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

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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
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
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Michael De Felippis
Chair, USP BIO1 – Peptides & Oligonucleotide Expert Committee

2:10 p.m. Adjourn