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