USP Workshop on Peptide and Oligonucleotide Therapeutics: Regulations and Quality Standards
April 9-10, 2024
USP Headquarters, Rockville, Maryland, USA

Agenda

Day One: Tuesday, April 9, 2024

8:00 a.m.	**Arrive at USP, Registration & Coffee**
8:30 a.m.	**USP Welcome and Opening Remarks** Fouad Atouf, Senior 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 Oligonucleotides Expert Committee
8:50 a.m. –10:35 a.m.	**Session I – Regulatory and Compendial Considerations** Session Chair: Ved Srivastava
8:55 a.m.	**Standards USP to Support Quality of Peptide and Oligonucleotide Therapeutics** Kevin Carrick, Senior Director Biologics Science & Standards, USP
9:20 a.m.	**European quality guidelines for synthetic peptides and oligonucleotides** Rene Thürmer, CMC reviewer and Deputy Head of the Unit Pharmaceutical Biotechnology, BfArM - Federal Institute for Drugs and Medical Devices, Germany
9:45 a.m.	**CMC Challenges in FDA-approved Synthetic Oligonucleotide Drugs** Lawrence Perez, Senior Pharmaceutical Quality Assessor, U.S. Food and Drug Administration
10:10 a.m.	**CMC Regulatory Experiences and Expectations for Peptides** Katharine Duncan, Senior Pharmaceutical Quality Assessor, U.S. Food and Drug Administration
10:35 a.m.	**Networking Break**
10:55 a.m. – 2:00 p.m.	**Session II – Starting Materials** Session Chair: Marc Lemaitre
11:00 a.m.	**Framework for Evaluating Impurity Risks in Starting Materials for Oligonucleotide API Manufacturing** David Butler, Chief Technology Officer, Hongene Biotech Corporation
11:25 a.m.	**Holistic control strategy of oligonucleotides starting materials** Martina Austeri, Director of Quality Control, Bachem AG, Switzerland
11:50 a.m.	**Networking Lunch**
1:00 p.m.	**UHPLC/MS method development of starting materials for Oligonucleotide Therapeutics** Dennis Rhodes, Assistant Director, Ionis Pharmaceuticals
1:25 p.m. – 2:00 p.m.	**Sessions I and II Panel Discussion/Q&A** **Moderators:** Marc Lemaitre and Ved Srivastava **Panelists:** Kevin Carrick, Rene Thürmer, Lawrence Perez, Katharine Duncan, David Butler, Martina Austeri and Dennis Rhodes

USP Workshop on Peptide and Oligonucleotide Therapeutics: Regulations and Quality Standards
April 9-10, 2024
USP Headquarters, Rockville, Maryland, USA

Agenda

2:00 p.m. – 4:45 p.m.	**Session III – Analytical Technologies** Session Chair: Gerhard Haas
2:05 p.m.	**Analytical toolbox to enable the synthesis and release of complex synthetic peptides** Tim Hellebrand, Senior Group Leader for Analytical Development, Bachem
2:30 p.m.	**Synthetic Oligonucleotide Impurity Analysis: Enhancing the Conventional Single Quad Method Using UPLC-ToF-MS** Ying Qing Yu, Biopharmaceutical Program Science Team Leader, Waters
2:55 p.m.	**Networking Break**
3:10 p.m.	**Improving TIDES product risk assurance with NMR spectroscopy** Anna Codina, Senior Director Biopharma and Strategic Market Development, Bruker BioSpin
3:35 p.m.	**Evaluate the need for bioassays in the context of control strategy for synthetic therapeutic peptides** Ranajoy Majumdar, Director (Scientific), Analytical Development Bioproducts Research and Development, Eli Lilly and Company
4:00 p.m.	**LC-HRMS-based Multi-attribute Method for Oligonucleotides (MAMO): Characterization and Impurity Profiling** Kui Yang, Senior Research Scientist, U.S. Food and Drug Administration
4:25 p.m.	**Panel Discussion/Q&A** **Moderators:** Gerhard Haas Panelists: Kui Yang, Ranajoy Majumdar, Anna Codina, Ying Qing Yu, and Tim Hellebrand
4:45 p.m. – 6:00 p.m.	**Networking Reception**

USP Workshop on Peptide and Oligonucleotide Therapeutics: Regulations and Quality Standards
April 9-10, 2024
USP Headquarters, Rockville, Maryland, USA

Agenda

Day Two: Wednesday, April 10, 2024

8:30 a.m.	**Arrive at USP, Registration & Coffee**
9:00 a.m. –10:40 a.m.	**Session IV – Manufacturing Strategies** Session Chair: Michael Verlander
9:05 a.m.	**Process improvements to effect more efficient and greener peptide synthesis** Chandrakant Kulkarni, Principal Scientist – Synthetic Peptide Department R&D Center, and Mohan Dhote, Head of Department, Synthetic Peptide, Enzene Biosciences
9:30 a.m.	**Comparison of different Synthesis Protocols Applied to Produce Therapeutic Oligonucleotides** Daniel Samson, Head Oligonucleotides, Bachem
9:55 a.m.	**Chemo Enzymatic Peptide Synthesis (CEPS) as a sustainable approach for therapeutic peptide manufacturing** Marco Macis, Research & Development Manager for Peptides API, Fresenius Kabi iPSUM
10:20 a.m.	**Panel Discussion/Q&A** **Moderators:** Michael Verlander **Panelists:** Mohan Dhote, Chandrakant Kulkarni, Daniel Samson, and Marco Macis
10:40 a.m.	**Networking Break (20 min)**
11:00 a.m.–12:40 p.m.	**Session V – Impurities and Control** Session Chair: Antonio Ricci
11:05 a.m.	**Assessing the Safety of Peptide-Related Impurities in Support of Commercial Control Strategy Development** Brian W. Pack, Executive Director, Eli Lilly and Company
11:30 a.m.	**Immunogenicity Risk Assessment of Peptide Drugs and their Impurities** Annie De Groot, Chief Science Officer and Chairman of the Board, EpiVax, Inc
12:00 p.m.	**Networking Lunch**
1:00 p.m.	**Toxicity and Immunogenicity Considerations for Oligonucleotide-Related Impurities: Impact on Control Strategy Development** Brian W. Pack, Executive Director, Eli Lilly and Company
1:25 p.m.	**In Vitro Immunogenicity Assays for the Evaluation of Generic Peptide Drug Products** Eric Pang, Senior Chemist, U.S. Food and Drug Administration
1:50 p.m.	**Panel Discussion/Q&A** **Moderators:** Antonio Ricci **Panelists:** Brian W. Pack, Annie De Groot, and Eric Pang
2:00 p.m.	**Workshop Wrap-up**

USP Workshop on Peptide and Oligonucleotide Therapeutics: Regulations and Quality Standards
April 9-10, 2024
USP Headquarters, Rockville, Maryland, USA

Agenda

	Michael De Felippis Chair, USP BIO1 – Peptides & Oligonucleotide Expert Committee
2:10 p.m.	**Adjourn**