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**

USP Workshops

Plastic materials and components used in the manufacturing of drug products

Understanding USP's approach to the testing and selection of plastic components used throughout drug manufacturing

April 16, 2019

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**