

**USP Workshop on Therapeutic Peptides and Oligonucleotides:
Regulations and Quality Standards
February 28, March 2 and 4, 2022 Virtual Workshop
DRAFT AGENDA~ December 17, 2021**

Session One, Monday, February 28, 2022: Regulatory and Compendial Considerations

- 10:00 a.m. EST** **USP Welcome**
Fouad Atouf
Vice President, 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*
- Session Co-moderated by Michael De Felippis and Marc Lemaitre**
 *USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and USP
 BIO1 Expert Committee members*
- 10:20 a.m.** **Developing Product-specific Guidances on Oligonucleotides for Generic Drug
Development**
Deyi Zhang
CDER, US FDA
- 10:45 a.m.** **Current CMC Regulatory Experiences and Expectations for Oligonucleotides**
René Thürmer
BfArM, Germany
- 11:10 a.m.** **USP Standards to Support Quality of Peptide and Oligonucleotide Therapies**
Julie Zhang and Sarita Acharya
USP
- 11:35 a.m.** **Break (10 min)**
- 11:45 a.m.** **Strategies to Demonstrate Comparability with Changes in Oligonucleotide
Manufacturing**
Nadim Akhtar
*USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee member,
and on behalf of EPOC Working Group*
- 12:10 p.m.** **Platform Approach to Oligonucleotide Product Development**
Elaine Fowler
AstraZeneca
- 12:35 p.m.** **Panel Discussion and Q&A Moderated by Michael De Felippis and Marc Lemaitre**
- 1:15 p.m.** **Adjourn**



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Session Two, Wednesday, March 2, 2022: Analytical Tools and Advances to Ensure Quality

- 10:00 a.m. EST** **Welcome to Session 2 and Highlights of Session 1**
Gerhard Haas
USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and USP BIO1 Expert Committee member
- Session Co-moderated by Gerhard Haas and Hong Jiang**
USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee members
- 10:20 a.m.** **Analytical Method Development for Critical Impurities in Phosphoramidites**
Dennis Rhodes
Ionis
- 10:45 a.m.** **Characterization of Low-level D-Amino Acid Degradation Impurities Using Liquid Chromatography-High Resolution Tandem Mass Spectrometry**
Baole Zhang
Hybio Pharmaceutical
- 11:10 a.m.** **In-depth Impurity Profiling of Synthetic Oligonucleotides by High Resolution Mass Spectrometry**
Kui Yang
Division of Complex Drug Analysis, Office of Testing & Research, OPQ, CDER, US FDA
- 11:35 a.m.** **Analytical Strategies for Characterization of Stereopure Platform Chemistry**
Philip Ross
Wave Life Sciences
- 12:00 p.m.** **Break (10 min)**
- 12:10 a.m.** **Novel Approaches for Mass Spectrometry Characterization of Highly Modified Synthetic RNA**
Giovanni Calderisi
Bachem, Switzerland
- 12:35 p.m.** **Evaluation of Chromatographic Techniques for Oligonucleotide Separation and Subsequent Detection by HRMS for Routine Testing**
Andrew Argo
Biogen
- 1:00 p.m.** **Panel Discussion and Q&A Moderated by Gerhard Haas and Hong Jiang**
- 1:45 p.m.** **Adjourn**



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Session Three, Friday, March 4, 2022: Manufacturing and Raw Material Considerations

- 10:00 a.m. EST** **Welcome to Session 3 and Highlights of Session 2**
Ved Srivastava
Member of USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee and USP BIO1 Expert Committee
- Session Co-moderated by Ved Srivastava and Nadim Akhtar**
USP Therapeutic Peptides and Oligonucleotides Workshop Steering Committee members
- 10:20 a.m.** **Fmoc Alpha Methyl Quaternary Amino Acid Supply Chain Development**
Mark Kerr
Eli Lilly & Company
- 10:45 a.m.** **Risk Assessment for a Nitrosamine Contamination of Peptide APIs Manufactured by Solid-Phase Peptide Synthesis (SPPS)**
Matteo Villain
Bachem Americas
- 11:10 a.m.** **Strategies for the Control of Impurities in Oligonucleotide Synthesis**
Hagen Cramer
QurAlis Corporation
- 11:35 a.m.** **Break (10 min)**
- 11:45 a.m.** **Quantitation of Impurities in Tirzepatide Peptide Fragments by High Resolution Ultra-High Pressure Liquid Chromatography-Mass Spectrometry (UHPLC-MS)**
Mark Strege
Eli Lilly & Company
- 12:10 p.m.** **Panel Discussion and Q&A Moderated by Ved Srivastava and Nadim Akhtar**
- 1:00 p.m.** **Adjourn**