

Virtual Prescription/Non-Prescription Stakeholder Forum
November 18-19, 2020
10:00 a.m. – 4:00 p.m.

Please note times are in Eastern Standard Time (EST)

WebEx details in registrant email

Draft agenda

(as of November 12, 2020, subject to change)

Theme: Working Together "Impact"

DAY ONE: Wednesday, November 18, 2020

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| 10:00 a.m. – 10:05 a.m. | Welcome/Introduction
Speaker: Jacqueline D. Starkes, Senior Stakeholder Affairs Coordinator USP |
| 10:05 a.m. – 10:20 a.m. | Opening Remarks
Speaker: Jaap Venema, Executive Vice President & Chief Science Officer USP |
| 10:20 a.m. – 10:30 a.m. | Stakeholder Forum Overview
Speaker: Jennifer Devine, Senior Vice President, Documentary Standards & Compendial Policy USP |
| 10:30 a.m. – 10:35 a.m. | Welcome/Kick-Off the Forum
Speakers: Anne Cook and Lisa Eichler-Johnson, Co-Chairs
Mid-West Compendial Discussion Group (MWCDG) |
| 10:35 a.m. – 11:15 a.m. | USP's Standards Engagement Model and What it Means for Stakeholders
Speaker: Jessica Simpson, Senior Manager, Compendial Operations USP
Discussion/Q&A |
| 11:15 a.m. – 11:30 a.m. | Compendial Process Improvement Project Team Final Update
Speaker: Phil Travis, Past-Chair, Compendial Process Improvement Project Team New Jersey Pharmaceutical Quality Control Association
Discussion/Q&A |
| 11:30 a.m. – 11:45 a.m. | Updates to the Accelerated Revision Process
Speaker: Elena Gonikberg, Principal Scientist USP
Discussion/Q&A |
| 11:45 a.m. – 12:00 p.m. | Q&A Session: Introduction to USP's Pending Monograph Process (PMP)
<i>Pre-watch: on-demand course Introduction to USP's Pending Monograph Process</i>
Speakers: <ul style="list-style-type: none"> • Amber Day, Program Manager, Standards Operations USP • Lana Bruney, Compendial Operations & Standards Food and Drug Administration • Discussion/Q&A |
| 12:00 p.m. – 1:00 p.m. | Lunch |

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1:00 p.m. – 2:20 p.m.

Building Trust through Documentary Standards

Speakers:

- Jaap Venema, Executive Vice President & Chief Science Officer | USP,
- Ashely Lumburg, Eurofins Lancaster Laboratories, Inc., Pharmaceutical Raw Materials, Senior Specialist - Compendial Liaison
- Lisa Eichler-Johnson, Co-Chair | MWCDG
- Jessica Simpson, Senior Manager, Compendial Operations | USP
- Rebecca Cambroner, Director, Digital Strategy & Delivery | USP
- Mario Sindaco, Vice President, Volunteer Compendial Operations | USP
- Moderator: Danita Broyles, Senior Market Development Manager | USP

2:20 p.m. – 2:30 p.m.

Afternoon Break

2:30 p.m. – 3:50 p.m.

Dialogue on the Future of Public Comments

Speakers:

- Anne M. Cook, Co-Chair | MWCDG
- Jessica Simpson, Senior Manager, Compendial Operations | USP
- Moderators: Danita Broyles, Senior Market Development Manager, and Peter R. Claise, Director, Product Management | USP

3:50 p.m. – 4:00 p.m.

Overview of Day One

Moderators: Anne Cook and Lisa Eichler-Johnson, Co-Chairs | MWCDG

DAY TWO: Thursday, November 19, 2020

10:00 a.m. – 10:05 a.m.

Welcome/Introduction

Speaker: Jacqueline D. Starkes, Senior Stakeholder Affairs Coordinator | USP

10:05a.m. – 10:20 a.m.

Opening Remarks

Speaker: Ronald T. Piervincenzi, Chief Executive Officer | USP

10:20 a.m. – 10:30 a.m.

Moderators: Day Two

Speakers: Anne Cook and Lisa Eichler-Johnson, Co-Chairs | MWCDG

10:30 a.m. – 10:45 a.m.

<1085.1> Use of Recombinant Reagents in The Bacterial Endotoxins Test - Photometric and Fluorometric Methods Using Recombinantly Derived Reagents

Speaker: Leslie Furr, Associate Scientific Liaison | USP

Discussion/Q&A

10:45 a.m. – 11:45 a.m.

Potential Alternate Bacterial Endotoxins Testing (BET) based on Chemical Analytical Methods – Opportunities for Industry

Speaker: Prabhakar Gruddanti, Principal Scientific Liaison Team Leader | USP

Moderator: Robert Shimahara, Director, Strategy Customer Development | USP

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- 11:45 a.m. – 12:00 p.m. **Analytical Instrument Qualification in the USP-NF: Establishing Fitness for Purpose**
Speaker: Lucy L. Botros, Scientific Liaison | USP
Discussion/Q&A
- 12:00 p.m. – 1:00 p.m. **Lunch**
- 1:00 p.m. – 1:15 p.m. **General Notices Project Team Final Update**
Speaker: Ruth Miller, Past-Chair, General Notices Project Team | Parenteral Drug Association
Discussion/Q&A
- 1:15 p.m. – 1:45 p.m. **Q&A Session on Pre-Read Topics:**
Please review before the meeting:
General Chapter <1469> Nitrosamine Impurities
Panel Discussion: Edmond Biba, Senior Scientific Liaison, Donald Min, Senior Scientific Liaison, and Ed Gump, Vice President, Small Molecules | USP
- 1:45 p.m. – 2:15 p.m. **Q&A Session on Pre-Read Topics:**
Please review before the meeting:
General Chapter <7> Labeling, Misti Spann, Scientific Liaison | Healthcare Quality & Safety Center, USP
Discussion/Q&A
- 2:15 p.m. – 2:30 p.m. **The 2015-2020 Stakeholder Volunteer Bodies Acknowledgement:**
 - Prescription/Non-Prescription SF Planning Committee
 - Compendial Process Improvement Project Team
 - General Notices Project TeamSpeaker: Jennifer Devine, Senior Vice President, Documentary Standards & Compendial Policy | USP
- 2:30 p.m. – 2:45 p.m. **Event Summary/Next Steps/Closing Remarks**
Speakers: Anne Cook and Lisa Eichler-Johnson, Co-Chairs | MWCDG