**USP Biologics Workshop; 4th Annual Workshop on Bio therapeutics and Peptides**
**February 05-06, 2018; Hyderabad; India**

**Day 1 – February 05, 2018 - Heparin and Protein**

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| **09:00 AM - 10:10 AM** | **Plenary Session** |
| **09:00 AM - 09:25 AM** | **Strategy Refresh for USP Biologics**<br>*Ranjan Chakrabarti, Ph.D., VP & Head, Global Bio Lab & Standards - USP, India* |
| **09:25 AM - 09:50 AM** | **Trends and Changing Landscape for Biotherapeutics**<br>*TBD* |
| **09:50 AM - 10:10 AM** | **Panel Discussion and Q&A** |
| **10:10 AM - 01:00 PM** | **Session 1 – Manufacturing Control and Analytical Characterization** |
| **10:10 AM - 10:35 AM** | **Analytical Characterization of Enoxaparin**<br>*Dama Venugopala Rao, Ph.D., Dr Reddy's Laboratories Ltd* |
| **10:35 AM - 11:00 AM** | **Best Practices for Viral Clearance during Monoclonal Antibody Manufacturing Process**<br>*Ralf Klein, Ph.D., Virusure, Germany* |
| **11:00 AM - 11:20 AM** | **Morning Tea Break** |
| **11:20 AM - 11:45 AM** | **Manufacturing Control and Analytical Characterization of Heparin sodium**<br>*Shu Zhou, Shenzhen Hepalink, China* |
| **11:45 AM - 12:10 PM** | **Analytical Characterization of Monoclonal Antibodies - by Mass Spectrometry**<br>*Utpal Tattu, Ph.D., Indian Institute of Science, India* |
| **12:10 PM - 12:35 PM** | **Challenges of Glycan Characterization in Glycoproteins**<br>*Chris Jones, Ph.D., Member: General Chapters Biological Analysis - USP, United Kingdom* |
| **12:35 PM - 01:00 PM** | **Panel Discussion and Q&A** |
| **01:00 PM - 02:00 PM** | **Lunch** |
| **02:00 PM - 03:40 PM** | **Session 2 – Regulatory and Life Cycle Management** |
| **02:00 PM - 02:25 PM** | **Current Regulatory Expectations for Therapeutic Monoclonal Antibodies in Europe**<br>*Detlef Bartel, Ph.D., Paul-Ehrlich Inst, Germany* |
| **02:25 PM - 02:50 PM** | **Setting of Test Specification for Biological Products**<br>*Dhananjay Patankar, Ph.D., Syngene International, India* |
| **02:50 PM - 03:15 PM** | **Regulatory Pathway for MAb's in ROW**<br>*Parisa Asvadi, Ph.D., Aurobindo Pharma, India* |
| **03:15 PM - 03:40 PM** | **Panel Discussion and Q&A** |
| **03:40 PM - 04:00 PM** | **Afternoon Tea Break** |
| **04:00 PM - 04:30 PM** | **Session 3 – Novel Technology** |
| **04:00 PM - 04:15 PM** | **CE in the Biopharmaceutical Industry from Cell Line Screening to Characterization and QC**<br>*Jim Thorne, Ph.D., SCIEX, United Kingdom.* |
| **04:15 PM - 04:30 PM** | **Platform method development for Innovator and Biosimilar Therapeutic proteins using cIEF and CE-SDS on Maurice**<br>*Annegret Boge, Ph.D., Biotechniques* |
| **04:30 PM - 04:35 PM** | **Closing Remarks & Adjourn** |

**Day 2 – February 06, 2018 - Insulin and Therapeutic Peptides**

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| **09:00 AM - 10:10 AM** | **Session 1 – Plenary Session** |
| **09:00 AM - 09:25 AM** | **Regulatory Considerations on Control Strategies for Therapeutic Peptide**<br>*USFDA Speaker (TBC)* |
| **09:25 AM - 09:50 AM** | **Characterization of Insulin and its analogues**<br>*Amarnath Chatterjee, Ph.D., Stelis Biopharma, India* |
| **09:50 AM - 10:10 AM** | **Panel Discussion and Q&A** |
| **10:10 AM - 12:30 PM** | **Session 2 – Manufacturing Control and Analytical Characterization** |
| **10:10 AM - 10:35 AM** | **Process development and characterization of Peptides to establish control strategies**<br>*Suzanne M. D'Addio, Ph.D., Merck, USA* |
| **10:35 AM - 11:00 AM** | **Impurity profiling for Peptide drugs**<br>*Gopal Vaidyanathan, Ph.D., Natco Research Center, India* |
| **11:00 AM - 11:20 AM** | **Morning Tea Break** |
| **11:20 AM - 11:45 AM** | **Designing of bioactive peptides containing thioamide: The fast, efficient, and inexpensive peptide synthesis**<br>*Jayanta Chatterjee, Ph.D., Indian Institute of Science, India* |
| **11:45 AM - 12:10 PM** | **Identity, Content and purity of Therapeutic Peptide by NMR**<br>*Edwin Kellenbach, Ph.D., Aspen, Netherlands* |
| **12:10 PM - 12:30 PM** | **Panel Discussion and Q&A** |
| **12:30 PM - 01:30 PM** | **Lunch** |
| **01:30 PM - 03:05 PM** | **Session 3 – Regulatory and Life Cycle Management of Therapeutic peptides** |
| **01:30 PM - 01:55 PM** | **Peptide ANDA: Regulatory perspective on Comparability studies**<br>*Michael Verlander, Proactive Quality Compliance, USA* |
| **01:55 PM - 02:20 PM** | **Establish Quality specifications for peptide drugs - A regulatory pharmaceutical approach**<br>*Rosario LoBrutto, Ph.D., Sandoz, USA* |
| **02:20 PM - 02:45 PM** | **Assessing the impact of functional excipients on peptide formulation attributes**<br>*Suzanne M. D'Addio, Ph.D., Merck, USA* |
| **02:45 PM - 03:05 PM** | **Panel Discussion and Q&A** |
| **03:05 PM - 03:25 PM** | **Evening Tea Break** |
| **03:25 PM - 03:55 PM** | **Session 4 – Novel Technology** |
| **03:25 PM - 03:40 PM** | **Speaker 1** |
| **03:40 PM - 03:55 PM** | **Tools for Bioseparations using Chromatography-LC and MS**<br>*Shimadzu* |
| **03:55 PM - 04:00 PM** | **Closing Remarks & Adjourn** |