

**USP Workshop on Peptide and Oligonucleotide Therapeutics:  
Regulations, Standards and Quality  
November 4-5, 2019  
USP Headquarters, Rockville, Maryland, USA  
~DRAFT AGENDA~ October 21, 2019**

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**Day Two: Tuesday, November 5, 2019**

- 8:30 a.m.**                    **Registration & Coffee**
- 9:00 a.m. – 11:50 a.m.**   **Session IV – Impurities and Immunogenicity**  
Session Chair: Renata Varga
- 9:05 a.m.                    **Purge-based Risk Assessment for Solvent and Small Molecule Impurities  
Generated During Oligonucleotide Manufacture**  
Jessica Stolee  
*Biogen*
- 9:30 a.m.                    **Product-related impurity quantitative and qualitative analyses in the context of  
Complex Generic peptide products**  
Liqing Gu  
*SGS West Chester*
- 9:55 a.m.                    **New Dogs/Old Tricks: Methods for Assessing the Immunogenicity of Peptide  
Drugs and Their Impurities**  
Anne De Groot  
*EpiVax, Inc.*
- 10:30 a.m.                    **Panel Discussion / Q&A**
- 10:45 a.m.**                    **Networking Break (20 min)**
- 11:05 a.m. – 2:05 p.m.**   **Session V – Novel Therapeutics and Analytical Strategies**  
Session Chair: Michael De Felippis  
*Chair, USP BIO1 – Peptides and Insulins Expert Committee*
- 11:10 a.m.                    **Tailor-made therapeutic peptides for accelerated clinical development**  
Stefania Pfeiffer-Marek  
*Sanofi-Aventis Deutschland GmbH*
- 11:35 a.m.                    **Peptide sameness: Challenges and regulatory requirements**  
Walter Cabri  
*Fresenius Kabi*
- 12:00 p.m.**                    **Networking Lunch**
- 1:00 p.m.                    **Discrimination of Strongly related Peptides and Detection of Peptide Aggregation  
by NMR**  
Edwin Kellenbach  
*Aspen Pharmacare*
- 1:25 p.m.                    **Cell Based Potency Assays for Peptides: Challenges and Strategies**  
Sabrina Rüggeberg  
*Sanofi*