Draft Agenda
As of January 4, 2019

Tuesday, April 16, 2019

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

8:30 – 8:50 a.m. Welcome and Overview of USP’s Approach to the Revision of USP <665> and <1665>
Michael Eakins, Ph.D.
USP Packaging & Distribution Expert Committee; <665> Expert Panel Member

8:50 – 9:20 a.m. Top Ten Comments Received from the 2017 PF Proposal. How Comments Were Addressed in Current PF Draft.
Desmond G. Hunt, Ph.D.
USP Packaging & Distribution Expert Committee; <665> Expert Panel Member

9:20 – 10:00 a.m. FDA’s Expectations for Plastic Manufacturing Components
Edwin Jao
U.S. FDA; <665> Expert Panel Member

10:00 – 10.30 a.m. <665> and <1665>: A Standardized Extraction Solution Protocol for Manufacturing Components and Systems
Dennis Jenke, MBA, Ph.D.
USP Packaging & Distribution Expert Committee; Chair, USP <665> 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
Ken Wong
USP Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel Member; Deputy Director, Single-Used Systems Qualification, Sanofi Pasteur

11:30 – 12:00 p.m. Q&A/Discussion

12:00 – 1:00 p.m. Lunch
1:00 – 1:30 p.m.  Benefits and Examples of Generating <665> Data: Equipment Supplier’s Perspective  
James Hathcock  
USP Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel Member; Sr. Director, Regulatory and Validation, Pall Biotech

1:30 – 2:00 p.m.  Utility of Generating <665> Data: Drug Manufacturer’s Perspective  
Weibing Ding, Ph.D.  
USP Expert Panel Member; Principal Scientist, Process Development, Amgen Inc.

2:00 – 2:30 p.m.  <665> Application of Biological Reactivity Testing  
U.S. FDA Speaker:TBA

2:30 – 3:00 p.m.  Q&A/Discussion

3:00 – 3:20 p.m.  Afternoon Break

3:20 – 3:50 p.m.  <1665> Example of a Risk Evaluation Protocol  
Dennis Jenke, MBA, Ph.D.  
USP Packaging & Distribution Expert Committee; Chair, USP <665> Expert Panel

3.50 – 4:50 p.m.  Panel Discussion: General Feedback on Chapters  
Weibing Ding, Ph.D., James Hathcock, Edwin Jao, Dennis Jenke, MBA, Ph.D., Ken Wong  
<665> Expert Panel Members

4:50 – 5:00 p.m.  Summary

5:00 p.m.  Workshop Adjourns