USP Workshop on Revision of Chapters <87>/<88> Biological Reactivity and Establishing a Standardized Extractable Procedure for Plastic Manufacturing Components and Systems
June 20-21, 2016
USP Meetings Center, Rockville, MD USA

Agenda

DAY ONE: Monday, June 20, 2016

8:00 – 8:30 a.m.	**Registration & Coffee**
8:30 – 9:00 a.m.	**Expectation and Goals for the <87> and <88> Workshop** Dan Norwood, MSHP, Ph.D., *Co-Chair, USP <87>/<88> Expert Panel*
9:00 – 9:30 a.m.	**Revision of USP's Biocompatibility Requirements for Materials of Construction (Plastics, Elastomers and Beyond): What are the Key Issues?)** Doug Ball, M.S., *Member, USP <87>/<88> Expert Panel*
9:30 – 10:15 a.m.	**Advancing Biocompatibility Evaluation into the 21st Century** David R Jones, Ph.D., *Medicines and Healthcare Products Regulatory Agency*
10:15 – 10:45 a.m.	**Break**
10:45 – 11:15 a.m.	**Regulatory Expectations for Biocompatibility Testing for Pharmaceutical Packaging Systems** Tim McGovern, Ph.D., *FDA*
11:15 – 11:45 a.m.	**Regulatory Expectations for Biocompatibility Testing for Medical Devices** Jennifer Goode, *FDA*
11:45 – 12:15 a.m.	**Q&A**
12:15 – 1:15 p.m.	**Lunch**
1:15 – 1:45 p.m.	**USP Proposal: Decision Tree for Determining Biocompatibility Testing—Risk Matrix Proposal** Cheryl Stults, M.A., Ph.D., *Co-Chair, USP <87>/<88> Expert Panel*
1:45 – 2:15 p.m.	**USP Proposal: Biological Activity/Biocompatability** John Iannone, *Member, USP <87>/<88> Expert Panel*
2:15 – 2:45 p.m.	**USP Proposal: Chemical Characterization** Doug Kiehl, M.S., *Member, USP <87>/<88> Expert Panel*
2:45 – 3:15 p.m.	**USP Proposal: Safety Evaluation and the Risk Assessment Process:** Toxicological and Biological Bill Beierschmitt, Ph.D., *Member, USP <87>/<88> Expert Panel Member*

3:15 – 3:45 p.m.	**Break**
3:45 – 5:00 p.m.	**Panel Discussion:** General Feedback on Proposal
5:00 – 5:15 p.m.	**USP Summary, Next Steps** Dan Norwood, MSHP, Ph.D., *Co-Chair, USP <87>/<88> Expert Panel*
5:15 p.m.	**Workshop Adjourns**

DAY TWO: Tuesday, June 21, 2016

8:00 – 8:30 a.m.	**Registration & Coffee**
8:30 – 8:50 a.m.	**Welcome and Overview of USP's Approach to Assessing Extractables and Leachables** Michael Eakins, Ph.D. *Vice-Chair, USP Packaging & Distribution Expert Committee*
8:50 – 9:35 a.m.	**What are the FDA's Regulatory Expectations?** Edwin Jao*, FDA*
9:35 – 9:55 a.m.	**User Expectation: What is the problem to be solved?** Weibing Ding, Ph.D*., Amgen* Ken Wong, Ph.D., *Sanofi Pasteur*
9:55 – 10:15 a.m.	**Vendor Expectation: What is the problem to be solved?** James Hathcock, Ph.D., Pall Corporation
10:15 – 10:30 a.m.	**Q&A/Discussion**
10:30 – 11:00 a.m.	**Break**
11:00 – 11:40 a.m.	**USP <661.3>: A Standardized Procedure for Extractables from Manufacturing Components and Systems** Dennis Jenke, MBA, Ph.D., *Chair, USP <661.3> Expert Panel*
11:40 – 12:10 p.m.	**Q&A/Discussion**
12:10 – 1:10 p.m.	**Lunch**
1:10 – 1:40 p.m.	**Rationale for the Risk Matrix in <661.3>/Testing Required Based on the Level of Risk** Cheryl Stults, M.A., Ph.D*., USP <661.3> Expert Panel*
1:40 – 2:10 p.m.	**Q&A/Discussion**
2:10 – 2:40 p.m.	**Rationale for the Standard Extraction Protocol used in <661.3>** Dennis Jenke, MBA, Ph.D., *Chair, USP <661.3> Expert Panel Member*
2:40 – 3:00 p.m.	**Q&A/Discussion**
3:00 – 3:30 p.m.	**Break**

3:30 – 4:45 p.m. **Three User Experience in Using the Protocol Outlined in <661.3>**

- James Hathcock, Ph.D, *Pall Corporation*
- Ray Colton, Ph.D., *VR Analytical*
- Piet Christiaens, Ph.D., *Toxikon*

Q&A/Discussion

4:45 – 5:00 p.m. **USP Summary, Next Steps**
Dennis Jenke, MBA, Ph.D.*, Chair, USP <661.3> Expert Panel*

5:00 p.m. **Workshop Concludes**