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# Resolution

## Pharmacopeial Cooperation and Convergence

USP will lead efforts to advance convergence around robust science-based standards across pharmacopeias. USP will focus efforts on those standards where convergence will have the most impact on global access to quality medicines.

## Year 3 Update

Through collaboration with other global pharmacopeias, USP works to advance convergence around robust, science-based quality standards. Pharmacopeial convergence helps increase global alignment on the definition of quality as well as the best practices used to measure quality to build capabilities among emerging pharmacopeias. Convergence also allows for reduction and/or elimination of redundant or even conflicting quality standards in local regions, which otherwise can create barriers to global access to quality medicines. In this way, convergence allows governments, manufacturers, and healthcare professionals to expand access to safe, quality medicines, improve patient safety and public health, and create a more resilient global medicines supply chain. One way convergence of quality standards makes this possible is through increased availability of quality ingredients for medicines made locally in regions of the world where they are needed most. USP supports convergence and capability building among emerging pharmacopeias through scientific exchange, training programs, and other stakeholder engagement activities.

Key areas of progress over the past fiscal year include:

**Pharmacopeial Discussion Group Collaboration –** USP worked with the Pharmacopeial Discussion Group (PDG), which originally included USP, the European Pharmacopoeia (EP), and the Japanese Pharmacopoeia (JP), to increase the reach and impact of PDG harmonization efforts.

- The Indian Pharmacopoeia Commission (IPC) joined the PDG in October 2022 as the inaugural participant in a pilot for expansion of group membership to include other prominent global pharmacopeias. IPC participated in PDG meetings and submitted implementation timelines for PDG standards. The one-year pilot is a critical step in the PDG's commitment to expand recognition of harmonized pharmacopeial standards and global convergence.
- The PDG drafted a commitment to confidentiality to emphasize that information required to support the PDG's efforts to harmonize excipient

monographs and general chapters would be handled confidentially by all involved parties. The commitments were signed by each participating pharmacopeia.

- The PDG reached consensus on harmonization of pharmacopeial standards for particle size analysis by dynamic light scattering. Particle size distribution is an important characteristic of dispersed systems such as emulsions, suspensions, and liposomal formulations. The harmonized language can be used to determine the average hydrodynamic particle size and the broadness of the size distribution of submicron particles dispersed in a liquid.
- The PDG added standards for three excipients – polysorbate 20, purified water, and water for injection – to its work program in response to stakeholder requests and will work towards their harmonization.

**China Engagement –** USP engaged in significant technical collaborations with the Chinese Pharmacopoeia (ChP), which built on a USP-ChP memorandum of understanding signed in Fiscal Year 2021, and formation of a USP-ChP working group on metal packaging in Fiscal Year 2022. The working group met monthly to determine key quality attributes for metal packaging systems and to incorporate feedback from colleagues at USP and ChP. By the end of the fiscal year, the group began developing an initial draft pharmacopeial chapter for further discussion.

**ICH Engagement –** USP has been an observer to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly since 2016 and participates in several ICH Expert Working Groups, including those on pharmaceutical continuous manufacturing, analytical procedures, viral clearance, and impurity assessment for control of extractables and leachables.

- USP contributed to the development of draft ICH guidelines in these areas and submitted related technical comments to help ensure alignment with USP standards and policies. A significant milestone in November 2022 was the completion of the ICH guideline Q13 on continuous manufacturing of drug substances and drug products.
- USP and its PDG partners led efforts to develop a maintenance procedure for the ICH technical guidelines on pharmacopeial interchangeability. A process allowing for parallel implementation of PDG text along with local text was developed to give ICH member pharmacopeias time to revise and update their respective pharmacopeias to fully align with the PDG text. This approach was formally approved by the ICH Assembly in June 2023.

## Planned for Remainder of the Cycle

- USP will work with PDG partners to evaluate lessons learned from the PDG expansion pilot and consider potential next steps. USP will lead efforts to enhance the efficiency of the PDG structure based on learnings from other models.
- USP will host the PDG's autumn 2023 meeting in Hyderabad, India. Afterwards, PDG and USP will convene India stakeholders to discuss harmonization-related topics.
- As USP, with its PDG partners, continues to focus on standards that will have the most impact on global convergence, emphasis will be placed on finalizing a harmonized standard for elemental impurities.

- USP will work with ChP to finalize a pharmacopeial chapter for metal packaging components.
- USP will continue to work toward harmonization of standards for excipients including polysorbate 20, purified water, and water for injection.
- USP will participate in the International Meeting of World Pharmacopoeias (IMWP) in November 2023 in Mexico City as part of IMWP's focus on identification of key topics that affect global pharmacopeias as well as developing principles for pharmacopeias in the area of environmental sustainability.

USP will conduct bilateral meetings with the EP, JP, and British Pharmacopoeia to identify key technical areas for future work. USP and the EP will continue to explore opportunities for joint webinars, including one on nitrosamines. USP and the JP will plan a joint workshop in 2024 focused on the value of pharmacopeias in enhancing the quality of medicines and strengthening the medicines supply chain.

## Contact

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