



**5th USP Workshop on Therapeutic Peptides:
Regulations, Standards and Quality
November 5-6, 2018
USP Headquarters, Rockville, Maryland, USA
~FINAL AGENDA~ October 24 2018**

Day One: Monday, November 5, 2018

- 8:00 a.m.** **Registration & Coffee**
- 8:30 a.m.** **USP Welcome**
Fouad Atouf, Ph.D.
Vice President, Global Biologics, USP
- 8:40 a.m.** **Workshop Overview**
Michael De Felippis, Ph.D.
Chair, USP BIO1 – Peptides and Insulins Expert Committee
- 8:50 a.m. –10:30 a.m.** **Session I – Regulatory Considerations**
Session Chair: Donna Christner, Ph.D.; Cory Evans, Ph.D.; Adam Fisher, Ph.D.
Government Liaison, USP BIO1 – Peptides and Insulins Expert Committee
- 8:55 a.m.** **Integrating Approaches from Different Product Modalities to Create Advanced Regulatory Strategies for Peptides**
Speaker: Allison Wolf, Ph.D., Eli Lilly
- 9:15 a.m.** **Setting of Peptide API Specifications**
Speaker: Jean-Marc Poudrel, Ph.D., PolyPeptide
- 9:35 a.m.** **European Regulatory Update on CMC Requirements for Synthetic Peptides**
Speaker: René Thürmer, Ph.D., BfArM
- 9:55 a.m.** **Follow up Discussion on FDA Guidance after Public Comments**
Speaker: Xiaohui (Jeff) Jiang, Ph.D., FDA
- 10:15 a.m.** **Panel Discussion / Q&A**
- 10:30 a.m.** **Networking**
Break (20 min)
- 10:50 a.m. –12:30 p.m.** **Session II – Manufacturing and Control Strategy Considerations**
Session Chair: Michael Verlander, Ph.D.
Member, USP BIO1 – Peptides and Insulins Expert Committee
- 10:55 a.m.** **Synthetic Peptide API Manufacturing: A Mini Review**
Speaker: Jon Rasmussen, Ph.D., PolyPeptide
- 11:15 a.m.** **High-Fidelity Flow Synthesis of Peptides and Proteins**
Speaker: Bradley Pentelute, Ph.D., MIT
- 11:35 a.m.** **Convergent Peptide Syntheses: A Platform for Commercial Peptide Manufacturing**
Speaker: Kevin Seibert, Ph.D., Eli Lilly

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- 11:55 p.m. **Development of Differentiated Peptide Therapeutic Products using an Innovative Formulation Technology**
Speaker: Jan Jezek, Ph.D., Arecor
- 12:15 p.m. **Panel Discussion/Q&A**
- 12:30 p.m. **Networking Lunch/Poster Presentation**
- 1:30 p.m. –3:30 p.m. **Session III – Analytical Technology**
Session Chair: Wilfried Arz, Ph.D.
Member, USP BIO1 – Peptides and Insulins Expert Committee
- 1:35 p.m. **One-Fell-Swoop Chromatography for In-Process Assay of Linaclotide**
Speaker: Daniel Studelska, Ph.D., Mallinckrodt
- 1:55 p.m. **Charge Variant Analysis of Therapeutic Peptides**
Speaker: Anuja Rane, Ph.D., TEVA
- 2:15 p.m. **Synthetic Therapeutic Peptide Structure Elucidation and Purity Analysis by NMR**
Speaker: Edwin Kellenbach, Ph.D., Aspen Pharm
- 2:35 p.m. **Just What the Doctor Ordered: How NMR Can Address Challenging Cases of Peptide Drug Characterization**
Speaker: Jordan Chill, Ph.D., Bar-Ilan University
- 2:55 p.m. **Quantitative HPLC determination of D-His-Glucagon with Proteolytic Sample Preparation**
Speaker: Michael Berger, Bachem
- 3:15 p.m. **Panel Discussion/Q&A**
- 3:30 p.m. –5:00 p.m. **Poster Presentation & Networking Reception**

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Day Two: Tuesday, November 6, 2018

- 8:30 a.m.** **Registration & Coffee**
- 9:00 a.m. –10:00 a.m.** **Session IV – Bioassay**
Session Chair: Gyongyi Gratzl, Ph.D.
Member, USP BIO1 – Peptides and Insulins Committee, and
Ken Miller, Ph.D.
Vice Chair, USP General Chapter Biological Analysis Expert Committee
- 9:05 a.m. **Cell-Based Bioassays in Compendial Standards**
Speaker: Maura Kibbey, Ph.D., USP
- 9:25 a.m. **Bioassay and a Phase Appropriate Control Strategy for Synthetic Therapeutic Peptides APIs**
Speaker: Scott Allen Frank, Ph.D., Eli Lilly
- 9:45 a.m. **Panel Discussion / Q&A**
- 10:00 a.m.** **Networking Break (20 min)**
- 10:20 a.m. –11:50 a.m.** **Session V – Impurities and Immunogenicity**
Session Chair: Gerhard Haas, Ph.D.
Member, USP BIO1 – Peptides and Insulins Committee
- 10:25 a.m. **Peptide Physical Stability and Non-Covalent Aggregation: Challenges and Solution**
Speaker: Norbert Nagel, Ph.D., Sanofi
- 10:45 a.m. **Therapeutic Peptide Aggregation Studies with Orthogonal Techniques**
Speaker: Gyongyi Gratzl, Ph.D., Hikma
- 11:05 a.m. **Immunogenicity and Impurities**
Speaker: Daniela Verthelyi, Ph.D., FDA
- 11:25 a.m. **Panel Discussion / Q&A**
- 11:50 a.m.** **Networking Lunch**
- 1:00 p.m. – 2:25 p.m.** **Session VI – Peptide Vaccines**
Session Chair: Ved Srivastava, Ph.D.
Member, USP BIO1 – Peptides and Insulins Committee
- 1:05 p.m. **Development of Personal Cancer Vaccine NEO-PV-01**
Speaker: Jesse Dong, Ph.D., Neon Therapeutics
- 1:25 p.m. **The GAPVAC Project: Active Personalization of Peptide Vaccines for Patients with Newly Diagnosed Glioblastoma**
Speaker: Norbert Hilf, Ph.D., Immatics



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- 1:45 p.m. **Current Regulatory Perspectives on Therapeutic Peptide Vaccines**
Speaker: S. Rafat Husain, Ph.D., FDA
- 2:05 p.m. **Panel Discussion / Q&A**
- 2:25 p.m.** **Workshop Wrap-up**
Michael De Felippis, Ph.D.
Chair, USP BIO1 – Peptides and Insulins Expert Committee
- 2:40 p.m.** **Workshop Concludes**