USP Workshop on Biotherapeutics and Peptides
Feb 20-21, 2017, Hotel Marigold
Hyderabad, India

Draft Agenda

Monday, February 20th 2017 - Day 1 - Biotherapeutics

8:00 a.m. **Registration**

9:00 a.m. **USP Welcome**

915 a.m. to 1030 a.m. **Plenary Session:**

1. Control Stratagies for Biotherapeutics - **Michael De Felippis, Eli Lilly**
2. EDQM Perspective in the field of recombinant DNA Products – **Gweneal Cirefice,EDQM**
3. Panel Discussion, Q&A

10:30 a.m. **Morning Break (Tea & Coffee)**

11:00 a.m. to 1:00 P.m. **Session I: Analytical Characterization**

1. Implementation of QBD Paradigm for Biologics - **Dhananjay Patankar**
2. Implementation of Biostatistics in interpreting Bioassay Results**- Steven Walfish, USP**
3. USP Compendial Approach to the Analysis of Biotherapeutics **– Kevin Carrick, USP**
4. Panel Discussion, Q&A

1:00 p.m. **Lunch Break**

2:00p.m. to 4:00 p.m. **Session III: Impurities**

1. FDA Perspective on Particulate matter in Biologic Formulations – **Ewa Marszal, CBER**
2. USP General Chapters for Measurement of Impurities in Recombinant Proteins**– Maura Kibbey, USP**
3. Control of Process Related Impurities in Biopharmaceutical Manufacturing - **Michael De Felippis, Eli Lilly**
4. Panel Discussion, Q&A

4:00 p.m. **Afternoon Break (Tea & Coffee)**

4:30p.m. to 5:00 p.m. **Session IV: Advances in Technology**

1. Role of Analytical Ultracentifugation (AUC) for analysis of Biotherapeutics – **Beckman**
2. Novel Techniques for characterization of Protein Therapeutics & Process Impurities - **Annegret Boge; Biotechniques**

5:00 p.m. **Adjourn, End of Day 1**

Tuesday, February 21st 2017 - DAY 2 - Peptides and Heparin

9:30 a.m. to 11:00 a.m. **Session I: Heparin**

1. Analytical tools for the determination of impurities in heparin– **C.S. Venkatesan, Gland Pharma**
2. USP Compendial Standards for Characterization of Heparin - **Kevin Carrick, USP**
3. Q&A

11:00 a.m. **Morning Break (Tea & Coffee)**

11:30 a.m. to 1 p.m. **Session I: Analytical Characterization of Peptides**

1. Advanced Analytics for Complex Peptide Characterization **– *Joseph Glajch, Momenta Pharmaceuticals***
2. Quality Attributes of Peptides and Analytical QbD considerations – **Rosario LoBrutto, Teva Pharmaceuticals, USA**
3. Panel Discussion – Q&A

1:00 p.m. **Lunch Break**

2:00 p.m. to 4:00 p.m. **Session III: Impurities of Peptides**

1. Compendial Approaches to Measurement of Impurities in USP Peptide Monographs**– Maura Kibbey, USP**
2. Combining qNMR and LC-MS/MS amino acid analysis for purity assignment of peptide reference materials **– TBD**
3. In depth understanding of Product Related Impurities – **Rakesh Shekhawat, Macleods Pharmaceuticals Ltd.**
4. Panel Discussion – Q&A

4:00 p.m. **Afternoon Break (Tea & Coffee)**

4:30 p.m. to 5:00 p.m. **Session IV: Advances in Technology**

1. CESI-MS a technique for the characterization and analysis of both intact and digested biopharmaceuticals - **SCIEX**
2. Advanced Technology for AAA for therapeutic peptides- **TBD**

5:00 p.m. **Closing Remarks & Adjourn – End of the Workshop**