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/Biocompatibility
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
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

3:15 – 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
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