Resolution III: 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.

In FY 2019 USP made great progress in our commitment to harmonized standards in several areas.

The Pharmacopeial Collaboration Task Force revamped its membership to represent critical facets of the USP, including USP’s global sites, and is defining a vision for collaboration beyond harmonization. The task force is identifying key harmonization principles, identifying opportunities that allow for convergence around quality standards and developing globally implementable modernized standards.

Ongoing collaboration with the European Pharmacopoeia and Japanese Pharmacopoeia, through the Pharmacopeial Discussion Group (PDG), has resulted in the implementation of direct expert engagement for multiple PDG standards as well as discussion about a mechanism to increase transparency of PDG activities to non-PDG pharmacopoeias through the International Meeting of World Pharmacopoeias (IMWP).

USP led efforts to develop a white paper on the Value of Pharmacopeial Standards, which was discussed at the 10th IMWP, to help promote value of the current and future direction of the work of global pharmacopoeias. Also, during this meeting, we finalized the framework for a collaboration model among pharmacopoeias; USP developed this framework with an endorsement from the European Directorate for the Quality of Medicines (EDQM).

Finally, through our official observer status to the ICH Assembly, we are working with FDA colleagues on prioritizing new and existing opportunities to partner on activities that are critical to ensuring medicines quality.

USP has successfully appointed experts to participate as observers to the ICH Expert Working Groups Q2/Q14 (Analytical Method Validation) and Q13 (Continuous Manufacturing). USP has also appointed experts to two separate strategic groups within ICH: the Informal Quality Discussion Group and the Informal Generics Discussion Group.

USP will continue to work with its valued partners to analyze the challenges facing global harmonization and prioritize collaboration on activities that improve global access to quality medicines, promote greater regional access to quality medicines, and increase visibility of pharmacopoeias and the value of public standards.

Key Accomplishments

- Revamped the Pharmacopeial Collaboration Task Force’s membership to include representation of global sites
- Implemented reforms such as a mechanism of direct engagement among experts at USP, the European Pharmacopoeia and the Japanese Pharmacopoeia, which allowed the advancement of multiple standards on the PDG workplan
- Developed a mechanism with PDG pharmacopoeias to increase transparency of PDG activities to non-PDG pharmacopoeias
- Led a working group on the development of a white paper on the Value of Pharmacopeial Standards.
- Finalized a USP-developed and EDQM-endorsed framework for a collaboration model among pharmacopoeias at the 10th annual IMWP
- Enhanced USP’s influence in ICH activities by nominating four internal USP experts to participate as observers to various ICH Expert Working Groups and Strategic Discussion Groups