



Dear Delegates, Observer Representatives and Meeting Attendees:

We were so pleased to see so many of you at the 2015 USP Convention Meeting this past week in Washington, DC.

Here are some highlights of the Convention Meeting to share with your organization.

We stand ready to walk shoulder to shoulder with you in the 2015-2020 cycle. Please contact us at membership@usp.org for additional information.

Nelufar Mohajeri
Director, Member and Professional Relations

USP
AND **YOU**
Shoulder to Shoulder on the Path
to Improve Global Health

Collaboration

Relevance

Quality

Impact





Highlights of the 2015 USP Convention Meeting

▶ **Esteemed Speakers:**

- **U.S. FDA's** Howard Sklamberg reiterated that the FDA works closely with regulators and state boards of pharmacy to adopt USP standards. He also outlined some of USP's programs where engagement with the US FDA has been especially relevant such as:
 - USP-India as a partner to US FDA in working with the Indian pharmaceutical industry.
 - USP's Spectral Library program, monograph modernization efforts, and the use of CD3 technology in combating counterfeit medicines.
 - Collaborations in addressing heparin adulteration, compounding issues, and food safety.

- **AMA's** Robert Wah emphasized the importance of working with USP on quality and safety of drugs, biosimilars, dietary supplements, and herbal medicines. He reminded us that global health is threatened by the prevalence of substandard products and many organizations can work with USP on its important activities to fight counterfeits. As drug cost spiral upward – particularly for biologic – Dr. Wah looks forward to seeing more discussion on this challenging topic.



Highlights of the 2015 USP Convention Meeting

▶ **Esteemed Speakers (continued):**

- **GPhA's** Ralph Neas stressed how the lives of patients and consumers are improved by providing timely access of drugs and medicines. He reminded us that many rely heavily on USP standards to ensure the quality of these products and shared a vision of a future where we all work together to make progress on high-quality, safe biological medicines. He hopes that all people will have access to high quality, safe and beneficial medicines.
- **APhA's** Thomas Menighan reminded us all that APhA promote consumer access and coverage so that pharmacists provide quality patient care and services. He also reminded us that USP has monographs for THC to assist pharmacists in considering medical use.
- **PhRMA's** John Castellani congratulated USP on its historic and global success in ensuring patients have access to high quality medicines and felt encouraged that the Convention Meeting was focused on partnerships and networks. He reminded us that we all have to keep pace with science by joining hands as collaboration is in the patient's interest.



Highlights of the 2015 USP Convention Meeting

▶ **Two Outstanding Panels:**

- Biologics:
- **Global public health** challenges include supply chain insecurity, manufacturers inability to comply, regulatory limits, and lack of pharmaceutical technical expertise. To address these, panelists recommended working through the existing regional platforms, supporting manufacturing sector to produce higher quality meds, and strengthening regulatory capacity. In addition, panelists suggested that vocal advocacy for quality medicines and standards to counter counterfeit and sub-standard medicines around the world must be strengthened. Panelists felt that USP has the capabilities to do more with industry, regulators and academia as it is not just a simple pharmacopeia but an organization that can be a great help to expand technical expertise and competencies.



Highlights of the 2015 USP Convention Meeting

- ▶ **Strategic discussions on USP's future directions in:**
 - USP's Monograph Modernization
 - Biologic Standards
 - Food Standards
 - Dietary Supplements and Herbal Medicines Standards
 - Compounding and Healthcare Quality Standards
 - USP's Engagement with the US FDA
 - USP's Engagement with Stakeholders
 - USP's Engagement with the Next Generation of Volunteers
 - Strengthening Regulatory Systems



Overview of 2015 USP Convention Meeting

▶ **Commonalities discussed:**

- We need to work together for quality patient care.
- Each organization has complimentary perspective. We must collaborate and weave these perspectives together to impact global health.
- USP can serve as a unique convener to bring together perspectives on complimentary capabilities for accelerating care and compliance.
- We also have shared challenges that we can address together.
- Our professions are divided by uncommon goals but we all want to positively impact global health

▶ **Asks:**

- Where are the missions and goals of your organization and USP aligned?
- Where does the day to day work of your organization and USP intersect?
- What are the unmet global health needs that we can collectively address? How can we do that? Why?
- How do we engage in networks of collaborations that are not just bilateral?
- Send us the ideas and help us identify areas where USP can participate in networks.
- Connect with membership@usp.org



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2015-2020 USP Council of Experts

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2015-2020 Resolutions

RESOLUTION 1—COLLABORATION WITH THE U.S. FOOD AND DRUG ADMINISTRATION

USP will increase communication and collaboration with the U.S. Food and Drug Administration (FDA) to promote alignment with FDA's regulatory and scientific policies from the inception of the standards planning and development process. USP will work with FDA, industry, and other stakeholders throughout the process to increase understanding of the regulatory impact of such proposals.

RESOLUTION 2—USP–NF MONOGRAPH MODERNIZATION

USP will meet the needs of U.S. Food and Drug Administration (FDA), industry, and other stakeholders for modern monographs within USP–NF. USP will work to eliminate the existing backlog of monographs in need of modernization and proactively evaluate and update monographs to maintain their relevance given scientific advances and evolving manufacturing and regulatory approaches. USP will work with industry and FDA to explore new strategies for sharing analytical methods and specifications needed to modernize monographs.

RESOLUTION 3—GLOBALLY HARMONIZED STANDARDS

USP will expand its commitment to harmonization of compendial standards by working with pharmacopoeias, the World Health Organization, and other stakeholders to determine optimal ways to advance and sustain globally harmonized standards.

2015-2020 Resolutions

RESOLUTION 4—USP’s QUALITY SYSTEMS

USP will continue strengthening its quality systems to ensure the timely and accurate delivery of public standards. USP will maintain its commitment to implementing a fully integrated, global approach to quality and will monitor its progress against specified metrics and objectives to achieve continuous improvement as measured by USP performance.

RESOLUTION 5—RESEARCH AND INNOVATION WITHIN USP

USP will cultivate a collaborative, robust research and innovation culture that will allow USP to continuously assess new technologies and capabilities relevant to its standards-setting activities, and to identify, prioritize, evaluate and develop new opportunities that further USP’s mission and respond to the needs of its stakeholders.

RESOLUTION 6—STANDARDS FOR BIOLOGICAL MEDICINES

USP will promote alignment with stakeholders to develop quality standards for biological medicines, ensuring that innovation and availability are facilitated and complemented.



2015-2020 Resolutions

RESOLUTION 7—QUALITY STANDARDS FOR COMPOUNDED MEDICINES

USP will continue working with stakeholders to develop and maintain practice and quality standards for sterile and non-sterile compounding. USP will increase the availability of its compounding standards, expand stakeholder engagement and education, and promote adoption of these standards by compounding professionals and regulatory authorities.

RESOLUTION 8—HEALTHCARE QUALITY STANDARDS

USP will collaborate with stakeholders to develop, strengthen, revise, and promote adoption of healthcare quality standards that address quality and safety related to the use of medications and that are of value to patients and practitioners.

RESOLUTION 9—QUALITY STANDARDS FOR DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

USP will expand development of standards for dietary ingredients and dietary supplements, focusing on new and high-impact areas, and engage with stakeholders to promote the awareness and adoption of its standards.



2015-2020 Resolutions

RESOLUTION 10—FOOD QUALITY AND INTEGRITY

USP will continue developing standards to improve the quality and integrity of **foods** and food components, including those used for vulnerable populations, and identify new products and services to meet the needs of stakeholders and increase USP's public health impact.

RESOLUTION 11—USP's GLOBAL PUBLIC HEALTH IMPACT

USP will increase its commitment to global public health by advocating for the use of quality standards around the world, enabling access to relevant standards, and working through global partnerships to strengthen systems that ensure access to quality foods and medicine.



2015-2020 Bylaws

Please note that all proposed amendments to the Bylaws were approved and adopted by the Convention Membership on April 25, 2015.

The 2015-2020 Bylaws will be posted on the USP web site in May 2015.



Additional Information

- ▶ Videos of the 2015 Convention Meeting will be available in May 2015 and a link will be sent to all Member and Observer organizations.
- ▶ Reports of the 2015 Convention Meeting will be at: <http://www.usp.org/2015-convention>
- ▶ Student perspective can be found at Maryam Khazraee's blog: <http://maryamgator.tumblr.com>
- ▶ For more information, contact us at membership@usp.org



2020

CONVENTION
M E E T I N G

See you in 5 years!