Control and Determination of Visible and Sub-visible Particulate Matter in Biologics
June 26-27, 2017
USP Headquarters, Rockville, Maryland, USA

Preliminary Agenda
(As of March 31, 2017 / Subject to Change)

Day One: Monday, June 26, 2017

8:00 a.m.	**Registration & Coffee**
8:30 a.m.	**USP Welcome and Workshop Overview**
8:40 a.m. – 10:25 a.m.	**Session I – Therapeutic Protein and Cell Therapy Products**
8:40 a.m.	**Managing Particulate Matter in Therapeutic Protein Products** *Jamie Moore, Ph.D., Senior Scientist & Director, Early Stage Pharma Development, Genentech Inc*
9:05 a.m.	**Current Regulatory Considerations for the Assessment of Visible and Subvisible Particulates in Therapeutic Protein Products.** *Rukman de Silva, Center for Drug Evaluation and Research, U.S. Food and Drug Silver Spring, Maryland, USA*
9:30 a.m.	**Managing Particulate Matter in Cell Therapy Products** *Dominic Clarke, Charter Medical, Ltd, Winston-Salem, North Carolina, USA*
9:55 a.m.	**Analysis of Submicron Particles in Blood Transfusion Products** *Silvia De Paoli, Center for Biologics Evaluation and Research, U.S. Food and Drug Silver Spring, Maryland, USA*
10:20 a.m.	Morning Break
10:45 a.m. – 12:00 p.m.	**Session II – Safety Impact and Evaluation of Particulate Matter**
10:45 a.m.	**Immunogenicity of Therapeutic Protein Aggregates** *Wim Jiskoot, Drug Delivery, Biologics Formulation Group, University Leiden*.
11:10 a.m.	**Safety Evaluation of Particulate Matter** *John Ayres, USP Visual Inspection Expert Panel*
11:35 a.m.	**Panel Discussion / Session I & II**
12:05 p.m.	**Lunch**
1:05 p.m. – 5:00 p.m.	**Session III – Sub-visible and Visible Particulate Matter Determination**
1:00 p.m.	**Improving Flow Imaging Microscopy Particle Classification through Deep Learning** *Neelima Chavali, Drug Product Technologies, Amgen, Thousand Oaks, CA*

1:25 p.m.	**Sub-visible particle characterization: Capabilities and limitations of current technology and implications for designing control strategies** *Atanas Koulov, Lonza Drug Product Services, Basel, Switzerland*
1:50 p.m.	**Usefulness and Issues of Flow Imaging Analysis for Evaluating Aggregates in Therapeutic Protein Injections** *Hiroko Shibata, National Institute of Health Sciences, Tokyo, Japan*
2:15 p.m.	**Visible Particles: Regulatory and Compendial Requirements** *John Shabushnig, USP Dosage Form Expert Committee Member*
2:40 a.m.	**Difficult to Inspection Products: Best Practices and Misconceptions** *Roy Cherris, USP Visual Inspection Expert Panel*
3:05 p.m.	**Afternoon Break**
3:30 a.m.	**Semi-Quantitative Analysis of Inherent Visible Particles for Biopharmaceutical Products** *Stephan Krause, Analytical Biotechnology, MedImmune, Gaithersburg, MD*
3.55 p.m.	**Development of Protein-Like Reference Material for Monitoring Visible Proteinaceous Particles in Biotherapeutics** *Dean Ripple, Ph.D., Bioprocess Measurements Group, NIST, Gaithersburg, MD* *Kristen Gonzalez, MedImmune, Gaithersburg, MD*
4:20 a.m.	**Panel Discussion / Session III**
5:00 p.m.	**End Day 1**

Day Two: Tuesday, June 27, 2017

8:00 a.m.	**Registration & Coffee**
8:30 a.m. – 12:00 p.m.	**Session IV – Manufacturing Control of Particulate Matter**
8:30 a.m.	**Particulate Matter in Biologics Originating from Packaging Components: Occurrence and Control Measures** *Fran DeGrazio Affairs and Technical Services, West Pharmaceutical Services, Lancaster, PA*
8:55 a.m.	**Particulate Formation During Fill & Finish Operations** *Cheng Her, Skaggs School of Pharmacy and Pharmaceutical Sciences University of Colorado*
9:20 a.m.	**Subvisible Particles Introduced by Excipients: Characterization and relevance on protein stability** *Andrea Hawe, Coriolis Pharma Research GmbH, Martinsried, Germany*
9:50 a.m.	**Silicone Oil Particles: Characterization, Control, and Assessment of Biological Impact** *Marisa Joubert, Attribute Sciences, Amgen, Thousand Oaks, CA*

10:20 p.m.	**Morning Break**
10:45 a.m.	**Visible Particles: What is "essentially/practically free from particles" and how to design an appropriate control strategy for visible particles in practice?** *Satish Singh, Lonza Drug Product Services, Basel, Switzerland*
11:10 p.m.	**Panel Discussion / Session IV**
12:00 p.m.	**Lunch**
1:05 a.m. –4:15 p.m.	**Session V – GMP Topics**
1:05 p.m.	**FDA cGMP Expectations with Respect to Visual Inspection and Particulate Matter** *Stephen Langille, Center for Drug Evaluation and Research, U.S. Food and Drug Silver Spring, Maryland, USA*
1:30 p.m.	**Practical Application of Statistical Tools for the Assessment of Particulate Matter in Injectable Products** *TBD*
1:55 p.m.	**Visual Inspection of Particulate Matter: Training, Training Sets and Setting Thresholds** *TBD*
2:20 p.m.	**Monitoring Particulate Matter and Inspection Effectiveness to Support 'Essentially Free' Testing** *Rob Miller, Sr. Manager Technical Services, Pfizer, Kalamazoo, Michigan*
2:55 p.m.	**Afternoon Break**
3:20 p.m.	**Panel Discussion / Q&A**
4:15	Wrap-up/Take
4:30 p.m.	**Workshop Adjourns**