Final Agenda

Tuesday, April 16, 2019

8:00 – 8:30 a.m. Registration & Coffee

8:30 – 8:40 a.m. Welcome and Overview of USP’s Approach to the Revision of USP <665> and <1665>
Michael Eakins, Ph.D.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel

8:40 – 9:00 a.m. Top Ten Comments Received from the 2017 PF Proposal: How Comments Were Addressed in Current PF Draft.
Desmond G. Hunt, Ph.D.
Principal Scientific Liaison, USP

9:00 – 9:30 a.m. Equipment Suitability for Manufacturing of Liquid Dosage Forms - FDA/OPF’s Perspective
Edwin Jao, Ph.D.
Government Liaison, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel

9:30 – 10:30 a.m. <665> and <1665>: A Standardized Extraction Solution Protocol for Manufacturing Components and Systems
Michael Eakins, Ph.D.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel

10:30 – 11:00 a.m. Morning Break

11:00 – 11:30 a.m. <665> and <1665>: Extraction Process for Manufacturing Components and Systems
Weibing Ding, Ph.D.
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel

11:30 – 12:00 p.m. Q&A/Discussion

12:00 – 1:00 p.m. Lunch
USP Museum will be open for self-guided tour
1:00 – 1:30 p.m.  Benefits and Examples of Generating <665> Data: Equipment Supplier's Perspective  
James Hathcock, Ph.D.  
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel

1:30 – 2:00 p.m.  Utility of Generating <665> Data: Drug Manufacturer’s Perspective  
Ken Wong, M.S.  
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel

2:00 – 2:30 p.m.  Q&A/Discussion

2:30 – 2:50 p.m.  Afternoon Break

2:50 – 3:20 p.m.  <1665> Example of a Risk Evaluation Protocol  
Michael Eakins, Ph.D.  
Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel

3:20 – 4:20 p.m.  Panel Discussion: General Feedback on Chapters  
Weibing Ding, Ph.D., James Hathcock, Ph.D., Edwin Jao, Ph.D., Ken Wong, M.S.  
<665>/<661.3> Expert Panel Members

4:20 – 4:30 p.m.  Summary

4:30 p.m.  Workshop Adjourns