9.03 Stakeholder Forums (a) Purpose. Stakeholder Forums shall be formed to enable an exchange of information and perspectives, with the ultimate goal of improving USP standards and information…

9.04 Project Teams (a) Purpose. Project Teams generally shall be formed to address a specific compendial topic (primarily process-oriented). Project Teams will function under a particular Stakeholder Forum.

Work with USP staff to proposed revisions and to provide stakeholder feedback on proposed revisions
Representation

- Midwest Compendial Discussion Group
- AAPS
- CHPA
- FDA
- PhRMA
- Western Compendial Discussion Group
- Association of Affordable Medicines (AAM)
- Calibration & Validation Group
- IPEC-Americas
- Parenteral Drug Association
- New Jersey Pharmaceutical Quality Control Association
Members suggested revising sections 5.20.10 Added Substances in Official Substances and 5.60.10 Other Impurities in USP and NF Articles.

Excipients EC is currently reviewing feedback on stim article- The Complexity of Setting Compendial Specifications for Excipients Composition and Impurities.

Based on EC decisions, the Project Team will help USP develop and review associated changes to the GN.
USP proposed changes to the USP-NF
  - Online only
  - Non-official print publication
  - Title change

Feedback was collected from stakeholders on the proposal through a Compendial Notice, the General Notices Project Team, the Compendial Process Improvement Project Team. And meetings with FDA.

USP is making adjustments to the proposal based on public feedback and will publish it in PF 45(3) May/June 2019.
Stay Connected
For questions or to join the Project Team
jcs@usp.org

Empowering a healthy tomorrow
Thank You

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