



**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**

Day One: Monday, November 4, 2019

- 8:00 a.m.** **Registration & Coffee**
- 8:30 a.m.** **USP Welcome**
Fouad Atouf
Vice President, Global Biologics, USP
- 8:40 a.m.** **Workshop Overview**
Michael De Felippis
Chair, USP Peptide and Oligonucleotide Therapeutics Workshop Steering Committee, and Chair, USP BIO1 – Peptides and Insulins Expert Committee
- 8:50 a.m. –10:35 a.m.** **Session I – Regulatory Considerations**
Session Chair: Ved Srivastava
USP Peptide and Oligonucleotide Therapeutics Workshop Steering Committee, and Member, USP BIO1 – Peptides and Insulins Expert Committee
- 8:55 a.m.** **Considerations in Developing Generic Peptide and Oligonucleotide Drug Products**
Deyi Zhang
CDER, FDA
- 9:20 a.m.** **CMC and Regulatory Challenges on Oligonucleotide Drugs**
Lawrence Perez
CDER, FDA
- 9:45 a.m.** **Challenges of Personalized Neoantigen-specific Therapeutic Vaccines**
Elena Gubina
CBER, FDA
- 10:10 a.m.** **CMC, Regulatory, and Quality Strategies for Production of Therapeutic Oligonucleotides – EU vs. US**
Marc Lemaitre
ML Consult LLC
- 10:35 a.m.** **Networking Break (20 min)**
- 10:55 a.m. –2:00 p.m.** **Session II – Analytical and Control Strategies**
Session Chair: Marc Lemaitre
USP Peptide and Oligonucleotide Therapeutics Workshop Steering Committee
- 11:00 a.m.** **Manufacturing Process and Control Strategy for GalNAc Conjugated siRNAs**
Lubo Nechev
Alynylam
- 11:25 a.m.** **Quality Attributes for siRNA**
Robert Duff
Amgen



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- 11:50 a.m. Networking Lunch**
- 12:45 p.m. Control Strategies and Analytical Test Methods for Peptide-Conjugates**
Thomas Wucherpennig
Bachem
- 1:15 p.m. Phase-Appropriate CMC Development for Synthetic Peptides**
Tanja Huth
Bachem
- 1:40 p.m. Sessions I and II Panel Discussion/Q&A**
- 2:00 p.m. –3:30 p.m. Session III – Novel Approaches for Characterization**
Session Chair: Gerhard Haas
*USP Peptide and Oligonucleotide Therapeutics Workshop Steering Committee, and
Member, USP BIO1 – Peptides and Insulins Expert Committee*
- 2:05 p.m. Computational Modeling of the Structure-Function Relationship in RNA**
Christina Bergonzo
NIST
- 2:30 p.m. Analytical Methods for Oligonucleotide Therapeutics**
Claus Rentel
Ionis Pharmaceuticals, Inc.
- 2:55 p.m. Considerations for Biophysical Characterization in Developing Peptide Biologics**
Ranajoy Majumdar
Eli Lilly and Co.
- 3:20 p.m. Chiral Purity Testing of Amino Acids by Supercritical Fluid Chromatography**
Gareth Murphy
Ipsen
- 3:45 p.m. Panel Discussion/Q&A**
- 4:00 p.m. –5:30 p.m. Networking Reception**



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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



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- 1:50 p.m. **Panel Discussion / Q&A**
- 2:05 p.m. **Workshop Wrap-up**
Michael De Felippis
Chair, USP BIO1 – Peptides and Insulins Expert Committee
- 2:15 p.m. **Adjourn**