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

May 6, 2025	**Day 1**
08:00AM – 08:15AM	**Opening Remarks (Chairs)**
08:15AM – 09:15AM	**Plenary Talk: Kelvin H Lee, Univ of Delaware** **NIIMBL: the National Institute for Innovation in Manufacturing Biopharmaceuticals**
09:15AM – 11:30AM	**Session 1: Advances in Cellular Expression and Upstream Production** **Chair: John Morgan, Purdue Co-Chair: Ning Liu (Eli Lilly)**
09:15AM– 09:40AM	**Teruhisa Mannen, Ajinomoto** **Corynex®: Highly scalable and sustainable microbial production platform for peptide drugs capable of non-canonical amino acid incorporation**
9:40AM – 10:05AM	**Tian Jun, Wuxi Biologics** **Advancing Cost-effectiveness and Robustness in Manufacturing by Process Innovation and Digital Application**
10:05AM – 10:30AM	**Sarah Mbiki, Regeneron** **Developing a Digital Twin for In Silico Medium Development**
10:30AM – 10:50AM	Single-Cell Biophysical Profiling and Machine Learning for Monitoring Recombinant AAV Production in Transfection-Based Processes Francesco Destro et al, MIT
10:50AM – 11:10AM	Novel Expression Systems for Biomanufacturing Zhen Ma, Merck & Co, Inc.
11:10AM – 11:30PM	Developing a Universal Label Free Cell Analysis Platform for Cell Therapy Manufacturing Eric Schmidt, Takeda
11:30AM – 12:30PM	**Lunch**
12:30PM – 3:00PM	**Session 2: Formulation and Delivery Approaches** **Chair: Sarena Horava, Eli Lilly**
12:30PM – 12:55PM	**Robert K. Prud'homme, Princeton University** **Lipid Nanoparticle (LNP) Processing: LNP Concentration Approaches and Cold Vacuum Spray Drying to Produce Dry Powders at Scale**
12:55PM – 1:20PM	**Ashish Garg, Eli Lilly** **Strategic Selection of Drug Substance Physical Forms to Facilitate Drug Product Manufacturing**
1:20PM – 1:40PM	In-Silico Particle Property Characterization Tools to Assess Manufacturability Risk for Small Molecule Formulation Indu Mathancheri, Sanofi
1:40PM – 2:00PM	Formulation of Unconjugated Antibodies as Precursors to Antibody-Drug Conjugates Robert Kuo, Merck & Co.

2:00 PM-2:20 PM	Predicting Subcutaneous Absorption of mAbs: A Machine Learning Approach to Evaluating Biologics Drug Delivery Kaoutar Abbou Oucherif, Eli Lilly
2:20PM – 2:40PM	An Automated Platform for Manufacturing Nanoparticles for Drug Delivery Applications Aniket Udepurkar, MIT
2:40PM- 3:00PM	Single-Use Bags as a Viable Solution for Long-Term Storage of mRNA and Lipid Nanoparticles Yuji Takeda, Sartorius
3:00PM – 3:15PM	**Break**
3:15PM – 4:45PM	**Panel Discussion: Regulatory Challenges and Progress for Novel Modality Products and Platforms** **Moderator: Paul Collins, Eli Lilly (Retired)** **Lead presenter: Tim Watson, Gilead Sciences** **Panelists: Celia Cruz, Eli Lilly, Erika Pfeiler, Valsource, and Li Zang, Abbvie**
4:45PM-4:50 PM	**Introduction to Reception by Ajinomoto**
4:50PM – 6:30PM	**Poster Session & Reception**
1	Advancing RNA Therapeutics: High-Throughput Screening and Scalable Production of Targeted Lipid Nanoparticles (LNPs) Samin Akbari et al., Sartorius
2	Activation, Transfection and Expansion of T Cells in a Novel, All-in-One, Fully Automated Cell Therapy Manufacturing Platform Priya Anandakumaran, et al., Sartorius
3	Investigation into the Critical Process Parameters for Lipid Nanoparticle Formulation in Impinging Jet Mixers Cedric Devos et al., MIT
4	Advancing upstream process with AI/ML – strategies and opportunities Zhuangrong Huang, Takeda
5	Wireless µLED-packed bed reactor for continuous photochemical transformations Esai Lopez et al., WPI
6	Lipid Nanoparticles (LNPs) By Co-Loading Versus Post-Loading, and the Scaleup of Lnp Processing Robert K. Prud'homme, Princeton University
7	Translation of Lnp Mixing Conditions By Micromixing Time Mapping Jingfan Yang et al., Eli Lilly
8	Investigating High Molecular Weight Species Formation for Complex, Non-Monoclonal Antibody Proteins Using a Hybrid Modeling Approach Ciara Young, Takeda
9	The Impact of Buffer in RNA-LNP Formulations: Mitigating Oxidation of Ionizable Lipid Tails and RNA-Lipid Adduct Formation Daniel Estabrook, Eli Lilly

May 7, 2025	Day 2
08:00AM – 08:15AM	**Opening Remarks (Chairs)**
08:15AM – 09:15AM	**Plenary Talk: Martin Johnson, Eli Lilly** **Title Flow Chemistry Concepts and Techniques Applied to Solid Phase Oligonucleotide Synthesis**
09:15AM – 12:30PM	**Session 3: Advances in Modalities with Chemical Transformations** **Chair: Neda Nazemifard, Takeda; Co-chair: Karthik Narsimhan, Abbvie**
09:15AM– 09:40AM	**Seongkyu Yoon, University of Massachusetts Lowell** **Development of inducible and producible cell-line for recombinant Adeno-Associated Virus (rAAV) Biomanufacturing**
09:40AM– 10:00AM	Towards the Development of Robust and Scalable Processes for Antibody Drug Conjugates Margaret Fettis-Koenders, AbbVie
10:00AM – 10:20AM	In-Silico Support for Process Intensification and Scale-up of ADC Processes Aparajita Dasgupta, Pfizer
10:20AM – 11:00AM	**Coffee Break and Networking**
11:00AM – 11:20AM	A Framework for Operation Forecasting of Pharmaceutical Production Daniel Casas-Orozco et al., Eli Lilly
11:20AM – 11:40AM	Continuous-Flow Peptide Synthesis: An Alternative Approach to Streamlined Production Ankur Kapil et al., Veranova
11:40AM – 12:00PM	Scalable Liquid Phase Peptide Synthesis Kevin Nagy, Snapdragon Chemistry Inc.
12:00 PM- 12:20 PM	Enhancing Mab Production Through Hybrid Modeling Assisted Real-Time Process Control R. Wheaton et al. Bristol Myers Squibb
12:20PM – 1:30PM	**Lunch** **Roundtable Discussion with Rescale (starts at 12:40PM in Auditorium):** **Unifying Compute, Data, and AI for Multidisciplinary Analysis in Pharmaceutical Development Derek McCoy and Viktor Rozsa, Rescale** **Additional information: https://rescale.com/lp/aiche-pd2m-2025/**
1:30PM – 3:30PM	**Session 4: Downstream Processing and Purification** **Chair: Olga Paley, Takeda; Co-chair: Wai Keen Chung, Bristol Myers Squibb**
1:30PM – 1:55PM	**Steve Cramer, RPI** **Advances in AAV and LVV Downstream Bioprocessing**
1:55PM – 2:15PM	Multi-Component Modeling of Host-Cell-Protein- and Antibody-Containing Heteroaggregates in Protein a Chromatography Soumitra Bhoyar, Amgen

2:15PM – 2:35PM	Removal of dsRNA Byproducts from mRNA Feeds with Affinity Chromatography Nathaniel Clark, Repligen
2:35PM – 2:55PM	Challenges and Development Tools for the Optimization of Flow-through Polishing Steps for the Purification of Bispecific Antibodies Jessica Hung et al., Bristol Myers Squibb
2:55PM – 3:15PM	Enhancing Aggregate Reduction Using Anion Exchange Hybrid Filter in an Immunocytokine Diabody Fusion Protein Purification Process Alex Way, AbbVie
3:15PM – 3:35PM	Advancing Downstream Workflows through AI, Computational Methods and Automation Terrence Dobrowsky, Takeda
3:35PM – 4:30 PM	**Closing Remarks and Open Networking**