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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 Our efforts since 2015 have eliminated outdated techniques and ensured that hazardous chemicals are identified and removed from processes.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 program—our science and standards—are 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 worldwide to more than 120 countries. 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 pharmaceutical products. 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 risk evaluation 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 ways that support capability building, increased scientific connectivity and enhanced programmatic relevance, as well as being 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 standards that we recommend and save lives. Increased collaborations, enhanced engagements and diverse voices through USP’s various 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 that are in the pipeline; 2) digital therapies, including traditional and next-generation 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 industry thought leaders, to help us navigate potential disruptors in the global pharmaceutical manufacturing and regulatory environment. This group is working on 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 volunteer model experience. We will pilot a more agile and flexible volunteer model for engaging stakeholders, allowing them to commit 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.

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

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LETTER FROM THE CHAIR

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

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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 United States and around the world. Just providing quality assurance for medicines, foods and dietary supplements is not enough. Our standards have a ripple effect on public health, supporting the public health response to the COVID-19 pandemic. We have worked closely 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.

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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.

**FOSTERING COLLABORATION**

**USP GOVERNING BODIES AND RELATED GROUPS**

<table>
<thead>
<tr>
<th>BOARD OF TRUSTEES (BoT)</th>
<th>USP CONVENTION</th>
<th>COUNCIL OF EXPERTS (CoE)</th>
<th>VOLUNTEER GROUPS UNDER CoE</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 MEMBERS elected by USP Convention, the Past Convention President, 3 at-large members appointed by the BoT, and the USP CEO, responsible for:</td>
<td>493 ORGANIZATIONS invited by Council of the Convention and BoT, responsible for:</td>
<td>25 CHAIRS of USP Expert Committees (ECs) elected by USP Convention, plus the USP Chief Science Officer who serves as CoE Chair, responsible for:</td>
<td>ECs</td>
</tr>
<tr>
<td>▶ Resolutions that guide USP policies and initiatives</td>
<td>▶ Adoption of USP policies and initiatives</td>
<td>▶ USP scientific and standards-setting decisions</td>
<td>Scientific experts who create, revise, review and approve standards for a specific topic area. Each is appointed for a five-year term.</td>
</tr>
<tr>
<td>▶ USP’s policies</td>
<td>▶ Adoption of USP policies and initiatives</td>
<td>▶ Standards-setting work of USP’s volunteer scientific expert groups</td>
<td>EPs</td>
</tr>
<tr>
<td>▶ USP’s finances</td>
<td>▶ Election of BoT and CoE</td>
<td>▶ Adherence to direction set forth by BoT and USP Convention</td>
<td>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.</td>
</tr>
<tr>
<td>▶ USP’s strategic direction</td>
<td></td>
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<td>JS3s</td>
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<td>Representatives from ECs who serve on subcommittees formed to address issues that affect multiple standards-setting areas.</td>
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**USP STAFF:** Support and shepherd the work of all governing bodies and related groups

**2015–2020 CYCLE AT A GLANCE**

**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 CYCLE BALLOTED AND APPROVED STANDARDS BY THE NUMBERS***

<table>
<thead>
<tr>
<th>707 Ballots</th>
<th>3,185 Items Balloted</th>
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<tbody>
<tr>
<td>1,948 New or Revised Documentary Standards Approved</td>
<td>710 Modernized Documentary Standards Approved</td>
</tr>
<tr>
<td>380 USP–NF, FCC and Supplements Standards Omitted</td>
<td>2,288 Reference Standard R&amp;C Lots Released</td>
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<tr>
<td>577 Reference Standard F Lots Released</td>
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*July 1, 2015, through May 1, 2020*
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:

**2015–2020 CYCLE REPORT**

**CoE KEY ACTIVITIES AND ACCOMPLISHMENTS**

**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 JSIs 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 with drug application and remove duplicative information from key general chapters. In addition, significant progress was made in identifying a sustainable model for engaging volunteers and leveraging their time and expertise in the next cycle. The GNs Advisory Group to help navigate potential disruptors in the global pharmaceutical manufacturing and regulatory environment and to help maintain the relevance of USP 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 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 model for engaging volunteers and leveraging their time and expertise in the next cycle. The GNs Advisory Group to help navigate potential disruptors in the global pharmaceutical manufacturing and regulatory environment and to help maintain the relevance of USP 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.

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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 <1227> 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...
**Guidance on Fragment Crystalizable Function Assays:**

The Biologics program published a new USP General Chapter (1108) assays to evaluate fragment crystalizable (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 10000 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 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.

**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

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 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.

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**Cycle Highlights:**

**BIOLOGICS**

<table>
<thead>
<tr>
<th>Cycle Highlights</th>
<th>BIOLOGICS</th>
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<tbody>
<tr>
<td><strong>8</strong> New General Chapters</td>
<td><strong>BIOMON</strong></td>
</tr>
<tr>
<td><strong>8</strong> Major General Chapter Revisions</td>
<td><strong>BIO2</strong></td>
</tr>
<tr>
<td><strong>15</strong> Minor General Chapter Revisions</td>
<td><strong>BIO3</strong></td>
</tr>
<tr>
<td><strong>10</strong> New Monographs</td>
<td><strong>BIO1</strong></td>
</tr>
<tr>
<td><strong>10</strong> Modernized Monographs</td>
<td><strong>BIO4</strong></td>
</tr>
<tr>
<td><strong>62</strong> Revised Monographs</td>
<td><strong>BIO5</strong></td>
</tr>
</tbody>
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**THE BIOLOGICS program developed new approaches that focused on performance standards designed for broad applicability throughout the product lifecycle.**
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

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
- 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

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 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.
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

“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
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

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.
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...
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 (DSAFE) 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 DSAFE 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 Phytotherapy. 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 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 policies.
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
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 good manufacturing practices (GMPs).

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 parental 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.

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’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).
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.


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:

- Conducted stakeholder outreach, including with industry at conferences and meetings
- Helped establish a Talc EP to test for asbestos
- Developed strategies in modern pharmaceutical development
- Worked on performance, elemental impurities and impurities in the Sucrose monograph
- Conducted stakeholder outreach, including with industry at conferences and meetings
- Helped establish a Talc EP to determine a method for asbestos testing in USP Talc

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

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

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

Cycle Highlights:

**EXCIPIENTS**

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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.
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
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.

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

Cycle Highlights:

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<td>Stimuli Articles</td>
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<td>Workshops</td>
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The work of Expert Volunteers impacts the quality control, packaging and supply integrity of drugs, as well as method validation and verification.

**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 <107> 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 GCCEC 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 GFCD EC was formed to provide recommendations for evaluating and adopting product performance tests and for developing innovative approaches to novel dosage forms.

**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
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 JSIs

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

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.

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

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 General Chapter <800> offers consistent standards to help protect approximately 8 million U.S. healthcare workers.
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 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 <17>–Parenterals—Product Quality Tests and General Notices changes. The NL EC also worked to clarify the expiration date format. USP General Chapter <17>–Labeling now provides a standardized format for year, month and day in numeric and alphanumerical 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:

• Convened the inaugural USP Informatics Workshop to showcase the expanding digital architecture in healthcare
• 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) to 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

New Monographs: 46
Monograph Revisions: 25
New General Chapters: 2
Major General Chapter Revisions: 3
Minor General Chapter Revisions: 14
Omissions: 5
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
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EXPERT VOLUNTEERS AND GOVERNMENT LIAISONS

Peter Harrington, EP
Bruce Harris, EP
Danielle Harris, EC
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Walter Hauck, EP
Karen Hauda, EC
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Douglas Hausner, EP
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