



Resolution

Year 1 Resolution Update: Efficiency in Standards Development and Revision

Resolution

USP will proactively evaluate and enhance the process for developing and updating standards to maintain and continuously optimize their impact. In doing so, USP will consider the perspectives and implications of process modifications from FDA, industry, practitioners, and other stakeholders. A focus of this work will be to explore new approaches for the efficient sharing of information that is critical to standards development, along with the information needed for the evaluation of fit-for-purpose analytical methods and specifications, and the integration of appropriate scientific and manufacturing advances into USP standards.

Alignment with USP's Mission

As science and technology advance and approvals of medicines increase, it will be important for USP to engage more effectively with FDA, industry, practitioners, and other stakeholders, and recognize the limited resources and other constraints impacting each organization and key constituents. This Resolution reaffirms USP's commitment to work collaboratively with FDA, industry, practitioners, and other stakeholders to maintain a modernized *USP-NF* compendia through efficient processes for continually

developing and revising standards. It also urges USP to work with FDA and industry on new approaches for sharing the information needed for efficient standards setting. Implementing new and better ways to share information among USP, FDA, and industry will enable a continually modernized *USP-NF* that advances access to quality medicines and helps ensure patient safety.

Year 1 Update

Key progress areas over the past fiscal year include:

Adapt-Transform-Progress – USP began implementing the Adapt-Transform-Progress initiative, designed to increase the efficiency and effectiveness of the standards-development process and systems. Multiple pilots for case-based staffing processes were completed this year and are being implemented, with additional pilots planned for the coming year. In addition, a Business Process Management System (BPMS) product to support reference standards production has been developed and is being progressively implemented. The discovery phase for development of a BPMS product to support documentary standards creation is slated to wrap up in the first quarter of year two.

Standards Engagement Model – A new approach for engaging volunteers and stakeholders in standards development has

been implemented. This model helps ensure that the right individuals are engaged at the right time to support a more iterative approach to standards development. The implementation began with more streamlined Expert Committees that have access to an expanding pool of Expert Advisors. The Expert Committees developed more targeted workplans that prioritize key challenges. To address those, the model leverages increased stakeholder engagement and better use of technology to obtain comprehensive input throughout the process. The result is intended to be a more agile and iterative approach to standards development. USP also has worked to analyze and streamline approaches for direct stakeholder engagement in support of the Standards Engagement Model and Science Quality Framework (see below). This has included employing new stakeholder engagement tools, including Open Forums, which have drawn hundreds of stakeholders to events targeted at specific standards-setting areas and challenges. It has also included changes to how USP solicits input through Stakeholder Forums and Project Teams.

Science Quality Framework – The framework forms the foundation for everything our Expert Bodies will accomplish during this cycle and comprises the following five strategic pillar topic areas: Evolving and Expanding Standards, Product and Substance Performance, Emerging Modalities, Technologies, and Quality Environment.

Government Liaison Program – A total of 208 government liaisons (GL) have been assigned for this cycle, of which 200 are from FDA; they serve in 254 GL program appointments across USP’s Expert Bodies.

To improve program collaboration between USP and FDA, USP has established a USP-FDA file sharing site for coordination and reporting.

Information Sharing – USP and FDA collaborated on approaches for specifying “disregard limits” in USP monographs and the control of nitrosamine impurities reported to be present in certain widely-used medications. USP also launched an online “knowledge hub” on nitrosamines to facilitate information exchange among a broad set of interested parties. USP continued to engage FDA on the need for a long-term and sustainable mechanism for general information exchange between FDA, USP, and industry.

Planned for Year 2

- ▶ USP will continue to pursue development of a BPMS-based product to support documentary standards creation and review and implement further case-based standards-development processes.
- ▶ USP will continue to evaluate opportunities to engage USP volunteers and other stakeholders in new and more targeted ways, especially based on learnings from recent virtual engagements, and for earlier engagement in the standards-development process.
- ▶ USP will continue to engage with FDA to facilitate greater information sharing to support the efficient development of product quality standards.

Contact

For additional information on this Resolution, contact Jeff Johnson at JJ@usp.org.

