



**USP Workshop on
Modernization of USP Packaging Standards for
Glass and Elastomeric Components
June 19-20, 2017
USP Meetings Center, Rockville, MD USA**

**Draft Agenda
(as of April 18, 2017)**

DAY ONE: Monday, June 19, 2017

Glass Containers

- 8:00 – 8:30 a.m.** **Registration & Coffee**
- 8:30 – 8:50 a.m.** **Welcome and Overview of Key Issues for the Revision of <660> and <1660>**
Michael Eakins Ph.D., *Vice-Chair Packaging & Distribution Expert Committee*
Co-Chair <660> Expert Panel
- 8:50 – 9:10 a.m.** **Revision of the Autoclave Cycle for Glass Grains and Surface Tests**
Alberto Biavati, *Member of <660> Expert Panel*
- 9:10 – 9:25 a.m.** **Use of Autotitrators for Glass Grains and Surface Tests Titration Methods**
David Lisman, *Nipro*
- 9:25 – 9:45 a.m.** **Glass Particles and Flakes: Description, Origin and Detection**
Daniel Haines, *Member of <660> Expert Panel*
- 9:45 – 10:00 a.m.** **Q&A**
- 10:00 – 10:25 a.m.** **Break**
- 10:25 – 10:45 a.m.** **Chinese Perspective on Pharmaceutical Glass**
Yonghua Gao, *Packaging & Distribution Expert Committee*
Co-Chair <660> Expert Panel
- 10:45 – 11:05 a.m.** **Japanese Pharmacopeia Perspective on Containers and Packaging**
Yukio Hiyama Ph.D., *National Institute of Health Sciences, The Ministry of*
Health Labour and Welfare, Japan
- 11:05 – 11:35 a.m.** **Glass Materials and Their Use in Packaging Systems: Regulatory**
Expectations
Charudharshini Srinivasan, *U.S. Food and Drug Administration*
- 11:35 a.m. – 12:00 p.m.** **Q&A/Panel Discussion**
- 12:00 – 1:00 p.m.** **Lunch**
- 1:00 – 1:30 p.m.** **Approach to Elemental Impurities in Glass Containers**
Danae Christodoulou, Ph.D., *U.S. Food and Drug Administration*

- 1:30 – 1:50 p.m. **Borosilicate Glass Formulations with Enhanced Chemical Stability**
Bettine Boltres Ph.D., *Member Packaging & Distribution Expert Committee*
Co-Chair <660> Expert Panel
- 1:50 – 2:10 p.m. **Aluminosilicate Glass Formulations with Enhanced Chemical Stability**
Robert Schaut, *Corning*
- 2:20 – 2:40 p.m. **Q&A/Panel Discussion**
- 2:40 – 3:00 p.m. **Break**
- 3:00 – 3:30 p.m. **Proposed Revision of Spectral Transmission Test**
Holger Roehl, *Member of <660> Expert Panel*
- 3:30 – 3:50 p.m. **Inner Surface Hydrolytic Test: New Approaches**
Carol Flynn, *Member of <660> Expert Panel*
- 3:50 – 4:15 p.m. **Glass Delamination: Predictive Screening Methods**
Daniele Zuccato, *Ompi*
- 4:15 – 4:50 p.m. **Q&A/General Discussion**
- 4:50 – 5:00 p.m. **USP Summary: Next Steps**
Bettine Boltres Ph.D., *Member Packaging & Distribution Expert Committee*
Co-Chair <660> Expert Panel
- 5:00 p.m. **Workshop Adjourns**

DAY TWO: Tuesday, June 20, 2017

Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems

- 8:00 – 8:30 a.m. **Registration & Coffee**
- 8:30 – 8:50 a.m. **Welcome and Overview of Key Issues for the Revision of <381> and Future Revision Topics**
Michael Eakins Ph.D., *Vice-Chair Packaging & Distribution Expert Committee*
Member <381> Expert Panel
- 8:50 – 9:00 a.m. **Topic for Consideration: Elastomers Used for Inhalation Drug Products**
Dan Norwood, Ph.D. *Member Packaging & Distribution Expert Committee*
Member <381> Expert Panel
- 9:00 – 9:30 a.m. **<381> Elastomeric Components Used For Injectable Drug Products Packaging/Delivery Systems**
Diane Paskiet, *Member Packaging & Distribution Expert Committee*
Chair <381> Expert Panel
- 9:30 – 10:00 a.m. **Elastomeric Materials and Their Use in Packaging Systems; Regulatory Expectations**
TBA, *U.S. Food and Drug Administration*

- 10:00 – 10:30 a.m.** **Data Supporting Elemental Impurities Extraction Conditions & Data Analysis for <381>**
Diego Zubriggen, *West Pharmaceuticals*
- 10:30 – 10:50 a.m.** **Break**
- 10:50 – 11:30 a.m.** **<1381> Evaluation of Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems**
Lisa Yoest, *Member <381> Expert Panel*
- 11:30 a.m. – 12:00 p.m.** **Round Table Discussion: Audience Q&A**
- 12:00 – 1:00 p.m.** **Lunch**
- 1:00 – 1:45 p.m.** **<382> and <1382> Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems**
Renaud Janssen, *Member Packaging & Distribution Expert Committee*
Member <381> Expert Panel
- 1:45 – 2:15 p.m.** **Vendor: Perspective on <381>, <1381>, <382> and <1382>**
Heinz Kirchmeyer, *Consultant, Member <381> Expert Panel*
Philippe LeGall, *Aptar, Member <381> Expert Panel*
- Drug Manufacturer: Perspective on <381>, <1381>, <382> and <1382>**
Lisa Yoest, *GSK, Member <381> Expert Panel*
Doug Kiehl, *Lilly, Member <381> Expert Panel*
- 2:15 – 3:15 p.m.** **Round Table Discussion: Audience Q&A**
- 3:15 – 3:40 p.m.** **Break**
- 3:40 – 4:45 p.m.** **Round Table Discussion: Audience Q&A (Cont'd)**
- 4:45 – 5:00 p.m.** **Workshop Summary**
Desmond Hunt, Ph.D., *Scientific Liaison, USP*
- 5:00 p.m.** **Workshop Adjourns**