Workshop on Synthetic Therapeutic Peptides–Regulations, Standards and Quality
November 14-15, 2016
USP Headquarters, Rockville, Maryland, USA

Final Agenda
(As of November 10, 2016)

Day One: Monday, November 14, 2016

8:00 a.m.	**Registration & Coffee**
8:30 a.m.	**USP Welcome** Tina Morris, Ph.D. *Senior Vice President, Science-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. –10:25 a.m.	**Session I – Raw Materials and Manufacturing** Chair: Michael Verlander, Ph.D. *Member, USP BIO1 – Peptides and Insulins Expert Committee*
8:50 a.m.	**High Quality Starting Materials: One Important Key to Success** Dirk Bachle, Ph.D., Bachem AG
9:15 a.m.	**Characterization of Starting Resins Used for SPPS** Daniel Samson, Ph.D., Bachem AG
9:40 a.m.	**Molecular Hiving Technology: Novel and Innovative Synthesis Technology for the Drug Substances of Peptide Therapeutics** Barry O'Connor, Ph.D., Jitsubo Co. Ltd.
10:05 a.m.	**Panel Discussion / Q&A (20 min)**
10:25 a.m.	**Morning Break**
10:40 a.m. –12:00 p.m.	**Session II –Interactive Session: Implementation of Appropriate cGMPs for Preclinical Through Phase III Drug Substance** Chair: Gary Erickson, Ph.D., CBL Biopharma First 10 minutes: Where are we today? and instructions. Break into 2 groups for 35' each, discuss, and then switch Group A: Chemistry oriented topics or GMP "elements" Group B: Analytical oriented topics or GMP "elements"
12:00 p.m.	**Lunch**
12:45 p.m.	**Reports from Interactive Session #1 Breakout Groups**

1:00 p.m. –2:30 p.m.	**Session III – Impurities** Chair: Wilfried Arz, Ph.D. *Member, USP BIO1 – Peptides and Insulins Expert Committee*
1:00 p.m.	**Combining qNMR and LC-MS/MS Amino Acid Analysis Results for Purity Assignment of Peptide Reference Materials** Marie-Pier Thibeault, M.Sc., National Research Council Canada
1:25 p.m.	**Nonclinical Pharmacology Issues for Setting Impurity Limits for Peptides** Stephanie Leuenroth-Quinn, Ph.D. Office of New Drugs, Nonclinical Pharmacology, CDER, U.S. FDA
1:50 p.m.	**Panel Discussion / Q&A (15 min)**
2:05 p.m.	**Afternoon Break**
2:20 p.m. –4:00 p.m.	**Session IV –Drug Substance and Drug Product Specifications** Chair: Michael De Felippis, Ph.D. *Chair, USP BIO1 – Peptides and Insulins Expert Committee*
2:20 p.m.	**From Critical Quality Attribute Assessment to Specification and Characterization** John Kim, Teva Pharmaceuticals
2:45 p.m.	**Setting Specifications for Therapeutic Peptides in Clinical Development** Daniel Samson, Ph.D., Bachem AG
3:10 p.m.	**Statistical Approaches to Aid the Development of Clinically Relevant Commercial Specification Acceptance Criteria** Kristi Griffiths, Ph.D., Eli Lilly and Co.
3:35 p.m.	**Panel Discussion / Q&A (25 min)**
4:00 p.m.	**Networking Reception**
5:00 p.m.	**End Day 1**

Day Two: Tuesday, November 15, 2016

8:00 a.m.	**Registration & Coffee**
8:30 a.m. –10:00 a.m.	**Session V – Advanced Analytical Technologies** Chair: Ved Srivastava, Ph.D. *Member, USP BIO1 – Peptides and Insulins Expert Committee*
8:30 a.m.	**Higher-Order Structure Comparability of Peptide Therapeutics** Renata Varga, Ph.D., Teva Pharmaceuticals Inc**.**

8:55 a.m.	**Advanced Analytical Techniques for the Evaluation of Peptide Therapeutics** Joseph Glajch, Ph.D., Momenta Pharmaceuticals
9:20 a.m.	**Panel Discussion / Q&A (20 min)**
9:40 a.m.	**Morning Break**
10:00 a.m. –12:30 p.m.	**Session VI – Regulatory Considerations** Moderator: Cory Evans, Ph.D., CVM, U.S. FDA
10:00 a.m.	**Peptide Vaccines Update** Elena Gubina, Ph.D., CBER, U.S. FDA
10:30 a.m.	**Regulatory Perspectives on Characterization of Quality Attributes of Therapeutic Peptides** Rene Thuermer, Ph.D., BfArM, Federal Institute for Drugs and Medical Devices, Germany
11:00 a.m.	**Scientific Considerations in Submitting Synthetic Peptide Drug Products as ANDAs Referencing Peptide Drug Products of rDNA Origin** Deyi Zhang, Ph.D., Office of Generic Drug, CDER, U.S. FDA
11:30 a.m.	**New USP Standards and Initiatives for Peptides** Dale Schmidt, M.S., USP
12:00 p.m.	**Panel Discussion / Q&A (30 min)**
12:30 p.m.	**Workshop Wrap-up** Mike De Felippis, Ph.D. *Chair, USP BIO1 – Peptides and Insulins Expert Committee*
1:00 p.m.	**Workshop Concludes/Lunch** Boxed lunches will be available