

# USP Open Forum – Excipients



February 11<sup>th</sup>, 9 a.m. to Noon | February 12<sup>th</sup>, 9 a.m. to Noon

## Setting Compendial Specifications for Excipient Composition, Organic and Inorganic Impurities

### Agenda

(as of February 8, 2021)

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

### DAY ONE: Thursday, February 11, 2021

#### Day One: Event Facilitator: Danita Broyles, Senior Market Development Manager | USP

- 9:00 a.m.                    **Introduction to the Open Forum Concept**  
Speaker: Jacqueline D. Starkes, Senior Stakeholder Affairs Coordinator | USP
- 9:05 a.m.                    **Welcome and Opening Remarks**  
Speaker: Jennifer Devine, Senior Vice President, Documentary Standards & Compendial Policy | USP
- 9:10 a.m.                    **Welcome and Opening Remarks from the 2020-2025 Council of Experts, Chairs**  
Speakers:
  - Otilia Koo, Chair, Complex Excipients
  - Chris Moreton, Chair, Excipients Test Methods
  - Eric Munson, Chair, Simple Excipients
- 9:15 a.m.                    **Overview of the Stakeholder Engagement Model (SEM) Tools**  
Speaker: Jessica Simpson, Senior Manager, Compendial Operations
- 9:30 a.m.                    **Goals and Objectives of the Excipient Open Forum**  
Speaker: Catherine Sheehan, Senior Director, Science-Excipients | USP
- Topic 1: Complexities of Setting Compendial Specifications for Excipient Composition and Impurities - Organic Impurities**
- 9:35 a.m.                    **Purpose of Stimuli Article. Overview of Guiding Principles and Approaches for Setting Specifications for Excipient Composition and Impurities**  
  
Speakers: Galina Holloway, Senior Scientific Liaison | USP and Richard Creekmore, Excipient Test Methods | Expert Committee, Vice-Chair
- 10:05 a.m.                    **Review of Survey responses**  
Speakers: Galina Holloway, Senior Scientific Liaison
- 10:15 a.m.                    **Break (5 mins)**

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- 10:20 a.m.                    **Historical and Current Overview of USP-NF Excipient Monograph Composition and Impurity Revisions**  
Speaker: Hong Wang, Senior Manager | USP
- 11:00 a.m.                    **Review of Pharmacopeial Discussion Group (PDG) Monographs with Impurity Revisions**  
Speaker: Jenny Liu, Senior Scientific Liaison | USP
- 11:40 a.m.                    **Q&A session**
- 11:50 a.m.                    **Day One Summary and Closing Remarks**  
Speaker: Galina Holloway, Senior Scientific Liaison | USP
- 12:00 p.m.                    **Adjourn**

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**DAY TWO: Friday, February 12, 2021**

**Event Facilitator: Yognandan Pandya, Associate Director, Industry Programs | USP**

- 9:00 a.m.                    **Welcome and Opening Remarks**  
Speaker: Catherine Sheehan, Senior Director, Science-Excipients | USP
- 9:05 a.m.                    **Introduction to the Open Forum Concept**  
Speaker: Jacqueline D. Starkes, Senior Stakeholder Affairs Coordinator | USP
- 9:15 a.m.                    **USP Addressing Maltol PF 46(2) Comments**  
Speaker: Peng Zhang, Scientific Liaison | USP
- 9:35 a.m.                    **USP Review of Stimuli Article’s Proposed Definitions relating to Excipient Composition**  
Speaker: Galina Holloway, Senior Scientific Liaison | USP

**Topic 1: Complexities of Setting Compendial Specifications for Excipient Composition and Impurities - Organic Impurities (Continued)**

- 9:55 a.m.                    **Summary and Next Steps**  
Speaker: Galina Holloway, Senior Scientific Liaison | USP

**Topic 2: Overview: Excipient Elemental impurities First Draft of Roadmap for Addressing Element-Specific Chapters and Stand-Alone Tests in Excipient Monographs**

- 10:10 a.m.                    **Update on USP Element Specific Chapters**  
Speaker: Kahkashan Zaidi, Principal Scientific Liaison, Team Lead, General Chapters | USP
- 10:25 a.m.                    **Overview of First Draft of Roadmap for Addressing Element-specific Chapters and Tests in Excipients Monographs**  
Speaker: Galina Holloway, Senior Scientific Liaison | USP
- 10:55 a.m.                    **Break (10 mins)**
- 11:05 a.m.                    **Topic 2: Summary and Next Steps**  
Speaker: Galina Holloway, Senior Scientific Liaison | USP

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11:15 a.m.

Q&A with Presenters

Presenters

- Chris Moreton | Chair, ETM
- Richard Creekmore | Vice-Chair, ETM
- Otilia Koo | Chair, CE
- Galina Holloway | USP
- Jenny Liu | USP
- Catherine Sheehan | USP
- Hong Wang | USP
- Kahkashan Zaidi | USP
- Peng Zhang | USP

Facilitators: Danita Broyles and Yognandan Pandya | USP

11:55 a.m.

**Day Two: Summary and Closing Remarks**

Speaker: Catherine Sheehan, Senior Director, Science-Excipients | USP

12:00 p.m.

**Adjourn**