Final Agenda

Tuesday, December 11, 2018

8:30 a.m.  Registration & Information

9:00 a.m.  USP Welcome and Opening Remarks
Speakers: Jacqueline Starkes, and Catherine Sheehan, USP

9:10 a.m.  Introduction of Chair
Speaker: Catherine Sheehan, USP

9:15 a.m.  Stakeholder Forum Overview
Speaker: Mark Hendrickson, Chair, Association for Accessible Medicines (AAM)
a. Discussion/Q&A

9:25 a.m.  Updates from the Fall 2017 Excipients Stakeholder Forum
Speaker: Mark Hendrickson, Chair, Association for Accessible Medicines (AAM)
a. Discussion/Q&A

9:35 a.m.  Call for Candidates Updates
Speaker: Melissa Bellon, USP
a. Discussion/Q&A

9:45 a.m.  General Notices Updates
Speaker: Jessica Simpson, USP
a. Discussion/Q&A

10:00 a.m.  Networking Morning Break

10:30 a.m.  Impurities in Excipients
Speaker: Joseph Zeleznik, Meggle; Galina Holloway, USP
a. The Complexity of Setting Compendial Specifications for Excipient Composition and Impurities Stimuli Article
b. Elemental Specific General Chapter Testing in Excipient Monographs
c. Discussion/Q&A

11:30 a.m.  An Introduction and Overview of USP Compounding Activities and the Role Excipients Play
Speaker: Brian Serumaga, USP
a. Discussion/Q&A
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12:00 p.m. Networking Lunch

1:00 p.m. Open Forum for Stakeholders. Topics suggested as of October 19, 2018
Speakers: All
   a. Impact of changes to excipients standards to the review and approvability of ANDAs-FDA has increased its attention and emphasis on the impact of excipients to overall drug product quality.
   b. Monograph Terminology-Challenges with customers and industries overall utilizing similar nomenclature to refer to vastly different products. Specifically, hydrolyzed collagen customer referring to monographs for Collagen (whole and not hydrolyzed). In this case, hydrolyzed collagen is called many things such as collagen peptide, hydrolyzed gelatin, and often-just collagen.
   c. Monograph Continuity- Some excipients are used in pharmaceuticals, nutritional and food products. Information is not shared across segments of USP so efforts are duplicated by industry.
   d. Discussion/Q&A

2:00 p.m. – 2:30 p.m. Networking Afternoon Break

2:30 p.m. Open Forum for Stakeholders (Continued)

3:50 p.m. Action Items/Closing Remarks
Speaker: Mark Hendrickson, Chair, AAM

4:00 p.m. Adjourn
Speaker: John A. Giannone, USP