Stakeholder Forum

USP Prescription/ Non-Prescription

April 11, 2022 | April 12, 2022
8:00am - 12:00pm ET
Virtual Meeting

Agenda

All times are in Eastern Daylight Time (EDT) – Washington, DC time zone

DAY ONE: Monday, April 11, 2022

Facilitator: Danita Broyles, Chair, Stakeholder Engagement Planning Committee

8:00 a.m. **Welcome, Rules of Engagement**
Facilitator: Danita Broyles, Chair, Stakeholder Engagement Planning Committee

8:10 a.m. **Opening Remarks**
Speaker: Dr. Ronald T. Piervincenzi, Chief Executive Officer | USP

8:20 a.m. **Mechanisms for Enhanced Stakeholder Engagement**
Speakers: Jennifer Devine, SVP, Documentary Standards & Compendial Policy; Ed Gump, Vice President, Small Molecules; Naiffer E. Romero, Senior Scientific Affairs Manager | USP and Danita Broyles, Chair | Stakeholder Engagement Planning Committee

a. Q&A/Discussion
b. Breakout sessions – Engaging Stakeholders in NEW Proactive Stakeholder Involvement Mechanisms
c. Breakout Reports

Description of the new USP Stakeholder Engagement Model (SEM) and its benefits to stakeholders

9:45 a.m. **USP Updates:**
Speakers: Trey White, Senior Director, Digital Platforms & Delivery, and Jessica Simpson, Senior Manager, Executive Secretariat | USP

a. Preview of the upcoming USP-NF/PF integrated platform
b. Overview of the Public Commenting Open Forum
c. Q&A/Discussion

10:15 a.m. **Break**

10:25 a.m. **Prioritization of Standards**
Speakers: Ed Gump, Vice President, Small Molecules; Christine Feaster, Vice President, Global Commercial Operations | USP; Mark Wiggins, Compendial Consultant with Global Pharmacopeia Solutions, LLC; | Joe Albanese, Consultant with Albanese Consulting, LLC

a. Standards, Monograph and Approach
b. Donations Process, Communications, and Increased Transparency
c. USP Processes for Prioritization and Development of Standards
d. Q&A/Panel Discussion

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Facilitator: Andrea Torbey, Senior Program Manager | USP

Panelists: Ed Gump, Vice President, Small Molecules; Christine Feaster, Vice President, Global Commercial Operations | USP; Mark Wiggins, Compendial Consultant with Global Pharmacopeia Solutions, LLC | Joe Albanese, Consultant | Albanese Consulting, LLC

11:50 a.m. **Day One Summary and Closing Remarks**
Facilitator: Kay M. Whiten, Vice-Chair, Stakeholder Engagement Planning Committee

12:00 p.m. **Adjourn**

Post Day One Event

Ask Me Anything Sessions

An opportunity for stakeholders to ask USP Subject Matter Experts questions related to the topics listed below

2:00 p.m. **Guidance on aspects of method validation for Companies**
Facilitator: Jose Zayas, CEO | Zaycor Healthcare Corporation

Panelists: Horacio Pappa, Senior Director, General Chapters; Brian Gilbert, Technical Services Manager II, and Steven L. Walfish, Senior Principal Scientist, General Chapters | USP

2:30 p.m. **Nitrosamines – Knowledge Sharing**
Facilitator: Anne Cook, QA Consultant – Compendial Affairs | Eli Lilly
Speaker: Naiffer E. Romero, Senior Scientific Affairs Manager | USP

DAY TWO: Tuesday, April 12, 2022

Facilitator: Kay M. Whiten, Vice-Chair, Stakeholder Engagement Planning Committee

8:00 a.m. **Welcome, Rules of Engagement**
Facilitator: Kay M. Whiten, Vice-Chair, Stakeholder Engagement Planning Committee

8:05 a.m. **Summary of Day One "What We Learned"**
Speakers: Danita Broyles, Chair, Stakeholder Engagement Planning Committee, and Jennifer Devine, SVP, Documentary Standards & Compendial Policy | USP

8:40 a.m. **Requested Cases for Monograph Modernization**
Speakers: Antonio Hernandez-Cardoso, Senior Principal Scientist | USP, and Jose Zayas, CEO | Zaycor Healthcare Corporation

a. Q&A/Discussion

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Discussion includes cases where modernization may be needed to replace some methods to ensure the inclusion of analysts who are differently-abled or to replace some organoleptic tests that may pose safety-based issues.

9:10 a.m. **USP Quality Commitment**
Speaker: Alice M. Tira, Vice President, Global Quality Systems | USP

9:25 a.m. **Errata Past, Present, and Future**
Speakers: Sarah R. Gaskin, Senior Manager, Publications Production, and Gabriel I. Giancaspro, Distinguished Scientific Fellow | USP

a. Q&A discussion is for both topics

Information sharing with external stakeholders on USP errata numbers and definition

9:40 a.m. **Break**

9:50 a.m. **Introduction to New General Chapter <1220> Analytical Procedure Life Cycle - Dialog between FDA, USP, & Industry**
Speaker: Amanda Guiraldelli, Scientific Affairs Manager | USP Overview

a. Q&A/Panel Discussion

Panelists: Mark D. Argentine | Eli Lilly; Amanda Guiraldelli, Scientific Affairs Manager; Horacio Pappa, Senior Director, General Chapters | USP and Yun (Jenny) Wang | U.S. FDA

An introduction to the chapter and rationale behind its creation, regulatory views of the chapter, and potential use cases in the industry

10:50 a.m. **CEO Conversations – a Fireside Chat with Dr. Ronald T. Piervincenzi, Chief Executive Officer**

Open dialogue based upon industry submitted questions facilitated by Danita Broyles, Chair, and Kay M. Whiten, Vice-Chair, Stakeholder Engagement Planning Committee

11:50 a.m. **Summary/Next Steps/Closing Remarks**
Speaker: Danita Broyles, Chair, Stakeholder Engagement Planning Committee

12:00 p.m. **Adjourn**