

2018 Status on the USP Resolutions

Resolution III: Globally Harmonized Standards - Transcript

Presenter:

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Resolution three. 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 2018, USP made great progress in our commitment to standards harmonization in several areas.

The Pharmacopeial Collaboration Task Force, a cross-functional task force created in our Compendial Science group, has developed a broader strategic vision for collaboration beyond harmonization. The task force will continually reform the Pharmacopeial Discussion Group (PDG), identify collaboration opportunities within the International Council on Harmonization (ICH), and work with the World Health Organization (WHO) to develop a more strategic framework for the International Meeting of the World Pharmacopoeias (IMWP).

Though USP's partnership with the European Pharmacopeia and Japanese Pharmacopeia, the Pharmacopeial Discussion Group (PDG) adopted several major reforms to its working procedure to improve efficiency, including a restructure of the meeting format to improve direct expert engagement and a change in the frequency of meetings to focus on strategic direction setting.

Also, USP presented a survey on the utility of the Good Pharmacopeial Practices (GPhP) at the 8th International Meeting of World Pharmacopoeias (IMWP) to help drive strategic discussions on the future direction of the work of global pharmacopoeias. At the 9th IMWP, USP, with EDQM endorsement, presented a framework for a collaboration model among pharmacopoeias, with the goal of finalizing the model at the next meeting.

Lastly, through our official observer status to the ICH Assembly, USP is working with our FDA colleagues on prioritizing new and existing opportunities to partner on activities that ensure quality in ICH.

Looking ahead to 2019 and beyond, USP will continue to work with our valued partners to analyze the challenges facing global harmonization and prioritize collaboration on activities that have the greatest impact on global public health.