



**USP Workshop on Therapeutic Peptides and Oligonucleotides:  
Regulations and Quality Standards  
March 1-5, 2021 Virtual Workshop**

**DRAFT AGENDA~ February 19, 2021**

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**Session One, Monday, March 1, 2021: Regulatory Considerations and Control Strategies**

- 10:00 a.m. EST**      **USP Welcome**  
Maura Kibbey  
*Senior Scientific Fellow, Global Biologics, USP*
- 10:10 a.m.            **Workshop Overview and Introduction to Session 1**  
Michael De Felippis  
*Chair, USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee,  
and Chair, USP BIO1 Expert Committee*
- 10:20 a.m.            **CMC and Regulatory Challenges of Oligonucleotide Drugs**  
Lawrence Perez  
*CDER, US FDA*
- 10:45 a.m.            **Considerations of Comparative Studies for Complex Synthetic Peptide Products**  
Jeff Jiang  
*The Sweetwood Group LLC*
- 11:10 a.m.            **CMC Regulatory Considerations for Oligonucleotides and Peptides: Similarities  
and Differences**  
René Thürmer  
*BfArM, Germany*
- 11:25 a.m.**            **Break (10 min)**
- 11:35 a.m.            **Regulatory Considerations for Setting Smart Starting Materials Specifications for  
Synthetic Oligonucleotides**  
Dominik Altevogt  
*F. Hoffman LaRoche*
- 12:00 p.m.            **Vendor Selection for Unusual Amino Acid Derivatives**  
Tobias Kapp and Heiko Rinderhagen  
*Bachem AG and Janssen-Cilag AG, respectively*
- 12:25 p.m.            **Panel Discussion and Q&A Moderated by Michael De Felippis & Michael Verlander**  
*USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and USP  
BIO1 Expert Committee members*
- 1:00 p.m.**            **Adjourn**



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***Session Two, Wednesday, March 3, 2021: Analytical Tools and Advances to Ensure Quality***

- 10:00 a.m. EST**      **Welcome to Session 2 and Highlights of Session 1**  
Marc Lemaitre  
*USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and  
USP BIO1 Expert Committee member*
- 10:20 a.m.      **Antisense Oligonucleotide Specification and Release Tests using a Risk-Based Platform Approach**  
Hong Jiang  
*Biogen*
- 10:45 a.m.      **Application of NMR Spectroscopy for characterization and identity testing of oligonucleotide drug molecules**  
Alfred Ross  
*Roche*
- 11:10 a.m.      **Method Development for Characterization of Synthetic Oligonucleotides by LC-MS**  
Brian Rivera  
*Phenomenex*
- 11:35 a.m.**      **Break (10 min)**
- 11:45 a.m.      **Recent advances in degradation product characterization of therapeutic oligonucleotides using liquid chromatography mass spectrometry**  
Michael Bartlett  
*University of Georgia*
- 12:10 p.m.      **Panel Discussion and Q&A Moderated by Rosario Lobrutto and Jessica Stolee**  
*USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee*
- 1:00 p.m.**      **Adjourn**



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***Session Three, Friday, March 5, 2021: Manufacturing and Formulation Approaches***

- 10:00 a.m. EST**      **Welcome to Session 3 and Highlights of Session 2**  
Gerhard Haas  
*USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and Vice Chair, USP BIO1 Expert Committee*
- 10:20 a.m.**      **Applications of Green Chemistry in Oligonucleotide Manufacturing**  
Yogesh Sanghvi  
*Rasayan Inc.*
- 10:45 a.m.**      **Drug Delivery Systems and Life Cycle Management for Peptides Beyond the Vial and Syringe**  
Chris Rhodes  
*Drug Delivery Experts*
- 11:10 a.m.**      **Terminal Sterilization of Oligonucleotide Drug Products**  
Nadim Akhtar  
*AstraZeneca*
- 11:35 a.m.**      **Break (10 min)**
- 11:45 a.m.**      **Synthesis of Tirzepatide by Native Chemical Ligation (NCL), a Once-weekly dual GIP and GLP-1 Receptor Agonist**  
Ankur Jalan and Michael E. Kopach  
*Eli Lilly & Co.*
- 12:25 p.m.**      **Panel Discussion and Q&A Moderated by Ved Srivastava and Gerhard Haas**  
*USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and USP BIO1 Expert Committee members*
- 1:10 p.m.**      **Adjourn**