# 4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality
## November 6-7, 2017
## USP Headquarters, Rockville, Maryland, USA

## Final Agenda

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### *Day One: Monday, November 6, 2017*

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| **8:00 a.m.** | **Registration & Coffee** |
| **8:30 a.m.** | **USP Welcome**<br>Fouad Atouf, Ph.D.<br>*Vice President, Global Biologics, USP* |
| **8:40 a.m.** | **Workshop Overview**<br>Michael De Felippis, Ph.D.<br>*Chair, USP BIO1 – Peptides and Insulins Expert Committee* |
| **8:50 a.m. –10:25 a.m.** | **Session I – GMP Manufacturing and Control Strategy Considerations**<br>Session Chair: Michael Verlander, Ph.D.<br>*Vice Chair, USP BIO1 – Peptides and Insulins Expert Committee* |
| 8:55 a.m. | **Higher Molecular Weight Peptides (HMWP) – Control Strategies and Acceptance Criteria**<br>Speaker: Daniel Samson, Ph.D., Bachem |
| 9:20 a.m. | **Analyzing complex peptides with ion mobility mass spectrometry and Hydrogen / deuterium exchange**<br>Speaker: Bradley B. Stocks, Ph.D., National Research Council Canada |
| 9:45 a.m. | **A Holistic Quality Control Strategy for Peptide APIs**<br>Speaker: Tobias Hauck, Ph.D., Bachem |
| 10:10 a.m. | **Panel Discussion / Q&A (15 min)** |
| **10:25 a.m.** | **Morning Break (20 min)** |
| **10:45 a.m. –12:15 p.m.** | **Session II – Analytical Characterization and Impurities**<br>Session Chair: Ved Srivastava, Ph.D.<br>*Member, USP BIO1 – Peptides and Insulins Expert Committee* |
| 10:50 a.m. | **LC Peak Purity Assessment Using a Novel LC-MS Data Processing Approach**<br>Speaker: Patrik Plattner, Ph.D., Bachem |
| 11:15 a.m. | **Can We Consider Peptides As Small Biologics? Application of Capillary Electrophoretic Techniques for Peptide Therapeutics**<br>Speaker: Renata Varga, Ph.D., Teva Pharmaceuticals |
| 11:40 p.m. | **Identification and Quantitation of Host Cell Protein Impurities in Peptide Biotherapeutics Using Liquid Chromatography - Mass Spectrometry**<br>Speaker: Xiaoshi Wang, Ph.D., FDA |
| 12:05 p.m. | **Panel Discussion/Q&A (15 min)** |

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| **12:20 p.m**. | **Lunch/Poster Presentation** |
| **1:20 p.m. –3:20 p.m.** | **Session III – Interactive Section- Impurities**<br>Session Moderators*:* Jon Holbech Rasmussen, Ph.D., PolyPeptide Laboratories,<br>Alexander Swietlow, Ph.D., PolyPeptide Laboratories,<br>Adam Fisher, Ph.D., FDA<br>Ved Srivastava, Ph.D Member, USP BIO1 – Peptides and Insulins Expert Committee |
| 1:25 p.m. | **Overview Presentation: Impurities in Peptide Manufacturing**<br>Speaker: Jon Holbech Rasmussen, Ph.D., PolyPeptide Laboratories |
| 1:45 p.m. | **Interactive section** |
| **3:20 p.m.** | **Afternoon Break (15 min)** |
| **3:35 p.m. –5:00 p.m.** | **Session IV – Analytical Methods Development, Validation and Novel Approaches**<br>Session Chair: Gerhard Haas, Ph.D.<br>*Member, USP BIO1 – Peptides and Insulins Expert Committee* |
| 3:40 p.m. | **Analytical Quality by Design Integration as part of Phase Appropriate Methods Validation and Transfer**<br>Speaker: Rosario LoBrutto, Ph.D., Sandoz, Inc. |
| 4:05 p.m. | **Peptide Identity and Content Determination: the Case for NMR**<br>Speaker: Edwin Kellenbach, Ph.D., Aspen Pharmacare |
| 4:30 p.m. | **Contribution of High Resolution Mass Spectrometry in Synthetic Peptides: Importance of Detailed Impurity Characterization for Better Manufacturing**<br>Speaker: David Cosquer, MSc., PolyPeptide Laboratories |
| 4:55 p.m. | **Panel Discussion / Q&A (15 min)** |
| **5:10 p.m.** | **Poster Presentation & Networking Reception** |

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### *Day Two: Tuesday, November 7, 2017*

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| **8:00 a.m.** | **Registration & Coffee** |
| **8:30 a.m. –10:00 a.m.** | **Session V – Peptide Formulation and Delivery**<br>Session Chair: Mike De Felippis, Ph.D.<br>Chair, USP BIO1 – Peptides and Insulins Committee |
| 8.35 a.m. | **Assessing the Impact of Functional Excipients on Peptide Formulation Attributes**<br>Speaker: Suzanne M. D'Addio, Ph.D., Merck Research Laboratories |
| 9.00 a.m. | **Oral Delivery of Peptides with Lipid-Based Self-Emulsifying Drug Delivery Systems**<br>Speaker: Vincent Jannin, Ph.D., Gattefosse |
| 9.25 a.m. | **Orally Delivered Peptides in Clinical Development**<br>Speaker: Nozer Mehta, Ph.D., Peptide Technologies LLC |
| 9:50 a.m. | **Panel Discussion / Q&A (15 min)** |
| **10:05 a.m.** | **Morning Break (20 min)** |
| **10:25 a.m. –12:05 p.m.** | **Session VI – Regulatory Considerations**<br>Session Chair: Adam Fisher, Ph.D., FDA |
| 10:30 a.m. | **Peptide ANDAs: Regulatory Perspective on Test and Reference Product Comparability Studies**<br>Speaker: Cameron J. Smith, Ph.D., FDA |
| 10:55 a.m. | **Regulatory Change Control for Peptide Starting Materials: A Case Study**<br>Speaker: Gerhard Haas, Ph.D., Bachem |
| 11:20 a.m. | **Scientific and Regulatory Considerations for Synthetic Peptides Referencing Peptide Drug Products of rDNA Origin**<br>Speaker: Eric Pang, Ph.D., FDA |
| 11:45 a.m. | **Panel Discussion / Q&A (15 min)** |
| **12:05 p.m.** | **Lunch/Poster Presentation** |
| 1:05 p.m. | **Workshop Wrap-up** |
| **1:30 p.m.** | **Workshop Concludes** |