

→ 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



Final Agenda

Tuesday, April 16, 2019

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|---------------------------|---|
| 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.
<i>Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel</i> |
| 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.
<i>Principal Scientific Liaison, USP</i> |
| 9:00 – 9:30 a.m. | Equipment Suitability for Manufacturing of Liquid Dosage Forms - FDA/OPF's Perspective
Edwin Jao, Ph.D.
<i>Government Liaison, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel</i> |
| 9:30 – 10:30 a.m. | <665> and <1665>: A Standardized Extraction Solution Protocol for Manufacturing Components and Systems
Michael Eakins, Ph.D.
<i>Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel</i> |
| 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.
<i>Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel</i> |
| 11:30 – 12:00 p.m. | Q&A/Discussion |
| 12:00 – 1:00 p.m. | Lunch
<i>USP Museum will be open for self-guided tour</i> |

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| 1:00 – 1:30 p.m. | Benefits and Examples of Generating <665> Data: Equipment Supplier's Perspective
James Hathcock, Ph.D.
<i>Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel</i> |
| 1:30 – 2:00 p.m. | Utility of Generating <665> Data: Drug Manufacturer's Perspective
Ken Wong, M.S.
<i>Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel</i> |
| 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.
<i>Member, <665>/<661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel; Co-Chair, <660> Containers-Glass Expert Panel</i> |
| 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.
<i><665>/<661.3> Expert Panel Members</i> |
| 4:20 – 4:30 p.m. | Summary |
| 4:30 p.m. | Workshop Adjourns |