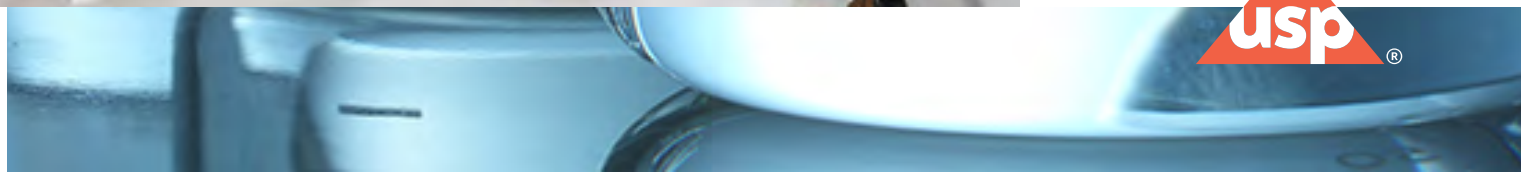



# 2015–2020 CYCLE REPORT

Report to the Board of Trustees on Council of Experts Activities from the Chief Science Officer





# 2015–2020 CYCLE REPORT

## TABLE OF CONTENTS


2–3 Letter From the Chair

4–5 Cycle at a Glance

6–7 CoE Key Activities

8–13 Biologics

14–19 Chemical Medicines

20–25 Dietary Supplements and Herbal Medicines

26–29 Excipients

30–33 Food Ingredients

34–39 General Chapters

40–44 Healthcare Quality and Safety

45–57 Our Expert Volunteers and Government Liaisons

On behalf of the Council of Experts (CoE) and USP staff, I am pleased to present this report on the 2015–2020 cycle activities and achievements of the CoE, its Expert Committees (ECs) and its Expert Panels.

We have made great progress creating proactive and continuous improvement at USP that will extend far into the next cycle. We have increased USP's global impact by providing a growing number of up-to-date, science-based public standards that serve as quality benchmarks for medicines, foods and dietary and herbal supplements in the U.S. and around the world. Just providing quality standards—as we have for more than 200 years—has never been enough at USP. That is why we also offer training on how to use our standards, explore new offerings that support capability building and continue to raise our voice as a thought leader and innovator in science. I want to highlight six of the CoE's many accomplishments over the past cycle and the key factors that have contributed to these successes.

**We are in the home stretch of our Up-to-Date marathon of monograph modernization.** Our efforts since 2015 have eliminated outdated techniques and ensured that hazardous chemicals are identified and removed from processes. Being on track to deliver on Up-to-Date is especially remarkable given that the ambition was significantly raised mid-cycle by adding key programs for priority monographs, Reference Standards and ATP, our organization-wide effort to adapt, transform and progress our approach to standards development in a sustainable and consistent way.

**I am proud of the comprehensive program USP has implemented to support the public health response to the COVID-19 pandemic.** I invite you to visit USP's COVID-19 content hub to read about our activities that are helping to secure the global supply chain for quality medicines, advocating for greater transparency and more diversity in the sources of medicines and their ingredients, and ultimately helping to build a stronger, more resilient supply chain. For example, the Compounding EC has provided key components through its rapid and robust response to address the urgent need for guidance on compounding hand sanitizers as well as conserving personal protective equipment. The work of USP's global public health mission—our science and standards—is needed now more than ever during times of urgent public health concerns because the world cannot go without quality medicines. We have made a major impact and the response from the stakeholder community and the U.S. Food and Drug Administration (FDA) has been extremely encouraging.

**Earlier in the cycle, USP also acted to help support the public health response to the opioid crisis in the U.S.** The Healthcare Quality and Safety EC formed a subcommittee to discuss potential USP approaches to address opioid and naloxone issues and provide recommendations to the EC. In addition, Chemical Medicines worked with the FDA to expedite the modernization of opioid monographs. This work supported the FDA Opioids Action Plan for reducing the impact of opioid abuse on American families and communities.

**We have extended the global reach of USP's more than 6,800 standards.** USP now provides documentary and physical Reference Standards in 91% of the world's countries—an increase from 85% during the previous cycle. *USP–NF Online,* the combination of the *United States Pharmacopeia* (*USP*) and the *National Formulary* (*NF*), has been visited more than 4.8 million times by more than 510,500 unique visitors since November 2018.

**We have expanded our work on training stakeholders** how to use our standards and educating them about their importance as quality benchmarks for medicines and other compendial articles. Among the numerous examples of outreach during the cycle, the Foods Program hosted an international symposium focused on tools for managing food allergens and combating food fraud. The Nomenclature and Labeling EC engaged with stakeholders on clarifying the expiration date format in labeling. USP staff provided presentations on our modernization and harmonization work related to quality standards for excipients at a recent Excipient World Conference and Expo.

**The Biologics program developed new approaches to standards** that focus on assays and technologies as the key factors in evaluating opportunities. These standards are applicable to a wide range of materials. They are used to support the performance of methods and processes applicable to classes and families of products throughout their lifecycle. This has been key to the diversification of the USP portfolio of products and services. The Biologics program is also exploring new offerings that support capability building, increased scientific connectivity and enhanced programmatic relevance, as well as becoming an influencer in the biopharmaceutical space.

Three key factors have contributed to our accomplishments over the past cycle: trust, collaboration and impact. Trust in USP is an essential ingredient that encourages public and healthcare provider confidence in the medicines that improve and save lives. Increased collaborations, enhanced engagements and diversified communication channels with the FDA have supported our successes and strengthened our relationship with the agency. Collaboration also connects us to scientists and stakeholders around the world who share the common goal of improving public health. Indeed, our enormous impact on billions of lives over the cycle was made possible by the hundreds of thousands of hours that were generously contributed by our Expert Volunteers and augmented by our dedicated staff. Thank you for your commitment to USP's mission.

While we celebrate these accomplishments, we are also looking ahead to the future and exploring new pathways of scientific leadership. We have established a structured approach to early scanning for innovations, technologies and other quality paradigms with the biggest potential impact. Notable areas of focus include 1) pharmaceutical continuous manufacturing, especially by the generics industry, including advanced technologies for faster, higher-quality production at potentially lower costs; 2) digital therapeutics, medical treatments that have digital formats or components that could help prevent, manage or treat a wide range of conditions; and 3) quantitative nuclear magnetic resonance (qNMR), a method for analyzing complex mixtures with greater accuracy to better ensure medicine purity.

In addition, USP has created a Quality Advisory Group, including quality thought leaders, to help us navigate potential disruptors in the global pharmaceutical manufacturing and regulatory environment. This group is proposing potential pathways that address these paradigm shifts and help maintain the relevance of USP's standards in the years to come.

From the standards we create to the partnerships and conversations we foster, we are committed to creating a culture where everyone feels fully empowered and valued and where they can contribute their full potential to accomplish our mission. Our focus on diversity and inclusion is intentional and designed to build a sense of true belonging.

USP is also reimagining the USP volunteer model experience. We will pilot a more agile and flexible volunteer model for engaging volunteers and leveraging their time and expertise in the next cycle. Participating ECs will be encouraged to leverage Expert Advisors who can share their expertise in a more ad hoc, flexible way without having to commit to a five-year cycle or participate in mandatory balloting activities.

# LETTER FROM THE CHAIR

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

USP envisions that such a flexible volunteer model will help USP attract a broader, more diverse audience and increase volunteer engagement.

In these extraordinary times, I send my warmest thanks and well wishes to all of our Expert Volunteers for everything you do in support of 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 and accomplishments over the past cycle have benefited consumers, patients and other stakeholders by helping to improve and protect public health in the U.S. and around the world.

# FOSTERING COLLABORATION

## CoE OVERVIEW

The Council of Experts (CoE), consisting of the 25 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) during the 2015–2020 cycle. JS3s were introduced at the outset of the cycle to facilitate communication and collaboration on topics that affect multiple standards-setting areas, especially USP Reference Materials.

# 2015–2020 CYCLE AT A GLANCE

## USP GOVERNING BODIES AND RELATED GROUPS

| BOARD OF TRUSTEES (BoT) | USP CONVENTION | COUNCIL OF EXPERTS (CoE) | VOLUNTEER GROUPS UNDER CoE |
|---|---|---|---|
| **9 MEMBERS** elected by USP Convention, the Past Convention President, 3 at-large members appointed by the BoT, and the USP CEO, responsible for:<br>▸ USP's policies<br>▸ USP's finances<br>▸ USP's strategic direction | **493 ORGANIZATIONS** invited by Council of the Convention and BoT, responsible for:<br>▸ Resolutions that guide USP policies and initiatives<br>▸ Adoption of *USP Bylaws*<br>▸ Election of BoT and CoE | **25 CHAIRS** of USP Expert Committees (ECs) elected by USP Convention, plus the USP Chief Science Officer who serves as CoE Chair, responsible for:<br>▸ USP scientific and standards-setting decisions<br>▸ Standards-setting work of USP's volunteer scientific expert groups<br>▸ Adherence to direction set forth by BoT and USP Convention | **ECs**<br>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.<br>**EPs**<br>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.<br>**JS3s**<br>Representatives from ECs who serve on subcommittees formed to address issues that affect multiple standards-setting areas. |

**USP STAFF:** Support and shepherd the work of all governing bodies and related groups

### 2015–2020 CYCLE BALLOTED AND APPROVED STANDARDS BY THE NUMBERS*

| | |
|---|---|
| **707** Ballots | **3,185** Items Balloted |
| **1,948** New or Revised Documentary Standards Approved | **710** Modernized Documentary Standards Approved |

| | | |
|---|---|---|
| **380** *USP–NF, FCC* and Supplements Standards Omitted | **2,288** Reference Standard R&C Lots Released | **577** Reference Standard F Lots Released |

*July 1, 2015, through May 1, 2020

## USP STANDARDS APPROVED IN 2015–2020 CYCLE

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.

# 2015–2020
## CoE KEY ACTIVITIES AND ACCOMPLISHMENTS

The CoE met 27 times from fiscal year (FY) 2016 through FY 2020. The following are highlights of its key activities and accomplishments in each FY of the cycle:

**Formed Closer Bonds and Met Stakeholders' Evolving Needs in FY16:** The CoE established stronger connections to other USP governance bodies, the Board of Trustees (BoT) and the USP Convention. The CoE implemented new strategies to foster the next generation of USP's Expert Volunteers. Guided by the framework of the 2015–2020 Convention Resolutions and the BoT-approved "Winning Ambitions" strategic plan, the CoE made significant strides in bringing standards up to date and explored new ways to expand and diversify USP's portfolio to meet new and technologically evolving stakeholder needs.

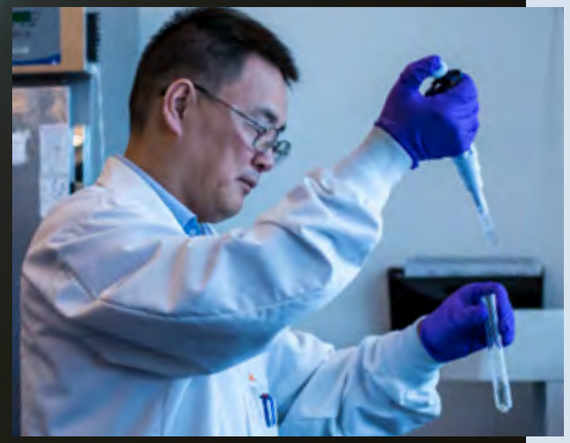
**Expanded Modernization and Discussed the Future of Compendial Architecture and CoE Structure in FY17:** The CoE broadened the scope of the Up-to-Date Winning Ambition to continuously modernize *USP–NF*. The CoE also conducted a rigorous assessment of the antibiotics portfolio to ensure their continued quality and suitability of use. In collaboration with JS3s and USP staff, the CoE made significant progress toward a revision of *USP* General Chapter <11> *USP Reference Standards,* which addresses the types, applications and uses of USP Reference Materials cited in *USP–NF* standards. The CoE also provided input to USP on multiple aspects of compendial architecture, including General Notices (GNs) and text hierarchy, the structure of documentary standards, general chapters, as well as monographs and Reference Standards of the future. In addition, the CoE began discussions on the structure of the next CoE.

**Reached Key Milestones and Developed New Approaches in FY18:** The CoE reached major milestones in CoE structure development for the 2020–2025 cycle, Up-to-Date and the Call for Candidates, USP's Expert Volunteer recruitment process. The Biologics program successfully initiated the development of performance standards that support product families, classes and technologies throughout the product lifecycle. The Compounding EC advanced its approach to align its standards and remove duplicative information from key general chapters. In addition, significant progress was made in identifying a sustainable path for developing standards for over-the-counter (OTC) products. USP explored the area of novel excipients, a key component in the development of safer and more effective drugs.

**Adopted New Strategies and Evaluated Opportunities in FY19:** The CoE, as part of USP's 2025 Strategy, adopted more flexible approaches to standards development. The Biologics program developed new approaches for evaluating opportunities that expanded its portfolio. The Compounding EC worked at providing a comprehensive set of standards to help ensure quality compounded formulations and safe handling of hazardous drugs throughout the healthcare system. USP created the Quality Advisory Group to help navigate potential disruptors in the global pharmaceutical manufacturing and regulatory environment and to help maintain the relevance of USP's standards in the years to come. Chemical Medicines worked with the FDA to expedite the modernization of opioid monographs and to support its Drug Competition Action Plan. The Foods program identified ways to protect the integrity of the supply chain and updated its guidance document on using targeted and non-targeted methods to prevent fraud.

**Collaborated on FDA Draft Guidance and Explored New Paths in FY20:** The FDA issued its draft guidance titled "Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process," the result of a two-year collaboration with USP staff. The Pending Monograph Process (PMP) provides a transparent and efficient pathway to align the development of monographs with FDA approval of the associated applications. By the end of the 2015–2020 cycle, USP had processed 112 PMP requests. Also in FY20, the CoE explored novel pathways for OTC medicines. USP began piloting a more agile and flexible volunteer model for engaging volunteers and leveraging their time and expertise in the next cycle. The GNs Project Team proposed adding a new subsection on Global Health Monograph information to the GNs. USP implemented a tripartite response to the COVID-19 pandemic, which included ensuring the safety and security of staff, adapting USP's operations and delivering on USP's public health mission.

The CoE reached major milestones in CoE structure development for the 2020–2025 cycle, Up-to-Date and the Call for Candidates, USP's Expert Volunteer recruitment process.



# BIOLOGICS

The Biologics program develops and modernizes standards for peptides, proteins, blood products, vaccines, antibiotics, carbohydrates, tissues and raw materials for manufacturing. USP is committed to ensuring that our approach evolves with the science of biologics and the needs of stakeholders, including patients, practitioners, industry and regulators.

## **USP Resolution-Related Activities** in Biologics

Throughout the 2015–2020 cycle, the Biologics program worked to fulfill Resolution VI, which called for USP to promote alignment with stakeholders to develop quality standards for biological medicines, thereby ensuring that standards facilitate and complement innovation and availability. USP Biologics ECs and EPs worked with stakeholders to develop innovative standards and resources for all phases of product development—from raw material to market—which helps to ensure that patients receive quality biologic therapies. In addition, the Biologics program developed new standards that support cutting-edge technologies, such as cell and gene therapies, to fulfill Resolution VI.

## **Key Activities** in Biologics

**Performance Standards:** The Biologics program developed new approaches that focused on performance standards designed for broad applicability throughout the product lifecycle. The program first identified and prioritized performance standards applicable to therapeutic proteins. Outreach efforts continued to successfully identify the most pressing manufacturer needs, such as standards that are widely applicable across a biologics product class. To meet this challenge, the Biologics program focused on creating performance standards for monoclonal antibodies and host cell proteins that have broad applications across multiple production sites. Several proof-of-concept studies were launched to address critical bottlenecks in manufacturing. In addition, USP scientists continually consulted with the ECs to confirm the relevance of these initiatives and to manage the paths to market. To engage industry, USP co-sponsored roundtables that brought together stakeholders from leading pharmaceutical companies and the FDA to discuss performance standards development.

**Monoclonal Antibody Performance Standards:** Three new physical performance Reference Standards were developed to help stakeholders address challenges associated with analytical characterization of monoclonal antibodies. These standards can be used as an independent control material for method development, training, method transfer, internal assay control support and standardization of physicochemical testing.

**CD34+ Cell Enumeration:** USP developed *USP* General Chapter <127> *Flow Cytometric Enumeration of CD34+ Cells* and a CD34+ Cell Enumeration System Suitability Reference Standard to help laboratory professionals working with CD34+ cells achieve consistent results. Consistency is critical when determining the viability of donor cells for lifesaving bone marrow and related stem cell transplant procedures.

**First Cell-Based Assay for Insulin Products:** Development of the first cell-based assay for insulin products was a major achievement of the Insulin EP of the Biologics Monographs 1–Peptides and Insulins (BIO1) EC. The cell-based assay provides an alternative to the animal assay in alignment with USP's commitment to reduction, refinement and replacement of animal testing.

**Host Cell DNA Standards and Methods:** The Biologics program published *USP* General Chapter <509> *Residual DNA Testing* to address longstanding industry needs for standardized methods to quantify host cell DNA impurities that occur during manufacturing. The chapter provides several

"Our extensive review of *USP* General Chapter <1223.1> was among our greatest accomplishments because of the many advantages, including precision and speed, to replacing microbiological antibiotic assays with modern chemical-based analytical methods. A completely new approach was introduced that can help deal with complex antibiotics for which purifying the different related substances may not be feasible. This is critical work for monograph modernization because **MILLIONS OF PATIENTS WORLDWIDE DEPEND ON THESE ANTIBIOTICS FOR FIGHTING SERIOUS OR SEVERE INFECTIONS**."

*— Pascal Anger, Ph.D., Chair, BIO4 EC*

# BIOLOGICS

## Cycle Highlights: BIOLOGICS

**8**
New General Chapters

**8**
Major General Chapter Revisions

**15**
Minor General Chapter Revisions

**10**
New Monographs

**10**
Modernized Monographs

**62**
Revised Monographs

validated methods, including a sample extraction procedure in combination with a quantitative polymerase chain reaction detection method. Two Reference Standards were also approved for compendial use with <509>, the *Escherichia coli* and Chinese Hamster Ovary Genomic DNA Reference Standards.

**Guidance on Fragment Crystallizable Function Assays:** The Biologics program published a new *USP* General Chapter <1108> *Assays to Evaluate Fragment Crystallizable (Fc)-Mediated Effector Function* in collaboration with the Function Assays EP of the Biologics Monographs 2–Proteins (BIO2) EC. This chapter provides guidance on the selection, development and validation of Fc function assays, including the measurement of low-affinity interactions observed with Fc gamma receptors and the impact of glycosylation on antibody effector function.

**Coagulation Factors:** The Coagulation Factors EP of the Biologics Monographs 3–Complex Biologics (BIO3) EC provided guidance and best practices for potency determination of coagulation factors and outlined the scope of general chapters numbered below 1000. Additionally, the EP defined the structure of a general chapter numbered above 1000 for potency testing for coagulation Factors VIII and IX, and proposed development of new Reference Standards for system suitability.

**Vaccine Standards:** USP continued its work developing guidance on testing viral vaccines and cutting-edge nuclear magnetic resonance-based tests for identifying product-specific vaccines. Physicochemical test chapters and quality standards for carrier proteins used in glycoconjugate vaccines were planned. USP Reference Standards and quality tests such as these allow manufacturers, regulators and control laboratories to test vaccines in development or on the market. They enable the development of better vaccines and detection of adulterated or mislabeled ones.

> **THERAPEUTIC PEPTIDES REPRESENT ONE OF THE FASTEST GROWING SEGMENTS IN THE PHARMACEUTICAL MARKET,** and public quality standards developed by USP play an important role in supporting this drug class. While the BIO1 EC had many outstanding achievements over the five-year cycle, I am proudest of the sheer volume of peptide-related documentary standards impacted by their efforts. This high level of productivity was in addition to their contributions in organizing four workshops focused on therapeutic peptides and advancing monographs for insulin products."
>
> *— Michael De Felippis, Ph.D., Chair, BIO1 EC*

**Raw Materials:** USP's Biologics staff and ECs initiated a portfolio of general chapters that provide best practices for standardizing critical raw materials used in biomanufacturing processes. They include materials used downstream in the process—or in steps with long holding times—that have a high impact on product quality. Efforts got underway to produce standards for cell culture media and other critical raw materials.

**Monograph Modernization:** USP's biologics monograph modernization efforts emphasized the use of orthogonal identification methods, preference for cell-based assays over animal-based assays, use of multiple Reference Standards to support a single monograph and inclusion of more system suitability Reference Standards. The Low Molecular Weight Heparin EP completed updates to the Heparin Sodium, Enoxaparin Sodium, Fondaparinux Sodium and Protamine Sulfate monographs. The FDA began considering the reintroduction of bovine heparin into the U.S. In alignment with the FDA's actions and recommendations, USP's Bovine Heparin EP spearheaded monograph and Reference Standards development. The panel convened stakeholders to discuss the topic at the 6th Workshop on the Characterization of Heparin Products in Brazil.

**Stakeholder Outreach:** USP Biologics continued to expand its events on hot topics intended to draw new biologics stakeholders. Recently, the Biologics team held its inaugural Biologics Stakeholder Forum in San Francisco. In addition, USP hosted a workshop on chemistry, manufacturing and controls issues for therapeutic peptides—an active standards-setting area. USP's 8th Bioassay Workshop included best practices for building potency assays for cell and gene therapy products. Other outreach highlights during the cycle included roundtables on 1) performance standards development for chromatographic column qualifications, 2) visible particles, 3) mRNA standardization, 4) gene therapy standardization and 5) quantitation of trace metals in cell culture media.

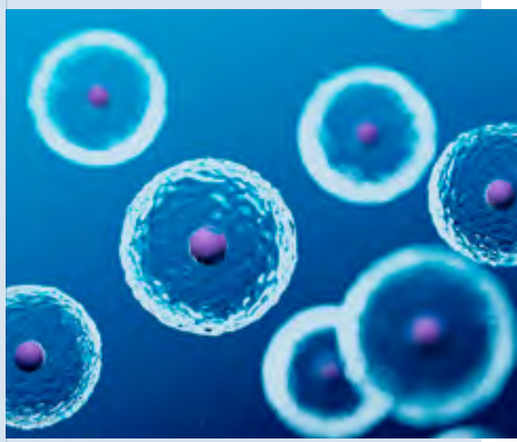
### Top EC Achievements

The following Biologics Monographs EC Chairs picked their EC's top achievements over the 2015–2020 cycle:

**Dr. Michael De Felippis, Chair of the BIO1 EC, said he is proud that the BIO1 EC:**

- Published *USP* General Chapter <1503> *Quality Attributes of Synthetic Peptide Drug Substances* in *Pharmacopeial Forum* (*PF*) 45(3) [May–Jun. 2019]; this chapter provides the framework for defining quality standards for peptide drug substances and drives consistency in the development and modernization of monographs.
- Revised the Glucagon and Glucagon for Injection monographs, the first to address both synthetic and rDNA forms of a peptide
- Implemented the Therapeutic Peptides Regulations, Standards and Quality Workshop series, which advanced USP's leadership in setting standards for this therapeutic class

The Biologics program developed new approaches that focused on performance standards designed for broad applicability throughout the product lifecycle.



# BIOLOGICS

**Dr. Michael Mulkerrin, Chair of the BIO2 EC, said he is proud that the BIO2 EC:**

- Transitioned its focus from product-specific standards to broadly applicable class standards for biologics products
- Engaged external stakeholders through roundtable discussions to develop broadly applicable standards
- Advanced the development of three monoclonal antibody standards

**Dr. Edward Chess, Chair of the BIO3 EC, said he is proud that the BIO3 EC:**

- Assessed modernization needs and established Up-to-Date plans for BIO3 general chapters and monographs
- Developed and approved new Reference Standards for 1) CD34+ Cell Enumeration System Suitability, 2) Prekallikrein Activator and 3) Coagulation Factor VIIa
- Formed the Coagulation Factors EP to develop a chapter on coagulation assays and to draft general test chapters for specific coagulation factors
- Started reviewing *USP* General Chapter <1223.1> *Validation of Alternative Methods to Antibiotic Microbial Assays*
- Reviewed draft *USP* General Chapter <426> *Histamine Test Method*

**Dr. Wesley Workman, Chair of the General Chapters–Biological Analysis (GCBA) EC, said he is proud that the GCBA EC:**

- Developed *USP* General Chapter <1049.1> *Design of Stability Studies for Biotechnology Product Development and Lifecycle Management*
- Developed *USP* General Chapters <509> and <1130> *Nucleic Acid-Based Techniques—Approaches for Detecting Trace Nucleic Acids* (*Residual DNA Testing*)
- Developed *USP* General Chapters <198> *Nuclear Magnetic Resonance Spectroscopy Identity Testing of Bacterial Polysaccharides Used in Vaccine Manufacture*, <1234> *Vaccines for Human Use—Polysaccharide and Glycoconjugate Vaccines*, <1235> *Vaccines for Human Use—General Considerations* and <1238> *Vaccines for Human Use—Bacterial Vaccines*

**Dr. Pascal Anger, Chair of the Biologics Monographs 4–Antibiotics (BIO4) EC, said he is proud that the BIO4 EC:**

- Assessed the modernization needs of its portfolio of monographs and established modernization plans
- Reviewed *USP* General Chapter <81> *Antibiotics—Microbial Assays*, which is anticipated to become official in December 2020

“The GCBA EC provided incredible value to the pharmaceutical industry through general chapters that clarified best practices and added new capabilities. The chapter on biotechnology stability study best practices will be one of the hallmarks of this cycle and will be a source of many future conference presentations. **THE DEVELOPMENT OF VACCINE CHAPTERS WILL BE A BASE THAT THE USP CAN BUILD ON IN THIS IMPORTANT AREA.** Additional performance standards and chapters developed by GCBA EC give the *USP* new capabilities. During this cycle, *USP* General Chapter <11> *USP Reference Standards* and General Notices were edited for clarity and better describe the elements of the USP Reference Standards program and management. It was my privilege to co-chair the subcommittee that delivered the General Chapter <11> project. These and many other accomplishments will be remembered far into the future.” *— Wesley Workman, Ph.D., Chair, GCBA EC*

# CHEMICAL MEDICINES

Chemical Medicines develops and revises monographs for drug substances and drug products. It 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.

> **OUR OVERALL GOAL IS TO HELP ENSURE THAT PATIENTS CAN TRUST THE QUALITY OF THEIR MEDICINES.** Our EC worked to achieve this by issuing new or revised monograph standards for hundreds of articles during the last cycle."
>
> *— Bernard Olsen, Ph.D., Chair of the CHM3 EC*

## **USP Resolution-Related Activities** in Chemical Medicines

Throughout the 2015–2020 cycle, Chemical Medicines continued to broaden its communication and collaboration with the FDA and its government liaisons on monograph development and validation, in alignment with Resolution I, through systems such as 1) the Cooperative Research and Development Agreement vehicle, 2) formation of an FDA OTC Drug Products Working Group and 3) regular meetings with the FDA's Center for Veterinary Medicine to cooperatively advance standards that impact animal health. In accordance with Resolution II, *USP–NF* Monograph Modernization, Chemical Medicines reduced the backlog of monographs that need modernization by collaborating with the FDA and industry stakeholders.

## **Key Activities** in Chemical Medicines

**The Critical Resources Information Sharing Priorities (CRISP) Initiative:** Collaboration and communication were key to the development of standards, especially when exchange of critical confidential information was needed. Through the CRISP Initiative, Chemical Medicines worked with the FDA and industry on various efforts to strengthen collaborations and develop potential pathways for the exchange of critical information. This work could significantly enhance the efficiency of the standards-development process.

**Compendial Communications:** Chemical Medicines worked with the FDA to enhance the compendial communication process. For example, to decrease rate-limiting *PF* discussions, USP developed an FDA-supported, streamlined, centralized process for sharing essential monograph revision information significantly earlier in the development process.

**Pending Monograph Process (PMP):** The PMP, a collaborative effort between USP and the FDA, provides a transparent and efficient pathway to align the development of monographs with FDA approval of the associated applications. Chemical Medicines worked with the FDA on establishing mutually beneficial best practices for this critical program. The FDA's long-awaited draft guidance for industry, titled "Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process," was issued in July 2019.

**Opioids Action Plan:** Chemical Medicines worked with the FDA to expedite the modernization of opioid monographs and to support the FDA Opioids Action Plan for reducing the impact of opioid abuse on American families and communities. Chemical Medicines also worked with the FDA on innovations in opioid standards, such as exploring the compendial role of an opioid screening test to safeguard the U.S. drug supply chain.

**OTC Medicines:** USP and the Chemical Medicines Monographs 6 (CHM6) EC worked with the FDA, industry and related organizations to help ensure that public standards for OTC products used by millions of people reflect the innovations and changes in healthcare and the marketplace. A USP OTC project team was formed to work with Chemical Medicines to develop a Work Plan and identify and pursue gaps in the compendial framework for OTC standards. USP, the FDA and industry, through the Consumer Healthcare Products Association (CHPA), then formed the OTC Drug Products Working Group to address

Throughout the 2015–2020 cycle, Chemical Medicines continued to broaden its communication and collaboration with the FDA.

Through the CRISP Initiative, Chemical Medicines worked with the FDA and industry on various efforts to strengthen collaborations and develop potential pathways for the exchange of critical information.

current barriers to OTC product standards by exploring innovative compendial pathways for OTC monographs that are flexible for industry and also meet the FDA's regulatory requirements. Toward those ends, a general principles document and a USP OTC drug product monograph mock-up were developed for stakeholder review.

**Patient Access to Affordable Medicines:** Chemical Medicines worked with the FDA to support its Drug Competition Action Plan. USP analyzed the FDA's list of off-patent products for which generic alternatives are unavailable. USP engaged the FDA—including senior leadership—as well as manufacturers, patient groups and other stakeholders to develop potential compendial monographs that will enable the development of quality generics for these priority medicines.

**Controlling and Monitoring Nitrosamine Contaminants:** Chemical Medicines initiated the development of Reference Standard materials for all six nitrosamine contaminants identified by FDA in angiotensin II receptor blockers and other drugs. Chemical Medicines also continued its work developing a general chapter framework for nitrosamines in these medicines to provide drug manufacturers with test procedures and approaches for controlling these impurities. USP laboratories are supporting this effort by researching, evaluating and identifying testing methods for monitoring these impurities in drug substances and drug products.

**Up-to-Date Initiative and Impurities:** As part of Resolution II, USP resolved to bring its compendia up to date so that USP standards reflect state-of-the-industry techniques for sufficiently monitoring drug quality, purity and strength. The success of the initiative is dependent, in large part, on modifications to the impurities section of a considerable portion of the monographs. Staff and volunteer scientific expert efforts to develop and carry out strategies for resolving impurities challenges became a top priority.

## Top EC Achievements

The following Chemical Medicines Monographs EC Chairs picked their EC's top achievements over the 2015–2020 cycle:

**Mr. Richard Blessing, Chair of the Chemical Medicines Monographs 1 (CHM1) EC, said he is proud that the CHM1 EC:**

- Accomplished numerous new monographs, modernizations, revisions and omissions
- Transferred General Chapter <81> and the associated antibiotic monographs to a new committee due to the unique concerns for those medicines
- Addressed a potential shortage for cidofovir, an antiviral medicine, by quickly removing a test with compliance implications through a Revision Bulletin

**Dr. Ernest Parente, Chair of the Chemical Medicines Monographs 2 (CHM2) EC, said he is proud that the CHM2 EC:**

- Accomplished numerous new monographs, modernizations, revisions and omissions
- Provided customer-focused solutions for continuous improvement
- Advanced work on the Opioid Monograph Revision Priority List from the FDA

**Dr. Bernard Olsen, Chair of the Chemical Medicines Monographs 3 (CHM3) EC, said he is proud that the CHM3 EC:**

- Accomplished numerous monograph modernizations, new monographs, revisions and omissions
- Streamlined the monograph omission process
- Initiated work to address genotoxic impurities in monographs

**Ms. Kim Huynh-Ba, Chair of the Chemical Medicines Monographs 4 (CHM4) EC, said she is proud that the CHM4 EC:**

- Submitted numerous modernizations, new monographs, revisions, omissions, new general chapters, revised general chapters and a *Stimuli* article
- Established new *USP* General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging* to provide a clear and effective USP public standard to meet patient and practitioner needs for sterile radiopharmaceuticals
- Worked in partnership with industry and the FDA to promptly resolve issues related to standards for psychiatric, psychoactive and neuromuscular therapeutic categories as well as for radiopharmaceuticals, imaging agents and aerosols

**Ms. Amy Karren, Chair of the Chemical Medicines Monographs 5 (CHM5) EC, said she is proud that the CHM5 EC:**

- Accomplished numerous modernizations, new monographs, revisions and omissions
- Actively provided technical comments on monograph revisions
- Collaborated via participation in JS3, Chemical Medicines Collaborative Groups and the Recruitment Ambassadors program

**Dr. Reinhard Walter, Chair of the CHM6 EC, said he is proud that the CHM6 EC:**

- Initiated the USP-FDA-CHPA Roundtable and maintained collaboration in a working group
- Developed an alternative USP monograph proposal for OTC drug products, replacing specific methods with general, adaptable procedures
- Initiated the Diphenhydramine Subcommittee

## Cycle Highlights: CHEMICAL MEDICINES

**265**
New Monographs
**972**
Modernizations
**502**
Omissions

**"What an indescribable thrill and reward it was for me, as a regular industry pharmacist, to be able to tap into the pool of peer expert experience from around the world and to discuss with USP, FDA and CHM6 EC experts, the possibilities of setting a public standard for monographed OTC products."**

*— Reinhard Walter, Ph.D., Chair of the CHM6 EC*

# DIETARY SUPPLEMENTS AND HERBAL MEDICINES

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*. These quality standards help protect and improve the health of millions of people who purchase dietary supplements and herbal medicines. In addition, the USP Verification Program, created specifically for these products, gives manufacturers the tools they need to help safeguard the health of consumers through quality assurance. Brands that display the USP Verified Mark signal to the public that what's on the label is what's in the bottle, allowing their verified products to stand apart from a majority of the competition.

## **USP Resolution-Related Activities** in Dietary Supplements and Herbal Medicines

Throughout the 2015–2020 cycle, increased public demand for dietary supplements—along with ongoing public safety concerns—accentuated the need for quality standards and the use of emerging technologies to help ensure the quality of dietary supplement and botanical products. To better address Resolution II, *USP–NF* monograph modernization, the BDSHM, NBDS and Food Ingredients (FI) ECs formed a Modern Analytical Methods Joint Subcommittee (JS) to develop monographs with validated analytical methods using more modern technology.

In alignment with Resolution III, on globally harmonized standards, USP staff provided input to the AOAC International, ASTM International, and International Organization for Standardization on standards-setting issues, such as botanical ingredients in traditional Chinese medicine.

In accordance with Resolution IX, which related to quality standards for dietary ingredients

Brands that display the USP Verified Mark signal to the public that what's on the label is what's in the bottle, allowing their verified products to stand apart from a majority of the competition.

> **As outgoing Chair of the NBDS EC, I AM VERY PROUD OF OUR MANY ACCOMPLISHMENTS OVER THIS CYCLE,** and I very much appreciate the commitment and efforts of our EC and EP members. I am also proud of and appreciate the support of the CoE as we established the Thomas S. Foster Award, which will recognize individual volunteer contributions for many years to come."
>
> *— Dennis Gorecki, Ph.D., Chair, NBDS EC*

and dietary supplements, USP's Dietary Supplement Standards Collaborative Group focused on modernizing and developing standards for high-impact dietary supplements including aloe, cranberry ingredients and probiotics.

To help fulfill Resolution XI, which related to increasing its commitment to global public health, USP prioritized monographs for development based partly on input from Brazil, China and India, and USP encouraged the adoption of science-based USP Standards to protect public health in Brazil, China, India and South Korea.

## **Key Activities** in Dietary Supplements and Herbal Medicines

***DSC Online:*** Launched in June 2019, this online-only resource provides an intuitive interface to help users navigate to *DSC* monographs, illustrations, regulatory guidances and reference tools used around the world to address quality in the dietary supplement industry supply chain. The *DSC* features step-by-step procedures and acceptance criteria to help manufacturers and ingredient suppliers demonstrate that their raw materials and finished dietary supplement products meet established specifications for identity, strength, purity, limits for contaminants, packaging and labeling.

**New Dietary Supplement Groups:** USP established the Dietary Supplements Admission Evaluation (DSAE) JS3 to review articles proposed for monograph development. USP also established the Probiotics EP of the NBDS EC to help develop standards for probiotics. In addition, USP began leading and coordinating the Dietary Supplements Quality Collaborative, a multi-stakeholder and cross-sector collaborative aimed at improving the quality and safety of products marketed as dietary supplements by raising awareness on several topics, including adulteration and risks to public health.

**DNA Methods for Botanical and Probiotic Identification:** The USP Project Team on the Botanical Library for DNA-Based Identification selected priority botanicals and provided multiple lots for building a botanical library. This work supported subsequent efforts to explore the development of species-specific, DNA-based methods for botanical identification of closely related species and led to the potential development of new genomic Reference Standards for probiotic strains.

**Green Tea Extracts:** The DSAE JS3 reviewed data on adverse effects, including hepatotoxicity, of green tea extracts. As part of USP's review, it formed the Green Tea Extract Hepatotoxicity (GTEH) EP, which conducted a comprehensive, systematic review on green tea extracts. In February 2020, the GTEH EP published its findings as a peer-reviewed journal article titled "United States Pharmacopeia (USP) Comprehensive Review of the Hepatotoxicity of Green Tea Extracts" in *Toxicology Reports*.

**Cannabis for Medical Purposes:** The Cannabis EP of the BDSHM EC finalized quality parameters for cannabis inflorescence in order to define the identity, composition and limit of contaminants. A manuscript articulating this work was developed to serve as a scientific resource that provides transparent, scientifically validated analytical methods and specifications. In April 2020, the peer-reviewed article entitled "Cannabis Inflorescence for Medical Purposes: USP Considerations for Quality Attributes" was published in the *Journal of Natural Products*. The principles outlined in the review article may serve as the basis of public quality specifications for cannabis inflorescence, which are needed to protect public health and to facilitate scientific research on cannabis safety and therapeutic potential.

**Publications about USP Botanicals Monographs:** In June 2018, the USP Dietary Supplements botanical team published an article, "Quality Specifications for Articles of Botanical Origin from the United States Pharmacopeia," in *Phytomedicine*. This article was developed to increase stakeholder understanding of USP botanical monographs and to help them establish suitable quality control methods for botanicals. In addition, BDSHM EC members and USP staff published an article, "Cinnamon and Cassia Nomenclature Confusion: A Challenge to the Applicability of Clinical Data," in *Clinical Pharmacology & Therapeutics* in September 2018. The article explains how USP standards for cinnamon and cassia can help resolve the ambiguity. BDSHM EC members and USP staff also published an article in *HerbalGram* titled "Quality Standards for Botanicals—The Legacy of USP's 200 Years of Contributions" in June 2020.

**Advocating Use of Public Standards:** USP signed a memorandum of understanding with the Food Safety and Standards Authority of India to support the recent recognition of USP Standards in India's health supplement regulations. In addition, USP encouraged the adoption of science-based USP Standards in Brazil, China and South Korea. Academic, industry and regulatory stakeholders were also engaged in the effort.

**Stakeholder Outreach:** Throughout the cycle, USP has hosted Dietary Supplements Stakeholder Forums for participants to openly discuss issues and share their perspectives on current and future USP

Cycle Highlights:

## DIETARY SUPPLEMENTS AND HERBAL MEDICINES

**97**
New Dietary Supplement Monographs

**15**
New *Herbal Medicines Compendium* Monographs

**29**
Modernized Monographs

**155**
Revised Monographs (includes 5 General Chapter Revisions)

**2**
New General Chapters

**4**
Major General Chapter Revisions

**8**
Roundtables

**6**
Stakeholder Forums

**4**
Workshops



**"The BDSHM EC has been very productive over the 2015–2020 cycle. An improved approach to our process yielded numerous new, revised or modernized monographs. In response to Resolution II, on monograph modernization, we cohosted a qNMR Summit and various roundtables, incorporated new high-performance thin-layer chromatography assays into many botanical monographs and founded the Modern Analytical Methods JS with the NBDS and FI ECs. This JS developed the first USP monograph (Choline Citrate) to use a Charged Aerosol Detector method, a qNMR method for Aloe and a flexible monograph (Pyrroloquinoline Quinone Disodium), allowing a choice of IR or NMR for identification. With the Green Tea Extract Hepatotoxicity EP, we completed and published a highly impactful comprehensive review with causality assessment and risk mitigation recommendations. PERHAPS MOST SIGNIFICANTLY, OUR CANNABIS EP FINALIZED QUALITY PARAMETERS FOR CANNABIS INFLORESCENCE IN ORDER TO DEFINE THE IDENTITY, COMPOSITION AND LIMIT OF CONTAMINANTS. THIS WAS PUBLISHED OPEN-ACCESS IN THE *JOURNAL OF NATURAL PRODUCTS*."**

*— Robin Marles, Ph.D., Chair, BDSHM EC*

standards-setting efforts. In May 2019, attendees discussed high-impact topics related to the quality of supplements, including hemp standards, pesticide residue limits, food allergen testing, probiotics and chewable gels ("gummies").

### Top EC Achievements

The following BDSHM and NBDS EC Chairs picked their EC's top achievements over the 2015–2020 cycle:

**Dr. Robin Marles, Chair of the BDSHM EC, said he is proud that the BDSHM EC:**

- Completed the GTEH EP Report (with members of the DSAE JS3) and successfully submitted it for peer-reviewed publication
- With the Cannabis EP, published a review article on cannabis inflorescence for medical purposes, with extensive online supplementary information, in the *Journal of Natural Products*
- Formed the Modern Analytical Methods JS as a key outcome of 1) increased emphasis on the CoE Collaborative Group approach to common challenges among ECs and 2) responsiveness to Resolution II on *USP–NF* monograph modernization

**Dr. Dennis Gorecki, Chair of the NBDS EC, said he is proud that the NBDS EC:**

- Established a Probiotics EP charged with developing standards for probiotics; related activities include publishing 1) *USP* General Chapter <64> *Probiotic Tests*, 2) seven monographs for various probiotic strains (and four others to be submitted to *PF*) and 3) "Improving End-User Trust in the Quality of Commercial Probiotic Products" in *Frontiers in Microbiology*, a leading peer-reviewed journal
- Collaborated with the BDSHM EC to establish the Dietary Supplements and Herbal Medicines Nomenclature JS and DSAE JS3; developed a common monograph review process with USP Scientific Liaisons; facilitated collaboration with the FI EC; and established the Thomas S. Foster Award, a volunteer-driven process that recognizes the efforts of an individual Expert Volunteer in an EC, Subcommittee, JS, JS3 or EP
- Identified gummies as a new dosage form and published associated monographs and performance standards, and developed and published *USP* General Chapter <2251> *Screening for Undeclared Drugs and Drug Analogues*

# EXCIPIENTS

USP's Excipient Monographs 1 and 2 (EM1 and EM2) ECs continually update excipient monographs and general chapters by introducing modern analytical techniques that help establish specifications for excipients as well as their components and impurities. These ECs help 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 good manufacturing practices (GMPs).

## **USP Resolution-Related Activities** in Excipients

Throughout the 2015–2020 cycle, USP's Excipient ECs were committed to fulfilling Resolutions II, III and IV, which called for up-to-date, globally harmonized standards and strengthened quality systems to benefit all stakeholders. Their work updating excipient monographs and general chapters has helped to ensure that excipients are fit for purpose and that they address potential threats from quality deficiencies that may arise in the absence of appropriate GMPs and the complexities of global supply chains that could otherwise elevate the risk of adulteration.

## **Key Activities** in Excipients

**New Excipient Monograph Titles:** The Excipient Nomenclature JS has been key to the excipients Up-to-Date initiative, excipient naming and development of the framework for the *Nomenclature Guidelines for Excipients*. The JS worked to develop a *Stimuli* article that explains how to develop official nomenclature for polymeric excipients, which are often used in specialized drug delivery systems such as biologic and parenteral drug products. The guideline aligns with the current thinking on naming individual product-based substances as defined in the FDA's draft guidance on using its Inactive Ingredient Database.

**Consequential Standards:** Work continued on consequential standards development, including standards for 1) organic and elemental impurities, 2) supplier qualification, 3) excipient performance, 4) high-use excipients such as glycerin, talc and lactose, and 5) novel excipients, key components in the development of safer and more therapeutically effective drugs.

**Novel Excipients:** USP staff fielded a novel excipients survey in February–March 2019. The online survey explored the views of more than 260 respondents who formulate medicines—or supervised others who formulate medicines—on the current state of excipient innovation. USP staff presented a summary of the survey results at the USP Excipient Stakeholder forum meeting at USP–U.S., Rockville, MD, in November 2019 and published the survey results in the June 2020 issue of *Pharmaceutical Technology*.

**Stakeholder Outreach:** USP staff attended international conferences throughout the cycle, delivering posters and presentations that focused on the value of 1) setting meaningful compendial specifications, 2) excipient composition and impurities, 3) performance, 4) variability, 5) modernizing monographs, 6) harmonizing quality standards for excipients, 7) developing better methodologies by utilization of advanced technologies to characterize excipients, 8) establishing guidelines for nomenclature and 9) an independent regulatory review pathway for novel excipients. Stakeholder engagement activities included excipients presentations at the 1) Excipient World Conference and Expo in National Harbor, MD; 2) International Pharmaceutical Excipients Council (IPEC) roundtable meeting in Shanghai, China; 3) International Symposium on the Critical Importance of Excipients in Drug Development in Seoul, South Korea; 4) ExcipientFest Asia meetings in Beijing, China; 5) International Association for Pharmaceutical Technology-IPEC meetings in Cologne and Frankfurt, Germany; 6) USP Excipients User Forums in Hyderabad and Mumbai, India; 7) Asia Pacific Economic Cooperation User Forums in

USP Excipient ECs worked on 19 excipient monographs identified by FDA as "high priority" for modernization.

The EM1 and EM2 ECs help 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.

Santiago, Chile, and as Center of Excellence hosts in the Philippines, Thailand, Indonesia and Malaysia; 8) USP Excipient Stakeholder Forum meetings at USP–U.S., Rockville; and 9) Farmacopea de los Estados Unidos Mexicanos (FEUM) meeting in Mexico. USP also hosted the following workshops: 1) the Impact of Nomenclature on Excipient Quality, Drug Product Development and Labeling Compliance Workshop in August 2019; 2) the IPEC educational session and poster at ExcipientFest in April 2017; and 3) the FDA-USP Excipients Workshop in February 2017.

**Modernizing High-Priority Excipient Monographs:** USP Excipient ECs worked on 19 excipient monographs identified by FDA as "high priority" for modernization. Issues with nonspecific identification, assay and impurity tests had left these excipients particularly vulnerable to adulteration. USP staff also worked on more than a dozen consequential high-priority excipient monographs and chapters via the Pharmacopeial Discussion Group Work Plan. USP held roundtable meetings, published *Stimuli* articles/revision proposals, and conducted surveys to help inform *USP* General Chapter <1174> *Powder Flow,* as well as Sucrose, Saccharin(s), Lactose(s), Talc, Glycerin and Polysorbate(s) monographs in *PF*. In addition, USP worked directly with pharmacopeias, the World Health Organization (WHO) and other stakeholders to advance and sustain globally harmonized standards. A bilateral harmonization effort between USP and the *Japanese Pharmacopoeia* identified five excipient monographs as "new for development." USP also partnered with WHO and global pharmacopeias to finalize "Good Pharmacopoeial Practices."

**Excipient Composition and Impurities:** The Excipient Impurities JS published a *Stimuli* article in *PF* 44(3) [May–Jun. 2018] titled "The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities."

A survey was launched concurrently to obtain feedback from stakeholders on the idea of developing an informational general chapter numbered above 1000 on excipient composition and impurities. Additionally, the Elemental Impurities JS of the EM1, EM2 and General Chapters–Chemical Analysis ECs collaborated on a draft roadmap proposal for removing seven USP element-specific impurities chapters that are referenced as well as stand-alone elemental impurities tests that are included in excipient monographs.

## Top EC Achievements

The following Excipient Monographs EC Chairs picked their EC's top achievements over the 2015–2020 cycle:

**Dr. Eric Munson, Chair of the EM1 EC, said he is proud that the EM1 EC:**

- Continuously updated the analytical technologies in new and existing monographs and general chapters to reflect modern pharmaceutical development
- Developed strategies in excipient monographs for testing elemental impurities and methods for incorporating historical data into monograph documents
- Conducted stakeholder outreach, including with industry at conferences and with the FDA at working group meetings

**Dr. Kate Houck, Chair of the EM2 EC, said she is proud that the EM2 EC:**

- Worked on performance, nomenclature and impurities issues related to 1) *USP* General Chapter <1059> *Excipient Performance*, 2) Inactive Ingredient Database Guidance and nomenclature alignment and 3) *Stimuli* article on excipient impurity and heavy metal roadmap
- Developed consequential monographs, including Polysorbates and Polyethylene Glycol, updated the Glycerin monograph, added inhalation requirements to the Lactose monograph and improved the assay and impurities in the Sucrose monograph
- Helped establish a Talc EP to determine a method for asbestos testing in *USP* Talc

### Cycle Highlights: EXCIPIENTS

**19**
New Monographs

**34**
Revised Monographs

**89**
Monograph Modernizations

**3**
Major General Chapter Revisions

**4**
*Stimuli* Articles

**6**
Journal Articles

**"As I reflect upon the past five years, I am most proud of the way in which the EC worked together to advance the state of USP excipient monographs. We proactively brought monographs up to date based upon input from USP Scientific Liaisons, EC members and the many stakeholders who provided input into the process, including the FDA, excipient industry and their representatives, and the pharmaceutical industry. Through our EC, USP brings together a broad consensus of opinions that result in quality excipients that help bring lifesaving therapeutics to people."**

*— Eric Munson, Ph.D., Chair, EM1 EC*

# FOOD INGREDIENTS

The Food Ingredients (FI) EC focuses on developing standards for food ingredients 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 dietary and food ingredients.

## **USP Resolution-Related Activities** in Food Ingredients

Throughout the 2015–2020 cycle, the FI EC aspired to be the definitive source of up-to-date science and standards for the quality of food ingredients that protect public health and the integrity of the food supply in accordance with Resolution X, which related to food quality and integrity. Toward those ends, the FI EC worked to identify and address emerging concerns related to new production technologies, new ingredients and a globalized food supply chain. The FI EC has aggressively worked to develop new tools and resources to help detect and prevent food fraud and adulteration, as well as to strengthen its relationships with domestic and international industry and government stakeholders.

## **Key Activities** in Food Ingredients

**Dietary Proteins:** The FI EC's Dietary Proteins EP continued its work on developing, validating and recommending new specifications and analytical tests for dietary proteins. Whey protein concentrate and whey protein isolate were among the prioritized matrices under study. This work supported the creation of new and modernized *FCC* monographs, identity standards, general tests and assays and USP Reference Materials, thereby protecting public health and improving confidence in the global food supply.

The FI EC aspired to be the definitive source of up-to-date science and standards for the quality of food ingredients that protect public health and the integrity of the food supply.

**Food Adulteration:** The FI EC approved the publication of "Guidance on Developing and Validating Non-Targeted Methods for Adulteration Detection." The Food Adulteration EP worked on revising and extending the "Food Fraud Mitigation Guidance," published in the *FCC*. Based on user feedback, the EP focused on the need for tools to identify high-priority ingredients in facilities that use a large number of ingredients, where it would be impractical to complete a full vulnerability assessment for all of the ingredients. The Food Adulteration Hazards Identification EP concluded its work, which resulted in a framework for categorizing food-fraud-related adulterants by their potential health hazard. This framework was used to categorize each adulterant in a Food Fraud Database and to identify those adulterants that pose a health hazard.

**Screening Toolbox:** The FI EC continued its efforts to develop a toolbox of screening methods and Reference Standards from the work of the Non-Targeted Method for Milk Ingredients EP. Earlier in the cycle, USP and the International Dairy Federation (IDF) signed a memorandum of understanding to collaborate on the development, identification, elaboration and dissemination of science-based standards at an international level with an aim to promote the safety, quality and integrity of dairy ingredients. USP's work with IDF included non-targeted methods for detecting adulteration in milk ingredients. Toward that end, the Non-Targeted Methods for Milk Ingredients EP created guidance on developing and validating applicable analytical methods. USP also released authentic and melamine-adulterated Skim Milk Powder Reference Standards and worked on additional adulterant Reference Standards.

**Honey EP:** The FI EC's Honey EP continued its work on developing a honey standard for the U.S. market that would be globally applicable. The EP considered different types of honey, including table honey, industrial honey and honey derived from specific plants and produced in different parts of the world. Authentication of pure honey is important to consumers and processors. Honey is susceptible to adulteration (including full replacement) with cheaper sweeteners as well as with products potentially containing unlawful and unapproved veterinary drug and pesticide residues and adulterants.

**Thanks to the initiatives and willingness of the FI EC and EPs to tackle really tough problems relating to food adulteration, THE USERS OF *FOOD CHEMICALS CODEX* NOW HAVE IDENTITY STANDARDS FOR COMPLEX SUBSTANCES (HONEY, PROTEINS AND OLIVE OILS FOR STARTERS) AND GUIDANCE ON FOOD FRAUD MITIGATION USING TOOLS such as non-targeted methods. The 2015–2020 cycle has been great, and I am proud to have been part of it."**

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

**Olive Oil Authenticity and Quality (OOAQ):** The FI EC approved the OOAQ EP's Identity Standard for Olive Oil, Refined. The EP discussed plans for creating similar identity standards for other olive oil products.

**Stakeholder Outreach:** Throughout the cycle, the Foods Program hosted symposiums and roundtables, including the 3rd International MoniQA Symposium on Food Fraud Prevention and Effective Food Allergen Management on October 30–November 1, 2019, at USP–U.S., Rockville. The program focused on 1) strategies, methods and tools for detecting and combating food fraud; 2) food allergen management tools and analytical methods; and 3) food law, regulatory issues and public standards. Roundtables focused on 1) advancing the tools available to companies and organizations for addressing economically motivated adulteration and other food fraud threats and 2) establishing a framework for developing *FCC* prebiotics standards and applying the framework to advance a draft standard for isomaltooligosaccharides.

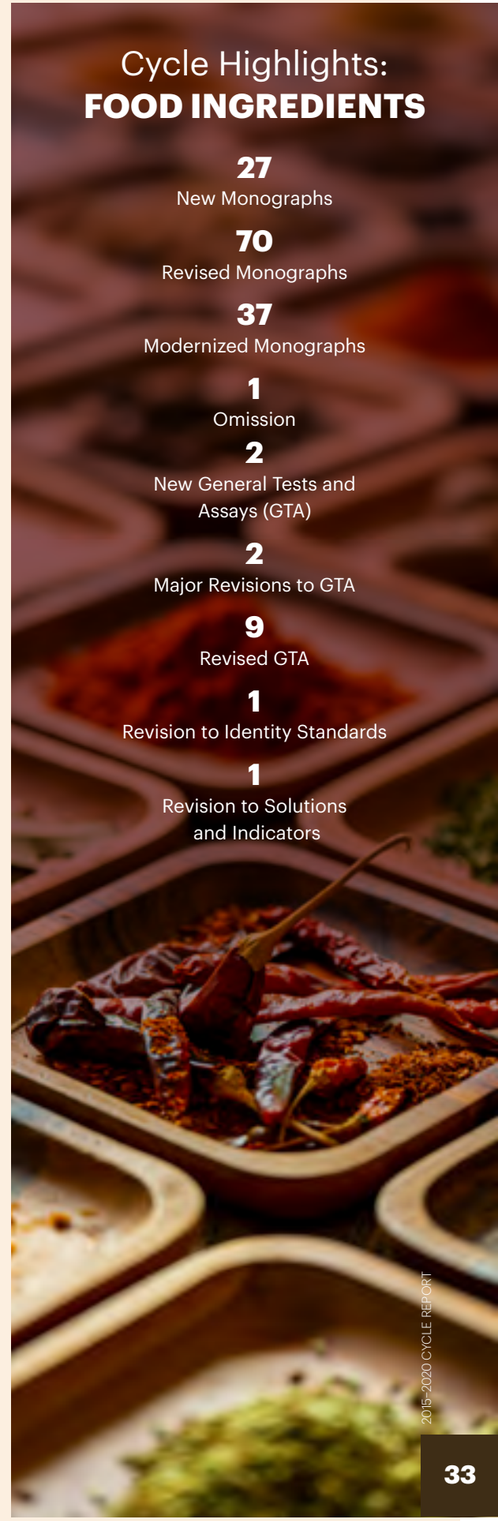
**Collaboration with Codex Alimentarius:** The FI EC continued to collaborate with the Codex Alimentarius Commission and its Committee on Food Import and Export Inspection and Certification Systems to develop a discussion paper on food adulteration. The EC also collaborated with the Codex Committee on Food Hygiene to develop a "Code of Practice for Allergen Management for Food Business Operators."

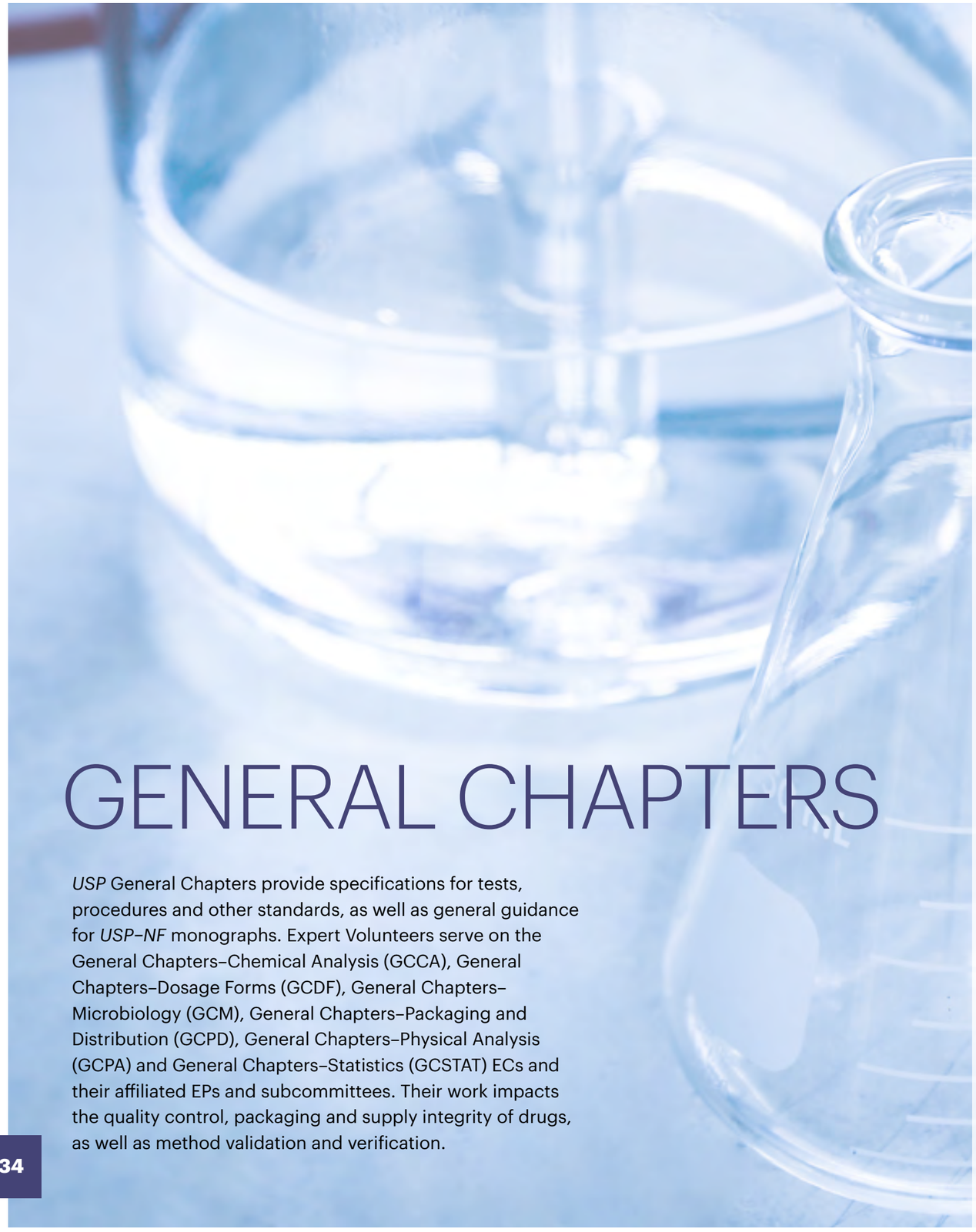
**New Logo:** The *FCC* adopted a new logo as part of the Foods program's work raising awareness about the *FCC* in the international food industry. The new logo is intended to support the Foods program's outreach and education strategy in countries with rapidly modernizing food industries.

## Top EC Achievements

**Dr. Jonathan DeVries, Chair of the FI EC, said he is proud that over the 2015–2020 cycle the FI EC:**

- Introduced identity standards for complex substances into the *FCC,* including Honey, Dietary Proteins and Refined Olive Oil
- Published the "Food Fraud Mitigation Guidance" and completed a Pre-Screening Guide
- Published *FCC* Appendix XVIII: USP Guidance Document on Developing and Validating Non-Targeted Methods for Adulteration Detection





# GENERAL CHAPTERS

*USP* General Chapters provide specifications for tests, procedures and other standards, as well as general guidance for *USP–NF* monographs. Expert Volunteers serve on the General Chapters–Chemical Analysis (GCCA), General Chapters–Dosage Forms (GCDF), General Chapters–Microbiology (GCM), General Chapters–Packaging and Distribution (GCPD), General Chapters–Physical Analysis (GCPA) and General Chapters–Statistics (GCSTAT) ECs and their affiliated EPs and subcommittees. Their work impacts the quality control, packaging and supply integrity of drugs, as well as method validation and verification.



**I am proud of the EC's accomplishments during the 2015–2020 cycle. Besides completing all of the assigned Work Plan, we also published nine new chapters. Several of these chapters received more than 90 comments, which indicates a high level of interest from key stakeholders. In addition, WE HAVE PROACTIVELY ENGAGED IN COLLABORATION WITH OTHER GENERAL CHAPTER ECS, LED THREE JSs AND PARTICIPATED IN FOUR OTHER JSs. Furthermore, we have created five outstanding subcommittees, all of which were empowered to tackle their assigned chapters. This approach not only facilitated efficient discussion and use of volunteer resources, but also created additional opportunities for subcommittee Chairs to further sharpen their leadership skills. Last but not least, Dr. Martin Coffey received the Thomas S. Foster Award for his outstanding contribution to the GCPA EC."** *— Xiaorong He, Ph.D., Chair, GCPA EC*

## **USP Resolution-Related Activities** in General Chapters

Throughout the 2015–2020 cycle, the *USP* General Chapters group was committed to accomplishing multiple Resolutions. Among the many examples, the Validation and Verification EP of the GCCA EC made progress in developing a lifecycle approach to analytical procedures and providing training and assistance to industry, as per Resolution I and Resolution II, which called for collaboration with the FDA and monograph modernization, respectively. *USP* General Chapters helped coordinate harmonization on the conductivity specification for Sterile Water for Injection, in accordance with Resolution III, globally harmonized standards. General Chapters developed a new family of chapters about analytical methodologies based on light-scattering phenomena, in accordance with Resolution V, research and innovation within USP, and Resolution VI, standards for biological medicines.

## **Key Activities** in General Chapters

**Quality Advisory Group Explores the Future of General Chapters:** A Quality Advisory Group was created as part of the development of a comprehensive strategy for the future of general chapters. This group includes thought leaders from the pharmaceutical industry who advise USP by identifying changes in quality paradigms and potential disruptors in a rapidly changing global pharmaceutical manufacturing and regulatory environment. In addition, this group will propose potential pathways to address these changes, thereby maintaining the relevance of USP's standards in the future.

**New Light-Scattering Chapters:** New general chapters were published to complete the entire spectrum of applications of light-scattering methodologies for assessing drug product quality attributes. These standards address many of the product testing requirements introduced in two FDA guidances for industry.

## Cycle Highlights: **GENERAL CHAPTERS**

**56**
New Proposed General Chapters in *PF*

**1**
New Monograph

**60**
Major General Chapter Revisions

**78**
Minor General Chapter Revisions

**15**
Monograph Revisions

**5**
Omissions

**34**
*Stimuli* Articles

**18**
Workshops

**Microbiology:** *USP* General Chapter <60> *Microbiological Examination of Nonsterile Products—Tests for Burkholderia cepacia Complex* became official, providing test methods for detecting *Burkholderia cepacia* complex bacteria that can contaminate aqueous products, overcome preservatives and cause infections. In addition, *USP* General Chapter <1071> *Rapid Microbial Tests for Release of Sterile Short-Life Products: A Risk-Based Approach* was published to help safeguard public health by providing rapid sterility test methods for short-shelf-life products that require prompt administration.

**Statistics:** The GCSTAT EC revised and balloted *USP* General Chapter <1010> *Analytical Data—Interpretation and Treatment*. The EC also began revising the USP bioassay suite of general chapters to include additional examples and explanations of bioassay development and analysis. The GCSTAT EC developed *USP* General Chapter <1210> *Statistical Tools for Procedure Validation*, a companion to *USP* General Chapter <1225> *Validation of Compendial Procedures*, which discusses aspects to consider before validations, as well as how to establish analytical performance characteristics of accuracy, precision and limit of detection. In addition, the Content Uniformity for Large Sample Sizes JS published a *Stimuli* article that extended the features of *USP* General Chapter <905> *Uniformity of Dosage Units* to larger sample sizes.

**Analytical Procedure Lifecycle:** The Analytical Procedure Lifecycle EP of the GCCA EC began finalizing the proposed new *USP* General Chapter <1220> *The Analytical Procedure Lifecycle*. In addition, the Validation and Verification EP of the GCCA EC wrote several *Stimuli* articles about the analytical procedure lifecycle. One recent paper focused on a proposal for a new informational general chapter numbered above 1000 that defines useful concepts and more fully addresses the entire procedure lifecycle. *USP* General Chapters was involved in the revision of International Conference on Harmonisation (ICH) Q2 Analytical Validation Guidance and the creation of a new ICH Q14 Guideline on Analytical Procedure Development.

**Advancements in Product Performance Testing:** The New Advancements in Product Performance Testing EP of the GCDF EC was formed to provide recommendations for evaluating and adopting product performance tests and for developing innovative approaches to novel dosage forms.

**THE LANDSCAPE OF DATA ANALYSIS CONTINUINGLY GROWS EVER MORE COMPLEX. In the context of new analytical tools and novel biological phenomena, the GCSTAT EC has continued its tradition of promoting advancement in and implementation of sound statistical methodology."**

*— Robert Singer, M.S., Chair, GCSTAT EC*

**Continuous Manufacturing:** A Pharmaceutical Continuous Manufacturing EP was formed with industry experts and members of the GCCA, GCDF and GCPA ECs. The multi-disciplinary EP developed a *Stimuli* article on the impact that continuous manufacturing will have on the future of drug product manufacturing, the existing regulatory framework and the regulatory expectations for continuous manufacturing. The article also helped standardize the definitions and terms used in pharmaceutical continuous manufacturing and outlined how risk management in pharmaceutical continuous manufacturing differs from batch manufacturing.

**Instrumental Method of Color Determination:** A *Stimuli* article developed by GCPA Solutions Subcommittee members proposed adding an instrumental method of color determination to *USP* General Chapter <631> *Color and Achromicity* to reflect available new technologies. The article, published in *PF* 44(4) [Jul.–Aug. 2018], is a step toward modernizing visual appearance assessments using quantitative instrumental methods.

**Stakeholder Outreach:** The *USP* General Chapters group continued to explore integrating newly tested technologies into documentary standards. To help meet this goal, the group held workshops to foster an environment conducive to examining innovative ideas. For example, the Computer Modeling—In Vitro and In Vivo Studies Workshop, held in October 2017 at USP–U.S., Rockville, allowed regulators, industry and academia to discuss the use of computer modeling and simulation to accelerate product development and reduce costs. In addition, the JS on Nanotechnology co-sponsored the Nanomedicines—Technical and Regulatory Perspectives Workshop at USP–U.S., Rockville, in March 2017.

## Top EC Achievements

The following General Chapters EC Chairs picked their EC's top achievements over the 2015–2020 cycle:

**Dr. James De Muth, Chair of the GCDF EC, said he is proud that the GCDF EC:**

- Reviewed and/or updated all of the chapters in the EC Work Plan
- Updated and/or omitted chapters and monographs
- Developed new chapters, including *USP* General Chapters

The work of Expert Volunteers impacts the quality control, packaging and supply integrity of drugs, as well as method validation and verification.

# GENERAL CHAPTERS

Throughout the 2015–2020 cycle, the *USP* General Chapters group was committed to accomplishing multiple Resolutions.

> **I'm proudest of the synergy of a great team of volunteers who worked tirelessly over the last cycle to accomplish the designated Work Plan and TO ADVANCE PUBLIC STANDARDS FOR THE QUALITY OF FINISHED PHARMACEUTICALS."**
>
> *— James De Muth, Ph.D., Chair, GCDF EC*

<607> *Pharmaceutical Foams—Product Quality Tests,* <1001> *In Vitro Release Test Methods for Parenteral Drug Preparations* and <1153> *Drug Products Containing Nanomaterials*

**Dr. Mary Foster, Chair, GCPD EC, said she is proud that the GCPD EC:**

- Updated packaging standards to address patient risk related to the leaching of chemical compounds from packaging material and systems
- Expanded distribution chapters to address the common risks associated with the storage and distribution of finished drug products
- Updated glass and elastomer standards to include new materials being used throughout the pharmaceutical industry

**Dr. Xiaorong He, Chair, GCPA EC, said she is proud that the GCPA EC:**

- Made an impact by developing new chapters, major revisions and harmonized chapters
- Delegated assignments and empowered Expert Volunteers to lead
- Established connections with other ECs

**Dr. David Hussong, Chair, GCM EC, said he is proud that the GCM EC:**

- Published *USP* General Chapter <1071>
- Published *USP* General Chapter <60>
- Published *USP* General Chapter <1085> *Guidelines on Endotoxins Test*

**Ms. Nancy Lewen, Chair, GCCA EC, said she is proud that the GCCA EC:**

- Published the *Stimuli* article titled "USP Perspective for Pharmaceutical Continuous Manufacturing"
- Developed a new suite of general chapters on analytical methodologies based on scattering phenomena
- Proposed the Total Organic Carbon Limit in the Sterile Water for Injection monograph based on roundtable discussion

**Mr. Robert Singer, Chair, GCSTAT EC, said he is proud that the GCSTAT EC:**

- Revised *USP* General Chapters <1010>, <1032> *Design and Development of Biological Assays,* <1033> *Biological Assay Validation* and <1210>
- Published four *Stimuli* articles
- Supported EPs and JSs

> **The accomplishment I'm most proud of for the 2015–2020 cycle is the way THE EC WORKED TIRELESSLY TO PROVIDE THE BEST POSSIBLE USP STANDARDS ACROSS ALL TOPICS FOR WHICH THE EC WAS RESPONSIBLE. Always focused on patient safety and mindful of potential impacts on the industry, the members of the GCCA EC presented the best in professionalism, dedication and commitment to good science, as did USP staff, without whose tireless support the EC's activities would not have been possible. Many new approaches to providing meaningful analytical solutions were established. I was truly proud of the GCCA EC's cumulative efforts throughout the last cycle."**
>
> *— Nancy Lewen, Chair, GCCA EC*

# HEALTHCARE QUALITY AND SAFETY

General Chapter <800> offers consistent standards to help protect approximately 8 million U.S. healthcare workers.

Expert Volunteers serve on the Healthcare Quality and Safety (HQS) EC, Nomenclature and Labeling (NL) EC, Compounding (CMP) EC, related EPs and subcommittees. Their work effectuates patient-centered approaches to safe and effective medicine use, naming and labeling standards for drug products and ingredients, the handling of hazardous drugs and the quality of compounded preparations. Together, these groups help build the safety net across the drug industry and healthcare system. Not only do they provide standards for what goes into a medicine and how it is named and labeled, but their standards also help ensure that once the medicine is in the hands of a healthcare team, it is prepared and handled safely. In addition, their standards for clear prescription labeling help patients take their medicines correctly so they can improve and protect their health.

## **USP Resolution-Related Activities** in Healthcare Quality and Safety

Throughout the 2015–2020 cycle, the HQS, NL and CMP ECs, as well as related EPs and subcommittees, worked to fulfill Resolutions VII and VIII, which called for quality standards for compounded medicines and healthcare, respectively.

## **Key Activities** in Healthcare Quality and Safety

**Compounding Appeals:** On June 1, 2019, USP published significant revisions to *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations,* and published the new *USP* General Chapter <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging.* After publication, USP received appeals on certain provisions in these chapters. Many volunteers were involved in handling these complex and historic appeals, which focused primarily on the beyond-use-date (BUD) provisions in <795> and <797>. As part of the USP appeals process, the CMP EC and the Chemical Medicines Monographs 4 EC (supported by the <825> EP) were the first groups to consider and decide on the issues raised. Four appellants requested further review by an appointed panel charged with considering the sufficiency of the process used by the respective ECs to develop

**THE LAST CYCLE HAS BEEN FULL OF REWARD, PROGRESS, BOLD NEW THINKING AND UNPRECEDENTED CHALLENGES.** I am proud to have been shoulder to shoulder with my brilliant and dedicated volunteer colleagues and talented USP staff in raising the bar for quality compounding standards."

*— Gigi Davidson, R.Ph., Chair, CMP EC*

Their work effectuates patient-centered approaches to safe and effective medicine use, naming and labeling standards for drug products and ingredients, the handling of hazardous drugs and the quality of compounded preparations.

and approve the chapters under appeal. This set of appeals marked the first time in USP history that formal appeals hearings were held before an appointed panel. For further information about these appeals, including a summary of the issues raised and the decisions made, please visit https://www.usp.org/compounding/compounding-appeals.

**Handling Hazardous Drugs:** To prepare stakeholders for the implementation of *USP* General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings,* USP delivered live courses on this topic, launched a six-and-a-half-hour e-learning course and published a comprehensive Frequently Asked Questions page on USP.org. General Chapter <800> offers consistent standards to help protect approximately 8 million U.S. healthcare workers and promote patient safety and environmental protection by minimizing hazardous drug exposure, avoiding unintended and repeated exposures and reducing the potential for adverse consequences.

**Opioids:** The HQS EC's Opioids/Naloxone Subcommittee continued its work on developing labeling, storage, disposal and counseling standards to help reduce opioid abuse. Earlier in the cycle, the Subcommittee, in collaboration with the USP Opioids Team, worked closely with stakeholders through roundtables and discussion forums to identify standards that may help improve patient safety in regard to the therapeutic use of opioids and naloxone.

**Labeling:** The NL EC worked to change the strength expression for Epinephrine Injection, Isoproterenol Hydrochloride Injection and Neostigmine Methylsulfate Injection products from a ratio to mg/mL. The use of ratios as an expression of drug concentration has been a source of administration errors. This standard became official in May 2016 to coincide with *USP* General Chapter <1> *Injections and Implanted Drug Products (Parenterals)—Product Quality Tests* and General Notices changes. The NL EC also worked to clarify the expiration date format. *USP* General Chapter <7> *Labeling* now provides a standardized format for year, month and day in numeric and alphanumeric formats. This change impacts all prescription drug products and OTC drug products, as well as dietary supplements that adhere to USP monographs. The revision was completed in 2020 and has an official date of September 1, 2023. Other revisions include the addition of labeling standards for animal drug products, providing formats for expressing units of measure and clarifying the use of abbreviations in labeling. In FY 2017, the HQS EC removed the teaspoon definition from *USP–NF* and added metric dosing for oral solutions to *USP* General Chapter <17> *Prescription Container Labeling* to help patients understand how to take their medications.

**Patient Safety:** More than 150 experts from around the world attended USP's inaugural Workshop on the Evolution and Advances in Compounding in May 2018 at USP–U.S., Rockville. Participants discussed the quality of compounding practices and medicines as well as standardizing compounded medicines to improve patient safety.

**Drug Allergy:** The Drug Allergy and Intolerance Classification EP of the HQS EC continued its work on mapping drug products for specified classes. The goal of this

classification is to help reduce preventable medication errors associated with patients' allergies and intolerance to medications. Earlier in the cycle, the EP defined an initial set of drugs associated with about 80% of allergies documented in patient records. The EP created classes and assigned drug codes to support electronic health record documentation.

**Parenteral Nutrition:** The HQS EC's Parenteral Nutrition Safety EP continued its work on a draft general chapter on standards for safe use of parenteral nutrition. The EP also proposed a plan to inform and meaningfully engage external experts and other stakeholders before publishing the proposed chapter for public comment.

**Drug Classification:** The HQS EC published Medicare Model Guidelines (MMG) Version 7.0 and Version 8.0 to address the current needs of Medicare Part D beneficiaries. This included updating USP Categories and Classes and adding newly covered Part D drugs under a collaborative agreement with the Centers for Medicare & Medicaid Services. USP also published an independent classification system in response to stakeholder input that it would be helpful to have a classification system beyond MMG. USP Drug Classification (USP DC) includes drugs outside of the Part D benefit and is updated annually.

**Top EC Achievements**

The following EC Chairs picked their EC's top achievements over the 2015–2020 cycle:

**Dr. Dennis Doherty, Chair of the HQS EC, said he is proud that the HQS EC:**

- Accomplished its work on the USP DC 2018, 2019 and 2020, and completed MMG Version 8.0
- Developed a proposed new general chapter addressing parenteral nutrition
- Successfully convened the Exchange of Compounded Drug Preparation Information in Health IT Systems EP to 1) develop compounded preparation interoperability across healthcare settings and 2) minimize medication errors from electronic prescription transmissions
- Convened the inaugural USP Informatics Workshop to showcase the expanding digital architecture in healthcare

Cycle Highlights:

## HEALTHCARE QUALITY AND SAFETY

**46**
New Monographs

**25**
Monograph Revisions

**2**
New General Chapters

**3**
Major General Chapter Revisions

**14**
Minor General Chapter Revisions

**5**
Omissions

**Dr. Stephanie Crawford, Chair of the NL EC, said she is proud that the NL EC:**

- Approved numerous monograph titles, including drug products (human and animal), drug substances, dietary supplements, compounded preparations, biologics and radiopharmaceuticals
- Reviewed and updated *Nomenclature Guidelines* and revised General Chapter <7>
- Continually developed and reviewed pronunciations of hundreds of drugs, drug substances, biologics and other entities as part of the Pronunciation Project

**Ms. Gigi Davidson, Chair of the CMP EC, said she is proud that the CMP EC:**

- Broadened stakeholder input into standards development, including outreach to radiopharmaceutical practitioners and allergenic extract and dermatologist prescribers
- Aligned and finalized significant revisions of General Chapters <795>, <797> and <800>
- Revised/modernized existing, and developed new, compounded preparation monographs
- Developed operational documents, decision trees and recommendations for healthcare stakeholders to rapidly adapt to drug and supply shortages during the COVID-19 pandemic



# OUR EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

# EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Nagarajan A, EP
Ana C. Abba, EC
Jibril Abdus-Samad, EC, EP
Grant Abernethy, EP
Eileen Abt, EP
Lopa Adhikary, EP
James Agalloco, EC
Amit Agarwal, EP
Rajiv Agarwal, EC, JS3
David Aguero, EP
Francisco Aguilar-Parrilla, EP
Mohammed K. Ahmed, EC
Emmanuel Akala, EC
Samuel Akapo, EC
James Akers, EC, EP
Michael Akers, EP
Ilgaz Akseli, EC, EP
Mahmoud Al Omari, EC
Mehrshid Alai, EC, EP
Timothy Albertson, EC
Dale Aldrich, EC, EP
Ali Al-Hakim, EP
Ali Mohammed Alhomaidan, EC
Shaukat Ali, EC, EP
Ahmad Almaya, EP
Abdullah Almohizea, EP
Ali M. Alsamil, EC
Gregory Amidon, EP
Nicolas Amiot, EP
Valerie Amspacher, EC
Jan Amstrup, EP
Gennady Ananchenko, EC
Om Anand, EP
Shalini Anand, EC
Christopher Anderson, EC, EP
Edwin Anderson, EP
Kristen Anderson, EC
Tania Andrade, EP
Pascal Anger, CoE, EC, EP
Benny Antony, EP
Fernando Antunes Lopes, EP
Marcus Araujo, EP
Juan Arciniega, EC
Saurabh Arora, EP
Vathani Arudchandran, EP
Wilfried Arz, EC, EP, JS3
Dilip Ashtekar, EC
Lisa Diggs Ashworth, EC
Yves Aubin, EP
Bianca Avramovitch, EC, JS3
Jane Axelrad, EC
Phil Ayers, EC, EP
John Ayres, EP
Parastoo Azadi, EC, JS3
Cynthia Bach, EP
Steven Baertschi, EP
Nana Bafi-Yeboa, EC, JS3
Danial Baker, EC, EP
Mary Baker, EC, EP
Douglas Ball, EP
Milton Ballard, EC, EP
Janet Balson, EC
Stephen Barat, EP
Amy Barker, EC
Matthew Barlow, EC, EP
David Barnes, EP
Kimber Barnett, EP
Julie Barrows, EC
Irene Bartoli, EP
Charles Barton, EP
Gus Bassani, EC
Jacinta Batson, EP
Steven R. Bauer, EP
Gregory Beck, EC, EP
Wolfgang Beck, EC
Christian Becker, EC
Gudrun Beckh, EP
Klaus Beckmann, EP
Tim Begley, EP
William Beierschmitt, EP
Robert Bell, EC, EP, JS3
Luca Benetti, EP
Anthony Bennett, EP
Corinne Bensimon, EP
Dan Berdovich, EP
Marti Bergana, EP
Svetlana Bergelson, EC, EP
James Bergum, EP
Eden Bermingham, EC, EP
Francesco Berti, EP
Maria Leticia Bertot, EP
Denise Bestwick, EP
Joseph Betz, EC, EP, JS3
Anthony Bevilacqua, EC, EP
Eric Beyssac, EP
Mahesh Bhalgat, EC
Sneh Bhandari, EP
Ashwinkumar Bhirde, EP
Shun Bi, EP
Alberto Biavati, EP
Lynn Blessing, EC
Richard Blessing, CoE, EC
Lawrence Block, EC, EP, JS3
Andrew Bluj, EC
Barbara Blum, EC, EP
Elizabeth Bobo, EP
Jeffrey Bodycomb, EP
Judy P. Boehlert, EP
Denise Bohrer, EP
Allan Bokser, EC
Seamus Boland, EC
David Bolliet, EP
Bettine Boltres, EC, EP
James R. Bond, EP
Thierry Bonnevay, EP
Jeri Ann Boose, EP
Dawn Boothe, EC
Vicky Borders-Hemphill, EC
Matthew Borer, EC, EP, JS3
Jon Borman, EP
Phil Borman, EP
Carlos Bortolotto, EP
Bruno Boulanger, EC
Joseph Boullata, EP
Heather Boux, EC, EP
Peter Bouza, EC
Marie-Eve Boyte, EP
Cindy Brach, EP
Mike Bradley, EC, EP
Glaucia Karime Braga, EC, EP
Jonathan Bray, EC
Thomas Brendler, EC
Michael Brent, EC, EP
Randolph Breton, EP
Michael Brewer, EC
Josef Brinckmann, EC
Adrian Bristow, EC, EP, JS3
Thomas Broadbent, EC
James Brodack, EP
James Brooks, EC, EP
Daniel Brown, EC
Janice Brown, EP
Lew Brown, EP
Paula Brown, EC, EP
Susan Brown, EP
Riekert Bruinink, EC
Lana Bruney, EC, EP
Christopher Bryant, EP
Robert Buehler, EP
Lucinda Buhse, EP
Robert Buice, EC, EP
Berit Hansen Bundgaard, EP
Richard Burdick, EC
Christopher Burgess, EC, EP
Pierre Burguiere, EP
Matthew Burke, EP
Chris Burns, EC, EP, JS3
Emilia Byrne, EP
Frances Byrne, EP
Sandra Caballero, EP
Tim Cabelka, EC, EP, JS3
Susan Cady, EC, EP
Chunsheng Cai, EP
Hong Cai, EC
Teresa Cain, EP
Angela Calderon, EC, JS3
Courtney Callis, EP
Robert Cambron, EC, EP
Tura Camilli, EC
Cristiana Campa, EP
Richard Cantrill, EC, EP
Ishan Capila, EP
Jack Cappozzo, EP
Thiago Cardoso Carvalho, EC, EP
Elizabeth (Betsy) Cariello, EC
Brian Carlin, EC, EP
Tage Carlson, EP
Geoff Carr, EC, EP
Jeffery Carrico, EC, EP
Frederic Carriere, EC, EP
Spencer Carter, EP
William Carter, EP
Peggy Casanova, EP
Steven Casper, EC, EP, JS3
Christophe Cavin, EP
Richard Neil Cawthorne, EC
Juan Cerdan-Diaz, EP
Wiley Chambers, EP
Chris Chandler, EC, EP
Audrey Chang, EP
Jane Chang, EC, EP
Richard Chang, EC
Yuan-Shiun Chang, EP
Pierre Chantal, EP
Coleman Chasteen, EP
Gaurav Chauhan, EP
Joseph Chebli, EP
Feng Chen, EP
John Chen, EP
Junshi Chen, EC
Pei Chen, EP
Shilin Chen, EP
Hwei-Fang Cheng, EC, EP
Roy Cherris, EP
Edward Chess, CoE, EC, EP, JS3
Albert Cheung, EP
Anissa Cheung, EC, EP
Kimberly Cheung, EP
Venkatesan Chidambaram, EP
Henry Chin, EC, EP
Grady Chism, EC
M. Shahabuddin K. Choudhuri, EP
Dilip Choudhury, EP
Stefan Christians, EC
Donna Christner, EC, EP
David Christopher, EC
Ian Chung, EC
Shan Chung, EP
Robin Churchill, EC, EP
Scott Ciarkowski, EP
Mary Lee Ciolkowski, EP
John Cipollo, EP
Peter Claessens, EP
David Claffey, EC
Severine Clavier, EP
Roger Clemens, EC
Lucia Clontz, EP
John Clos, EC

# EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Martin Coffey, EC, EP
Michael Cohen, EC
Ewart Cole, EP
Maegen Colehour, EP
Gregory Connelly, EP
John Connelly, EP
Thomas Connor, EP
Nicole Cook, EP
Maggie Coombs, EC
Charlotte Corbett, EP
Frank Corniello, EP
Diane Demichele Cousins, EC
Carrie Coutant, EP
Daniel Crane, EP
Stephanie Crawford, CoE, EC, EP
Richard Creekmore, EC, EP
Bryan Crist, EP
Jill Crouse-Zeineddini, EC, EP
Celia Cruz, EP
Anthony Cundell, EC, EP
Paul Curry, EC, EP
Kevin Dahl, EP
Joan Dalla Riva Toma, EP
Mukul Dalvi, EC
Deirdre D'Arcy, EP
Mike Darj, EC, EP
Helen Darling, EC, EP
Debashis Das, EC
Nila Das, EP
Vivek Dave, EC
Gigi Davidson, CoE, EC
Cindy Davis, EP
Terry Davis, EP
Swapan De, EC, EP
Josep Maria de Ciurana Gay, EC
Michael De Felippis, CoE, EC
James De Muth, CoE, EC, EP
Matthew Decan, EC
Mark Decerbo, EC, EP
Lowri Dejager, EP
Francette Delaloge, EP
Barthelemy Demeule, EC, EP
Sheila Deneau, EC, JS3
Claudio Denoya, EP
Steven Dentali, EC, EP
Allegra Depietro, EP
Ian F. Deveau, EC
Radhika Devraj, EP
Jonathan DeVries, CoE, EC, EP
Lawrence Deyton, EP
Frank Diana, EP
Natalia Diaz, EP
Thomas Difeo, EC, EP
Michelle Dillahunt, EC
Shulin Ding, EC
Weibing Ding, EP
Maryna Dmitriieva, EP
Phong Do, EP
D.J. Doan, EC
Elizabeth Chen Dodson, EP
Dennis Doherty, CoE, EC, EP
Julie Dohm, EC
John Dolan, EC, EP
Gay Dolin, EP
Zedong Dong, EC
Jinhui Dou, EC, JS3
Gerard Downey, EP
Melanie Downs, EP
Simona Dragan, EC
Jason Dreabit, EC
Sheila Dreher-Lesnick, EC, EP
Gary du Moulin, EP
Alain Duguet, EC
John Duguid, EP
Ian Duncan, EP
Francis Dwulet, EP
Michael Eakins, EC, EP
Andrew Ebert, EC, EP
Ruth Ebiasah, EC
Chaim Eidelman, EC
Edmund Elder, EC
Lutz Elflein, EP
Christopher Elkins, EP
Stephen Ellison, EP
Jama Elmi, EC
Mahmoud A. ElSohly, EP
Doreen Elston, EP
Sytze Elzinga, EP
Stephanie Emory, EC, EP
Tina Engel, EC, EP
Erika Englund, EC
Natalia Epshtein, EC
Okponanabofa Eradiri, EC
David Erickson, EP
Joachim Ermer, EP
Ofelia Espejo Gonzalez, EP
Cory Evans, EC, EP
William Evans, EP
Jaap Evers, EC, EP
Mirella Ezban, EC
Raafat Fahmy, EC, EP
Anna Fan, EP
David Fay, CoE, EC, EP
Enrique Fefer, EP
Shirley Feld, EP
Facundo Fernandez, EP
Stephanie Ferrari, EP
Elizabeth Igne Ferreira, EC
Marina Feschenko, EP
Gregory Fieldson, EP
David Fillar, EP
Michele Fiscella, EP
Adam Fisher, EC, EP
Sean Fitzgerald, EP
Jonathan Fitzsimmons, EP
Jeffrey Fleitman, EC, EP
Edward Fletcher, EC, EP
Carol Rea Flynn, EP
Daniel Folmer, EC, EP
Ryan Forrey, EC
Mary Foster, CoE, EC, EP
Nikoletta Fotaki, EP
Joe Fotso, EP
Bruce Fowler, EC, EP
Eleanor Freeman, EP
Tim Freeman, EC, EP
Carl Frey, EC, EP
Rick Friedman, EC
Olaf Friedrich, EP
Jacob Froehlich, EC
Roland Froetschl, EP
Christophe Fuerer, EP
Michael Furness, EC, EP
Leslie Furr, EC
Bernhard Fussnegger, EP
Stefan Gafner, EC
Sunil Gairola, EP
Wendy Galbraith, EP
Christopher Galliford, EC
Umesh Gangadharmath, EP
Sushil Gangwal, EC
Boyan Gao, EP
Quanyin Gao, EC
Zongming Gao, EC, EP
Norberto Garcia, EP
Thomas Garcia, EP
Diego Garcia Gonzalez, EP
Samuel Gardner, EP
Fred Gattas, EP
Ben Gauthier, EP
Olivier Germay, EP
Annick Gervais, EP
Luigi Ghidorsi, EP
Michael Ghobrial, EC
Mary Ghods, EC, EP
Mohamed Ghorab, EC, EP
Tapash Ghosh, EC, EP
Devinder Gill, EP
Gurpreet Gill-Sangha, EC
Timothy Gilmor, EC
Michel Girard, EC
Patrick Giraudeau, EP
Lucy Gisonni-Lex, EP
Joseph Glajch, EC, EP
Peter Glassman, EC
Jill Glosson, EP
Jennifer Gogley, EC
Yuri Goldberg, EC
David Goldfarb, EC, EP
Lillie Golson, EC, EP
Anne Gondran, EP
Thomas Gonyon, EP
Carmen Gonzalez, EC
Mario Gonzalez, EC, EP
David Good, EP
Jennifer Goode, EP
Dennis Gorecki, CoE, EC, EP, JS3
Edisa Gozun, EC
Catherine Graeff, EP
Rebekah Granger, EP
Gyongyi Gratzl, EC, EP
Elaine Gray, EC, EP, JS3
Vivian Gray, EC, EP
Damon Green, EC, EP
Richard Green, EP
Chris Grinnell, EP
Ernest Groman, EP
Geoffrey Grove, EP
Joerg Gruenwald, EC, JS3
Emanuel Guadagnino, EP
Dana Guazzo, EC, EP
Marco Guerrini, EP
Roy Guharoy, EC, EP
Dennis Guilfoyle, EC
Claudia Guillaume, EP
Maya Guncheva, EP
Mickey Eugene Gunter, EP
Dean Guo, EC, EP, JS3
Yin Guo, EP
Rajesh Gupta, EC, EP
Kathleen Gura, EP
Bill Gurley, EC, EP, JS3
Felicitas Guth, EC
Colleen Guthrie, EC
Saul Gylys, EP
Linan Ha, EC
Gerhard Haas, EC, EP
Morten Hach, EC, EP
Jonathan Hache, EP
Daniel Haines, EP
Takashi Hakamatsuka, EP
Einat Haleva, EC, EP, JS3
Richard Hall, EP
Tom Hall, EP
William Hallett, EC
Don Halterman, EP
Blake Hamann, EC
Thomas Hämmerle, EP
John Hammond, EC, EP
Faye Han, EP
Jian-Hwa Han, EP
Bruno Hancock, EC, EP
Sukhdev Handa, EC, EP, JS3
Anthony Hanlon, EP
Martin Hansen, EP
Swarna Hapuarachchi, EP
Humcha Hariprakasha, EC, EP
James Harnly, EC, EP, JS3

# EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Peter Harrington, EP
Bruce Harris, EP
Danielle Harris, EC
Philip Haselberger, EP
James Hathcock, EP
Walter Hauck, EP
Karen Hauda, EC
Douglas Hauke, EP
Robert Hausam, EP
Douglas Hausner, EP
Kan He, EP
Lijuan He, EC
Luhong He, EP
Xiaorong He, CoE, EC, EP
John Heaney, EP
Ralph Heasley, EC
Mohammad Heidaran, EC
James Heimbach, EP
William Heller, EP
Philippe Henry, EP
Mark Henson, EP
Andre Hermans, EP
John Herries, EC, JS3
Linda Herzog, EP
William Hess, EC, EP
Anthony Hickey, EC
Jana Hildreth, EP
Gordon Craig Hill, EP
John Hinshaw, EC, EP
Monica Hirschhorn, EP
Stephen Hoag, EC, EP
Hank Hoang, EP
Elizabeth Hobbs, EP
Jeffrey Hofer, EP
Lauren Hoffman, EP
Raymond Hohl, EC
Steve Holroyd, EP
Susan Homire, EC
Xiaoxu Hong, EP
Moshe Honick, EC, EP
David Hopp, EC, JS3
Michael Hornig, EP
Christopher Hosty, EP
Kate Houck, CoE, EC, EP
Michael Houghton, EC
Deborah Houston, EC, EP
Keith Howard, EP
Yong Hu, EC
Gloria Huang, EC
Xiao Ping Huang, EP
Mario Hubert, EC
Deborah Huck-Jones, EC
Christopher Hudalla, EP
Laura Huffman, EC, EP
Ruud Hulspas, EP
Gregory Hunter, EC, EP
Robert Hunter, EP
Latiff Hussain, EC
Munir Hussain, EC, EP
Stephen Hussey, EP
David Hussong, CoE, EC, EP
Mai Huynh, EC
Kim Huynh-Ba, CoE, EC, EP
Chung Hyun, EC
Ronald Iacocca, EP
John Iannone, EP
Robert Iser, EP
Qamrul Islam, EC
Gregory Israelson, EP
Karthik Iyer, EC, EP
Rupa Iyer, EC
Joseph Jablonski, EP
Scott Jackson, EP
Steven Jacobs, EP
Thomas Jacques, EP
Monika Jain, EC
Michael Jankowski, EP
Vincent Jannin, EP
Renaud Janssen, EC, EP
Edwin Jao, EC, EP
Sastry Jatavallabhula, EP
Arya Jayatilaka, EC, EP
Eric Jayjock, EP
Dennis Jenke, EC, EP
Matthew Jenkins, EP
Brenda Jensen, EC, EP
Gerard Jensen, EP
Keith Jensen, EP
Anne Jespersen, EC, EP, JS3
Benjamin Jeyaretnam, EP
Young Jhon, EC
Shen Ji, EP
Kristian Johansen, EP
Bruce Johnson, EP
Holly Johnson, EP
Kent Johnson, EC, EP
Philip Johnson, EP
Claude Jolicoeur, EP
Chris Jones, EC, EP
Jacquin Jones, EC, EP
Michael Jones, EP
Scott Jordan, EC, EP, JS3
Joy Joseph, EC, EP
Jose Juarez, EP
Felix Montero Julian, EP
Eliangiringa Kaale, EP
Balaji Kadri, EP
Ravi Kalyanaraman, EP
Mahendra Kapoor, EP
Amy Karren, CoE, EC
Dhanalakshmi Kasi, EC
Ravindra Kasliwal, EC, EP
Eric Kastango, EP
Greg Kaster, EC, JS3
C.K. Katiyar, EP
Joseph Katzenmeyer, EP
John Kauffman, EC, EP
Simleen Kaur, EC
Assad Kazeminy, EC, EP
David Keire, EP
Edwin Kellenbach, EP
David Keller, EP
Elizabeth Kelley, EC
Michael Kennedy, EC, EP
Shaun Kennedy, EP
James Kenney, EC, EP
Zohar Kerem, EP
Andrea Kerrigan, EC
Eric Kesslen, EC, EP
Sridevi Khambhampaty, EC
Ikhlas Khan, EC, EP, JS3
Saeed Khan, EC
Johannes Khinast, EP
Surender Khurana, EP
Douglas Kiehl, EC, EP
Patricia Kienle, EC, EP
Loice Kikwai, EC, EP
John Kilbourne, EP
Erin Kim, EC
Yeong Shik Kim, EP
Younsook Cho Kim, EC
Linda Kim-Jung, EC
Kathryn King, EP
Marion King, EC, JS3
Stephen King, EP
Jonathan Kingsbury, EP
Paul Kippax, EP
Heinz Kirchmeyer, EP
Duane Kirking, EC, EP
Robert Klasson, EC
Donald Klein, EC, EP
Sandra Klein, EP
Brent Kleintop, EC, EP
Katrina Klett, EP
Lori Klopf, EC
Richard Ko, EC, EP, JS3
Michael Koberda, EC, EP
Jianmei Kochling, EP
Grace Kocks, EC
Andreas Koerner, EP
Hwee-Ling Koh, EP
Rohit Kolhatkar, EC
Otilia Koo, EC
Anna Kooser, EC
Maxwell Korang-Yeboah, EC
Hemant G. Koshia, EC
Satyanarayana Kota, EP
Pramod Kotwal, EP
Elisabeth Kovacs, EP
Johannes Kraemer, EC, EP
Elizabeth Kramer, EP
Jette Kreiberg, EP
Jens Krogh Rasmussen, EP
Thijs Kroon, EP
Dana Krueger, EC, EP, JS3
Markus Krumme, EP
Scott Kuhns, EP
Prashant Kumar, EP
Jeremy Kunkel, EC, EP
Francisco Kuribrena, EP
Bogdan Kurtyka, EC
Joseph Kutza, EP
Wilberforce Kwiringira, EP
Kai Kwok, EC
Victoria Kyeyune, EC
Pauline Lacroix, EC, JS3
Michael Laird, EP
Kim Lamey, EP
Richard Lane, EP
Thomas Langdon, EP
Gerd Langenbucher, EP
Stephen Langille, EC, EP
David Lansky, EC, EP
Gregory Larner, EP
Peter Larsson, EC
Clara Lau, EP
David Lau, EC
Ronald Lauback, EP
Devalina Law, EC
Rosilend Lawson, EC
Max Lazar, EP
Jeremy Lebel, EP
Dave LeBlond, EC, EP
Pierre Lebrun, EP
Christina Lee, EP
Hyoung Lee, EP
Kwangmoon Lee, EC
Patricia Lee, EP
Sau Lee, EC, EP
Michele Lees, EP
Russell Leftwich, EP
Philippe Legall, EP
Steven Leinbach, EC, EP
Stefan Leiner, EC, EP
Patrice Leone, EP
Jeffrey Lessman, EP
Ralph Lessor, EP
Nancy Lewen, CoE, EC, EP
David Lewis, EC, EP
Jerome Lewis, EC, EP
Todd Lewis, EC
Hanlin Li, EP
Hongmei Li, EC
Huijuan Li, EC
Jing Li, EC, EP, JS3
Kevin Li, EP
Min Li, EC, JS3
Ping Li, EP

# EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Qing Li, EP
Weijun Li, EP
Xihao Li, EC
Jennifer Q. Liang, EC
June Liang, EC
Catherine Liloia, EP
Judy Lin, EC, EP
Tsai-Lien Lin, EC
Jennifer Lind, EC
Robert Linhardt, EP
Oscar Liu, EC, JS3
Suli Liu, EP
Yang Liu, EP
Rosario Lobrutto, EP
Lye Theng Lock, EP
Paul Lockwood, EP
Raimar Loebenberg, EC, EP
Heather Lombardi, EC
David Long, EC, EP
Michelle Long, EP
William Long, EC
Michael Longmire, EP
Archie Lovatt, EP
Raymond Love, EC, EP
Vivian Loveless, EP
Tieraona Low Dog, EC, EP, JS3
Xujin Lu, EP
Zhengfei Lu, EP
George Lunn, EC
Shuangcheng Ma, EP
Wendy Mach, EC, EP
Leeann Machiesky, EP
Andrew Mackey, EP
Donald MacLean, EC
Bhawanishankar Madhira, EP
Russell Madsen, EC, EP
Robert Magaletta, EP
Paul Mahan, EP
Patrick Mahn, EP
Edward Malawer, EP
Amir Malek, EC, EP
Dan Malinowski, EC
Annarapu Malleswarareddy, EC, EP
Brad Mangrum, EP
Rezaul Mannan, EP
Jaime Marach, EP
Robin Marles, CoE, EC, EP, JS3
Oneka Marriott, EC, EP
Ewa Marszal, EC, EP
Gregory Martin, EC, EP
Jerold Martin, EP
Vikki Martin, EC
Marilyn Martinez, EP
Nuno Matos, EC, EP
John Mauger, EC, EP
Russell Maus, EC
Joan May, EC, EP
Robert Mayer, EC
Lori McCaig, EC, EP
Anne McCasland-Keller, EP
Robert McClure, EP
Diane McColl, EC, EP
Karen McCullough, EC
Amy McDaniel, EP
Melissa McDiarmid, EP
Gerald McEvoy, EP
Timothy McGovern, EP
Pauline McGregor, EC, EP
Kevin McLean, EP
Ken Mead, EP
Jeffrey Medwid, EC, EP
Juris Meija, EC
Jeremy Melanson, EP
Randa Melhem, EC
Armen Melikian, EC
Robert Mello, EC
Phil Merrell, EC
John William Metcalfe, EC
Richard Meury, EC, EP
Marian Meyer, EC
Steven Meyerhoffer, EP
Aurelie Mieze-Richard, EP
Michel Mikhail, EP
Frank Milek, EP
Yana Mille, EC, EP
Kenneth Miller, EC, EP
Michael Miller, EP
Paul Miller, EP
Sara Miller, EP
Colin Minchom, EC
Beth Minter, EC
Anthony Mire-Sluis, EC, EP
Mishale Mistry, EP
Brian Mitchell, EP
Jolyon Mitchell, EC
Amit Mitra, EP
Ashim Mitra, EP
Ranjan Mitra, EP
Anjan Mittal, EP
Toru Miura, EP
William Mixon, EC
Jingjie Mo, EP
Sanja Modric, EP
Adil Mohammad, EP
Ganapathy Mohan, EP
Rosalynn Molden, EP
Dominic Moore, EC
Richard Moreton, EC, EP, JS3
Roger Moroney, EP
Cynthia Morris-Kukoski, EP
Magdi Mossoba, EP
Diane Mould, EP
Laura Moussa, EC
Ned Mozier, EC, EP, JS3
Michael Mulkerrin, CoE, EC
Matthew Mullarney, EC, EP
Pierre-Alain Muller, EC, EP
Barbara Mulloy, EP
Eric Munson, CoE, EC
Andrew Murphy, EC
Kelly Murphy, EP
Leanne Murray, EP
Jasmine Musakhanian, EC, EP
John Musil, EC
Fernando Muzzio, EP
Richard Myers, EC, EP, JS3
Dattatraya Naik, EP
Prabu Nambiar, EC, EP
Jose Napolitano, EP
Hari Narayanan, EP
Linda Narhi, EP
Tanja Natterer, EP
Mirtha Navarro, EC
Victor Navarro, EP
James Neal-Kababick, EC, EP, JS3
Karunakar Neelam, EC, EP
Sesha Neervannan, EP
Michael Nelson, EP
Phil Nethercote, EC, EP
Mariann Neverovitch, EC
David Newton, EC, EP
Paul Newton, EP
Juliet Nguyen, EP
Richard Nguyen, EC, JS3
Nina Ni, EC, EP
Neal Nichols, EP
Cornelia Nickenig, EP
Søren Kåre Nielsen, EC
Brian Niland, EC
Ishai Nir, EP
Pallavi Nithyanandan, EC, EP
Patrick Noland, EC, EP
Anna Nordin, EP
Scott Norris, EC
Daniel Norwood, EC, EP
Rachel Novak, EC
Jasmina Novakovic, EC, JS3
Adrian Nunn, EP
Lars Nygaard, EP
Sarai Obando, EC
Thomas O'Connor, EP
Dominik Odenbach, EC
Kevin O'Donnell, EP
Steven Oh, EC
Anthony Okinczyc, EC
Bernard Olsen, CoE, EC, EP
Raphael Ornaf, EC, JS3
Todd Osiek, EP
Robert Osterberg, EC, EP
Andrea Ottesen, EC
Mikhail Ovanesov, EP
Veena Pai Raiker, EP
Mary Paine, EP
Pilar Pais, EC, EP
Devinder Pal, EC, EP
Anthony Palmieri, EP
Marco Pane, EC, EP
Mark Papich, EC, EP
Ajay Parashar, EC
Bhavin Parekh, EP
Ernest Parente, CoE, EC, EP
Jose Parisi, EP
Ruth Parker, EP
Jonathan Parks, EC
Bruna Parma, EP
Alan Parr, EC, EP
Richard Parrish, EP
Donald Parsons, EC
Diane Paskiet, EC, EP
George Patani, EP
Dhananjay Patankar, EC, JS3
Ashvin Patel, EP
Brij Patel, EP
Kuldip Patel, EP
Tejal Patel, EP
Jennifer Patro, EC
Guido Pauli, EC, JS3
Venkateswara Pavuluri, EC
Anitra Payne, EP
Justin Pennington, EC
Ginette Pepper, EC, EP
Deborah Perfetto, EC
Carl Perini, EP
Frank Perrella, EC
Ben Perston, EP
Joseph Perz, EC
Kent Peterson, EP
Naidu Petla, EC
Matthew Pfefferkorn, EP
Erika Pfeiler, EC
Melissa Phillips, EP
Julie Pier, EC, EP
David Pipes, EP
Stacey Platzer, EP
Laura Pogue, EP
Martha Polovich, EP
Luisa Fernanda Ponce De Leon, EP
James Ponto, EC, EP
Guirag Poochikian, EC
Bert Pöpping, EC, EP
Cisse Porsby, EP
Reto Portmann, EP
Jean-Marc Poudrel, EC
Tammy Powell, EP
Luci Power, EP
Seth Powsner, EP
Lee Poye, EP
Rajan Pragani, EC, JS3

# EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Narasimha Prasad, EP
Jessica Priem, EC
Nicole Provost, EC, EP
Robert Przygoda, EP
Chetan Pujara, EC, EP
Jianwei Qin, EP
Zhihao Peter Qiu, EC
Anisul Quadir, EC
Oscar Quattrocchi, EC, EP
Krishnaswamy Raghavan, EP
Nausheen Rahman, EP
Ziyaur Rahman, EC
Kimberly Rains, EP
Natarajan Rajagopalan, EP
Radhika Rajagopalan, EC
Sundaram Ramachandran, EP
Bala Ramanathan, EP
Karthik Ramani, EP
Muthukumar Ramaswamy, EC
Vijaya Ramesh, EC
William Randolph, EP
Sam Raney, EP
Marilene Rangel, EP
Michael Rankin, EP
Ashutosh Rao, EC, EP
Pradyumna Rao, EP
Rao Rapaka, EP
Neil Ravenscroft, EP
Andre Raw, EP
G. Joseph Ray, EP
Elizabeth Read, EC, EP
Shahnaz Read, EC, EP
Elizabeth Rebello, EC
Gaby Reckzuegel, EP
David Reed, EC
Bhagwant Rege, EC
Eike Reich, EC
Cindy Reid, EC
Marcus Reidenberg, EC, EP
Lars Reimann, EP
Thomas Reinders, EC, EP
Veronika Reisinger, EP
Gurvinder Singh Rekhi, EC
Volker Rekowski, EP
James Rice, EC, EP
Peter J. Rice, EC, JS3
Sarah Richer, EP
Steven Richter, EP
Cynthia Rider, EP
Anthony Ridgway, EC
Peter Rigsby, EC
Marian Rinken, EP
Dean Ripple, EP
Syed Rizvi, EP
Jennifer Roark, EP
Scott Roberts, EP
George Robinson, EP
Helmut Rockstroh, EC, EP
Harold Rode, EC, EP, JS3
Jason Rodriguez, EP
Amy Roe, EC, EP, JS3
Holger Roehl, EP
David Roesti, EC, EP
David Rogers, EC, EP
Jeff Rohrer, EC, EP
Agusti Jordi Romero, EP
Roman Romero Gonzalez, EP
Thomas Rosanske, EC
Steffen Rosen, EP
Kara George Rosenker, EC
William Rosenthal, EP
Bruno Rossi, EP
Abby Roth, EC
Sara Rothman, EC, EP
Michael Ruberto, EP
Raimon Rubires, EC
Gwen Rucker, EC, EP
N. Lee Rucker, EP
Allen Rudman, EC
Andrew Rugaiganisa, EP
Steve Rumbelow, EC, EP
Tracy A. Rupp, EC
Marcia Rusjan, EP
Ethan Russo, EP
Martin Rutstein, EP
Melody Ryan, EC, EP
Jack Saad, EP
Shobhan Sabnis, EC
Gordon Sacks, EP
Wendy Saffell-Clemmer, EC, EP
Masahiro Sakagami, EC, EP
Iffaaz Salahudeen, EC, JS3
Matthew Sanchez, EP
Dennis Sandell, EC, EP
Mary Ellen Sanders, EP
Maria Ines Santoro, EC, JS3
Camilla Santos, EP
Leandro Santos, EP
Luisa Saraiva, EP
Murugan Saravanan, EC
R.D. Satzger, EC, EP
Zuben Sauna, EC, EP
Anita Sawyer, EP
Melissa Schaefer, EC
Maureen Schanck, EP
Silke Schepelmann, EP
Dieter Scherer, EC
Emmanuel Scheubel, EP
Martin Schiestl, EP
Paul Schiff, EC
Jennifer Schimmel, EC
Deborah Schmiel, EC
Jean Schoeni, EC, EP
Timothy Schofield, EC, EP
Peter Scholl, EP
David Schuck, EC
Michael Schuemann, EP
Joanne Schwartzberg, EC, EP
Jeff Schwartzenhauer, EC
Stephan Schwarzinger, EP
Mark Schweitzer, EC, EP
Joseph Scimeca, EP
Myke Scoggins, EC, EP
Suzanne Sechen, EC
Robert Seevers, EC, EP
Alan Segrave, EP
Mary Seibel, EC, EP
Donna Seibert, EC
Mauricio Seigelchifer, EC, EP
David Seres, EP
Barbara Serr, EC
John Shabushnig, EC, EP
Hamid Shafiei, EC
Millie Shah, EC
Rakhi Shah, EC, EP
Vivek Shah, EP
Balajee Shanmugam, EC
Maged Sharaf, EC
David Sharknas, EP
Chandana Sharma, EP
Hemant Kumar Sharma, EC
Vaneet Sharma, EP
Steven Shaw, EP
Nadine Shehab, EC
Eric Sheinin, EC
Rakesh Shekhawat, EP
Timothy Shelbourn, EC, EP
Meiyu Shen, EC
Xiaobin Shen, EC
Shangmei Shi, EC, EP
Zhenqi Shi, EP
Hiroko Shibata, EP
Judy Shimoni, EP
Nilesh Shinde, EC
Deborah Shnek, EP
Ed Shneyvas, EP
Robert Shrewsbury, EC
Zachary Shriver, EC, EP
Akhtar Siddiqui, EC
Roger Simonds, EP
Donald Singer, EC
Robert Singer, CoE, EC, EP
Hameraj Singh, EC, JS3
Satish Singh, EP
Mark Skasko, EC
William Skea, EP
Michael Skibic, EC
Raymond Skwierczynski, EC, EP
Rostyslaw Slabicky, EC, EP
Alexa Smith, EP
Angele Smith, EC
Patricia Sokol, EC, EP
Glenn Sokoloski, EP
Fabio Soldati, EC, EP, JS3
Teri Soli, EC, EP
Brian Solow, EP
Aniko Solyom, EC
Cynthia Sommers, EC
Perceval Sondag, EP
Fenhong Song, EC
Haowei Song, EP
Dan Sorensen, EC, EP
Varley Sousa, EP
John Spink, EP
Shelly Spiro, EP
Jan Srbek, EC
Charudharshini Srinivasan, EP
Jannavi Srinivasan, EC, EP
Ved Srivastava, EC
Buffy Stahl, EP
Linda Starr-Spires, EP
Richard Stebbings, EP
Nomi Steen, EP
Ralf Stegmann, EP
Robert Steininger, EP
Dennis Stephens, EC
Andy Stergachis, EP
Benjamin Stevens, EC, JS3
Marla Stevens-Riley, EC
Jonathan Stewart, EC
Paul Stinavage, EC
Erika Stippler, EC
Ann Stohlman, EC, EP
Joseph Stowell, EC
Seth Strawbridge, EP
Greg Strossman, EP
Charity Strothers, EP
Dirk Stueber, EP
Cheryl Stults, EC, EP
Jason Suggett, EC, EP
Naoki Sugimoto, EP
Karunakar Sukuru, EC
Connie Sullivan, EC, EP
Darryl Sullivan, EC, EP
Calvin Sun, EC, EP
Huimin Sun, EC
Yichun Sun, EC
Zhigang Sun, EC, EP
Teresa Surowy, EP
D. Robert Sutherland, EP
Colleen Sutton, EP
Scott V.W. Sutton, EC, EP
Kalavati Suvarna, EC
Aleksander Swietlow, EC
Kelly Swinney, EP
Jennifer Swisher, EP
Kevin Swiss, EC, EP
Frank Switzer, EC

# EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Ami Fazlin Syed Mohamed, EP
Christina Szabo, EC, EP
Mary Szorik, EP
Neeru Takiar, EC, EP
Philippe Talaga, EP
Ajay Taluja, EC
Cecilia Tami, EC
Charles Tan, EC
Neeraj Tandon, EP
Thomas Tarantelli, EP
William Taraszewski, EC
Carmen Tartera, EP
Kelly Taylor, EP
J. Russell Teagarden, EC, EP
Max Tejada, EP
Monica Tejwani, EC, EP
Allen Templeton, EC, EP
Kailas Thakker, EP
Colleen Thomas, EC
David Thomas, EP
Jennifer Thomas, EP
Rene Thuermer, EP
Joern Thyme, EP
Thomas Tice, EC, EP
Edward Tidswell, EC, EP
Stephen Tindal, EP
Kristina Toliver, EP
Gary Tomaino, EP
Jacqueline Tordik, EC
Pearle Torralba, EP
Viet Hung Tran, EP
Giordano Trazzi, EC
Michael Trehy, EC
Keith Trettin, EP
Bernhardt Trout, EP
Yiying Tsai, EC, EP
Tony Tse, EP
Jiasheng Tu, EC, EP
Danny Tuck, EC
Saleh Turujman, EC, EP
Jeanne Tuttle, EC, EP
Katherine Tyner, EC
Yoko Uematsu, EC, EP
Katherine Ulman, EP
Roy Upton, EP
Sumathi V Rao, EC
Patrick Vallano, EP
Kevin Van Cott, EP
Edwin van den Heuvel, EC
Mark van Ooij, EP
Drew Van Orden, EP
Saskia van Ruth, EP
Glenn Vanbuskirk, EP
Peter Vandeberg, EC
Maureen Vander Fliet, EP
Yvan Vander Heyden, EP
Martin Vanderlaan, EC
Christina Vegge, EP
Harika Vemula, EP
Ubrani Venkataram, EP
Michael Verlander, EC, EP
Charles Vesey, EC
Allison Vidimos, EC
Alex Viehmann, EC
Kathy Vieson, EP
Ofelia Villalva-Rojas, EP
Claudia Vincenzi, EC
Luciano Virgili, EC
Ram Vishwakarma, EP
Christian Viskov, EC, EP
Gordon Vrdoljak, EP
Nicole Vu, EP
Madhusudan Vudathala, EP
Matthias Wacker, EP
James Wagner, EC, EP
Amy Walia, EP
Donald Walker, EP
Michael Walsh, EP
Reinhard Walter, CoE, EC
Fengqiang Wang, EP
Hailin Wang, EC, EP
Hu Wang, EP
Lili Wang, EP
Selina Wang, EP
Weihong Wang, EP
Xiaoping Wang, EC
Yan Wang, EC
Yuchang Wang, EP
Yun Wang, EP
Yuwen Wang, EP
Zhenyu Wang, EC
Terri Warholak, EC
Anne Warner, EP
Kevin Warner, EC, EP
John Watts, EP
Andrew Waye, EP
Edward Waysek, EC
Kara Weatherman, EP
James Webber, EP
Darin Weber, EC
Gregory Webster, EP
Paul Wehling, EP
Vera Weinstein, EP
Caroline R. Weinstein-Oppenheimer, EP
William Weiss, EP
Jane Weitzel, EC, EP
Eloise Helen Welfare, EC, EP
Richard Wendt, EC, JS3
Eric Wenger, EP
Dennis West, EP
Thomas Wheat, EP
Kylen Whitaker, EC, EP
John Whyte, EC
Tobias Wiezorek, EP
John Willenbrock, EP
Zeena Williams, EC
Martin Williamson, EC, EP, JS3
Benjamin Wilson, EP
Scott Wilson, EP
Carl Winter, EP
Bert Wognum, EP
Stefanie Wohlrab, EP
Allison Wolf, EP
Steve Wolfgang, EC, EP
Ken Wong, EP
Surapote Wongyai, EP
Jeffrey Woodruff, EP
Gillian Woollett, EC
Wesley Workman, CoE, EC, EP, JS3
Pat Worthington, EP
Timothy Wozniak, CoE, EC, EP
Bingyuan Wu, EC
Chao Wu, EP
Di Wu, EP
Fan Wu, EC, EP
Fang Wu, EP
Geoffrey Kuangshi Wu, EC
Larisa Wu, EP
Wanying Wu, EP
Yongning Wu, EC, EP, JS3
Dale Wurster, EC, EP
Joshua Wurzer, EP
Jo Wyeth, EC
Min Xia, EC
Li Xiong, EC, EP
Hao Xu, EP
Renliang Xu, EP
Xiaoming Xu, EC
Sam Yaghmour, EP
Betsy Yakes, EP
Joseph Yakupkovic, EC
Ryan Yamagata, EP
Teruhide Yamaguchi, EC
Bing-Shiou Yang, EC
Harry Yang, EC
Jinchuan Yang, EP
Jingyue Yang, EC, EP
Timothy Yasika, EC
Patrick Yat, EC
Mehran Yazdanian, EC
Sri Rama Krishnaiah Yellela, EC
Lynn Yeoman, EP
Hsiang Shonna Yin, EC, EP
Lisa Yoest, EP
Gao Yonghua, EC, EP
Stephen Young, EP
Xavier Ysern, EC
Kate Yu, EP
Liangli Yu, EC
Yaozuo Yuan, EC
Brenda Yuzdepski, EC
Earl Zablackis, EC, EP
Stanislav Zakharkin, EP
Steven Zbylut, EP
Lingmin Zeng, EP
Jonathan Zeszotarski, EP
Geoff Zhang, EC, EP
Jin Zhang, EC, EP
Jingwei Zhang, EP
Ying Zhang, EP
Yongqiang Zhang, EP
Jin Zhao, EC, EP
Yiwei Zhao, EP
Zhongzhen Zhao, EP
Hong Zhou, EP
Wei Zhu, EP
Steve Zigler, EC, EP
Yuda Zong, EC, EP
Anthony Zook, EP
Peng Zou, EC
Joerg Zuercher, EP
Susan Zuk, EP
Neal Zupec, EP