, and manufacturers working worldwide to accelerate

the development of safe and effective COVID-19 vaccines and treatments. Visit www.usp.org/covid-19 for more information about USP's COVID-19 response, which includes supporting front-line workers impacted by shortages of critical drugs and personal protection equipment and helping to build a more resilient global medicines supply chain.

Mass Spectrometry (MS)-Based Host Cell Proteins (HCP) Analysis:

The HCP Standards Expert Panel of the BIO2 EC began drafting a new informational general chapter on MS-based approaches for identifying and quantifying HCPs from host organisms—such as bacteria, yeast, or plants—in cell lines used to develop medicinal products through recombinant technology. The HCP EP's initial focus has been on "high-risk" HCPs of concern, such as those reported to impact patients or products and those detected in high abundance in products. The documentary standard is anticipated to accompany *USP General Chapter <1132> Residual Host Cell Protein Measurement in Biopharmaceuticals*. This work aligns with Resolution III, on quality standards that help to safeguard patients and meet stakeholders' needs.

The Biologics Group Supported the Following Virtual Workshops:

- The USP-Asia-Pacific Economic Cooperation (APEC) pilot virtual workshop, titled "Starting and Raw Materials for Advanced Therapies," held on March 1-9, 2021, in Washington, DC, and March 2-10, 2021, in Singapore, convened 154 attendees, including government regulators, international academics, and industry experts. The workshop presenters shared guidance on best practices for manufacturing advanced therapies. Following the successful pilot, USP was conferred full Center of Excellence status at the May 19, 2021, APEC Regulatory Harmonization Steering Committee meeting. This USP Workshop and other stakeholder outreach events help fulfill Resolution VII, on education and training for industry and healthcare professionals.

- The "USP Workshop on Raw Materials for Manufacturing of Biologics: Best Practices and Quality Standards," held on April 12, 14, and 16, 2021, convened 479 attendees, including government regulators, international academics, and industry experts. The workshop presenters focused on upstream raw materials for manufacturing biologics, including recombinant proteins, cell and gene therapies, and vaccines. Presentations and case studies addressed the control and evaluation of raw materials, strategies to minimize process variability due to these materials, and supplier risk management.
- The "USP Workshop on Therapeutic Peptides and Oligonucleotides: Regulations and Quality Standards," held on March 1, 3, and 5, 2021, convened 429 attendees, including government regulators, international academics, and industry experts. The workshop presenters shared best practices, success stories, and information on public standards setting for therapeutic peptides and oligonucleotides. Both of these product classes are rapidly growing, with novel modifications and formulations for virtually every therapeutic area. Best practices and guidance are critically needed to expedite quality products coming to the global market.

The Biologics Group Supported the Following USP Education On-Demand Courses and Webinars:

- "Implementing Improved Analytical Methods to Support Vaccine Quality." Analytical methods ensure the identity, purity, and potency of vaccines. This course presented opportunities to advance novel methods in pharmaceutical quality control and global control laboratories.

- "USP Standards to Support the Quality of Potency Measurements." USP's innovative public standards range from best practices for the development, validation, and analysis of bioassays in general to more specific issues, such as analyzing fragment crystallizable receptor assay function and replacing in vivo assays with new in vitro assays. This course presented the current state of documentary standards and new biologics Reference Standards that support product quality and consistency over time.
- "Bringing COVID-19 Vaccines and Therapeutics to the Global Community." This course featured a panel discussion with leaders in biologics development, quality, distribution, and manufacturing as well as suppliers of some of these common items who shared their experience and strategies to mitigate risks to getting products to patients around the world.
- "What's New in Biologics? Focus on USP's Vaccine Initiatives." This webinar provided information on USP standards that support vaccine testing and USP's toolkit initiatives to support the assurance of vaccine identity and quality in the marketplace. Sample toolkits were shared for feedback from webinar participants.
- "What's New in Biologics? Standards to Support Advanced Therapies." In this webinar, experts in advanced therapy product development, manufacturing, regulatory activities, and standards setting discussed the standards that help ensure the quality of cell and gene therapy products as well as the tools used to advance these products to patients more efficiently while maintaining high quality.



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

The BIO1 EC had a very productive first year of the new cycle with activities impacting both documentary and Reference Standards. Highlights of these accomplishments include the following:

- Developed a proposed new general chapter that provides guidance on the minimum quality attributes required for starting materials used in the manufacture of synthetic therapeutic peptides;
- Revised the *Bivalirudin, Bivalirudin for Injection, Teriparatide, and Glucagon* monographs;
- Approved multiple Reference Standard Candidate Evaluation Packages; and
- Hosted the 2021 USP Virtual Workshop on Therapeutic Peptides and Oligonucleotides, which attracted participants from industry, regulatory agencies, and academia to discuss important topics related to setting standards for these rapidly growing therapeutic classes."

FY21 Highlights: Small Molecules

- 51** New Monographs Published in *PF*
- 30** New Monographs Published in the Compendium
- 186** Monograph Modernizations and Revisions Published in *PF*
- 193** Monograph Modernizations and Revisions Published in the Compendium
- 61** Omissions Published in *PF*
- 72** Omissions Published in the Compendium



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 (SM3), Small Molecules 4, Small Molecules 5, and Over-the-Counter 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 lifecycle to small molecule manufacturers and regulatory agencies worldwide.

Key Activities in Small Molecules**Remdesivir Resource Builds Trust in Medicines:**

The global supply-and-demand imbalances caused by the COVID-19 pandemic have created a surge in substandard and falsified (SF) treatments in some regions of the world. To help safeguard patients from such counterfeit drugs and build the public's trust in COVID-19 treatments, USP has released "[USP Methods to Assist in Detecting Falsified Remdesivir](#)." This resource can help global regulators, manufacturers, and quality control laboratories determine the identity and strength of authentic remdesivir, an antiviral drug approved as a COVID-19 treatment or authorized for temporary use in approximately 50 countries worldwide. These efforts align with Resolution III, on quality standards that help to safeguard patients and meet stakeholders' needs; Resolution VIII, on collaborating with global regulators and other partners to strengthen regulatory systems; and Resolution XV, on expanding USP's public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.

A task force of USP subject matter experts, including staff from Small Molecules and USP-India, developed the remdesivir resource with Expert Volunteers from around the world, who

provided scientific guidance and review. Drug innovator Gilead Sciences, Inc., supported USP by donating sample materials and methods. The remdesivir resource includes methods and procedures for identifying remdesivir in the presence of various impurities and analytical methods for detecting SF active pharmaceutical ingredients (APIs). USP-India's Compendial Development Laboratory collaborated with a global team to help develop and evaluate the remdesivir identification and assay methods. USP-India is also working on developing educational content for the remdesivir resource as per Resolution VII, which relates to education and training for industry and healthcare professionals.

Safeguarding Patients From Nitrosamine**Impurities in Medicines:**

Nitrosamine impurities were identified in some angiotensin II receptor blockers used to treat high blood pressure and heart failure in 2018. Subsequently, nitrosamine impurities have been found in additional drug products. In response, the Small Molecules group collaborated with the General Chapters group, USP laboratories, and Expert Volunteers serving on USP's Nitrosamine Impurities Joint Subcommittee (JS) to develop *USP General Chapter <1469> Nitrosamine Impurities*, published in *PF* 46(5) [Sep.–Oct. 2020]. This chapter provides information, tools, and recommendations to help users understand potential sources of nitrosamine impurities, assess risk, and establish control strategies and suitable methods to detect nitrosamines. Following the open comment period, the JS finalized <1469>, the General Chapters–Chemical Analysis EC balloted it, and the chapter was included in *USP-NF 2021, Issue 3*. It is anticipated to become official on December 1, 2021. Numerous stakeholder events, including webinars and presentations, followed the initial publication of the chapter. This work addresses Resolution III, on being a recognized scientific leader in public quality standards to help protect patient and consumer safety; and Resolution VII, on education and training.



“In FY21, the Small Molecules group made significant contributions to the development of quality standards for medicines, including addressing the hazards of nitrosamines in the drug supply and helping to protect COVID-19 patients globally from poor-quality or falsified remdesivir. The fact that we have achieved all of this during a year of challenges—including working entirely virtually due to the pandemic, managing our 5-year cycle transition to new ECs, and leaning forward to make transformational improvements to the way we work—truly shows the passion and commitment of the Small Molecules team.”

Edwin L. Gump, Ph.D., Vice President, USP Small Molecules



Collaborative Pilot Project on Bulk Drug Monographs for Use in Compounding:

USP initiated a new pilot project in support of an FDA request to develop drug substance monographs for some bulk drug substances that are included on FDA’s bulk drug substance list for use by compounding pharmacies seeking to operate under section 503A of the federal Food, Drug, and Cosmetic Act. Four drug substances have been considered for this pilot project based on FDA’s prioritization. Small Molecules ECs are collaborating on this pilot project with the FDA, USP’s Global Analytical Development Laboratory, and industry sponsors. The long-term goal is to develop and validate analytical test methods with appropriate limits for these APIs and to publish the monograph proposals in *PF*. This work aligns with Resolution I, on collaboration with the FDA and other stakeholders on health priorities.

Modernization Through the Global Substance Registration System (G-SRS): USP has explored opportunities to implement the G-SRS as the primary means of modernizing the processes and methods by which USP identifies, curates, and publishes fundamental data elements related to substances. This work aligns with current informatics standards that have regulatory support. The G-SRS would provide a single

source of USP’s chemical information to be leveraged by USP production processes that need to include chemical information. These efforts have helped to fulfill Resolution VI, on creating core digital solutions that leverage USP data and standards to improve public health; and Resolution XIV, regarding operational excellence.

Dictionary of U.S. Adopted Names (USAN) and International Drug Names:

The Chemical Information team, in collaboration with the Information Technology and Reference Standards Evaluation teams, contributed content (i.e., chemical information and updated structures) and reviewed the 2021 edition of the *USP Dictionary of USAN and International Drug Names*, which was published for the first time using information from USP’s G-SRS system. This resource is the leading reference for nonproprietary drug names and chemical structures. In addition, the *USP Dictionary* includes international nonproprietary names, brand names, unique ingredient identifier codes, official *USP–NF* names, molecular weights, graphic formulas, pharmacologic and therapeutic categories, and pronunciations. This work addresses Resolution XIV, regarding operational excellence, continuous improvement, stakeholder responsiveness, and transparency.

Reporting Thresholds Virtual Roundtable:

On November 16–24, 2020, USP hosted the “Reporting Thresholds Virtual Roundtable” with the collaboration of USP’s Small Molecules, General Chapters, Compendial Policy, Legal, and Global External Affairs groups. The goal of the roundtable was to address FDA concerns regarding reporting thresholds in USP monographs. Industry stakeholders were provided an opportunity to consider different approaches, exchange scientific perspectives, explore solutions, and offer policy recommendations. Based on the feedback from this roundtable, USP staff worked with members of the CoE to further develop a new approach for addressing reporting thresholds in monographs. This new approach, referred to as User-Defined Reporting Thresholds, was shared with stakeholders at a roundtable on June 29, 2021. Based on the feedback that USP has received, this new approach may provide a solution to this longstanding issue. These efforts align with Resolutions I and II, on collaboration with FDA and other stakeholders and the efficient sharing of information that is critical to standards development, respectively.

Nitrosamine Impurities in Pharmaceuticals

Virtual Workshop: Small Molecules supported the virtual workshop “Nitrosamine Impurities in Pharmaceuticals,” held on April 7–8, 2021, with approximately 400 worldwide participants from industry, academia, regulators, and other pharmacopeias. This workshop—hosted by USP in collaboration with the Association for Accessible Medicines, the Indian Pharmaceutical Alliance, and the International Generic and Biosimilar Medicines Association—provided participants with a forum to understand industry challenges as well as regulatory requirements and expectations to address current challenges and learn strategies to avoid recurrence. Separately, the USP Small Molecules group supported a *Pharmaceutical Technology* Editors’ Series Webcast titled “Genotoxic Impurities and Drug Quality—Lessons From the Nitrosamine Contamination Crisis”

on July 14, 2020. This USP Workshop and the stakeholder forum noted below help to fulfill Resolution VII, on education and training for industry and healthcare professionals.

Prescription/Nonprescription (P/NP)

Stakeholder Forum: More than 100 stakeholders from industry, government, and academia attended USP’s virtual P/NP Stakeholder Forum on November 18–19, 2020. Participants were provided an opportunity to exchange information and perspectives on current and developing P/NP quality topics. Attendees provided feedback on key presentations, such as the impacts posed to end-users’ development processes from small changes to, and the online functionality of, USP resources.

“These are the CoE and SM3 EC accomplishments I am most proud of:

- We have made diversity, equity, inclusion, and belonging part of our daily dialogue. USP recruitment efforts will utilize this concept to build healthy volunteer pools.
- We have enhanced the transparency of the standards-setting process by eliminating the final discussion component.
- We have maintained the pace of standards-setting despite the challenges brought by the COVID pandemic.”

Eric Kessler, Ph.D., Chair, SM3 EC



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 Reference Standards 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

Collaborating on Cannabis Quality: The DSHM Program Unit Team (PUT) participated in meetings with industry as well as panel discussions with state regulators and other standards-development organizations following the publication of quality attributes for cannabis inflorescence in the *Journal of Natural Products*. Subsequently, ASTM International adopted the USP Cannabis EP recommendations for cannabis inflorescence as a part of its guidelines for industry. Separately, USP provided public comments to the [FDA draft guidance](#) on cannabis quality considerations for clinical research and to state regulators on a proposed rule and

state bill. The DSHM group's efforts related to cannabis and its related compounds support 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 will help address quality-related concerns as well as support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

Quality Specifications for Cannabidiol (CBD):

The BDSHM EC and its Cannabis EP are developing quality specifications for CBD as a drug substance. These include analytical methods and acceptance criteria for CBD identification, quantitative estimation, and contaminant limits. Because CBD may be purified from the cannabis or hemp plant or chemically produced, suitable methods were provided to analyze related compounds and impurities derived from hemp as well as synthetic processes.

Pyrrolizidine Alkaloid (PA) Contaminants: PAs are organic compounds, many of which exhibit hepatotoxic, genotoxic, carcinogenic, and mutagenic activities. They are naturally present in plants and weeds that grow among agricultural crops and can contaminate the harvest. To help industry stakeholders develop and produce high-quality products, USP worked to develop *USP General Chapter <1567> Pyrrolizidine Alkaloids as Contaminants*. This proposed new informational general chapter addresses PA chemistry, dietary exposure to PAs, toxicology, and the regulatory status of PAs in Europe. To help inform this

“Working with the other ECs in the DSHM Collaborative Group, the NBDS EC has started establishing trans-USP mechanisms for monograph modernization, implementing new technologies, and developing digital Reference Standards that support USP’s Science Quality Framework goals. The NBDS EC contributed to the remdesivir resource, a timely effort to advance global health during the COVID-19 pandemic. In addition, the NBDS EC has been actively engaging stakeholders and intramural USP scientists to advance standards-setting and leverage synergies by applying modern analytical methods.”

Guido F. Pauli, Ph.D., Chair, NBDS EC



FY21 Highlights: Dietary Supplements and Herbal Medicines

Submitted to PF

- 24** New Monographs
- 13** Modernizations
- 2** Omissions
- 2** New General Chapters
- 21** Revisions

Published in the Compendium

- 1** Major General Chapter Revision
- 19** New Monographs
- 6** Monograph Modernizations
- 21** Monograph Revisions

25 New Reference Standard (F Lot) Releases

DSC 2021 launched with **14** new and **4** modernized admission evaluation summaries; **36** added monographs, general chapters, and appendices; and **71** revised standards

“USP botanical dietary supplement standards have a potentially huge impact on protecting the health of consumers. Although healthcare practitioners are rightly skeptical of many of the health claims associated with botanical dietary supplements, U.S. consumers spent billions of dollars on herbal supplements in 2020. Pandemic-stimulated sales spiked by March 2020 and remained up in mid-June 2020. The BDSHM EC has been working on new monographs (e.g., cannabidiol) and revisions to existing monographs for many high-demand botanicals. We’ve hosted Open Forums on Elderberry Standards Development and Multi-Ingredient Dietary Supplement Products, to ensure we address stakeholders’ needs.”

Robin Marles, Ph.D., M.Sc., Chair, BDSHM EC



general chapter before its anticipated publication in *PF* 47(6) [Nov.–Dec. 2021], USP convened a virtual Open Forum to collect stakeholder feedback. These efforts align with Resolution II, on the efficient sharing of information that is critical to standards development; and Resolution III, on quality standards that help to safeguard consumers and meet stakeholders’ needs.

Multi-Ingredient Dietary Supplement Products:

A wide variety of dietary supplement products are not covered by existing monographs due to the diversity of possible dietary ingredient combinations and levels. To help manufacturers of multi-ingredient dietary supplement products develop the appropriate quality tests to meet current Good Manufacturing Practice (GMP) requirements, the NBDS and BDSHM ECs have developed a proposed new *USP* General Chapter <2800> *Multi-Ingredient Dietary Supplement Products—Development of Quality Tests*. To help inform <2800> before its anticipated publication in *PF* 47(5) [Sep.–Oct. 2021], USP convened a virtual Open Forum on May 6, 2021. These efforts align with Resolution II, on the efficient sharing of information that is critical to standards development; and Resolution III, on developing quality standards that address stakeholders’ current and future needs.

Cutting-Edge Probiotics Research: The USP Probiotics EP of the NBDS EC developed a manuscript titled “Improving and Comparing Probiotic Plate Count Methods by Analytical Procedure Lifecycle Management,” which was accepted for publication in *Frontiers of Microbiology*. The article presents cutting-edge research on applying analytical procedure lifecycle management to the enumeration of probiotics. It was coauthored by an EP subteam that included Expert Volunteers from the NBDS EC and the General Chapters—Measurement and Data Quality EC, demonstrating new flexibility in sharing expertise across ECs to align with Resolution II, on information sharing; and Resolution XIV, on modeling operational excellence.

Botanical Identification Using DNA-Based Methods:

USP staff collaborated with industry and FDA laboratories to investigate the use of species-specific polymerase chain reaction (PCR)-based methods for botanical identification. This work, submitted to the peer-reviewed international journal *Planta Medica*, investigated the orthogonal use of DNA-based methods and chromatographic methods for the identification of three ginseng species and presented the strengths and challenges associated with genomic methods. The work helps to fulfill

Resolution I, on collaboration with FDA; and Resolution III, on developing innovative and agile approaches to address current and future needs of industry and other stakeholders.

DSHM Expands Its International Activities: The DSHM PUT has been expanding USP’s global public health impact. USP staff developed an article titled “Pharmacopeial Standards for the Quality Control of Botanical Dietary Supplements in the United States,” which included perspectives from the European Directorate for the Quality of Medicines & HealthCare, the *Chinese Pharmacopoeia*, Health Canada, and the *American Herbal Pharmacopoeia*. USP explored developing future workshops on dietary supplement quality following USP staff presentations to and discussions with the Republic of Korea’s National Institute of Food and Drug Safety and Brazil’s National Health Surveillance Agency. In addition, USP staff participated on a panel about botanical products with regulators from Latin America. These activities address Resolution XIII, on coalition building; and help to fulfill Resolution XV, on expanding USP’s public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.

Virtual Visiting Scientist Helps Develop Botanical Monographs:

Dr. Yanhong Shi of Shanghai University of Traditional Chinese Medicine worked with the DSHM PUT as a virtual visiting scientist. Dr. Shi helped develop three botanical monographs from USP’s high-priority list for publication in *PF*. USP is piloting the virtual Visiting Scientists Program, which is designed to develop scientists committed to pharmacopeial work and foster international recognition and harmonization of USP standards in alignment with Resolution XIV, on culture of excellence; and Resolution XV, on impact expansion.



“We are proud of the DSHM PUT’s FY21 progress in supporting USP’s public health mission. We hosted three successful virtual open forums and supported international outreach to industry and regulators about dietary supplement quality. We disseminated information about our medical cannabis publication among researchers and regulators, helping to make USP a leading voice in defining cannabis quality to benefit patients globally. In addition, our Probiotics Expert Panel conducted cutting-edge research on the growing field of probiotics and was the first to apply analytical procedure lifecycle management to the enumeration of probiotics.”

Kit Goldman, Ph.D., Director, DSHM; and Michael Rashed, MBA, DSHM Regions and Program Operations Lead

EXCIPIENTS



Excipients—considered “inactive” ingredients in medicine—actually play an essential role in delivering APIs to their targets and can comprise up to 90% of a medication. Therefore, 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 that they address potential threats from the complexities of global supply chains and quality deficiencies that may arise in the absence of appropriate GMPs. Expert Volunteers who serve on the Simple Excipients (SE) and Complex Excipients ECs develop new and revise existing monographs and their associated Reference Standards 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

Methanol Contamination in Hand Sanitizers:

In July 2020, FDA alerted the public to a sharp increase in hand sanitizer products that were labeled to contain ethanol (also known as ethyl alcohol) but had tested positive for methanol contamination. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the skin and can be life-threatening when ingested, according to the FDA. With input from FDA, USP proposed revisions to the Alcohol, Dehydrated Alcohol, Isopropyl Alcohol, and Azeotropic Isopropyl Alcohol monographs. USP published a [Notice of Intent to Revise](#) to inform stakeholders about proposed revisions and encourage them to provide feedback.

Subsequently, Revision Bulletins for [Alcohol](#) and [Dehydrated Alcohol](#) were posted to strengthen the *Identification* section of the monographs by including a *Limit of Methanol* test as an additional *Identification C* test. USP also updated its “[Hand Sanitizer Toolkit](#),” which includes a resource of excerpted *USP–NF* and *Food Chemicals Codex* monographs related to alcohol-based hand sanitizers (AbHS). USP additionally updated its [Frequently Asked Questions](#) about its revisions to the USP Alcohol and Dehydrated Alcohol monographs. The SE EC posted Revision Bulletins for the Isopropyl Alcohol and Azeotropic Isopropyl Alcohol monographs on July 30, 2021, with a six-month extended implementation time. This provides stakeholders the time to implement additional changes introduced in the *Limit of Volatile Impurities* test, including the addition of methanol as a specified impurity and the use of an external reference standard to quantify the methanol, similar to the Alcohol monographs.

In addition, USP staff worked with the Nomenclature and Labeling EC and FDA on various options for potentially revising the official monograph titles and including other isopropyl alcohol concentrations in the USP monographs. This work aligns with Resolutions I and II, on collaboration with FDA and other stakeholders on health priorities, and efficiency in standards development and revisions, respectively.

Exploring Complex Excipients: Natural and synthetic excipients used in complex new generic dosage forms may require advanced analytical methods to identify and characterize

“The COVID-19 pandemic has highlighted the value of USP standards across a number of disciplines in addressing global public health needs. In the SE EC, the need for high-quality alcohols for use in hand sanitizers was recognized both at the scientific level and with the general public, as ingestion of hand sanitizers, which are mostly alcohol, that are contaminated with methanol can result in blindness or even death. The SE EC worked closely with the FDA and key stakeholders to enable the consistent identification of methanol and the mitigation of methanol contamination of alcohols.”

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

FY21 Highlights: Excipients

- 5 New Monographs Published in *PF*
- 5 Revised Monographs Published in *PF*
- 18 Modernized Monographs Published in *PF*
- 2 New General Chapters Published in *PF*
- 1 Minor General Chapter Published in *PF*
- 1 *Stimuli* Article
- 7 F Lot Releases
- 2 Modernized Monographs (Interim Revision Announcements) Official in November 2020
- 9 Modernized Monographs Published in *USP-NF 2021, Issue 1*
- 1 Revised Monograph Published in *USP-NF 2021, Issue 1*
- 2 Modernized Monographs Published in *USP-NF 2021, Issue 2*
- 2 New Monographs Published in *USP-NF 2021, Issue 3*
- 5 Revised Monographs Published in *USP-NF 2021, Issue 3*
- 1 Major General Chapter Revision Published in *USP-NF 2021, Issue 1*



the physicochemical properties that are critical to their function and performance. Using an iterative approach, the newly formed ETM EC has developed two proposed new general chapters that cover synthetic polymeric excipients: *USP General Chapter <313> Molecular Weight and Polymer Chain Length Determination for Polypropylene Glycol Fatty Ethers* and *USP General Chapter <314> Molecular Weight Determination for Copolymers Containing Alkyl Methacrylate or Alkyl Acrylate*. Both are anticipated to be published for public comment in *PF* 47(5). Research and development work to support the <314> proposal was summarized and presented as a science poster at USP 2021 Science Week. The poster was awarded third place by USP-India.

The ETM EC's approach will help stakeholders identify advanced methods that establish excipient quality specifications used in existing and emerging modalities. It also facilitates the EC's exploration of additional analytics for characterizing these complex excipient polymer types. This work is in accordance with Resolutions II and III, on proactively developing standards for optimum impact

and being a scientific leader in public quality standards, respectively.

Roadmap on Excipient Elemental Impurities (EI)

The Excipients ECs released their first draft of a roadmap to address the use of tests for EI in *USP-NF* excipient monographs. The ECs posted a [General Announcement](#) in August 2020 that provided information about the draft roadmap and requested stakeholder feedback on the following: 1) implementing the proposed approach for addressing EIs in excipient monographs, 2) identifying excipients for which EI tests are needed, and 3) obtaining scientific information on typical levels of EIs and methodologies used. Comments received on the roadmap have been reviewed by the Excipient and General Chapters EI JS. The next steps are to prioritize the monographs that include EI tests identified for deletion and revision, based on the data submitted by stakeholders. This work aligns with Resolution V, on the development of innovative standards and solutions.

Specifications for Excipient Composition and Organic/Inorganic Impurities: The 730 registrants from 24 countries who attended the

virtual USP Excipient Open Forum on February 11–12, 2021, had the opportunity to engage with USP on the challenges of developing compendial specifications for excipients' composition and organic and inorganic impurities. The purpose of the meeting was to level set the attendees' understanding of USP's standards-setting processes and stakeholder engagement model and, most importantly, to let them know how to get involved and manage the impact. Participants were encouraged to provide input on the activities of the Excipient and General Chapters EI JS, which is proposing definitions and guidelines as well as, possibly, developing a proposed informational general chapter. The meeting also addressed stakeholder comments on *PF* proposals to modernize the Assay and impurity specifications in the Maltol and Sucrose monographs and helped to identify a path forward for developing excipient compendial specifications. These and the following Excipient group outreach activities align with Resolution VII, on education and training for industry and healthcare professionals.

Ensuring Quality Hand Sanitizer Production During COVID-19

AbHS are an important element in infection prevention, especially during a pandemic. However, when quality is compromised, AbHS can be less effective against infection transmission and can also lead to user harm. COVID-19-related supply chain pressures created global shortages that have led to new vendors, materials, and production pathways to meet demand. These fast-paced changes have caused quality incidents to emerge regionally and globally.



More than 1,000 registered attendees participated in USP's six virtual global seminars, held on February 23–25, 2021, about ensuring quality AbHS production and safe use. Each event was tailored to meet the needs of manufacturers in the U.S., Latin America, India, and Africa as well as healthcare practitioners in the U.S., India, and Africa.

Manufacturing Alcohol to Combat a Public Health

Emergency: Alcohol manufacturers, distributors, and brokers—regardless of whether they are new to the market—need to take steps to ensure quality when producing alcohol for use in drug products, such as AbHS. Approximately 242 attendees had the opportunity to participate in USP's virtual Open Forum on January 27–28, 2021. Presenters and panelists from USP, FDA, and industry addressed the regulatory and compendial requirements for manufacturing alcohol used in drug products. In addition, presenters discussed USP's services, programs, and standards that are available to help companies meet quality requirements.

New Developments in Excipients: The Excipients group collaborated with the American Association of Pharmaceutical Scientists (AAPS) and other stakeholders on a virtual workshop, "Latest Developments in Excipients That Are Relevant to Formulation, Analytical, and Manufacturing," on November 11–12, 2020. Sessions focused on poly(lactide-co-glycolide) excipients, GMPs and supplier qualification, EI, and *USP General Chapter <1059> Excipient Performance*. The next step is to publish the workshop summary in an AAPS-related journal.

“During Fiscal Year 2021, the newly formed ETM EC, with the support of USP staff, reached out to stakeholders using the Stakeholder Engagement Model to support development and updating of: USP General Chapter <1078> Good Manufacturing Practices for Bulk Pharmaceutical Excipients in collaboration with a Visiting Scientist and Expert Advisors and USP General Chapter <1074> Excipient Biological Safety Evaluation Guidelines. In addition, the ETM EC has worked to expand compendial approaches to help the Excipient ECs identify better methods for the characterization of excipients through the development of new general chapters.”

Chris Moreton, Ph.D., M.Sc., B.Pharm., Chair, ETM EC

Expert Volunteers who serve on the Food Ingredients (FI) EC focus on developing

standards for FI to ensure the identity, quality, and purity of food additives, processing aids, flavors, colors, and other substances used in food production. 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 U.S. and internationally. The FI EC works closely with the Botanical Dietary Supplements and Herbal Medicines and Non-Botanical Dietary Supplements ECs to coordinate the development of standards for substances that are used as both food and dietary ingredients.

Key Activities in Food Ingredients

Monographs for Hemp-Derived Substances:

New, proposed standards defining purity and quality attributes with appropriate acceptance criteria for hemp seed protein and hemp seed oil food ingredients were published in the *FCC Forum* in June 2021. Both are targeted for publication in *FCC, Thirteenth Edition*. These proposals work to fulfill Resolution X, which encourages USP to leverage its scientific expertise and collaborate with stakeholders on developing scientific resources on cannabis, cannabis-derived products, and cannabis-related compounds.

“In a year when satisfying face-to-face collaborative efforts were replaced with electronically tiled squares filled with initials and an occasional face and/or voice, the FI EC was able to complete its efforts relevant to our mission. That said, this fiscal year’s efforts included:

- Continued vigorous actions regarding food fraud mitigation
- Advances in standards to reduce fraud in honey and honey-based ingredients
- Advances in standards to reduce fraud in olive oils and olive oil-based ingredients
- Initiated efforts to align the FCC monograph for ethanol with other USP monographic documentation because of alcohol-based sanitizer issues arising from significant increases of usage due to the COVID-19 pandemic
- Initiated efforts regarding hemp proteins and oils destined for food ingredient use
- Initiated efforts to modernize FCC methods including reduction in the use of hazardous or environmentally challenging reagents for testing to meet FCC specifications
- Coordinated FCC nomenclature efforts with the nomenclature efforts of the broader USP organization”

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

Safeguarding Patients With a Revised Alcohol

Monograph: USP posted an *FCC Ethyl Alcohol Immediate Standard* on October 12, 2020, to address FDA’s concerns about hand sanitizer products that were labeled to contain ethanol (also known as ethyl alcohol) but tested positive for methanol. Also known as wood alcohol, methanol can be toxic when absorbed through the skin and can be life-threatening when ingested, according to the FDA. The Foods team also explored plans to address additional quality issues related to ethyl alcohol for use in foods and alcoholic beverages. This work aligns with Resolution I, on collaboration with the FDA, industry, and other stakeholders by identifying shared priorities, based on scientific principles, and leveraging USP’s capabilities to help advance patient safety and public health. It also addresses Resolution III, on quality standards that help to safeguard patients and meet stakeholders’ needs.

Promoting FCC, Twelfth Edition, Second

Supplement: The *Second Supplement to FCC 12* was published in March 2021. It includes a significant new identity standard for Virgin Olive Oil and Extra Virgin Olive Oil, new general tests for the analysis of dietary proteins, and updates to multiple standards and appendices. The Foods PUT promoted the *FCC* via attendance

“There are few things as important to our everyday health as the food we eat. So, it’s not surprising that consumers are becoming more interested in knowing where their food comes from and knowing that it’s made with safe, authentic, quality ingredients. In addition, regulators continue to focus on the health risks that stem from poor food integrity, and the food industry is seeking more and better ways to address the increasing complexity of the global supply chain. That’s why USP helps manufacturers ensure that the ingredients they produce, procure, and use are of sufficient purity and quality to be used in food products. We offer regulators, manufacturers, and retailers standards and tools to help ensure food safety and integrity.”

Steven Gendel, Ph.D., Senior Director, Science-Foods

and presentations at multiple conferences. USP-India collaborated with the Foods PUT to help raise awareness among regional stakeholders. They participated in the 7th Annual Food Quality & Safety Congress Asia 2021, which was held virtually on February 16-17, 2021. USP-India also launched a survey to better understand food manufacturers’ requirements. This work addresses Resolution II, on the efficient development, revision, and sharing of information that is critical to standards development; and Resolution XV, on expanding USP’s public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.

New FCC Analytical Materials Program:

The Foods team hosted a virtual roundtable on February 2, 2021, to gather information and help design the new *FCC Analytical Materials (FAMs)* program. FAMs are intended to be fit for purpose for the food industry and food testing

laboratories. The roundtable discussion will help USP gather stakeholder input on key questions such as which FAMs are most needed and how USP can leverage *FCC* standards and materials to best serve the needs of potential users. This roundtable aligns with Resolution II, on the efficient sharing of information that is critical to standards development.

Protecting Food Supply Chains: The Foods group participated in two webinars aimed at increasing stakeholder awareness of the risks that food fraud poses to food safety and integrity and how public standards in the supply chain help mitigate these risks. These webinars, “Introducing the *Food Chemicals Codex (FCC)* Standards for Food Ingredients” and “How to Protect Supply Chain Integrity Using Ingredient Standards,” were held virtually on July 9 and August 19, 2020, respectively. These webinars help to fulfill Resolution VII, on education and training for industry and healthcare professionals.

FY21 Highlights: Food Ingredients

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|----|---|----|--|
| 1 | New Appendix Published in <i>FCC Forum</i> | 1 | Appendix Major Revision Published in the Compendium |
| 6 | New Monographs Published in <i>FCC Forum</i> | 4 | Monograph Modernizations Published in the Compendium |
| 18 | Monograph Revisions Published in <i>FCC Forum</i> | 20 | Monograph Revisions Published in the Compendium |
| 1 | Monograph Modernization Published in <i>FCC Forum</i> | 2 | New Appendix General Tests Published in the Compendium |
| 5 | Errata Published in the Compendium | 5 | New Monographs Published in the Compendium |



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 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 (GCPA), and General Chapters—Statistics ECs and their affiliated EPs and SCs. 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 Chapter on Nitrosamine Impurities: The GCCA EC collaborated with the Small Molecules group and USP laboratories to develop *USP* General Chapter <1469> *Nitrosamine Impurities*.

The chapter is included in *USP-NF 2021, Issue 3*, and is anticipated to become official on December 1, 2021. It provides guidance and recommendations for identifying the potential presence of nitrosamines, establishing controls, and developing analytical procedures used to monitor nitrosamine levels. This work helps to fulfill Resolution III, on being a recognized scientific leader in public quality standards to help protect patient and consumer safety.

Quantitative Nuclear Magnetic Resonance

(qNMR) Measurements: The General Chapters group published a *Stimuli* article that introduced the key concepts of analytical target profile and target measurement uncertainty as the principal benchmarks used for validating analytical procedures based on qNMR. The article, expected to form the basis for the adoption of qNMR for compendial use, was titled “Quantitative Nuclear Magnetic Resonance (qNMR), a Metrological

FY21 Highlights: General Chapters

- 9 New General Chapters Published in *PF*
- 6 New General Chapters Official in the Compendia
- 15 Major General Chapter Revisions Published in *PF*
- 12 Major General Chapter Revisions Official in the Compendia
- 16 Minor General Chapter Revisions Published in *PF*
- 14 Minor General Chapter Revisions Official in the Compendia
- 1 Omission
- 6 *Stimuli* Articles

Method—Proposed Revisions to the *USP* General Chapters on NMR, *Nuclear Magnetic Resonance Spectroscopy* <761> and *Applications of Nuclear Magnetic Resonance Spectroscopy* <1761>.” The qNMR EP has been aggressively revising <761> and <1761>, with drafts anticipated to be submitted for publication in *PF* 47(6). This work aligns with Resolution II, on developing and updating standards to maintain and continuously optimize their impact and sharing information that is critical to standards development.

Non-Animal Assays and Reagents in *PF*: In accordance with its commitment to transition to non-animal, science-based assays and reagents, *USP* published *USP* General Chapter <1085.1> *Use of Recombinant Reagents in the Bacterial Endotoxins Test—Photometric and Fluorometric Methods Using Recombinantly Derived Reagents* in *PF* 46(5) for public comment. These efforts

help to fulfill Resolution III, on developing innovative and agile approaches to address current and future needs of industry, regulators, practitioners, consumers, and patients.

Quality Advisory Group (QAG): The QAG, created as part of a comprehensive strategy to address quality paradigm shifts, is chaired by a member of the CoE. The group includes quality thought leaders from the pharmaceutical and other industries who advise *USP* by identifying changes in quality paradigms and potential disruptors in a rapidly changing global pharmaceutical manufacturing and regulatory environment. COVID-19 is accelerating some of these shifts. A QAG paper that focuses on the paradigm shifts and explores possible solutions has been submitted for publication. These activities are in accordance with Resolution I, on collaboration with stakeholders by identifying shared priorities; and Resolution III, on identifying emerging trends and developing innovative and agile approaches in evolving global regulatory environments.

Medical Device JS: A JS of the GCDF, GCPA, GCM, GCPD, Nomenclature and Labeling, and Healthcare Information and Technology ECs was formed to review and refine the vision of future medical device standards in *USP-NF*. The JS assessed the workload and needs for these standards, as per Resolution V, on exploring the development of quality standards on healthcare innovations that address patient and public health needs.

Analytical Procedure Life Cycle: The GCCA EC published *USP* General Chapter <1220> *Analytical Procedure Life Cycle* in *PF* 46(5). The chapter represents several years of work by Expert Volunteers and was balloted and approved for inclusion in *USP-NF 2022, Issue 1*. This work supports Resolution III, on quality standards that provide innovative and agile approaches to address stakeholders’ current and future needs.

Rapid Microbiological Methods: The GCM EC reviewed the comments received on two new 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*. Both were published in *PF* 46(6) [Nov.–Dec. 2020] and anticipated to go to ballot for official publication. Other suitable alternate microbiological methods based on solid-phase cytometry, PCR, flow cytometry, and matrix-assisted laser desorption/ionization-time to flight mass spectrometry were in various stages of development. A chapter on rapid nucleic acid test-based methods for mycoplasma testing is being developed and targeted for publication in *PF* for public comments in FY22. This work relates to Resolution II, on the efficient sharing of information critical to standards development.

Recombinant Reagent Study Protocol: USP staff, in collaboration with the Endotoxin SC, was designing a study protocol for comparing the commercially available recombinant factor C reagents with natural limulus amoebocyte lysate (LAL) reagents extracted from horseshoe crabs. The study result may potentially be used to support a proposed USP General Chapter <1085.1> *Use of Recombinant Reagents in the Bacterial Endotoxins Test—Photometric and Fluorometric Methods Using Recombinantly Derived Reagents*. USP laboratory work was underway on an alternate chemical analytical method based on the liquid chromatography-tandem mass spectrometry analysis of the lipid A component analysis for endotoxin testing. On June 11, 2021, USP posted a General Announcement requesting data from stakeholders who have performed comparability experiments of recombinant reagents and LAL reagents. The USP Endotoxins and Pyrogens SC was also planning to organize an Open Forum or workshop to further engage stakeholders to discuss topics related to recently published data and the path forward for <1085.1>, as per Resolution VII, on education and training for industry and healthcare professionals.

Process Analytical Technology (PAT): The PAT SC of the GCCA EC completed an outline for a *Stimuli* article that addresses and positions USP's thinking on the pharmacopeial and regulatory framework for real-time release testing and the lifecycle management of high-impact PAT procedures. This work relates to Resolution II, on the efficient sharing of information that is critical to standards development.

Analytical Instrument Qualification: A JS of the GCCA and GCMDQ ECs was establishing a framework for instrument qualification as part of the lifecycle management of an analytical procedure. This included identifying the appropriate qualification requirements and uncertainty criteria that demonstrate an analytical instrument's fitness for purpose. The JS planned to publish their thinking and framework in a series of *Stimuli* articles to solicit feedback from stakeholders on the framework as per Resolution II, on information sharing for standards development.

Harmonized General Chapter Major Revision: The GCPA EC formally approved revisions to the harmonized USP General Chapter <941> *Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction (XRPD)*. The [Notice of Adoption of Harmonized Standard](#) was posted on April 30, 2021. The anticipated official date is May 1, 2022. This activity aligns with Resolution XI, on pharmacopeial cooperation and convergence.

Mutagenic Impurities (MI) and Potential Mutagenic Impurities (PMI): USP's General Chapters, Small Molecules, and Regulatory Affairs groups collaborated with FDA to explore different compendial routes to address MI and PMI in USP monographs. Several proposals had been discussed with FDA staff in order to establish a short-term communication strategy, including Compendial Notices and mid- and long-term solutions that align with International Conference on Harmonisation M7 guidelines. Introducing a new section in General Notices

and/or revising relevant general chapters have been considered as well as other mechanisms of nonofficial alerts, in accordance with Resolution I, regarding collaboration with FDA and other stakeholders on health priorities.

Reporting Thresholds in USP–NF

Monographs: The General Chapters group on June 29, 2021, supported a USP virtual roundtable about reporting thresholds in USP monographs. The event focused on collaboration for incorporating a user-determined reporting threshold. This strategy, built on the hybrid approach to reporting thresholds outlined at the November 2020 USP roundtable, would replace prescriptive numeric reporting threshold values in monographs with a link to detailed guidance elsewhere in *USP–NF*, supporting the user's determination of an appropriate value. The roundtable agenda included presentations from USP and FDA and opportunities for open discussion and questions about the proposal. This roundtable and the presentations described below help to fulfill Resolution VII, on education and training for industry and healthcare professionals.

Pharmaceutical Continuous Manufacturing:

USP staff provided a virtual presentation titled “Pharmaceutical Continuous Manufacturing (PCM): The Role of Compendial Standards to Ensure the Quality of Manufacturing and the Product” at the AAPS 2020 PharmSci 360 Workshop on November 12, 2020. This presentation addressed the significance of proper material characterization and the important role of material properties in the design and control of processing in a continuous manufacturing train. Separately, the General Chapters group provided virtual presentations on compendial topics at six national and international conferences, workshops, and webinars on topics including nitrosamine impurities, supplier qualifications, and dissolution method development.

“I am humbled by the strong and consistent efforts that our GCM EC has performed to stay in front of the industry by evaluating the latest advances in methodology and manufacturing. Our SCs worked hard to update the valuable sterilization technologies chapters and microbiology best practices. Simultaneously, our efforts are ongoing to evaluate new bacterial endotoxin methods. Quality attribute testing for cell and gene therapies to detect microbial and mycoplasma contamination will benefit from the new chapters being written for innovative methods for the short shelf-life sterile products. And a new chapter to help increase much-needed knowledge of microbiological control of cell and gene therapies is being developed.”

Donald Singer, M.S., Chair, GCM EC

“USP has been doing a phenomenal job producing high-quality standards and engaging stakeholders despite challenges posed by the COVID crisis. I am inspired by USP's vision and its commitment to foster diversity and inclusion. I feel privileged to have the opportunity to Chair the GCPA EC. Our committee will continue to contribute to USP's Science Quality Framework in several areas such as continuous manufacturing and analytical technologies.”

Xiaorong He, Ph.D., Chair, GCPA EC

“The new GCMDQ EC has accomplished a lot in its first year. The new, proposed USP General Chapter <1220> *Analytical Procedure Life Cycle* is the culmination of 10 years of collaboration involving publishing more than eight *Stimuli* articles, organizing five workshops, and having countless discussions. A podcast discussing *Total Error and Measurement Uncertainty* is the first of many podcasts to come, providing a new way to connect with USP customers. The EC is now pivoting to providing training and education on the analytical procedure life cycle. It is also expanding the application of life cycle management to specific monographs and other general chapters. This is exciting and rewarding work because the life cycle approach focuses on fitness for intended use, thus ensuring the quality of medicines to protect patients.”

Jane Weitzel, B.Sc., Chair, GCMDQ EC

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 approaches to 1) enhanced quality, accessibility, and equity of medication practices; 2) data and digital tools designed to improve the use of standards in knowledge sharing, decision making, and reporting; and 3) quality medication and treatment tailored to the individual characteristics of each patient.

HQS is focused on addressing the needs of patients, healthcare professionals, and overall public health, including standards and solutions for naming and labeling drug products and ingredients, safe medication use, drug formulary classification, sterile and nonsterile compounded preparations, and the handling of hazardous drugs.

Expert Volunteers serve on the Compounding (CMP), Healthcare Information and Technology (HIT), Healthcare Safety and Quality (HSQ), and Nomenclature and Labeling (NL) ECs and related EPs and SCs. Together, these volunteers deliver quality standards and solutions that are beneficial to healthcare professionals, healthcare systems, and other stakeholders working to address patient care needs.

Key Activities in Healthcare Quality and Safety

Vaccine Handling Toolkit: The “[COVID-19 Vaccine Handling Toolkit](#)” brings operational strategies assembled in a single resource to the front lines of the COVID-19 vaccination effort and addresses potential efficiency gaps while helping to maintain safety and quality. The goal is to help build public trust, get more shots in arms, and help end the pandemic. Toward those ends, the HSQ EC collaborated with Expert Volunteers from the CMP, HIT, NL, and General Chapters–Packaging and Distribution (GCPD) ECs to update the “COVID-19 Vaccine Handling Toolkit” and associated ancillary guides for maximizing doses of the Pfizer-

BioNTech and Moderna COVID-19 vaccines. Our work helped increase the supply of the Pfizer and Moderna vaccines by more than 53 million doses. The revisions consist of updated storage and handling requirements for specific COVID-19 vaccines to align with manufacturers as well as considerations to help safely and efficiently prepare vaccines to minimize waste while maintaining quality. This activity aligns with Resolution V, on exploring the development of solutions that address patient and public health needs.

Hand Sanitizer Toolkit: Alcohol-based hand sanitizers (AbHS) are an important element in infection prevention, especially during the COVID-19 pandemic. COVID-19-related supply chain pressures have created global shortages that have led to new vendors, materials, and production pathways to meet demand. These fast-paced changes have caused an emergence of quality incidents regionally and globally. To help ensure quality AbHS production during COVID-19, USP provided updates to its “[Hand Sanitizer Toolkit](#)” throughout FY21. The CMP EC provided key components through its rapid and robust response to address the urgent need for guidance. This work aligns with Resolution IX, which relates to compounding.

Sterile Compounding: The CMP EC updated its “[Operational Considerations for Sterile Compounding During the COVID-19 Pandemic](#).” The operational strategies were based on stakeholder input and developed in anticipation of challenges that could arise during the COVID-19 pandemic. The document is not a USP compendial standard; rather, it reflects options developed by the USP CMP EC, based on its scientific and professional expertise, with input from stakeholders and regulatory agencies at the federal and state levels. Visit www.usp.org/compounding for more information on this and other COVID-19-related compounding resources. This work helps to fulfill Resolution IX, which calls for collaboration with stakeholders on standards to help ensure the quality of compounded drug preparations.

Medicine Supply Map: The HSQ EC collaborated with members of the CMP, NL, and GCPD ECs as well as USP’s Digital and Innovation division to provide feedback on drug shortages to the Medicine Supply Map initiative. USP’s [Medicine Supply Map](#) aims to help identify vulnerabilities and deliver insights that can guide risk mitigation strategies and investment in supply chain resilience. This work helps to fulfill Resolution V, on the development of quality standards and solutions to help stakeholders safeguard the quality of promising healthcare innovations that address patient and public health needs.

Update on Labeling General Chapters: The NL EC announced revisions to USP General Chapter <7> *Labeling* to help prevent confusion among patients and healthcare workers about product expiration dates. To address these public safety concerns, the EC agreed on the use of certain expiration date format changes designed to improve readability and minimize misinterpretations about year, month, and day. The changes have implications for labels for all drug products and dietary supplement products that comply with USP standards. For that reason, and to address potential implementation concerns, the new requirements have an extended official date of September 1, 2023. Learn more about the changes in the EC’s July 31, 2020, [announcement](#). Separately, the HSQ EC announced two revisions to USP General Chapter <17> *Prescription Container Labeling* that provide a framework for developing an opioid warning label to mitigate misuse of opioids and promote accurate dosing of pediatric liquid medications to help reduce unintentional underdosing or overdosing of children. The official date for these revisions is December 1, 2021. This work helps to fulfill Resolution III, on quality standards that help to safeguard patients and meet stakeholders’ needs.

Mitigating Two-Component Vaccine Errors: The HSQ EC collaborated with the Institute for Safe Medication Practices to provide strategies for reducing errors that can occur when patients



“*The CMP EC hit the ground running this cycle, gathering stakeholder input, doing research, and working tirelessly on the <795> and <797> revisions, compounded preparation monographs, and resources related to COVID-19. EC members also volunteered on a Joint Subcommittee to create the Vaccine Handling Toolkit, joined an EP on radiopharmaceuticals, presented at USP’s Global Seminar Series, and taught live webcast classes on compounding. I am honored to work with these exceptional volunteers and staff who are dedicated to ensuring patients have access to quality compounded preparations. I’m looking forward to continuing our work as we move through the cycle.*”

Brenda Jensen, M.A., Chair, CMP EC

“*We kicked off the cycle to complete work from the previous cycle in the digital exchange of compounded prescriptions and allergies/allergens. Creating digital standards in these areas will reduce medication errors, ultimately improving patient safety. Members have worked to not only create digital standards but also ensure awareness and education through development of articles for publication in these areas.*”

Jeanne Tuttle, B.S.Pharm., Chair, HIT EC



FY21 Highlights: Healthcare Quality and Safety

- 1 New Monograph Published in PF
- 4 Monograph Revisions Published in PF
- 2 Minor General Chapter Revisions Published in the Compendium
- 4 Monograph Revisions Published in the Compendium
- 6 New Monographs Published in the Compendium
- 1 Omission Published in the Compendium

are administered only one component of two-component vaccines. Such errors can result in reduced efficacy, the need to revaccinate patients, and increased healthcare costs. The vaccines involved are for meningitis and are unrelated to those being developed for COVID-19. This collaborating group also provided safe practice strategies for storing, preparing, dispensing, and administering these vaccines as intended. The manuscript articulating this work was published November 2020 in the peer-reviewed journal *Pharmaceutical Medicine*. This work relates to Resolution II, on the efficient sharing of information that is critical to standards development; and Resolution III, on quality standards that help to safeguard patients and meet stakeholders' needs.

Beyond-Use Date (BUD) Provisions in USP General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations:

USP continued its stakeholder engagement activities to foster input on the BUD provisions in General Chapters <795> and <797>. These activities followed a final decision on formal appeals to these chapters, which recommended that the CMP EC further engage with stakeholders on issues pertaining to BUDs. USP and the CMP EC remain committed to moving forward in an open, transparent, balanced, and timely manner.

USP conducted a series of structured interviews with stakeholders to better understand the landscape and perspectives around the BUD provisions in <795> and <797>. Based on feedback from the interviews, USP hosted a virtual roundtable on July 28, 2020, to gather additional stakeholder perspectives and concerns surrounding the BUD provisions in the remanded chapters. Participating panelists included a diverse group of human and veterinary compounding experts and stakeholders. Members of the CMP EC provided a brief overview of the BUD provisions in <795> and <797>, how the remanded text differs from the currently official text, and the factors the CMP EC considered in developing the revised provisions. Through a series of targeted discussion questions, panelists then offered their perspectives on BUDs and engaged in dialogue around how the provisions could be further revised and improved to address stakeholder concerns.

The key findings from the roundtable forum helped inform the design and format of the virtual Open Forum USP hosted on September 15, 2020. More than 1,400 stakeholders registered for the open event and were able to participate through a virtual discussion board. The CMP EC is using the learnings and feedback from all of the outreach activities to inform the revision process for <795> and <797>. For the latest updates, visit <https://www.usp.org/compounding/>

“Points of pride for the NL EC over the past year included the following:

- **Approved dozens of monograph titles including drug products, drug substances, dietary supplements, and compounded preparations.**
- **General Chapter <7> established a standard format to clearly delineate the expiration date in efforts to avoid mixing up months and years—year 4 numerical digits; month 2 digits or if alphabetical three letters to avoid confusing March and May.**
- **<7> was the most downloaded USP General Chapter in June 2021 possibly in review of labeling definitions following posting of USP's Hand Sanitizer Toolkit as part of the Preventatives portion of the COVID-19 Initiative.**
- **For labeling considerations, USP convened the Prescription/Non-Prescription Stakeholder Forum, as well as the Labeling Roundtable for Multi-Entity Anesthetic Drug Products.”**

Stephanie Y. Crawford, Ph.D., MPH, Chair, NL EC



[compounding-appeals](#). This work aligned with Resolution IX, on compounding.

Stakeholder Outreach on Quality Hand Sanitizer

Production: Approximately 240 registered attendees had the opportunity to participate in USP's virtual Open Forum, titled “Manufacturing Alcohol to Combat a Public Health Emergency: Insights on Regulatory and Quality Requirements,” held on January 27–28, 2021. Presenters and panelists from USP, FDA, and industry addressed the regulatory and compendial requirements for manufacturing alcohol used in drug products. In addition, presenters discussed USP's services, programs, and standards that are available to help companies meet quality requirements. In addition, more than 1,000 registered attendees participated in USP's six virtual global seminars, held February 23–25, 2021, on ensuring quality AbHS production and safe use. Each meeting was tailored to meet the needs of manufacturers in the U.S., Latin America, India, and Africa as well as healthcare practitioners in the U.S., India, and Africa. These stakeholder events align with Resolution VII, on education and training for industry and healthcare professionals.

Labeling Roundtable: The NL EC on June 8, 2021, hosted a virtual roundtable with healthcare provider associations to

discuss the labeling of epinephrine-containing anesthetic drug products. The roundtable fostered open and robust discussion about viable label formats related to the NL EC's 2016 change to single-entity drug products that contained a ratio as the expression of strength. The ratio expression was removed to reduce potential medication errors and to align with common drug strength formats; however, there remains a subset of multi-entity drug products that still use the ratio expression, all of which contain epinephrine. Stakeholders at the roundtable shared potential education avenues for healthcare providers regarding future label changes. This USP roundtable helps to fulfill Resolution VII, on education and training for industry and healthcare professionals.

Veterinary Compounding Roundtable: The CMP EC held a virtual roundtable discussion with veterinary compounding stakeholders on March 10, 2021. The roundtable was attended by 59 attendees, including participants representing the American Veterinary Medical Association, FDA, state boards of veterinary medicine, veterinary practitioners, compounding pharmacists, and others. The discussion outcomes will help inform the CMP EC's next steps as it considers standards for compounded veterinary medicines. This work aligns with Resolution VII, on education and training for industry and healthcare professionals; and Resolution IX, which relates to compounding.

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Bill Hess, GL
Tobias Hess, EC
Anthony Hickey, EC
Monica Hirschhorn, EP
Stephen Hoag, EC, EP
Lauren Hoffman, EC, EP
Steve Holroyd, EP
Moshe Honick, GL
David Hopp, EC
Kate Houck, EC, EP
Yong Hu, GL
Greg Huang, GL
Ziao Ping Huang, EP
Mario Hubert, EC
Deborah Huck-Jones, EP
Christopher Hudalla, EP
Laura Huffman, GL
Ruud Hulspas, EP
Gregory Hunter, GL
Stephen Hussey, EP
David Hussong, EC, EP
Richard Hutchinson, EC
Mai Huynh, GL
Kim Huynh-Ba, CoE, EC, EP
Scott Jackson, EP
Monika Jain, EC
Young Jang, EP
Michael Jankowski, EP
Renaud Janssen, CoE, EC, EP
Edwin Jao, GL
Sastry Jatavallabhula, EP
Arya Jayatilaka, EC, EP
Dennis Jenke, EC, EP
Brenda Jensen, CoE, EC, EP
Anne Munk Jespersen, EC, EP
Young Jhon, GL
Shen Ji, EP
Angela Jimenez-Valencia, GL
Sumedha Jogalekar, GL
Holly Johnson, EC, EP

Philip Johnson, EP
Chris Jones, EP
Scott Jordan, EC, EP
David Joseph, GL
Joy Joseph, EC
Stancy Joseph, GL
Vivek Joshi, EP
Carla Juliani, EC
Juijeong Jung, GL
Amy Karren, CoE, EC
Dhanalakshmi Kasi, GL
Ravindra Kasliwal, GL
Greg Kaster, EC
Chandra Kant Katiyar, EP
Simleen Kaur, GL
Edwin Kellenbach, EC
David Keller, EP
Elizabeth Kelley, GL
Sharon Kelly, GL
Zohar Kerem, EP
Eric Kessler, CoE, EC, EP
Umesh Kestur, EC
Ibrahim Khan, EC
Ikhlas Khan, EP
Mamunur Rashid Khan, EP
Bina Khaniya, GL
Surender Khurana, GL
Philip Kiddy, EP
Douglas Kiehl, EC, EP
Patricia Kienle, EC, EP
John Kilbourne, EP
Younsook Kim, GL
Michael Kimball, EC
Linda Kim-Jung, GL
Kathryn King, GL
Paul Kippax, EP
Doug Kirkpatrick, GL
Robert Klasson, EC
Donald Klein, EC
Sandra Klein, EP
Katrina Klett, EP
Richard Ko, EC, EP
Michael Koberda, EC, EP

Sheela Kochuparambilchellappan, GL
Rohit Kolhatkar, GL
Vidula Kolhatkar, GL
Michael Komenda, EP
Otilia Koo, CoE, EC
Anna Kooser, GL
Lois Kotkoskie, EC
Igor Koturbash, EC
Viliam Kovac, EP
Jette Kreiberg, EP
Mansi Krishan, EC
Anita Krishnan, EP
Jens Krogh Rasmussen, EP
Dana Krueger, EC, EP
Francisco Kuribrena, EP
Joseph Kutza, EP
Stephen Langille, EC, EP
David Lansky, EC, EP
Marianne Larsen, EP
Rosilend Lawson, GL
Max Lazar, EP
Pierre Lebrun, EP
Christina Lee, GL
Heewon Lee, EC
Jun Lee, GL
Steven Leinbach, EC, EP
Pallavi Lele, GL
Marc Lemaitre, EC
Elizabeth Lessey-Morillon, GL
Nancy Lewen, CoE, EC, EP
Jerome Lewis, EC, EP
Hanlin Li, EP
Hongmei Li, GL
Huijuan Li, EC
Huijun Li, EP
Jing Li, GL
Kevin Li, EP
Min Li, EC
Ping Li, EP
Qing Li, EP
Shaoping Li, EP
Weijun Li, EP
Zhirui Lian, EP

Chenggang Liang, EC
June Liang, GL
Songping Liao, EC
Catherine Liloia, EP
Fangming Lin, EC
Tsai-Lien Lin, GL
Oscar Liu, EC
Suli Liu, EP
Zhenzhen Liu, GL
Raimar Loebenberg, EC
Daneli Lopezperez, GL
Archie Lovatt, EP
Raymond Love, EC, EP
Vivian Loveless, EP
Tieraona Low Dog, CoE, EC, EP
Xuijin Lu, EC, EP
Yihong Lu, EC
Zhengfei Lu, EC, EP
Joseph Lubega, EC
Johan Lundqvist, EC
Elise Luong, GL
Shuangcheng Ma, EP
Andrew Mackey, EP
Russell Madsen, EC, EP
Paul Mahan, EP
Amir Malek, EC, EP
Mohanraj Manangeeswaran, GL
Brad Mangrum, GL
Jaime Marach, EP
Robin Marles, CoE, EC, EP
Ewa Marszal, GL
Gregory Martin, GL
Timothy Martin, GL
Marilyn Martinez, GL
Nuno Matos, EC, EP
John Mauger, EC, EP
Russell Maus, EC
Ian Mayers, GL
Lori McCaig, EC, EP
Karen McCullough, EC
Mary-Jeanette McGarry, GL
Timothy McGovern, GL
Kevin McLean, EP

Jeffrey Medwid, GL
Juris Meija, EC
Jeremy Melanson, EP
Robert Mello, EC
Janet Mendonca, GL
John Metcalfe, GL
Richard Meury, EC, EP
Matthew Meyer, EC
Steven Meyerhoffer, EP
Ito Michiho, EP
Jeremy Mihalov, GL
Yana Mille, GL
Paul Miller, EP
Colin Minchom, EC
Beth Minter, EC
Anthony Mire-Sluis, EP
Ashley Mishoe, EP
Mishale Mistry, GL
Jolyon Mitchell, EC
Ranjan Mitra, EP
Soumya Mitra, GL
Toru Miura, EP
Jingjie Mo, EP
Ali Mohamadi, GL
Adil Mohammad, GL
Benjamin Moore, EP
Dominic Moore, EC
Chris Moreton, CoE, EC, EP
Beth Morgan, EC
Whitney Moro, EC
Ned Mozier, EC, EP
Partha Mukherjee, EC
Md Muniruzzaman, GL
Eric Munson, CoE, EC
Kelly Murphy, EP
Leanne Murray, EP
Jasmine Musakhanian, EP
Poulomi Nandy, GL
Jose Napolitano, EP
Linda Narhi, EC, EP
Mirtha Navarro, EC
James Neal-Kababick, EC, EP
Michael Nelson, EP

Mariann Neverovitch, EC
Cornelia Nickenig, EP
Soeren Kaare Nielsen, EP
Ishai Nir, EP
Patrick Noland, EC
Scott Norris, GL
Jasmina Novakovic, EC
Sarai Obando, GL
Lynn O'Briant, EP
Yuko Ogata, EP
Raphael Ornaf, CoE, EC
Robert Osterberg, EC, EP
Andrea Ottesen, GL
Mikhail Ovanosov, GL
Pilar Pais, EC, EP
Lisbeth Palm, EP
Tao Pan, GL
Marco Pane, EP
Mark Papich, EC, EP
Bhavin Parekh, EP
Shreya Parekh, EC
Ernest Parente, EC, EP
Jose Parisi, EP
Sherry Parker, EP
Pavel Parkhomyuk, EC
Jonathan Parks, EC
Alan Parr, EP
Richard Parrish, EP
Leonid, Parunov, GL
George Patani, EP
Ashvin Patel, EP
Paresma Patel, GL
Guido Pauli, CoE, EC
Venkateswara Pavuluri, GL
Rahul Pawar, GL
Justin Pennington, CoE, EC
Ginette Pepper, EC, EP
Lawrence Perez, GL
Tyler Peryea, GL
Bhakti Petigara, GL
Gabriel Picard, EP
Julie Pier, EC, EP
Stacey Platzer, EC, EP

Carrie Plucinski, GL
Luisa Fernanda Ponce De Leon, EP
James Ponto, EP
Guirag Poochikian, EC
Bert Pöpping, EC, EP
Cisse Porsby, EP
Reto Portmann, EP
Tammy Powell, EC, EP
Lee Poye, EP
Narasimha Prasad, EP
Linda Pugh, EC
Chetan Pujara, EP
Xin Qi, EP
Haiou Qu, GL
Oscar Quattrocchi, EC, EP
Nausheen Rahman, EP
Natarajan Rajagopalan, EP
Radhika Rajagopalan, EC
Sundaram Ramachandran, EP
Bala Ramanathan, EP
Sam Raney, GL
Ashutosh Rao, GL
G. Joseph Ray, EP
Elizabeth Rebello, EC
David Reed, EC
Gail Reed, EC
Eike Reich, EC
Lars Reimann, EC, EP
Thomas Reinders, EC
Veronika Reisinger, EP
Gurvinder Singh Rekhi, EC
Da Ren, EP
Kimberly Reustle, EC
Hamid Rezaei, EC
Rick Rhoads, EC
Antonio Ricci, EC
Kevin Rice, GL
Dean Ripple, EP
Jennifer Roark, EP
Helmut Rockstroh, EC, EP
Amy Roe, EC, EP
Holger Roehl, EC, EP
David Roesti, EC, EP

Jeffrey Rohrer, EC, EP
Shauna Roman, EC
Agusti Jordi Romero, EP
Steffen Rosen, EP
Kara Rosenker, GL
Jason Rossi, GL
Jean-Marc Roussel, EC
Meng Rowland, GL
Raimon Rubires, EC
Gwen Rucker, EC, EP
Lydia Ruffner, EC
Tracy Rupp, GL
Ethan Russo, EP
Martin Rutstein, EP
Melody Ryan, CoE, EC, EP
Jack Saad, EP
Mark Sacchetti, EC
Vishal Sachdeva, GL
Wendy Saffell-Clemmer, CoE, EC
Masahiro Sakagami, EC, EP
James Salas, EC
Matthew Sanchez, EP
Mary Ellen Sanders, EP
Maria Ines Santoro, EC
Camilla Santos, EC, EP
Leandro Santos, EP
Murugan Saravanan, EC
Sumona Sarkar, EC
Dieter Scherer, EP
Emmanuel Scheubel, EP
Jean Schoeni, EC, EP
Timothy Schofield, EC, EP
Michael Schuemann, EP
William Schumacher, EP
Jeff Schwartzenhauer, EC
Stephan Schwarzingler, EP
Mark Schweitzer, EC, EP
Myke Scoggins, EC
Suzanne Sechen, GL
Robert Seevers, EP
Alan Segrave, EP
Mary Seibel, CoE, EC, EP
Donna Seibert, EC

Mauricio Seigelchifer, EC, EP
Daniela Selaya, GL
Barbara Serr, EC
John Shabushnig, EC, EP
Hamid Shafiei, GL
Vivek Shah, EP
Kabir Shahjahan, GL
Maged Sharaf, EC
Chandana Sharma, EP
Hemant Sharma, EC
Vijay Sharma, GL
David Shaw, EP
Eric Sheinin, EC
Timothy Shelbourn, EC, EP
Meiyu Shen, GL
Xiaobin Shen, EC
Christine Sherman, EC
Shangmei Shi, EP
Nilesh Shinde, EC
Ed Shneyvas, EC
Robert Shrewsbury, EC
Anjali Shukla, GL
Akhtar Siddiqui, GL
Irwin Silverstein, EC
Roger Simonds, EP
Donald Singer, CoE, EC
Hameraj Singh, EC
Satish Singh, EC, EP
Jay Sirois, EP
Raymond Skwierczynski, EP
Rostyslaw Slabicky, EC, EP
Amy Smith, EP
Angele Smith, GL
Teri Soli, EP
Aniko Solyom, EC
Cindy Sommers, GL
Perceval Sondag, EC, EP
Haowei Song, EP
Dan Sorensen, EP
Lucia Sousa, EC
Lori Spafford, EP
Bruno Spieldenner, GL
Shelly Spiro, EC, EP

Stephanie Sproule, EC
Jan Srbeek, EC
Charudharshini Srinivasan, GL
Jannavi Srinivasan, GL
Ved Srivastava, EC
Michelle Stafford, GL
Ralf Stegmann, EP
Michael Steller, GL
Marla Stevens-Riley, GL
Paul Stickings, EC
Paul Stinavage, EC
Jessica Stolee, EC
Dwight Stoll, EC
Joseph Stowell, EC
Seth Strawbridge, EP
Gregory Stromberg, EP
Dirk Stueber, EP
Vaughn Robert Stultz, EC
Yongchao Su, EC
Karunakar Sukuru, EC
Connie Sullivan, EC, EP
Calvin Sun, EC, EP
Huimin Sun, EC
Zhigang Sun, EC, EP
Colleen Sutton, GL
Kalavati Suvarna, GL
Kevin Swiss, EC, EP
Frank Switzer, GL
Ami Fazlin Syed Mohamed, EP
Christina Szabo, EP
Mary Szorik, EP
Charles Tan, CoE, EC
Neeraj Tandon, EC, EP
Carmen Tartera, GL
Monica Tejwani, EC, EP
Kailas Thakker, EP
Michelle Then, EC
Daniel Tholen, EC
Colleen Thomas, GL
Steven Thomas, EC
Lawrence Thompson, EP
Tom Tice, EC, EP
Edward Tidswell, EC, EP

Kamal Tiwari, GL
Rohit Tiwari, GL
Mike Tobyn, EC
Kristina Toliver, GL
Gary Tomasio, EP
Virginie Treyvaud Amiguuet, GL
Tony Tse, EP
Jiasheng Tu, EC, EP
Pengfei Tu, EP
Saleh Turujman, GL
Jeanne Tuttle, CoE, EC, EP
Yoko Uematsu, EC, EP
Katherine Ulman, EC, EP
Richard van Breemen, EC
Kevin Van Cott, EP
Edwin van den Heuvel, EC
Mark van Ooij, EC, EP
Drew Van Orden, EP
Peter Vandeberg, EC
Christina Vegge, EP
Dama Venugopalarao, EC
Michael Verlander, EC, EP
Swati Verma, GL
Charles Vesey, EC
Carlos Vidotti, EC
Kathy Vieson, EP
Alvaro Viljoen, EC
Ofelia Villalva-Rojas, EP
Luciano Virgili, EC
Christian Viskov, EC, EP
Gabriel Vivo-Truyols, EC
Gordon Vrdoljak, EP
Matthias Wacker, EC, EP
Heather Wade, EC
Stephan Walch, EC
Donald Walker, EP
George Wall, EC
Michael Walsh, EP
Reinhard Walter, EC
Charlene Wang, GL
Fengqiang Wang, EP
Haofan Wang, GL
Hu Wang, EP

Lei Wang, EP
Selina Wang, EP
Ting Wang, EC
Wailin Wang, GL
Xiaoping Wang, EC
Yan Wang, GL
Youmin Wang, GL
Zhenyu Wang, EC
Zhouxi Wang, GL
Kevin Warner, EC, EP
Andrew Waye, EP
James Webber, EP
Darin Weber, EC, EP
Gregory Webster, EC, EP
Janice Weightman, EC
Caroline R. Weinstein-Oppenheimer, EP
Aaron Weisbuch, GL
William Weiss, EP
Jane Weitzel, CoE, EC
Eloise Welfare, EC, EP
Eric Wenger, EP
Dennis West, EC, EP
Kylan Whitaker, EC
Tobias Wiezorek, EP
Marc Wiles, EC
Daniel Willett, GL
Martin Williamson, EC, EP
Scott Wilson, EP
Michael Wisser, EC
Stefanie Wohlrab, EP
Allison Wolf, EC, EP
Steve Wolfgang, GL
JoEllen Wolicki, GL
Gillian Wollett, EC
Ken Wong, EP
Robyn Wong, EC
Surapote Wongyai, EP
Chao Wu, EP
Fan Wu, EC
Wanying Wu, EP
Wei-Hua Wu, GL
Joshua Wurzer, EP
Jo Wyeth, GL

Min Xia, EC
Dongyue Xin, EC
Hao Xu, EP
Mingzhe Xu, EC
Xiaoming Xu, GL
Sam Yaghmour, EP
Brian Yan, GL
Harry Yang, EC
Jinchuan Yang, EP
Jingyue Yang, GL
Patrick Yat, EC
Mehran Yazdanian, EP
Min Ye, EP
Wei Ye, GL
Ann Yellowlees, EC
Judy Yeung, EP
Huzeyfe Yilmaz, GL
Hsiang Shonna Yin, EC, EP
Emnet Yitbarek, GL
Gao Yonghua, EC, EP
Kurt Young, EC
Christopher Yu, EP
Jing Yuan, GL
Yang Yuan, GL
Yaozuo Yuan, EC
Hongfei Yue, GL
Brenda Yuzdepski, EC
Earl Zablackis, CoE, EC, EP
Ben Zhang, EC
Fangfang Zhang, EC
Jin Zhang, GL
Le Zhang, GL
Sophia Zhang, EC
Xiaohua Zhang, EC
Ying Zhang, EP
Jin Zhao, EC
Yiwei Zhao, EP
Yuan Zhao, EC
Zhongzheng Zhao, EP
Ningjia Zheng, EC
Deliang Zhou, EC
Ying Zhou, EP
Yingi Zhou, GL

Rui Zhu, GL
Wei Zhu, EC, EP
Ahmed Zidan, GL
Steve Zigler, EC, EP
Sarah Zimmermann, GL
Yuda Zong, GL
Chaozhong Zou, EP
Karina Zuck, GL
Joerg Zuercher, EC
Neal Zupec, EP
Andrew Zych, GL