

USP Prescription/Non-Prescription Stakeholder Forum
Monday, July 9, 2018

USP Update on Chemical Medicines:

Chemical Medicines Plan for 2018-2020 and Beyond

Bruk Alemayehu, MBA, Vice President, Chemical Medicines



2018 – 2020 and Beyond



- ▶ Continue to optimize standards setting processes and systems to improve quality and productivity through an Up-To-Date (UTD) framework
- ▶ Continue to implement Process and Quality improvement recommendations.
- ▶ Continue to develop new and modernized monographs to support Up-To-Date.
- ▶ Work on Omitting monographs for obsolete medicines from the USP-NF to make the compendia as current as possible for industry and FDA,
- ▶ Continue collaboration with FDA and CHPA in the development of OTC compendial pathways
- ▶ Strengthen relationships with Industry and FDA to help modernize + develop new high priority monographs

In FY 19



- ▶ Work to improve standard development process and systems
- ▶ Develop capacity to solicit and use external stakeholder feedback to increase quality and output
- ▶ We will continue working with industry to Increase monograph donations with timely availability
- ▶ Develop and begin to deliver on a roadmap of QISP priorities through end of cycle
- ▶ Operationalize QISP policy decisions including metrics to measure effectiveness/success
- ▶ Define better quality operational metrics



Expanding scope to include a more strategic and integrated approach to improving operational efficiency and strengthening quality



usp
Up-To-Date



Systems & Processes

Quality & Policy



Documentary Standards



Reference Standards

Quality & Policy + Systems & Process Initiatives



▶ Quality & Policy:

- Examine the effectiveness of USP's current scientific practices and policies in order to further improve the quality and scientific integrity of documentary and reference standards
- Identify gaps, areas for improvement, and training opportunities.

▶ Systems and Process:

- Examine and document interdependences and capabilities to seek to develop streamlined processes and increase efficiency
- Improve 'data-driven' informed decision making within the organization

Thank You



Empowering a healthy tomorrow