

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

11:50 a.m. Networking Lunch

12:45 p.m. Control Strategies and Analytical Test Methods for Peptide-Conjugates

Thomas Wucherpfennig

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