



Resolution

Collaboration with FDA and Other Stakeholders on Health Priorities

USP will continue its commitment to collaboration with FDA, industry, and other stakeholders by identifying shared priorities based on scientific principles and leveraging USP's capabilities to help advance patient safety, public health, innovation, and access to quality medicines.

Year 3 Update

Advancing patient safety and increasing access to quality medicines is as complex as it is critical. To maximize USP's impact in these efforts, the organization continues to prioritize collaboration with diverse stakeholders – including FDA and other global regulators, industry, and healthcare providers – as it works to identify, seek alignment on, and address top priorities. As the global medicines supply chain has grown more complex, and biomedical advancements arrive with greater frequency, USP encounters new challenges and opportunities that benefit from collaboration. Through new and longstanding collaborations, USP has advanced quality and supported a more resilient global medicines supply chain.

Key areas of progress over the past fiscal year include:

Asia-Pacific Economic Cooperation Forum – USP's collaborations with the Asia-Pacific Economic Cooperation (APEC) forum

and FDA resulted in two key stakeholder events during the year.

- ▶ 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 over 500 stakeholders from 45 countries representing regulatory agencies, industry, academia, nonprofits, and multilateral organizations. The two-day meeting featured knowledge-sharing and discussion of topics aimed at advancing global supply chain resilience, including public health priorities, the impact of the COVID-19 pandemic, impurities, and resources available to help ensure supply chain security. The event stemmed from ongoing work of the USP-APEC Center of Excellence for the Medical Product Supply Chain, and USP's service on the Steering Committee of the Global Medical Product Quality and Supply Chain Integrity Priority Work Area,

chaired by FDA. Through the latter efforts, USP was announced in April 2023 as the new host of the APEC Supply Chain Security Toolkit, which now resides permanently on the USP website.

- ▶ In May 2023, the USP-APEC Center of Excellence for Advanced Therapies held a two-day virtual training on chemistry, manufacturing, and control challenges involved in chimeric antigen receptor (CAR) T-cell therapy. FDA and key industry leaders provided insights into the development and manufacturing of CAR T-cell therapy to address knowledge gaps between academia and real-life applications. More than 150 regulators involved in product assessment and registration from APEC economies and other regulatory bodies participated in the webinar and dialogue. The event stemmed from USP's ongoing service on the Steering Committee for the Advanced Therapies Priority Work Area, which is co-led by FDA and the Singapore Health Sciences Authority.

FDA's Drug Competition Action Plan –

USP continued its work supporting FDA's list of Off-Patent, Off-Exclusivity Drugs without an Approved Generic (the OPOE list) under FDA's Drug Competition Action Plan to help increase patient access to important generic drug therapies. Over the past year, USP published five new official monographs associated with five different drug products on the OPOE list in the *U.S. Pharmacopeia-National Formulary (USP–NF)*. Since 2017, USP has developed a total of 19 monographs associated with 18 drug products on the OPOE list.

- ▶ USP established a program to identify and prioritize development of monographs associated with complex generics on the OPOE list and pursued related collaboration with stakeholders.

- ▶ USP's Generics Access Plan website content was expanded to include links to draft monographs proposed in *Pharmaceutical Forum* to further promote development of monographs that would support access to OPOE items.
- ▶ Relationship-building efforts between USP and FDA communications teams led to dissemination of key USP messaging across FDA communications channels, including the agency's Generic Drugs Updates email listserv, which goes to 97,000+ subscribers.

Compounding – USP continued to develop monographs to help ensure the quality of products on FDA's list of bulk drug substances that can be used in compounding drug products. (See *Compounding Resolution* update.)

Partnering for Education – FDA and USP collaborated on several educational efforts to advance key health priorities:

- ▶ Agency subject matter experts participated in multiple USP-organized events during the year – including those focused on cell and gene therapies, and nitrosamine impurities – and addressed queries from industry and other stakeholders.
- ▶ The Biologics Sector of the USP Convention collaborated with FDA's Center for Drug Evaluation and Research (CDER) to develop an infographic that can inform dialogue between patients and healthcare providers on the quality of biosimilars. The infographic, launched in September 2022, was developed with input from multiple stakeholders, including patient advocacy organizations, innovator and generic manufacturing trade organizations,

healthcare societies, and payor and pharmacy benefit manager groups.

FDA Engagement in USP Convention

Sector Meetings – FDA staff from CDER’s Office of Therapeutic Biologics and Biosimilars spoke at several USP Convention Sector meetings, including discussions on mitigating vaccine hesitancy and misinformation, and provided updates on the agency’s Biosimilar User Fee Amendments (BsUFA) III Regulatory Research Pilot Program. "

FDA-India Engagement – USP built on pre-pandemic engagements with FDA’s India office, initiating further collaborations with the agency on priorities for the region aimed at strengthening medicines supply chain resilience. These priorities include regulatory strengthening, addressing nitrosamine impurities, and lowering barriers to adoption of advanced manufacturing technologies.

- ▶ FDA’s India office participated in the USP Convention’s regional chapter meeting, which provided a venue to connect with regional regulators and understand their priorities. This further facilitated FDA’s visits to respective Southeast Asian countries and meetings with regional regulators. Key priorities for continued engagement include scientific areas prioritized for extensive advocacy and capacity building (e.g., nitrosamines and quality compliance), identification and support of emerging pharmaceutical manufacturers, and continuous manufacturing.
- ▶ USP held a workshop on nitrosamines in February 2023 in India, convening 270 participants from industry and regulatory agencies.

Global Engagement to Address Impurities

– USP engaged stakeholders globally around solutions to help control the risk of impurities

in medicines, including through related USP standards and training. (See *Impact Expansion* Resolution update.)

- ▶ USP collaborated with FDA and global regulators to develop mitigation strategies to address diethylene glycol–contaminated medicines. USP also worked with the Vietnam National Institute of Drug Quality Control to initiate a pilot on testing for nitrosamine impurities to strengthen post-marketing surveillance of angiotensin receptor antagonists (sartans).
- ▶ USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority.
- ▶ USP deepened its engagement with regulators in Latin America, the Asia-Pacific, and the Middle East and North Africa regions to address challenges posed by the potential for nitrosamine impurities in medicines and to build awareness of compendial and non-compendial solutions.
- ▶ USP continued to expand and diversify its Nitrosamine Exchange online community, adding about 2,000 new members, including members from 30 new countries.
- ▶ USP worked with the Indian Pharmaceutical Alliance (IPA) to cosponsor the 2023 USP Workshop on Nitrosamine Impurities in Hyderabad, India.

U.S. Government Supply Chain

Engagement – USP continued to share data and data-derived insights from USP’s Medicine Supply Map with the White House, FDA, and other federal agencies to inform policy decisions in support of increasing supply chain resilience. (See *Evidence Generation to Inform Policy* Resolution update.) USP is also working with the Administration for Strategic Preparedness and Response to analyze key starting



materials for a set of critical medicines to address potential supply chain vulnerabilities.

Engagement with Policymakers – USP worked to address pharmaceutical supply chain challenges by engaging with Congress and through related policy development. In March 2023, USP staff testified before the Senate Homeland Security and Governmental Affairs Committee on the capabilities of the USP Medicine Supply Map and ways that related insights can help prevent or mitigate supply chain disruptions. USP also submitted a statement to the House Energy and Commerce Committee regarding drug shortages. USP has also submitted several responses to general requests for information from policymakers on issues relating to drug shortages and supply chain issues.

Planned for Remainder of the Cycle

- ▶ USP will work with FDA and APEC stakeholders to make strategic updates to the APEC Supply Chain Security Toolkit for Medical Products, and will collaborate with partners such as the Alliance for Safe Online Pharmacies to further disseminate and accelerate uptake of the toolkit in key regions and countries.
- ▶ USP will continue to expand its work in support of FDA's Drug Competition Action Plan to prioritize standards that

support specific complex generics and aim for more publicly facing deliverables co-authored with FDA to address key public health issues.

- ▶ USP will continue dialogue with FDA to encourage technical and science policy interactions outside of USP on topics like impurities, nitrosamines, complex generics, and excipient quality.
- ▶ USP will continue to strengthen its collaboration with FDA's India office on key scientific priorities as well as advocacy and capability building activities.
- ▶ USP will convene global conversations to bring together FDA subject matter experts and industry on key quality-related topics.
- ▶ USP will seek additional opportunities for FDA to engage USP Convention Members to inform, share solutions, and promote trust around shared priorities.
- ▶ USP will continue to engage with FDA and other stakeholders at various levels to demonstrate our portfolio of resources under development to strengthen supply chain resilience.

Contact

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