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 Tandom 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**