



XIII Resolution

Coalition Building

USP will lead and power a stakeholder movement for quality to advance public health and patient safety.

Year 3 Update

The medicines supply chain is complex, so strengthening its resilience to help ensure patients have the quality medicine they need when they need it requires many perspectives, broad expertise, and holistic approaches. Through engagements with the USP Convention, and building and participating in coalitions, USP connects with other leaders around the world to elevate and advance critical conversations that inform strategies, action, and policies to help build a stronger and more resilient medicines supply chain.

Key areas of progress over the past fiscal year include:

USP Convention Sectors – The USP Convention hosted 11 sector meetings during the year, convening members to share updates, receive input, and discuss issues of shared priority. Chaired by leaders in their respective fields and members of the Council of the Convention, sector engagements inform USP’s work and expand its impact.

Highlights include:

- ▶ The Convention’s Innovation Sector launched with a four-part series addressing learnings from COVID-19, 3D printing, digital interoperability, and sustainability in pharmaceutical manufacturing.
- ▶ The Convention’s Excipients Sector launched with a joint meeting held with the Generic Medicines Sector. The sectors discussed the risk of nitrosamines and mitigation strategies.
- ▶ The Dietary Supplements Sector developed a resource – “Choosing Quality: Dietary Supplements – Information for Pharmacists Advising Consumers on Quality Considerations.” The sector continues to collaborate with the Healthcare Practice Sector to distribute the resource to pharmacists and pharmacy students.
- ▶ The USP Convention and FDA released an infographic to help practitioners and patients have informed conversations about the quality of biosimilars. Conceived from dialogue during a Biologics Sector meeting, the resource continues to be distributed widely via Convention Member organization networks and FDA forums.

USP Convention Regional Chapters – The Regional Chapters continued to bring together Convention Members, deepening valuable relationships, sharing best practices, and advancing critical dialogues. Each Chapter is chaired by a member of the Council of the Convention who is a respected leader in medicine quality. Highlights include:

- ▶ The European Regional Chapter launched with 14 Member Organizations representing diverse perspectives, including regulatory authorities, pharmacopeias, practitioners, and manufacturers. The inaugural hybrid meeting addressed supply chain resilience, pharmaceutical environmental sustainability, convergence, managing the reduction of nitrosamines, and opportunities to contribute as an Expert Volunteer.
- ▶ The Asia Pacific Regional Chapter hosted a hybrid meeting in connection with the Asia-Pacific Economic Cooperation (APEC) Medical Product Supply Chain Dialogue. The chapter meeting, which convened 20 organizations from 10 countries, addressed nitrosamines, excipients quality, post-marketing surveillance, substandard and falsified medicines, and pharmaceutical continuous manufacturing around the region.

Asia-Pacific Economic Cooperation

Forum – As part of the U.S.'s 2023 host year activities for the APEC forum, USP and FDA co-sponsored the APEC Medical Product Supply Chain Dialogue in April at USP headquarters in Rockville, MD. The event convened more than 500 stakeholders from 45 countries representing regulatory agencies, industry, academia, nonprofits, and multilateral organizations. The two-day meeting featured knowledge-sharing and dialogue aimed at advancing global supply chain resilience. This included discussion of

public health priorities, the impact of the COVID-19 pandemic, impurities, and resources available to help ensure supply chain security. (See *Collaboration with FDA and Other Stakeholders on Health Priorities Resolution* update.)

Coalitions for a Resilient Supply of

Quality Medicines – USP continues to merge its knowledge, expertise, and capabilities with those of other leading organizations to maximize impact. USP enhanced its role in some coalitions and joined others this year, as follows:

- ▶ For the End Drug Shortages Alliance, comprised of health systems, manufacturers, distributors, and other supply chain stakeholders, USP's Vimala Raghavendran, Vice President of Informatics Product Development, serves as Vice Chair of the Transparency and Redundancy Committee. As part of the alliance, USP hosted a roundtable focused on communications before, during, and after a drug shortage. USP also participated in various rapid response actions, including after the closure of Akorn Pharmaceuticals.
- ▶ The Healthcare Industry Resilience Collaborative, founded by Mayo Clinic and Banner Health, was developed to champion and lead standards and best practices in healthcare supply chain resiliency. Member activities include supply chain mapping and monitoring, resiliency risk assessments, resiliency score carding, and application of resiliency key performance indicators.
- ▶ The Duke-Margolis Supply Chain Consortium was developed to identify effective policy solutions that promote a resilient medicines supply chain with advanced manufacturing capabilities and, ultimately, reduce the frequency and severity of drug shortages.

- ▶ The Alliance for Safe Online Pharmacies (ASOP) is dedicated to addressing the growing public health threat of illegal online drug sellers through strategic efforts around the globe. USP's Carrie Harney, Vice President, U.S. Government and Regulatory Affairs, serves as President of the ASOP Board of Directors.
- ▶ The Alliance for Building Better Medicine is a consortium of U.S.-based advanced pharmaceutical manufacturers and researchers with a mission to reduce the cost of manufacturing pharmaceuticals by using novel chemical and engineering innovations to improve the way critical medicines are made in the U.S.
- ▶ The USP Convention Dietary Supplements Sector and Healthcare Practice Sector will partner with additional organizations to distribute the dietary supplements resource to pharmacists and pharmacy students.
- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit for Medical Products, hosted on USP.org. USP will also work with partners such as ASOP to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ USP will engage Convention Membership in activities for the 2025 – 2030 cycle, including proposed Resolutions and amendments to the Bylaws.

Planned for Remainder of the Cycle

- ▶ The USP Convention will launch its seventh regional chapter, the Sub-Saharan Africa Chapter.

Contact

For additional information on this Resolution, contact Shelley Whiddon at shelley.whiddon@usp.org.