

**The New Frontiers in Pharmaceutical Drug Substance and Drug Product CMC for Novel Modalities  
May 6-7, Lexington MA**

**Preliminary Program: Subject to change | TBA: To be Announced**

<b>May 6, 2025</b>	<b>Day 1</b>
08:00AM – 08:15AM	Opening Remarks (Chairs)
08:15AM – 09:15AM	Plenary Talk: <b>Kelvin H Lee</b> , Univ of Delaware: Title TBA
<b>09:15AM – 12:00PM</b>	<b>Session 1: Advances in Cellular Expression and Upstream Production Chair: John Morgan, Purdue Co-Chairs: Marianthi Ierapetritou, Univ. of Delaware; Ning Liu (Eli Lilly)</b>
09:15AM– 09:40AM	<b>Corynex®: Highly Scalable and Sustainable Microbial Production Platform for Peptide Drugs Capable of Non-Canonical Amino Acid Incorporation Teruhisa Mannen, Ajinomoto</b>
09:40AM– 10:20AM	Coffee break
10:20AM – 10:40AM	<b>Tian Jun, Wuxi Biologics Title TBA</b>
10:40AM – 11:00AM	<b>Sarah Mbiki, Regeneron Title TBA</b>
11:00AM – 11:20AM	Single-Cell Biophysical Profiling and Machine Learning for Monitoring Recombinant AAV Production in Transfection-Based Processes Francesco Destro et al, MIT
11:20AM – 11:40AM	Novel Expression Systems for Biomanufacturing Zhen Ma, Merck & Co, Inc.
11:40AM – 12:00PM	Developing a Universal Label Free Cell Analysis Platform for Cell Therapy Manufacturing Eric Schmidt, Takeda
12:00PM – 12:50PM	Lunch
12:50PM – 3:30PM	<b>Session 2: Formulation and Delivery Approaches Chair: Sarena Horava, Eli Lilly; Co-Chair: Marian Gindy, Merck</b>
12:50PM – 1:15PM	<b>Robert K. Prud'homme, Princeton University Title TBA</b>
1:15PM – 1:40PM	<b>Strategic Selection of Drug Substance Physical Forms to Facilitate Drug Product Manufacturing Ashish Garg, Eli Lilly</b>
1:40PM – 2:00PM	In-Silico Particle Property Characterization Tools to Assess Manufacturability Risk for Small Molecule Formulation Indu Mathancheri, Sanofi

2:00PM – 2:20PM	Formulation of Unconjugated Antibodies As Precursors to Antibody-Drug Conjugates Robert Kuo, Merck & Co.
2:20 PM-2:40 PM	Predicting Subcutaneous Absorption of mAbs: A Machine Learning Approach to Evaluating Biologics Drug Delivery Kaoutar Abbou Oucherif, Eli Lilly
2:40PM – 3:00PM	Break
3:00PM – 3:20PM	An Automated Platform for Manufacturing Nanoparticles for Drug Delivery Applications Aniket Udepurkar, MIT
3:20PM- 3:40PM	Single-Use Bags as a Viable Solution for Long-Term Storage of mRNA and Lipid Nanoparticles Yuji Takeda, Sartorius
3:40PM – 5:10PM	<b>Panel Discussion: Regulatory Challenges and Progress for Novel Modality Products: Moderator: Paul Collins, Eli Lilly (Retired) Lead presenter: Tim Watson, Gilead Sciences</b> Panelists: TBA
5:10PM – 6:45PM	<b>Poster Session &amp; Reception</b>
<b>May 7, 2025</b>	<b>Day 2</b>
08:00AM – 08:15AM	<b>Opening Remarks (Chairs)</b>
08:15AM – 09:15AM	<b>Plenary Talk: Martin Johnson, Lilly</b> <b>Title TBA</b>
09:15AM – 12:00PM	<b>Session 3: Advances in Modalities with Chemical Transformations</b> <b>Chair: Neda Nazemifard, Takeda; Co-chair: Karthik Narsimhan, Abbvie</b>
09:15AM– 09:45AM	<b>Development of Inducible and Producing Cell-Line for Recombinant Adeno-Associated Virus (rAAV) Biomanufacturing</b> <b>Seongkyu Yoon, University of Massachusetts Lowell</b>
09:45AM– 10:00AM	<b>Coffee break</b>
10:00AM – 10:20AM	Towards the Development of Robust and Scalable Processes for Antibody Drug Conjugates Margaret Fettis-Koenders, AbbVie
10:20AM – 10:40AM	Aparajita Dasgupta (Pfizer) Title: TBA
10:40AM – 11:00AM	A Framework for Operation Forecasting of Pharmaceutical Production Daniel Casas-Orozco et al., Eli Lilly
11:00AM – 11:20AM	Continuous-Flow Peptide Synthesis: An Alternative Approach to Streamlined Production

	Ankur Kapil et al., Veranova
11:20AM – 11:40AM	Scalable Liquid Phase Peptide Synthesis Kevin Nagy, Snapdragon Chemistry Inc.
11:40AM – 12:00PM	<b>TBA</b>
12:00PM – 1:00PM	<b>Lunch</b>
1:00PM – 3:30PM	<b>Session 4: Downstream Processing and Purification</b> <b>Chair: Olga Paley, Takeda; Co-chair: Wai Keen Chung, Bristol Myers Squibb</b>
1:00PM – 1:30PM	<b>Steve Cramer – RPI</b> <b>Title TBA</b>
1:30PM – 1:50PM	Multi-Component Modeling of Host-Cell-Protein- and Antibody-Containing Heteroaggregates in Protein a Chromatography Soumitra Bhoyar, Amgen
1:50PM – 2:10PM	Removal of dsRNA Byproducts from mRNA Feeds with Affinity Chromatography Nathaniel Clark, Repligen
2:10PM – 2:30PM	<b>Challenges and Development Tools for the Optimization of Flow-through Polishing Steps for the Purification of Bispecific Antibodies</b> <b>Jessica Hung et al., Bristol Myers Squibb</b>
2:30PM – 2:50PM	<b>Break</b>
2:50PM – 3:10PM	<b>Enhancing Aggregate Reduction Using Anion Exchange Hybrid Filter in an Immunocytokine Diabody Fusion Protein Purification Process</b> <b>Alex Way, Biologics Purification Development, AbbVie</b>
3:10PM – 3:30PM	<b>TBA</b>
3:30PM – 4:00PM	<b>Panel Discussion: The future of Novel Modalities</b>
4:00PM – 4:30PM	<b>Closing remarks (Chairs)</b>