Cambridge Healthtech Institute's

18TH ANNUAL BIOPROCESSING SUMMIT

Register by April 10 for Savings up to $500

AUGUST 10-13, 2026 | BOSTON, MA

OMNI BOSTON HOTEL AT THE SEAPORT + VIRTUAL

Transforming Bioprocessing for the Digital Age

2026 PROGRAMS

- UPSTREAM PROCESS
- DOWNSTREAM & FORMULATION
- INTENSIFICATION & DIGITALIZATION
- MODERNIZING ANALYTICS
- GENE THERAPY, RNA, AND LNPs
- CELL THERAPY
- EMERGING MODALITIES

PLENARY KEYNOTE SPEAKERS

MONDAY: COMPLEX MODALITIES

Ran Zheng, PhD
Former CEO,
Landmark Bio

Melissa J. Moore, PhD
Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics

Jennitte L. Stevens, PhD
Chief Technical Operations Officer, insitro

Weichang Zhou, PhD
CTO, MediLink Therapeutics

WEDNESDAY: DIGITALIZATION AND AI

Anthony Mire-Sluis, PhD
Senior Vice President, Global Quality, Gilead Sciences

Susan Hynes
Global Head, Quality, GSK

Lynn Bottone
Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.

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BioprocessingSummit.com

Transforming Bioprocessing
for the Digital Age

As emerging technologies, advanced data strategies, and AI-driven solutions reshape how biologics are developed and manufactured, the **Bioprocessing Summit** stands at the forefront of this transformation.

Now in its 18th year, the Summit has become one of the industry's most influential and comprehensive gatherings, bringing together the global community of scientists, engineers, technology innovators, and executives who are driving the digital evolution of bioprocessing.

This is where leaders across process development, scale-up, manufacturing, quality, and analytics convene to share data, exchange ideas, and advance best practices for biologics, antibodies, cell and gene therapies, RNA, and new for 2026, peptide and oligonucleotide medicines.

Beyond the science, the Bioprocessing Summit is where the bioprocessing community connects. Designed to foster meaningful engagement, the event offers extensive networking opportunities—from receptions and breakout discussions to informal meetups—creating space for collaboration, partnership building, and new ideas to take shape.

When the industry gathers to explore the technologies and strategies shaping the future of biologics manufacturing, this is where it happens.

2026 PLENARY KEYNOTES

Monday, August 10 | 5:00 – 6:00 PM

Manufacturing Complex Modalities

Ran Zheng, PhD
Former CEO,
Landmark Bio

Melissa J. Moore, PhD
Chair, Board of Directors,
Waterfall Scientific; Board
Member, Tessera Therapeutics

Jennitte L. Stevens, PhD
Chief Technical Operations
Officer, insitro

Weichang Zhou, PhD
CTO, MediLink
Therapeutics

Wednesday, August 12 | 4:20 – 5:15 PM

The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality

Anthony Mire-Sluis, PhD
Senior Vice President, Global
Quality, Gilead Sciences

Susan Hynes
Global Head, Quality,
GSK

Lynn Bottone
Senior Vice President, Quality Operations,
Environment Health & Safety, Pfizer Inc.

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18TH ANNUAL
BIOPROCESSING SUMMIT
August 10-13, 2026 • Boston, MA
Omni Boston Hotel at the Seaport + Virtual

#CHIBioprocessingSummit

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18TH ANNUAL
BIOPROCESSING SUMMIT

	AUGUST 10 SYMPOSIUM + TRAINING SEMINARS	AUGUST 11-12	AUGUST 12-13
Stream 1 **UPSTREAM PROCESS**	Novel & Alternative Expression Systems	Cell Line Development & Engineering	Cell Culture & Upstream Processing
Stream 2 **DOWNSTREAM & FORMULATION**	TS: Formulation, Development, and Manufacturing	Formulation, Stability & Delivery	Advances in Purification & Recovery
Stream 3 **INTENSIFICATION & DIGITALIZATION**	TS: Introduction to Machine Learning for CMC and Biomanufacturing	Intensified & Continuous Bioprocessing	Digital Transformation & AI in Bioprocess
Stream 4 **MODERNIZING ANALYTICS**	TS: Introduction to CMC for Biotherapeutic Products: Bioprocessing and Analytical	Analytical Intellgence	Next-Generation Analytical Methods
Stream 5 **GENE THERAPY, RNA, AND LNPs**	RNA and LNP Production and Formulation	Gene Therapy CMC & Analytics	Gene Therapy Manufacturing
Stream 6 **CELL THERAPY**	Cell Therapy Analytics	Gene Therapy CMC & Analytics	Cell Therapy CMC & Manufacturing
Stream 7 *New:* **EMERGING MODALITIES**	CMC for ADC & Next-Generation Conjugates	Oligonucleotide and Peptide CMC and Manufacturing	Advances in Purification & Recovery

STREAM #1
UPSTREAM BIOPROCESSING

This Upstream Bioprocessing stream spans the full spectrum of upstream innovation—from designing next-generation production cell lines to optimizing culture systems and exploring novel expression hosts—and provides a comprehensive look at the tools, strategies, and technologies advancing today's upstream development. The **Cell Line Development & Engineering** conference dives into host cell engineering strategies, vector optimization, clone selection, and stability; while the **Cell Culture and Upstream Processing** conference explores scaling up strategies, improving process robustness, optimizing mid-stream processes, and implementing digital biomanufacturing. The pre-conference symposium on **Novel & Alternative Expression Systems** showcases the various alternative host systems—bacterial, yeast, insect, plant, and cell-free—and their adaptiveness to today's biomanufacturing needs.

Conference Programs

AUGUST 10

Symposium: Novel & Alternative Expression Systems — View Program »

AUGUST 11-12

Cell Line Development & Engineering — View Program »

AUGUST 12-13

Cell Culture & Upstream Processing — View Program »

Novel & Alternative Expression Systems

Alternative Hosts. Optimal Products. New Possibilities.

Monday, August 10

7:30 am **Registration Open and Morning Coffee**

8:30 **Organizer's Welcome Remarks**

BACTERIA AND YEAST HOSTS

8:35 **Chairperson's Remarks**
Matt Anderson-Baron, PhD, CoFounder & CEO, Future Fields

8:40 **Engineering Yeast's Secretion Pathway for Manufacturing**
Will Parker, Graduate Researcher, Engineering, North Carolina State University

Engineering yeast's secretion pathway offers a powerful strategy to enhance the manufacturing of valuable proteins, enzymes, and biopharmaceuticals. By optimizing protein folding, vesicle trafficking, and export mechanisms within yeast cells, researchers can significantly increase secretion efficiency and product yield. Advances in genetic engineering and systems biology enable precise pathway modifications, reducing intracellular bottlenecks. These improvements position yeast as a scalable, cost-effective platform for industrial biotechnology and sustainable biomanufacturing.

9:10 **Development and Manufacturing of Ultra-Stable Insulin Using New Insulin Proteins in Bacteria and Yeast**
Hua Tu, PhD, CEO, Metabulin Inc.

We are developing an ultra-stable insulin analog using advanced protein engineering and formulation technologies from UT Southwestern. Our approach addresses fundamental biophysical instabilities such as fibrillation, aggregation, and stress sensitivity, that limit current insulin products. Importantly, elimination of fibril formation enables substantially greater flexibility in formulation design and pharmacokinetic optimization.

9:40 **Using a Baculovirus Platform for the Manufacturing of Antigens Aimed at Immune System Modulation**
Martin Linhult, PhD, CMC Lead, Diamyd

This presentation highlights the use of a baculovirus expression platform to efficiently produce recombinant antigens designed to modulate immune responses. It will discuss key considerations in construct design, expression, and purification, along with the platform's advantages for generating complex antigens.

10:10 **Single-Step Bacterial Secretion to Produce Growth Factors and Cytokines**
Julie Ming Liang, PhD, Co-Founder & CSO, Opera Bioscience

Growth factors and cytokines are commonly used media reagents with a market valued at $740M. These proteins are manufactured in *E. coli* as inclusion bodies, requiring solubilization and refolding. Opera Bioscience has developed the type 3 secretion system (T3SS) in Salmonella for single-step secretion of soluble heterologous proteins, achieving up to 90% purity before purification. We will present Opera's progress on the secretion and production of growth factors and cytokines.

10:40 **Sponsored Presentation** *(Opportunity Available)*

11:10 **Networking Coffee Break**

MAUFACTURING SCALE UP OF INSECT CELL LINES

11:25 **Solving and Scaling Protein Expression Challenges with a Multicellular Platform: Transgenic Drosophila Melanogaster**
Matt Anderson-Baron, PhD, CoFounder & CEO, Future Fields

The expansive genetic toolkit for Drosophila melanogaster allows for stable expression of bioactive proteins. Illustrated through multiple case studies, we will discuss genetic strategies on optimizing protein expression, including tissue-specific and inducible expression. This novel approach has the potential to overcome recombinant protein expression difficulties associated with conventional systems.

11:55 **Next-Generation Insect Cell Lines for Biomanufacturing through Functional Genomics**
Arya Kumar Surjeet, PhD, Senior Researcher, Department of Entomology, College of Agriculture, Food and Environment, University of Kentucky

Next-generation insect cell lines offer powerful alternatives for recombinant protein and vaccine production, yet their full potential remains underexplored. This talk highlights how functional genomics, transcriptomics, and single-cell approaches are being used to systematically characterize and engineer insect cell platforms. By integrating omics-driven insights with cell line development, we demonstrate strategies to enhance productivity, stability, and biomanufacturing relevance of insect expression systems.

12:25 pm **Luncheon Presentation to be Announced** THOMSON

12:55 **Session Break**

E. COLI AND *N. BENTHAMIANA* EXPRESSION SYSTEMS

1:30 **Chairperson's Remarks**
Julie Ming Liang, PhD, Co-Founder & CSO, Opera Bioscience

1:35 **Metabolomics-Guided Insights into Recombinant Protein Solubility in *E. coli* Expression Systems**
Snehal Ganjave, PhD, Specialist, Pharmaceutical Chemistry, University of California- San Francisco

Recombinant production of disulfide rich proteins in *E. coli* is hindered by host redox imbalance, misfolding and aggregation. In our study, we combined untargeted metabolomics of two *E. coli* strains (BL21 (DE3) and SHuffle) with manipulation of fusion tags (thioredoxin) and induction temperature to identify metabolic signatures associated with soluble vs insoluble expression. Our findings reveal actionable metabolome based indicators of host performance and provide a roadmap for rational expression platform design.

2:05 **Australia's First Biopharm—Development of a Pilot-Scale Recombinant Protein Production Platform in *N. benthamiana***
Julia Solonenka, PhD Candidate, Center for Agriculture and the Bioeconomy, Queensland University of Technology

Biopharming harnesses plants as an emerging platform for recombinant protein production, offering a promising alternative to traditional expression systems. I will introduce our *Nicotiana benthamiana*-based expression system and the pioneering work of Australia's first biopharming initiative. Our aim was to develop a plant-based biologic to combat parasitic worms in livestock. This presentation encapsulates a three-year project of developing, scaling, and testing a plant-based recombinant protein in clinical studies from start to finish.

2:35 **Sponsored Presentation** *(Opportunity Available)*

3:05 **Networking Refreshment Break**

CHALLENGES OF ALTERNATIVE CELL LINES FOR LARGE-SCALE MANUFACTURING

3:20 **KEYNOTE PRESENTATION: Novel Expression Systems for Biomanufacturing**
Zhen Ma, PhD, Director, Process R&D Enabling Technologies, Novel Expression Systems, Merck

In the Process R&D Enabling Technologies group at Merck, we have recently established the Novel Expression Systems team to identify the most suitable hosts for the engineering and expression and of various biomolecules. We are exploring *Bacillus subtilis* and *Komagataella phaffii* (previously known as *Pichia pastoris*) as promising hosts that capitalize on the advantages of protein secretion.

3:50 **Overcoming Manufacturing Challenges of Rapid, Cell-Free Production of Proteins**
Richard Spanggord, PhD, Senior Director, Manufacturing Science & Technology, Sutro Biopharma Inc.

Cell-free protein synthesis unlocks high-throughput biologics discovery and machine learning–driven protein engineering. By decoupling cell growth from protein production, it enables rapid expression in just 5-8 hours using preprepared, stable extracts. Unlike cell-based systems, it offers precise control over reaction conditions, efficient incorporation of non-natural amino acids, and production of complex molecules from diverse scaffolds—all with a single extract. This flexibility accelerates design–build–test cycles and supports parallel screening at scale.

4:20 **Networking Refreshment Break and Transition to Plenary Keynote**

Novel & Alternative Expression Systems

Alternative Hosts. Optimal Products. New Possibilities.

PLENARY KEYNOTE SESSION

5:00 **PANEL DISCUSSION: Manufacturing Complex Modalities**




Moderator: Ran Zheng, Former CEO, Landmark Bio
As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
Melissa J. Moore, PhD, Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics
Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 **Welcome Reception in the Exhibit Hall with Poster Viewing**

7:00 **Close of Novel & Alternative Expression Systems Symposium**

> "Great opportunity to network with colleagues and learn about the latest in bioprocessing!"
>
> *— Jerry M., PhD, Senior Vice President, Process Development, Amgen*

Monday, August 10

4:20 pm Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

5:00 PANEL DISCUSSION: Manufacturing Complex Modalities




Moderator: Ran Zheng, Former CEO, Landmark Bio
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6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

Tuesday, August 11

7:30 am Registration and Morning Coffee

8:15 Organizer's Welcome Remarks

EXPRESSION SYSTEMS & VECTOR ENGINEERING

8:20 Chairperson's Remarks
Christina S. Alves, PhD, Head, US Biologics Process Development, Takeda

8:25 KEYNOTE PRESENTATION: Cell Line Design Strategies for Improving Biotherapeutic Expression
Jack J. Scarcelli, PhD, Senior Director, Head of Cell Line Development, Sanofi
While the advent of targeted and semi-targeted integration expression systems reduced risk of cell-line instability, it has simultaneously increased focus on expression-vector engineering to enhance titer and quality. This presentation examines expression improvements achieved through strategic vector design, including optimization of vector topologies and the inclusion and use of genetically-encoded reporter proteins. These approaches enable the development of a robust expression system capable of addressing increasingly complex portfolios.

8:55 Strong Tunable Synthetic Promoters for Recombinant Protein Expression
Shuang Wei, PhD, Senior Scientist, Merck
We have developed a novel, synthetic, tunable promoter system for recombinant protein expression in CHO cells. It delivers a threefold productivity increase over the CMV promoter with enhancer and shows good long-term stability. This promoter can significantly boost biologics manufacturing, enabling higher yields and consistent performance. Its tunability also supports optimized expression for difficult-to-express molecules such as multispecific antibodies.

9:25 A New Antibody Expression Vector for Higher Yield, Faster Cell-Line Development, and Improved Stability
Zhiwei Song, PhD, CSO, Nexa Biologics, Singapore
Leveraging two proprietary technologies, we developed a novel antibody expression vector that increases yield, accelerates cell-line development, and improves stability. It features a mutated glutamine synthetase (GS) selection marker with reduced enzymatic activity to enhance selection stringency and generate highly productive, stable clones. It also incorporates an enhanced CMV promoter containing a proprietary DNA insert to boost expression. Together, these innovations increase bulk pool antibody expression four- to five-fold.

9:55 Precision in Process: Advanced Assays and Workflows Using Cedex Bioanalyzers. Roche
Ryan Lybarger, Roche CustomBiotech

10:25 Coffee Break in the Exhibit Hall with Poster Viewing

11:05 Optimizing TI-CHO Platforms: Process Acceleration and Chromatin-Driven Expression Variability
Kavya Ganapathy, PhD, Postdoctoral Research Fellow, Genentech
This talk presents two advances in TI-CHO development: SPEED-MODE, a streamlined workflow that significantly shortens cell-line–development timelines through targeted process refinements, and a mechanistic study explaining why clones with identical integration sites display wide productivity differences. Rather than promoter methylation or histone modifications, chromatin accessibility and transcriptional regulation emerge as key drivers of expression variability.

11:35 Leveraging SSI CHO for Exogenous PAM Enzyme Co-Expression to Enhance Fusion Peptide Processing
Laura Zielewicz, PhD, Principal Scientist, Pfizer Inc.
As molecule complexity increases, expression platforms must be engineered to support specialized biosynthetic requirements. For certain fusion peptide molecules, biological activity depends on efficient c-terminal amidation catalyzed by peptidylglycine a-amidating monooxygenase (PAM), which was limited to ~50% by endogenous PAM activity for this molecule. To address this, engineered PAM was co-expressed using a site-specific integration (SSI) platform, enabling controlled PAM expression, and increasing peptide amidation to as high as ~90%.

12:05 pm What Does Secretion Look Like in a Single Cell?
Nathan E. Lewis, PhD, GRA Eminent Scholar and Professor, Center for Molecular Medicine Complex, Department of Biochemistry and Molecular Biology, University of Georgia
Bioproduction occurs in tanks, but protein synthesis and secretion happen in the single cell. Thus, it is of great value to understand protein secretion, at the single-cell level. To do this, we deployed SEC-seq, a single-cell RNA-sequencing method that simultaneously quantifies protein secretion at the single-cell level. Using this, we investigated the transcriptional differences of single cells in IgG-producing pools, and derivative high and low producer clones.

12:35 Transition to Lunch

12:45 Luncheon Presentation to be Announced Catalent

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

CLONE SCREENING & SELECTION FOR HIGH-PRODUCING CELL LINES

2:00 Chairperson's Remarks
Nathan E. Lewis, PhD, GRA Eminent Scholar and Professor, Center for Molecular Medicine Complex, Department of Biochemistry and Molecular Biology, University of Georgia

2:05 KEYNOTE PRESENTATION: Adaptive Development: Aligning Cell-Line Optimization with Process Improvements for Enhanced Speed and Productivity
Christina S. Alves, PhD, Head, US Biologics Process Development, Takeda
Accelerated biotherapeutics development, coupled with the need for cost-effective production, necessitates innovation in cell line and process technologies. By integrating streamlined workflows, innovative genetic tools, automation, and process intensification strategies we have developed a platform for monoclonal antibodies and adjacent modalities. Through this work the importance of constant iteration between cell line optimization and process improvements emerged as a key factor in establishing a robust, productive protein biologics platform.

2:35 High-Throughput Bio-Layer Interferometry (BLI)-Based Screening of Chain Pairing for Bispecific Antibody Cell Line Development
Jackson Leong, PhD, Senior Scientist, Cell Culture Process Development, Denali Therapeutics Inc.
Correct heavy- and light-chain pairing is a critical quality attribute for bispecific antibodies, yet early clone selection in cell-line development often relies primarily on titer. We present a high-throughput Bio-Layer Interferometry (BLI)–based assay to screen chain pairing directly from culture supernatant, enabling rapid,

orthogonal assessment of assembly during fed-batch production and improving clone elimination decisions in bispecific cell-line development workflows.

3:05 **Structurally Interacting RNA (sxRNA)—A Novel Approach to Isolating High Productivity CHO Cell Clones**
Susan Sharfstein, PhD, Professor of Nanoscale Science and Engineering, University at Albany
Current methods for isolating high-producing CHO clones employ antibiotic and/or metabolic selection (e.g., DHFR/MTX, GS/MSX). These approaches are time-consuming, labor-intensive, and yield variable productivities. We developed a novel strategy that integrates a miRNA into the expression vector, co-transcribed with the gene of interest. The miRNA enables translation of a reporter mRNA (e.g., GFP or CD4), permitting efficient selection of high producers by FACS or magnetic beads.

3:35 **Presentation to be Announced**

Demeetra

3:50 **Sponsored Presentation** *(Opportunity Available)*

4:05 **Refreshment Break in the Exhibit Hall with Poster Viewing**

4:40 **Realizing the Potential of Transposase-Mediated Integration for CHO-Based Vaccine Antigen Production**
John Ruano, PhD, Principal Scientist, GSK
Transposase-mediated semi-targeted transgene integration (STI) offers substantial advantages over random integration for the development of stable, high productivity CHO cell lines. Despite increasing implementation of transposases in monoclonal antibody Cell Line Development (CLD), their performance for other recombinant proteins has not been widely demonstrated. Presented here is the successful establishment of a transposase-mediated STI CLD platform for vaccine antigens.

5:10 **Screening Methods to Identify Clones with Favorable Meabolic Signatures**
Hillary Miller, PhD, Principal Scientist, Cell Engineering and Analytical Sciences, Johnson & Johnson Innovative Medicine

5:40 **Interactive Breakout Discussions**
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

6:30 **Close of Day**

Wednesday, August 12

8:00 am **Registration and Morning Coffee**

GENE THERAPY & VIRAL VECTOR MANUFACTURING

8:30 **Chairperson's Remarks**
Susan Sharfstein, PhD, Professor of Nanoscale Science and Engineering, University at Albany

8:35 **Plasmid Engineering for AAV Production and Increased Safety**
Azadeh Sarfallah, PhD, Senior Scientist, Applied Viral Sciences, Genentech Inc.
To improve rAAV production safety, this study optimized Rep-Cap plasmid architecture to prevent unintended packaging of plasmid sequences. Findings revealed that upstream backbone elements, rather than the downstream P5 promoter, drove non-specific Rep78 expression. By replacing these elements with an alternative and removing the P5 promoter, high viral titers were maintained while eliminating replication-competent AAV (rcAAV) formation. These refinements ensure the efficacy and safety of gene-therapy vectors.

9:05 **Advancing AAV Manufacturability Toolbox for Early Programs and Beyond**
Metewo Selase Enuameh, PhD, Associate Director, Vector Core Cell Line Development, REGENXBIO, Inc.
In recombinant Adeno-Associated Virus (rAAV) delivered gene therapy, continuous improvement of established manufacturing processes to optimize product quality and production yields is desirable to further reduce manufacturing costs and regulatory risks. Using cell line development and engineering, plasmid and process optimization, plus technological advancements and innovation, we demonstrate how we achieved our current state of the art NAVXpress platform process, while maintaining high product purity.

9:35 **Presentation to be Announced**

ThermoFisher SCIENTIFIC
ProteinBioSolutions

10:05 **Coffee Break in the Exhibit Hall with Poster Viewing**

ALTERNATIVE EXPRESSION PLATFORMS TO SPEED BIOLOGICS/VACCINE PRODUCTION

10:45 **Accelerating Antibody Fragment Discovery through AI-Integrated Ribosome Display and Cell-Free Protein Synthesis**
Jean-Sebastien Maltais, PhD, Research Officer, Medical Devices, National Research Council Canada
The increasing demand for faster and animal-free approaches to therapeutic antibody development underscores the importance of advancing AI-guided, *in vitro* platforms for the discovery of single-chain variable fragments (ScFvs). By integrating cell-free display technologies with machine learning–driven sequence analysis, the approach enables high-throughput screening and characterization of ScFvs with improved affinity, stability, and developability, accelerating therapeutic antibody discovery while reducing costs and ethical constraints.

11:15 **Image-Based Toolkit to Track Recombinant HPV VLP in Yeast for Vaccine Upstream Process Development**
Nicole Smiddy, PhD, Assoc Principal Scientist, Vaccines Analytical R&D, Merck & Co.
A deeper understanding of upstream process parameters modulating recombinant protein assembly outcomes enables targeted bioprocess development. We developed an image- driven toolkit, which includes high content confocal microscopy, super resolution microscopy, and cryoET. These techniques were applied to yeast expressing L1 from different HPV types and sampled over a time course under different growth conditions. The results uncovered distinct patterns between protein localization, intracellular changes, cell growth conditions, and protein yield.

11:45 **Transition to Lunch**

11:50 **Luncheon Presentation to be Announced** GBB Great Bay Bio

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Close of Cell Line Development & Engineering Conference**

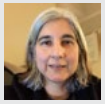
Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

SCALING UP STRATEGIES & CHALLENGES

1:00 **Chairperson's Remarks**
Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University



1:05 **KEYNOTE PRESENTATION: Converting Low-Seed Processes to Intensified Fed-Batch Processes through Smart Media Design and PAT Controls**
Sarwat Khattak, PhD, Head of Cell Culture and Cell Line Development, Biogen
Intensified fed-batch and high-density seed strategies are increasingly adopted to improve upstream efficiency while minimizing operational complexity. This presentation demonstrates how N-1 perfusion, smart media design, and PAT-enabled control can be combined to convert low-seed platform processes into intensified fed-batch processes. Across multiple programs, this strategy achieved ~2X improvements in space–time yield and ~30% shorter production durations, while maintaining product quality and avoiding full perfusion at production scale.

1:35 **Optimizing Scale-Up Strategies for Monoclonal Antibody Production in a Government Facility**
Jishna Ganguly, MSc. Senior Scientist, Walter Reed Army Institute of Research (WRAIR)
Scaling up monoclonal antibody (mAb) production from bench-scale to pilot-scale bioreactors is a complex process that requires optimizing operating parameters to maintain consistent hydrodynamic and mass-transport conditions. This talk highlights process characterization at bench-scale bioreactors and scale-up strategies to 40L or larger GMP production, focusing on ensuring regulatory compliance and product quality within a government laboratory setting.

2:05 **Scaling Up TFF for Upstream Continuous Processing: Applications of Mechanistic Modeling**
Ashna Dhingra, Bioprocess Technologies & Engineering Scientist, AstraZeneca
Tangential flow filtration (TFF) enables scalable CHO cell retention for perfusion culture, however, resulting filter fouling reduces product recovery. We present a first-principles model combining cell kinetics, fluid mechanics, and fouling dynamics to predict membrane performance and product-sieving profiles across scales and projects. Our predictive framework demonstrates how operational parameters and filter geometry influence product sieving while providing insights into fouling mechanisms, membrane efficiency, and flux distributions.

2:35 **Developing & Scaling-up Intensified Fed-Batch Processes**
Jose M. Gomes, Senior Principal Scientist & Manager, Bioprocess R&D, Pfizer Inc.

3:05 **Sponsored Presentation** *(Opportunity Available)*

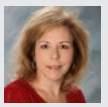
3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK

4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences
Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**


Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

MIDSTREAM OPERATIONS: POSITIONING FOR DOWNSTREAM SUCCESS

8:00 **Chairperson's Remarks**
Sarwat Khattak, PhD, Head of Cell Culture and Cell Line Development, Biogen

8:05 **Mid-Stream Bioprocessing of Gene Therapy Vectors: Setting the Stage for Successful Purification**
Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University
Midstream bioprocessing critically determines the recovery and purity of gene therapy products. This presentation examines how midstream decisions (harvest timing, depth filtration, tangential-flow filtration) set the stage for successful purification. We discuss the impact of midstream processing on chromatographic operations and the resulting quality attributes of adeno-associated virus, lentivirus, and adenovirus. Leveraging process optimization frameworks, we demonstrate how midstream excellence enables robust purification workflows that ensure therapeutic efficacy and safety.

8:35 **Optimization of the Harvest Process for AAV-Based Gene Therapy Manufacturing**
Yixuan Ming, PhD, Downstream Process Development Scientist, Technology Development, Genentech Inc.
This study evaluates alternative nucleases/methods for the harvest of AAV vectors after upstream production. By analyzing the impact of various nucleases/methods under diverse conditions, we assessed process performance, product quality, and downstream Cost of Goods (CoG). Our findings provide critical insights for optimizing the harvest process, balancing robust process with economic efficiency in gene therapy manufacturing.

9:05 **Optimizing an AAV Harvest Process Development of a Mixing Scale-Down Model for Enhanced Filtration Performance**
Yaozhong Zhang, PhD, Senior Scientist, Purification Process Development, Genomic Medicine CMC, Sanofi Group
In Sanofi's AAV manufacturing platform, the harvest process typically involves a flocculation step, where mixing plays a critical role. Developing a robust mixing scale-down model is essential. Floc formation dynamics were characterized in real time using EasyViewer technology. The developed scale-down model demonstrated excellent predictive performance. Implementation of the optimized flocculation conditions resulted in a two-fold increase in depth filter throughput.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

IMPROVING CELL CULTURE PROCESSES AND MANUFACTURING

10:15 **Increasing Cell Culture Process Robustness through Raw Material and Metabolic Understanding**
Delia Lyons, Principal Scientist, Process Sciences, AbbVie Inc.
Consistency and robustness in cell-culture processes are critical for the reliable production of biologics. This presentation will showcase studies describing strategies applied to identify potential sources of variability—and strategies to mitigate them. To this end, we use a proactive risk-assessment approach to identify potential raw-material variability and apply data-driven mitigation strategies. Additionally, we use omics tools to unravel complex molecular interactions.

10:45 **Mechanistic Modeling Frameworks for Predicting Multispecific Co Culture Dynamics and Enabling Real Time Process Control**
Bhanu Chandra Mulukutla, PhD, Senior Principal Scientist, Group Leader, Process Development, Pfizer Inc.
This presentation introduces mechanistic modeling frameworks developed to predict the complex dynamics of multispecific co-culture systems, providing a quantitative foundation for understanding and monitoring process behavior across varying conditions.

11:15 **Harvest Process Characterization Case Study**
Ricky Okafor, Associate Scientist, Upstream Process Development, Alexion Pharmaceuticals
Advances in cell culture have increased cell-culture densities and productivities but also elevated submicron particles, challenging the clarification step. Addressing this, a non-platform harvest process beyond typical centrifugation and depth-filtration was developed. Harvest process characterization was conducted to ensure process robustness and product quality consistency. This presentation describes the risk-based approach used to identify potential critical-parameters and the study performed to evaluate their harvest performance and product quality attribute impact.

11:45 **Sponsored Presentation** *(Opportunity Available)*

12:15 pm **Transition to Lunch**

12:20 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 **Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing**

DIGITAL TWINS AND *IN SILICO* STRATEGIES IN UPSTREAM PROCESSES

1:30 **Chairperson's Remarks**
Anastasia Nikolakopoulou, PhD, Principal Scientist, Data Sciences Process Modeling, Sanofi

1:35 **Cell Culture Digital Twins Enabling Efficient Scale-Up and Tech Transfer**
Brooke Tam, PhD, USP Modeling Expert, Sanofi
Digital twins are valuable for efficiently transferring complex processes from the laboratory to manufacturing scale and ensuring consistent results at different manufacturing sites. Here, we discuss case studies in the application of cell culture digital twins to tech transfer programs and demonstrate how modeling has allowed us to meet aggressive timelines and better serve the patients who need our products.

2:05 **Model-Driven *in silico* Strategies for Upstream Bioprocess Development**
Zhuangrong Huang, PhD, Senior Staff Engineer, Takeda Pharmaceutical Co. Ltd.
This talk will present the application of AI/ML to enhance mAb production in CHO cells. This AI tool automates rapid extraction of data from native file formats into structured templates powered by LLMs and performs *in silico* simulations to recommend optimal conditions for user-defined targets. By enabling intuitive and efficient exploration of complex datasets, the platform democratizes data access, accelerates insight generation, and supports data-driven decision-making.

2:35 **Digital Twins in Bioprocessing: Industrial Showcases for Biosimilar Development, Viral Vectors, Media Optimization, UF/DF, and End-to-End Process Control**
Mark Duerkop, CEO, Novasign GmbH
This presentation explores how digital twins, combining mechanistic process understanding, AI, and process data, enable smarter, faster bioprocess development and control. Six industrial use cases demonstrate the value of digital twins: accelerated biosimilar development using PAT and glycan modeling; reduced experimental effort in viral vector process design; media optimization through time-resolved nutrient uptake prediction.

3:05 **Autonomous Bioprocess Digital Twins for Next-Generation Biomanufacturing**
Dong-Yup Lee, PhD, Professor, Head, Process Design & Systems Engineering Lab; Head, BioProcess Digital Twin Lab, Sungkyunkwan University
The future of bioprocessing is autonomous. I will show how a CHO digital twin fuses genome-scale metabolic modeling with PAT-driven AI to forecast VCD and titer in real time. By introducing an XAI-guided, Bayesian optimization–enabled adaptive control framework, we move beyond black-box prediction to closed-loop, GMP-relevant decision-making—updating setpoints, recipes, and feeding trajectories on the fly. The result is interpretable, high-performance control that enables transparent, end-to-end bioprocess optimization.

3:35 **Close of Summit**

STREAM #2
DOWNSTREAM & FORMULATION

The **Downstream Processing & Formulation** stream offers a comprehensive look at the strategies, technologies, and best practices advancing harvest, purification, stability, and drug product development for today's myriad range of biotherapeutics. The **Formulation, Stability, and Delivery** conference delivers cutting-edge, data-driven approaches for optimizing high- and low-concentration proteins, combination therapies, and novel modalities with practical strategies to control impurities, implement novel excipients, and enhance stability. The **Advances in Purification & Recovery** conference tackles the toughest purification challenges for complex biologics and advanced proteins including bi/trispecifics, AAVs, EVs, hexameric IgGs etc., while exploring advances in next-gen chromatography, 3D printing, mechanistic modeling, and automation. The pre-conference training seminar on **Formulation, Development, and Manufacturing of Biopharmaceutical Drug Products** presents modern approaches to achieve stable and patient-friendly drug products. Together, the 3 conferences in this stream empowers attendees with practical tools and expert guidance to streamline development, reduce risk, and elevate product performance.

Conference Programs

AUGUST 10

Training Seminar: Formulation, Development, and Manufacturing — View Program »

AUGUST 11-12

Formulation, Stability & Delivery — View Program »

AUGUST 12-13

Advances in Purification & Recovery — View Program »

**Training Seminars will be offered in person only*

Training SEMINARS
By Cambridge Healthtech Institute

Monday, August 10
8:30 am – 4:20 pm

TS2A: Formulation, Development, and Manufacturing of Biopharmaceutical Drug Products

INSTRUCTOR:
Danny Chou, PhD, President and Founder, Compassion BioSolution, LLC

This training seminar offers a forum on how to develop sound formulations for biologic drugs, including modern approaches to achieve stable and patient-friendly drug products. The instructor will cover the fundamental knowledge and best practices that will provide the attendee with the necessary tools to be proficient in both the art and science of biopharmaceutical formulation development. Case studies will be presented to demonstrate how to incorporate QbD concepts to do risk assessment, design multivariate experiments, and assess critical quality attributes including subvisible particle characterization in order to develop robust formulation for bulk drug substance or final drug product in the context of designated container closure systems. This course utilizes real-world examples and interactive discussion.

Present a Poster & Save $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure an onsite poster board and/or ensure your poster is included in the conference materials, your full submission must be received, and your registration paid in full by June 26, 2026.

Register and indicate that you would like to present a poster. Once your registration has been fully processed, we will send an email with a unique link and instructions for submitting your materials.

Reasons you should present your research poster at this conference:

- Your research will be seen by our international delegation, representing leaders from top pharmaceutical, biotech, academic and government institutions
- Discuss your research and collaborate with other attendees
- Your poster presentation will be published in our conference materials
- Receive $50 off your registration

LEARN MORE »

Monday, August 10

4:20 pm Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

5:00 PANEL DISCUSSION: Manufacturing Complex Modalities




Moderator: Ran Zheng, Former CEO, Landmark Bio
As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
Melissa J. Moore, PhD, Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics
Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

Tuesday, August 11

7:30 am Registration and Morning Coffee

8:15 Organizer's Welcome Remarks

OPTIMIZING FORMULATION DEVELOPMENT

8:20 Chairperson's Opening Remarks
Danny Chou, PhD, President and Founder, Compassion BioSolution, LLC

8:25 Optimizing Formulation Development of Novel Molecules
Shahid Uddin, PhD, Senior Director, Formulation Development and Laboratory Operations, Immunocore

It's vital to ensure appropriate assessment of molecules at the early research phase is carried out to risk mitigate movement into the development phase. This ensures the best risk of success with minimal usage of resources and finances. This presentation will highlight the procedures for assessing developability and also showcases the challenges associated with administering low concentration biologics.

8:55 Formulation Development Toolbox for Biologics
Can Araman, PhD, Senior Manager, Excipients R&D, Merck

Formulation of classical and next-generation biologics is a challenging area of R&D. Continuous efforts are being made to enhance the shelf life of low- and high-concentration formulations. In this talk, we will deep dive into the different aspects of biologics formulation with a special focus on stability and solubility enhancement. We will present recent advances in this area, especially in excipient space.

9:25 High-Throughput Pre-Formulation Platform Enables Formulation and Developability Assessment with Minimal Material Consumption
Zhenyu Gu, PhD, Executive Director, CMC, Analytical Sciences, Xencor

A plate-based platform for pre-formulation screening was developed and utilized for early-stage programs under limited material and compressed timelines. The platform combines orthogonal high-throughput stress studies, plate-based concentrating, and innovative analytical/characterization methods to evaluate key attributes including viscosity, stability, and excipient compatibility with minimal material consumption. Beyond enabling more efficient DoE-driven formulation development, the platform also supports early developability screening of research molecules to identify leads with balanced CMC properties.

9:55 Presentation to be Announced

UNCHAINED LABS

10:25 Coffee Break in the Exhibit Hall with Poster Viewing

11:05 The Tetris Talk: Getting Masked Antibodies to Actually Fit
Daniëlle van Wijk, PhD, Principal Scientist, Byondis

During development of masked antibodies at Byondis, elevated high–molecular-weight (HMW) levels emerged despite earlier optimization. To ensure these molecules "fit" the existing platform, two strategies were applied: 3D charge-based modeling to refine molecular design and reduce aggregation propensity, and identification of formulation conditions that minimize HMW formation. Both approaches enabled robust development of masked antibody therapeutics.

MANAGING IMPURITIES, SUB-VISIBLE, AND VISIBLE PARTICLES

11:35 Mechanistic Understanding of Metal-Induced Oxidative Instability in Antibody-Drug Products
Emma Ren, Senior Associate Scientist, Regeneron

Metal-induced oxidative instability of antibody and surfactants can impact on the quality, efficacy, and safety of drug products. This work systematically evaluated the impact of transition metals (Fe and Cu) on the stability of antibodies and PS80 in biotherapeutic formulations. The results showed that PS80 degradation is mitigated with increased concentrations of antibody, indicating that acting as an ROS scavenger, antibodies can effectively protect PS80 from oxidation by metal impurities.

12:05 pm Managing Impurities, Sub-Visible, and Visible Particles with a Focus on Regulatory Compliance and Risk Mitigation
Christina Vessely, PhD, RAC, Founder and Principal Consultant, Biopharma Pathways LLC

Effective control of impurities—especially sub-visible and visible particles—is critical to biologic product quality and regulatory compliance. This presentation outlines a streamlined, risk-based approach to detecting, characterizing, and mitigating particulate matter across development. Key regulatory expectations and practical case examples illustrate how proactive investigation, documentation, and cross-functional decision-making reduce compliance risks and support reliable, inspection-ready manufacturing.

12:35 Transition to Lunch

12:45 LUNCHEON PRESENTATION: Streamlined Sequential Chromatography for the Purification of Recombinant Nanobody-Fc Fusion Protein

SUNRESIN

Simona Serban, Global Director Life Science Applications, Global Life Science Applications, Sunresin

The presentation highlights advancements in chromatography purification using engineered recombinant Protein A, showcasing its enhanced alkaline stability, and binding capacity. The rProteinA affinity resin was used alongside ion exchange and hydrophobic chromatography resins in the sequential purification of a nanobody-Fc fusion molecule, to achieve over 95% purity. We emphasize the importance of resin selection in overcoming the complexities associated with biomolecule purification.

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

LEVERAGING AI, MACHINE LEARNING, AND COMPUTATIONAL TOOLS

2:00 Chairperson's Remarks
Samiul Amin, PhD, Professor of Practice, Chemical Environmental and Materials Engineering and Director (ECAP), University of Miami

2:05 Accelerating Drug Product Development of Generics and Biosimilars
Slobodanka (Dina) Manceva, PhD, Associate Director, Drug Product Development, Civica

Drug product development for small-molecule generics and biosimilar biologics diverges due to molecular complexity and regulatory expectations. Generics leverage defined chemistry, predictive tools, and BE-driven prototypes, while biosimilars require deeper analytics, DS-DP understanding, and formulations that preserve structural integrity. This review highlights key challenges and phase-appropriate strategies—including AI-enabled modeling, machine-learning-driven analytics, platform formulations, and risk-based similarity assessments—to accelerate development and deliver robust, approvable products.

2:35 KEYNOTE PRESENTATION: Stability and Rheology Control of High-Concentration Biotherapeutic Formulations through Advanced Characterization and AI/ML

Samiul Amin, PhD, Professor of Practice, Chemical Environmental and Materials Engineering and Director (ECAP), University of Miami

This talk will discuss strategies to overcome a key hurdle in biopharmaceutical development: creating stable, high-concentration monoclonal antibody (mAb) formulations that remain stable, manufacturable, and injectable. Combining advanced characterization techniques such as microrheology (DWS), DLS, and microfluidic viscosity (NanovisQ) measurements with AI/ML, new insights into how pH, salts, and temperature impact aggregation/viscosity are obtained. These results offer a practical framework for accelerating formulation timelines and improving quality of mAb therapeutics.

3:05 Leveraging AI and Kinetic Modeling to Accelerate Vaccine-Formulation Development and Stability Prediction

Sahar Esmaeili Samani, Scientist, Vaccine Drug Product Development, Sanofi

The rapid development of safe, effective vaccines requires advanced AI-driven tools to streamline formulation and stability assessment. This presentation highlights Bayesian optimization (BO) and machine learning (ML) for formulation development, and Advanced Kinetic Modeling (AKM) for shelf-life prediction. Applied to a fragile lyophilized vaccine, BO confirmed optimal excipients, while AKM accurately predicted two-year stability at 2–8°C, demonstrating robust, data-driven acceleration of vaccine development and stability forecasting.

3:35 The Rise of Modular Manufacturing: Scalable Solutions to Accelerate Novel Therapy Development

Bella Neufeld, Vice President, Operations, New Product Development, Teknova

Novel therapeutic development is focused on increasingly individualized solutions, requiring smaller, more customized batches of reagents and buffers to be used across the clinical pipeline as companies scale from research to process development and into commercialization. Existing bioprocessing infrastructure was not designed to manufacture these next-generation therapies, forcing the industry to look for research-and-clinical-grade reagent formulations that are easily customizable, scalable, and efficiently manufactured. Teknova has been able to leverage their modular manufacturing platform to help novel therapy developers across cell and gene therapy, mRNA, and next-generation antibodies (ADCs and multispecifics) accelerate their breakthroughs to get into the clinical faster. Find out more about what criteria novel therapy developers should be considering when evaluating reagent solutions.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

4:40 Machine Learning–Assisted Image Analysis of Sub-Visible Particles in Biologics Drug Products: A Comparative Study Using Micro-Flow Imaging (MFI) and FlowCam

Yi Li, Principal Scientist, Gilead Sciences Inc.

A novel image-based deep-learning workflow was developed to accurately identify inherent, intrinsic, and extrinsic subvisible particles (SvP). The workflow incorporates transfer-learning feature extraction, ground truth label cleaning via AI similarity search, and modern computer vision models to achieve fast and robust classifications. This comparative, cross-platform study highlights the value of modern object-detection architectures in enhancing SvP identification and reducing dependency on confirmatory tests, thereby improving process understanding within biologics development.

5:10 Computational Prediction of Viscosity for Multispecific Antibodies

Sudeep Adhikari, PhD, Postdoctoral Researcher, Stevens Institute of Technology

Predicting viscosity is essential for developing high-concentration antibody formulations for subcutaneous delivery. While monoclonal antibodies are well studied, multispecific antibodies introduce added structural complexity. We present a multiscale computational workflow combining automated structure generation, all-atom molecular dynamics, and a one-bead-per-domain coarse-grained model. Predicted relative viscosities agree with experimental trends, enabling early assessment of viscosity risk and mechanistic insight for antibody therapeutics.

INTERACTIVE BREAKOUT DISCUSSIONS

5:40 Interactive Breakout Discussions

Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

6:30 Close of Day

WEDNESDAY, AUGUST 12

8:00 am Registration and Morning Coffee

ADVANCES IN STABILITY, ANALYTICAL, AND DELIVERY METHODS

8:30 Chairperson's Remarks

Kruti Soni, PhD, Senior Scientist, Biologics Drug Product Development, Biogen

8:35 Holistic Strategy of Developing and Delivering High-Quality Biotherapeutics to Patients

Kevin Zen, PhD, Principal Consultant, Biologics CMC Consulting

Developing successful biologics requires a holistic strategy from discovery to commercialization. The nomination of biotherapeutics to CMC development focuses on biological activity, product quality, and stability. The CMC focuses not only on maximizing product yield and purity but also mitigate manufacturing process impurities to ensure product is safe and stable. This presentation will provide a holistic approach under regulatory compliance to develop and deliver high-quality final drug products to patients.

9:05 Accelerating Drug Product Development: Design, Execution, and Analysis of High-Throughput Liquid Formulation Screening

Hanlin Ouyang, PhD, Associate Principal Scientist, Analytical Enabling Capability, Merck

9:35 Presentation to be Announced

9:50 Presentation to be Announced

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Single-Particle Analysis Technology for Applications in Both Vaccines and Therapeutics

Sabrina Leslie, PhD, Associate Professor, Physics, The University of British Columbia

Lipid nanoparticles delivering mRNA vaccines and therapeutics are effective but inefficient—and heterogeneous in size, shape, and composition. Optimizing them requires single-particle characterization in solution under conditions connected to live cells. I present the CLiC (Convex Lens-induced Confinement) platform for quantitative single-particle imaging, combining label-free interferometric scattering (iSCAT) with multi-channel fluorescence to measure nanoparticle size, mRNA payload, mass, and dynamics in cell-like conditions (Boateng et al., Nano Lett. 2025).

11:15 Comparative Analysis of Laser Diffraction Techniques to Evaluate Particle Sizing of Protein Formulations

Rahul Misra, PhD, Scientist, Biophysics and Process Analytical Technology, Sanofi

We assessed two laser diffraction techniques-Mastersizer 3000 and Microtrac Sync to study the particle sizing of adsorbed vaccine antigens and adjuvants and compared the performance of techniques in terms of particle size distribution, resolution and precision. Laser diffraction is a gold standard in biopharmaceuticals industry for size characterization of adsorbed protein antigens, adjuvants and large size aggregates. Microtrac SYNC is an advancement of Mastersizer performing shape and size analysis simultaneously.

11:45 Transition to Lunch

11:50 Luncheon Presentation to be Announced

12:20 pm Refreshment Break in the Exhibit Hall with Poster Viewing

12:30 Close of Formulation, Stability & Delivery Conference

Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

MECHANISTIC MODELING, AUTOMATION & PROCESS OPTIMIZATION

1:00 **Chairpeson's Remarks**
Khushdeep Mangat, PhD, Associate Director, GMU Purification Process Development, Sanofi Group

1:05 **Applied Automation and Mechanistic Modeling for Purification Development of Challenging Molecules under Accelerated Timelines**
Scott H. Altern, PhD, Senior Scientist I, AbbVie Inc.
This talk presents a case study in the practical application of automation and mechanistic chromatography modeling in early-stage (FIH) purification process development. High-throughput screening and modeling are used in conjuction to support PD and subsequent tech transfer of a cation-exchange polishing step for an mAb with high aggregate burden. Overall, the proposed workflow allowed for timeline acceleration, process improvement, and de-risked tech transfer, enabling the toxicology study to support IND.

1:35 **Enabling Process Characterization Activities via Mechanistic Modeling of Chromatography for a Protein-A Capture Step**
Spyridon Konstantinidis, PhD, Principal Scientist, Merck
Bioprocessing 4.0 leverages digital tools including mechanistic chromatography modelling to enhance process understanding. We developed Protein A capture and cation exchange polishing models, calibrated with linear gradient and step elution experiments under varying load conditions. These models were used in a digital workflow to determine proven acceptable ranges of process parameters and rank them. Comparison with experimental process characterization shows models can effectively guide and accelerate process characterization campaigns.

2:05 **Utilizing Advanced Modeling Techniques for Investigating and Optimizing Buffer Exchange in Ultrafiltration/Diafiltration (UF/DF) Processes**
Chadakarn Sirasitthichoke, PhD, Senior Process Engineer, MS&T Systems and Engineering, Bristol Myers Squibb Co.
Adequate mixing and buffer exchange during ultrafiltration/diafiltration (UF/DF) are critical for robust downstream bioprocess performance, particularly when mechanical agitation is constrained by equipment or operating limits. In this study, computational fluid dynamics (CFD) modeling was applied to evaluate hydrodynamics, mixing efficiency, and buffer exchange performance in a large-scale UF/DF vessel operated without active agitation during diafiltration.

2:35 **3D Imaging for Enhancing Design of 3D-Printed Chromatography Columns**
Thomas F. Johnson, PhD, Lecturer, Biochemical Engineering, University College London
3D-printed chromatography columns provide advantages over conventional packed bed resins, in particular, control over the multiscale structure that can be tailored to the needs of the separation. However, possible disparities between design and fabricated columns lessens this benefit. We apply 3D imaging to evaluate and compare printed structures to original CAD files to refine the design process, creating more effective separation capabilities for emergent biological products.

3:05 **Presentation to be Announced**

CYGNUS TECHNOLOGIES
part of Maraval LifeSciences

3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK

4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences
Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**



Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

CHROMATOGRAPHY PLATFORM DEVELOPMENT & INNOVATION

8:00 **Chairperson's Remarks**
Ronit Ghosh, PhD, Senior Scientist II, Biologics Purification Development (Operation Science and Technology), Abbvie Bioresearch Center

8:05 **KEYNOTE PRESENTATION: Next-Generation Cation Exchange Chromatography Platform Process Development for Biologics Purification**
Lihua Yang, PhD, Senior Prinicpal Research Scientist, BioProcess Purification Development, AbbVie, Inc.
This study evaluated five cation exchange (CEX) resins using three mAbs to identify optimal resins and develop a CEX process with superior dynamic binding capacity (DBC), impurity clearance, recovery yield, and robustness. In addition to experimental approaches, a mechanistic model was utilized to streamline the programming process as well as offering the potential to significantly reduce or even replace labor-intensive laboratory experiments in future process development.

8:35 **Chromatographic Control of dsRNA Impurities Using a Mixed Mode Method with Platform Potential**
Sabeen Nadir, Scientist, Pfizer Inc.
In vitro transcription enables large-scale mRNA production but generates difficult-to-remove double-stranded RNA (dsRNA) impurities. Existing chromatographic approaches for dsRNA removal are limited by scalability and manufacturing cost. We report a mixed-mode PrimaS monolith chromatography method that selectively clears dsRNA from 1–10 kb mRNA under RNA-compatible conditions, preserving integrity. Up to eightfold clearance of linear and structured dsRNA was achieved, supporting its potential as a platform purification solution.

9:05 **Hydrophobic Interaction Chromatography (HIC) as an Innovative Platform for High Purity and Yield ASO Manufacturing**
Juan P. Cueva, Scientist, Bioprocess Development, Biogen
This presentation introduces Hydrophobic Interaction Chromatography (HIC) as a powerful, aqueous alternative to traditional anion exchange and reverse-phase methods for ASO purification. We demonstrate how retaining the 5' hydrophobic blocking group enables a high dynamic binding capacity, allowing for an efficient bind-and-elute process. Our data highlights a systematic optimization of salt types and stepwise gradients to achieve >90% product yield with superior resolution of failure sequences and process-related impurities.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

VIRAL VECTOR & EXTRACELLULAR VESICLE PURIFICATION

10:15 **Enhancing Sanitization for AVB Sepharose Resin in AAV Vector Purification**
Albert Kao, Senior Scientist, Purification Development, Genentech, Inc.
This talk shares an enhanced pre-use sanitization strategy for AVB Sepharose resin in adeno-associated virus (AAV) production. By evaluating various alcohol, acid, and NaOH combinations against environmental microbial contaminants and assessing the identified combination in AAV resin re-use studies, we offer a solution that enhances microbial control without compromising resin performance or product quality.

10:45 **Adeno-Associated Viral Vector Stability during Affinity Chromatography with Camelid Ligands**
Lukas Bongers, PhD Student, Gene Therapy Technical R&D, Roche Diagnostics GmbH
The presented dataset characterizes the impact of affinity chromatography process conditions on quality attributes of AAVs. We can thereby provide information to support a decision for or against direct loading after harvest versus prior concentration by TFF and add to the general understanding of AAVs as a product and the potential influence of proess conditions on yield losses, aggregation, and transduction efficiency.

11:15 **Chromatin Removal by Fibrous Chromatographic Media Enables Safer, Large-Scale EV Production**
Tomas Mesurado, PhD Student, Acib GmbH
We have developed a scalable, enzyme-free, closed workflow using fibrous chromatographic media before tangential flow filtration (TFF) to selectively remove extracellular chromatin (DNA/histones) from extracellular vesicle (EV) preparations. This strategy prevents proinflammatory responses while preserving EV yield and identity. Moreover, the use of fibrous chromatographic media improves purity, safety, and manufacturability, de-risking late-stage development and enabling GMP-compliant, large-scale EV production.

11:45 **Sponsored Presentation** *(Opportunity Available)*

12:15 pm **Transition to Lunch**

12:20 **Luncheon Presentation to be Announced** GORE

12:50 **Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing**

PURIFICATION OF COMPLEX & EMERGING MODALITIES

1:30 **Chairperson's Remarks**
Lihua Yang, PhD, Senior Prinicpal Research Scientist, BioProcess Purification Development, AbbVie, Inc.

1:35 **Low Molecular Weight (LMW) Species Control in Bispecific Antibody Purification Process**
Lingling Xia, PhD, Principal Research Scientist I, Purification Process Development—ADC, PDS&T-BDL, AbbVie Inc.
In biologics manufacturing, product-related impurities must be managed through a comprehensive strategy aligned with ICH Q6B guidelines. The emergence of new biologic modalities, such as bispecific antibodies, transpacific antibodies, and DVDs, has increased the complexity of impurity control due to the unique molecular structures and expanded impurity spectrum. This presentation focuses on low molecular weight species and discusses control strategies developed through downstream purification process optimization for those novel modalities.

2:05 **Application of MabSelect SuRe 70 to Improve Capture Purification of a Bispecific Antibody for Phase I Manufacturing**
Nicholas Delatorre, Principal Scientist, CMC, Third Arc Bio
We present the evaluation and optimization of MabSelect SuRe 70 for capture purification of a bispecific antibody in comparison with an alternative Protein A resin. MabSelect SuRe 70 demonstrated higher dynamic binding capacity, improved specific product recovery, and increased monomer purity. Further process improvements were achieved through optimization of elution conditions to enhance resolution and host cell protein (HCP) clearance.

2:35 **Purification Process Development and Manufacturing of a Novel tsAb for Tumor Therapy**
Yanhuai (Richard) Ding, PhD, Senior Director, CMC DS/DP, EvolveImmune Therapeutics
This talk discusses purification process development strategies for a novel trispecific antibody (tsAb) intended for tumor therapy. It will highlight approaches to optimize downstream processing and support efficient, scalable manufacturing of complex antibody formats.

3:05 **Purification and Analytical Strategies to Overcome Production Challenges for Hexameric IgGs**
Rujin Cheng, PhD, Principal Scientist, Biotherapeutics, ImmunEdge
Hexameric IgGs are a class of complex biologics that offers unique pharmacokinetics and pharmacodynamic properties due to their high valency, molecular weight, or hydrodynamic radius. Despite their attractive profile for certain therapeutic indications, technical challenges in purification and analytics hinder their broader application. This talk aims to demystify some of the challenges by providing comprehensive molecule analysis/illustration and a couple of successful examples where key problems are identified and resolved.

3:35 **Close of Summit**

STREAM #3
INTENSIFICATION, DIGITALIZATION, & AI

This integrated **Intensification, Digitalization & AI** stream unites breakthrough advances in continuous bioprocessing with the transformative power of data, modeling, and machine learning to redefine how biomanufacturing is designed and operated. Spanning end-to-end continuous platforms, intensified upstream and downstream operations, real-time process control, digital twins, and AI-driven optimization, the program highlights how leading organizations are accelerating development, increasing productivity, and improving biomanufacturing efficiency. Complemented by a hands-on training seminar on Machine Learning for CMC and Biomanufacturing, this stream equips scientists and engineers with both the strategic vision and practical tools needed to implement smart, adaptive, and future-ready bioprocesses.

Conference Programs

AUGUST 10

Training Seminar: Introduction to Machine Learning for CMC and Biomanufacturing — View Program »

AUGUST 11-12

Intensified & Continuous Bioprocessing — View Program »

AUGUST 12-13

Digital Transformation & AI in Bioprocess — View Program »

Introduction to Machine Learning for CMC and Biomanufacturing

*Training Seminars will be offered in person only

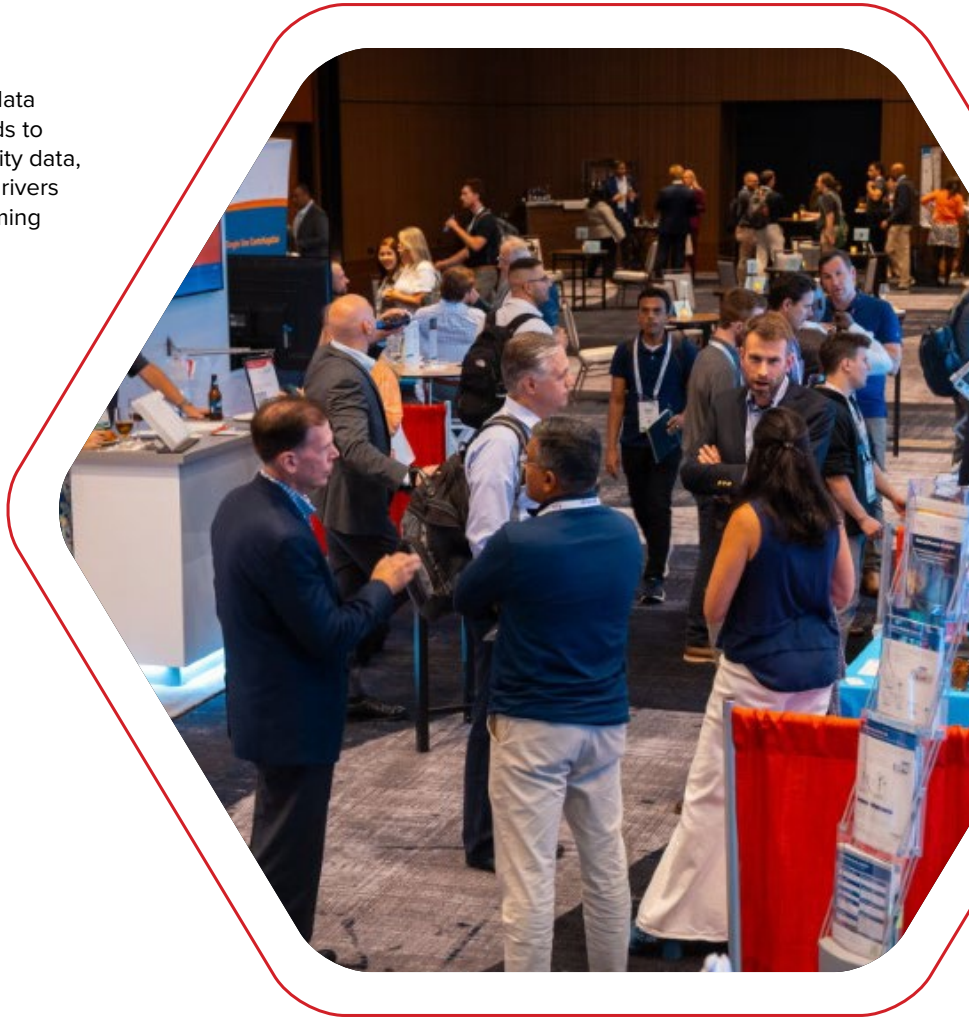
Training SEMINARS
By Cambridge Healthtech Institute

Monday, August 10
8:30 am – 4:20 pm

TS3A: Introduction to Machine Learning for CMC and Biomanufacturing

INSTRUCTOR:
Claus Wirnsperger, Senior Machine Learning Engineer, DataHow AG

This training seminar aims to provide an overview and advanced insight into data analytics and modeling methodologies for process data. Fundamental methods to visualize high-dimensional and highly correlated bioprocess and product quality data, will be presented. These methods will help to identify the important process drivers as well as to forecast the process and product quality behavior. Hands-on coding and brainstorming sessions will be used to solve case studies from the biopharmaceutical industry.



> The wealth and diversity of industry-based conversations and networking enabled great take-aways to implement and advise in my company.
>
> *— Nicole P., Teva Pharmaceuticals*

Monday, August 10

4:20 pm Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

5:00 PANEL DISCUSSION: Manufacturing Complex Modalities




Moderator: Ran Zheng, Former CEO, Landmark Bio
As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
Melissa J. Moore, PhD, Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics
Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

Tuesday, August 11

7:30 am Registration and Morning Coffee

8:15 Organizer's Welcome Remarks

INTENSIFIED & PERFUSION UPSTREAM PROCESSES

8:20 Chairperson's Remarks
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

8:25 Driving Down Cost by Powering up Productivity: Intensified and Perfusion Bioprocessing with NISTCHO
Hussain Nuruddin Dahodwala, PhD, IBBR NIST-UMD
The transition from traditional fed-batch to high-density perfusion strategies is a critical strategy for enhancing productivity in biopharmaceutical manufacturing. Using the NISTCHO, a standardized Chinese Hamster Ovary (CHO) platform producing the cNISTmAb monoclonal antibody, reference cell line, we demonstrate how perfusion-based processes can significantly reduce costs while maximizing product yield.

8:55 Media Development for Intensified Bioprocessing to Improve Productivity
Yuxin Liu, Senior Scientist, Sanofi Group
This talk explores how targeted media design enables intensified bioprocessing by supporting higher cell densities, sustained productivity, and improved product quality. It will highlight strategies for optimizing nutrient composition, feeding approaches to enhance manufacturing efficiency in biologics production systems.

9:25 Characterizing Cellular Responses to Diverse Feeding Strategies in High-Intensity Dynamic Perfusion Bioprocesses
Peter Amaya, PhD, Associate Director, AstraZeneca
This presentation explores how different feeding strategies influence cellular behavior and performance in high-intensity dynamic perfusion bioprocesses.

9:55 Sponsored Presentation *(Opportunity Available)*

10:25 Coffee Break in the Exhibit Hall with Poster Viewing

11:05 KEYNOTE PRESENTATION: Intensified Fed-Batch and Continuous CHO Cell Cultures for Biologics Manufacturing
Weichang Zhou, PhD, CTO, MediLink Therapeutics
Innovative strategies are applied to enhance the productivity of fed-batch and continuous CHO cell cultures for biologics manufacturing. Raman spectroscopy, a real-time process analytical technology (PAT) tool, is utilized for process control. The ultra-intensified fed-batch platform, integrating N–1 perfusion and intermittent perfusion, increases productivity by 4–6 fold, while continuous perfusion cultures achieve significantly improved daily productivity through advanced cell lines, media, and process control.

11:35 Stable Perfusion Cultures of Mammalian Cells for Integrative Continuous Bioprocessing
Duk Jae Oh, PhD, Professor, Integrative Bioscience & Biotechnology, Sejong University
The perfusion culture of mammalian cells producing biopharmaceuticals is essential for integrative continuous bioprocessing, which has been explored extensively for benefits in biomanufacturing. For seamless integrative continuous bioprocessing, connecting the upstream cell culture processes to the downstream purification processes, 'the long-term stability' of perfusion cultures needs to be strongly secured. In this presentation, author's research experience on perfusion cultures and efforts for stable long-term perfusion cultures will be shared.

12:05 pm Capacitance-Automated Feed in Continuous Bench-Scale Bioreactors
Lorraine Peters, Assoc Scientist, Cell Culture Fermentation Sciences, AstraZeneca
Capacitance probes can be used to automate nutrient feed in continuous perfusion bioreactors based on cell-specific glucose consumption rate and viable cell volume. By enabling more frequent online measurements, these probes offer improved nutrient feeding in a perfusion bioreactor compared to traditional once-daily offline measurements, enhancing process robustness and eliminating offline instrument variability. The research assesses the effectiveness of using online capacitance versus traditional offline control strategies.

12:35 Transition to Lunch

12:45 Luncheon Presentation to be Announced cytiva

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

CONTINUOUS DOWNSTREAM PROCESSING & NOVEL MODALITIES

2:00 Chairperson's Remarks
William Whitford, Founder, Oamaru BioSystems

2:05 Optimizing Throughput, Mass Indices, and Cost of Goods in Continuous, Precipitation-Based mAb Downstream Processing
Todd M. Przybycien, PhD, Professor and Head, Chemical and Biological Engineering, Rensselaer Polytechnic Institute
In a bid to sustainably meet the growing need for mAbs, we have developed a fully continuous, precipitation-based downstream process, drawing inspiration from the plasma fractionation industry. This new downstream process can be greater in capacity, less raw material-intensive, and significantly cheaper than the platform process. We'll describe the genesis, evolution, and optimization of the process in terms of mAb critical quality attributes and sustainability metrics, and the path forward.

2:35 FEATURED PRESENTATION: From Batches to Flow: Transforming Downstream Processing into a Continuous Enterprise
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University
Continuous bioprocessing offers transformative potential but faces persistent scale-down challenges. In downstream operations, maintaining stable micro-scale flow rates is critical, and continuous solid–liquid separation remains a bottleneck. Two-stage microfiltration and single-fiber scale-down models support more reliable parameter transfer. Robust precipitation or flocculation, effective buffer and fluid management, and advanced soft-sensor concepts for real-time CQAs together enable integrated, long-running processes that can ultimately support carbon-neutral biopharmaceutical manufacturing.

3:05 Unlocking the Potential of an ADC Platform through Development of a Continuous Decapping Reaction
Becky Chmielowski, PhD, Principal Scientist, Merck & Co.
Antibody conjugation through mAb-engineered cysteine sites is a method to achieve drug-to-antibody (DAR) selectivity for ADCs. This

talk describes utilization of process analytical tools (PAT) to develop a continuous, ultrafiltration decapping reaction. HP-IEX monitored real time decapping of mixed thiol caps. A redox probe correlated redox potential to decapping efficiency. Continuous decapping was scaled to generate multi-kilogram quantities of decapped mAb, which resulted in high-purity ADC.

3:35 **Unlocking Manufacturing Intelligence: The AI Advantage in Regulated Environments**
Katie Farley, Vice President of Product , MasterControl Inc.
Bioprocessing manufacturers range from paper-based to digitally mature. Learn actionable strategies for implementing purpose-built, compliant AI that delivers measurable ROI—reducing quality review time by ~30% while keeping humans central to decisions. Discover how to balance innovation with compliance and maximize AI's business impact in manufacturing.

4:05 **Refreshment Break in the Exhibit Hall with Poster Viewing**

FLEXIBLE PLATFORMS AND INTEGRATED CONTINUOUS BIOMANUFACTURING

4:40 **How "Flexible" Platform Design Paradigm Enables Innovation to Support Highly Intensified Processes**
Jonathan K. Romero, PhD, Distinguished Scientist, BioProcess Research & Development, Merck Research Laboratories
Process intensification in bioprocessing seeks to boost productivity, reduce environmental impact, and accelerate biopharmaceutical development. It involves major changes in equipment and process design, such as moving from batch to continuous or hybrid processing. Choosing among these modes requires balancing productivity, throughput, PQ, GMP practicality, and flexibility. We will use past batch and continuous manufacturing learnings and performance data to shape future flexible, high-capacity operating paradigms across the product lifecycle.

5:10 **iCAP: Integrated Continuous and Automated Platform for Plasmid Production**
Juergen Mairhofer, CEO & Co-Founder, enGenes Biotech GmbH
Plasmid DNA is vital for gene therapies, viral vectors, and mRNA vaccines, but remains limited by costly, low-yield batch processes. iCAP delivers continuous, automated production using genetically stabilized *E. coli*, enabling long-term plasmid replication in bioreactor cascades. Integrated alkaline lysis, purification, and digital-twin–driven control ensure high throughput and autonomy. Modular and scalable, iCAP reduces costs, boosts sustainability, and supports decentralized DNA vaccine and continuous therapeutic production.

5:40 **Biomanufacturing Strategies for the Production of Recombinant Protein in *E. coli* and *Lactococcus lactis***
Prashant Mainali, PhD, Scientist, Microbial Cell Bioprocessing, A STAR (Agency of Science, Technology and Research)
This presentation will compare the production of Fibroblast Growth Factor-2 (FGF2) using two microbial hosts with distinct bioprocess characteristics, necessitating different strategies for process optimization. The presentation will also demonstrate how kinetic modeling can be directly translated into operational decisions for continuous and perfusion cultures. These concepts will be broadly applicable to the continuous manufacturing of recombinant proteins for biopharmaceutical, cultivated meat, and serum-free media applications.

6:10 **Close of Day**

WEDNESDAY, AUGUST 12

8:00 am **Registration and Morning Coffee**

DIGITAL TOOLS, PAT & PROCESS MONITORING

8:30 **Chairperson's Remarks**
Hussain Nuruddin Dahodwala, PhD, IBBR NIST-UMD

8:35 **KEYNOTE PRESENTATION: Perfusion Cell Culture in Large Scale Manufacturing**
Glen R. Bolton, PhD, Executive Director, Late Stage Bioprocess Development, Amgen, Inc.

9:05 **Development of a Raman Model for Continuous Monitoring of Detergent Viral Inactivation**
Kurtis Denny, Engineer I, Cell Culture Development, Biogen
A 785 nm Raman-based model was developed as an online measurement for the detergent concentration in a continuous viral inactivation (VI) step. In the VI step, detergent is continuously added to a concentrated bioreactor perfusate stream. The Raman flow cell was first calibrated using a bank of previously generated perfusate samples spiked to varying detergent levels to generate a PLS model with an estimated accuracy of 0.02% w/v.

9:35 **Sponsored Presentation** *(Opportunity Available)*

10:05 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:45 **Digital Twin for Continuous Lyophilization of Biotherapeutics in Suspended Vials**
Prakitr Srisuma, PhD, Postdoctoral Researcher, Chemical Engineering, MIT
This talk discusses the world's first digital twin for continuous lyophilization of biotherapeutics in suspended vials. This digital twin consists of a state-of-the-art mechanistic model, a state observer for real-time tracking of the residual moisture, a highly efficient framework for uncertainty analysis, and a novel dynamic optimization algorithm. Combining all components, this virtual representation of the continuous lyophilization system can be used for improving the manufacturing in real time.

11:15 **AI-Augmented Digital Shadows Empower Bioprocess Intensification**
William Whitford, Founder, Oamaru BioSystems
Digital shadows provide a near real-time, data-driven, virtual representation of bioreactors and processes—providing exceptional power in the study of process performance. An AI-augmented digital shadow integrates multivariate data with hybrid mechanistic machine-learning models to simulate what-if scenarios, infer unmeasured states, and recommend optimal CPP ranges. Through multivariate pattern recognition, ranking of stimulatory and limiting phenomena, and mapping of high-dimensional design spaces, AI digital shadows enable efficiency in process intensifications.

11:45 **Transition to Lunch**

11:50 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Close of Intensified & Continuous Bioprocessing Conference**

Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

TRANSFORMING ANALYTICS, WORKFLOW, AND WORKFORCE FOR THE DIGITAL AGE

1:00 **Chairperson's Remarks**
Moo Sun Hong, PhD, Assistant Professor, Department of Chemical and Biological Engineering, Seoul National University

1:05 **Structured Approach to Develop and Deploy AI/ML Predictive Models for Commercial Biologics Manufacturing**
Sivashankar Sivakollundu, PhD, Associate Director, Robustness and Digital Strategies, Bristol Myers Squibb
Achieving consistent yield and quality in modern commercial biologics manufacturing requires strong process understanding, integrated data systems, and predictive modeling. A structured AI/ML framework was applied using multi-year manufacturing data to develop hybrid and machine learning models that accurately predict key drivers of yield and product quality. The program incorporated automated data pipelines, parameter contextualization, and governance through routine review forums.

1:35 **Harnessing the Power of AI and Digital Twins for Regulatory Tasks**
Srividya Narayanan, MDS, MSc, Regulatory Affairs, Northeastern University
This presentation will demonstrate how data-driven regulatory intelligence can revolutionize bioprocessing by automating compliance workflows, predicting process deviations, and accelerating scale-up decisions. Through real-world case studies and simplified AI workflows, attendees will see how raw manufacturing and quality data become actionable insights—transforming weeks-long regulatory tasks into minutes.

2:05 **Engineering the Workforce System for Digital and AI-Enabled Bioprocessing Performance—A Case Study in Quantitative Talent Framework for Sustaining Throughput, Compliance, and Digital Adoption**
Jason Beckwith, PhD, DBA, Senior Vice President, Talent Science for Biopharma, BioTalent
Digital and AI transformation in bioprocessing often underperforms not due to technology, but because workforce systems are misaligned with process complexity. This talk introduces a quantitative framework for engineering workforce performance in regulated bioprocessing environments. It shows how instability, leadership dependency, and mis-sequenced retain-retrain-recruit-automate decisions create execution risk, and how organisations can intervene earlier to sustain throughput, compliance, and digital adoption.

2:35 **KEYNOTE PRESENTATION: Transforming Pharmaceutical Manufacturing with Advanced Analytics and SMART Manufacturing**
Monitha Harilkumar, PhD, former Director, Data & Digital Acceleration Lead, Roche
Advanced analytics and SMART manufacturing are reshaping pharmaceutical production by integrating real-time data, automation, and intelligent decision systems. These technologies enable predictive monitoring, process optimization, and improved quality control across the manufacturing lifecycle. By leveraging sensors, digital twins, and machine learning, manufacturers can enhance efficiency, reduce variability, and ensure regulatory compliance. The result is more agile, resilient, and cost-effective pharmaceutical manufacturing capable of delivering high-quality medicines faster and more reliably.

3:05 **Presentation to be Announced**

3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

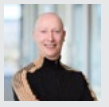
PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK

4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences
Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**





Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

MODELING AND PROCESS CONTROL

8:00 **Chairperson's Remarks**
Mark Duerkop, CEO, Novasign GmbH

8:05 **Hybrid Modeling of CHO Cell Cultures for mAb Production via Metabolic Phase Integration**
Moo Sun Hong, PhD, Assistant Professor, Department of Chemical and Biological Engineering, Seoul National University
Understanding metabolic shifts in CHO cells is critical for enhancing productivity and process control in mAb manufacturing. This presentation introduces a hybrid modeling framework designed to identify the occurrence of metabolic shifts and their associated conditions. Clustering is used to segment concentration and process data into distinct metabolic phases, and phase-specific hybrid models are then trained to learn biological rate terms using a sparse, interpretable approach.

8:35 **Control Strategies for Integrated Continuous Purification of Monoclonal Antibodies**
Anastasia Nikolakopoulou, PhD, Principal Scientist, Data Sciences Process Modeling, Sanofi
Integrated continuous purification (ICP) involves highly interacting and synchronous unit operations, presenting unique challenges that require a control architecture to consistently meet product specifications and mitigate process deviations. This work presents automated control strategies for continuous viral inactivation and ultrafiltration/diafiltration within an end-to-end ICP platform. The developed model-based control approaches, maintained critical process parameters within ranges under representative perturbations of the ICP process, enhancing operational reliability across diverse process conditions

9:05 **How to Transform Bioprocess Analytics in Digital and Autonomous Landscapes—Steering for Success**
Dhanuka Wasalathanthri, PhD, Associate Director, Biologics Development, Bristol Myers Squibb
Biologics process development landscape is getting increasingly adoptive to digital transformation and autonomous bioprocess technologies, which creates opportunities to elevate the analytical testing and development operational model. This talk features a clear vision, roadmap, and case studies of lab automation and digital transformation efforts measured against main KPI's such as speed and productivity for in-process analytics for bioprocess development and manufacturing.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

MODELING AND PROCESS CONTROL *(CONT.)*

10:15 **Advancing Downstream Process Development of Multivalent Nanobody Therapeutics through Mechanistic Modeling**
Lijuan Li, PhD, Associate Director, Process Modeling, Global CMC Development, Data Sciences, Sanofi
Nanobody molecules are an emerging class of biologics whose multivalent formats pose unique purification challenges due to structural flexibility and complex interactions. We developed the first high-fidelity mechanistic chromatography model for a Nanobody molecule, capturing complex elution behavior and all critical quality attributes to support late-stage process development. The validated model enables robust design space definition, scale-up across, and a predictive, digitally driven filing alternative to traditional empirical workflows.

AUTONOMOUS BIOMANUFACTURING

10:45 **Autonomous Lipid Nanoparticle Engineering**
Peter Sagmeister, PhD, Guest Scholar, Chemical Engineering, Massachusetts Institute of Technology
We present an automated, data-rich platform for nanoparticle manufacturing that enables rapid, material-efficient identification of critical process parameters while ensuring reproducibility and regulatory relevance. The system integrates an impinging jet mixer with real-time, spatially resolved dynamic light scattering, coordinated through advanced control software, database management, and a user-friendly interface. Future integration of Bayesian optimization and automated Design of Experiments will further accelerate process development, demonstrated using model drug delivery systems.

11:15 **Role of Machine Learning in Continuous mAb Manufacturing Automation**
Naveen Gurupatham Jesubalan, PhD Candidate, Chemical Engineering, Indian Institute of Technology
The talk focuses on the role of exploring different ML/DL models, starting from simple PLS to RL, in the automation of a continuous manufacturing platform. More specifically, how ML helps monitor CQAs in real time. Followed by that, the role of ML/DL models, along with mechanistic models, in controlling unit operations, including filtration and chromatography, in response to unexpected changes in CQAs.

11:45 **Presentation to be Announced**

12:15 pm **Transition to Lunch**

12:20 **Luncheon Presentation to be Announced**

12:50 **Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing**

DIGITAL TWINS AND *IN SILICO* STRATEGIES IN UPSTREAM PROCESSES

1:30 **Chairperson's Remarks**
Anastasia Nikolakopoulou, PhD, Principal Scientist, Data Sciences Process Modeling, Sanofi

1:35 **Cell Culture Digital Twins Enabling Efficient Scale-Up and Tech Transfer**
Brooke Tam, PhD, USP Modeling Expert, Sanofi
Digital twins are valuable for efficiently transferring complex processes from the laboratory to manufacturing scale and ensuring consistent results at different manufacturing sites. Here, we discuss case studies in the application of cell culture digital twins to tech transfer programs and demonstrate how modeling has allowed us to meet aggressive timelines and better serve the patients who need our products.

2:05 **Model-Driven *in silico* Strategies for Upstream Bioprocess Development**
Zhuangrong Huang, PhD, Senior Staff Engineer, Takeda Pharmaceutical Co. Ltd.
This talk will present the application of AI/ML to enhance mAb production in CHO cells. This AI tool automates rapid extraction of data from native file formats into structured templates powered by LLMs and performs *in silico* simulations to recommend optimal conditions for user-defined targets. By enabling intuitive and efficient exploration of complex datasets, the platform democratizes data access, accelerates insight generation, and supports data-driven decision-making.

2:35 **Digital Twins in Bioprocessing: Industrial Showcases for Biosimilar Development, Viral Vectors, Media Optimization, UF/DF, and End-to-End Process Control**
Mark Duerkop, CEO, Novasign GmbH
This presentation explores how digital twins, combining mechanistic process understanding, AI, and process data, enable smarter, faster bioprocess development and control. Six industrial use cases demonstrate the value of digital twins: accelerated biosimilar development using PAT and glycan modeling; reduced experimental effort in viral vector process design; media optimization through time-resolved nutrient uptake prediction.

3:05 **Autonomous Bioprocess Digital Twins for Next-Generation Biomanufacturing**
Dong-Yup Lee, PhD, Professor, Head, Process Design & Systems Engineering Lab; Head, BioProcess Digital Twin Lab, Sungkyunkwan University
The future of bioprocessing is autonomous. I will show how a CHO digital twin fuses genome-scale metabolic modeling with PAT-driven AI to forecast VCD and titer in real time. By introducing an XAI-guided, Bayesian optimization–enabled adaptive control framework, we move beyond black-box prediction to closed-loop, GMP-relevant decision-making—updating setpoints, recipes, and feeding trajectories on the fly. The result is interpretable, high-performance control that enables transparent, end-to-end bioprocess optimization.

3:35 **Close of Summit**

STREAM #4
MODERNIZING ANALYTICAL DEVELOPMENT

Achieving speed and accuracy in modern bioprocessing requires a synergy between computational tools and advanced laboratory techniques. The **Modernizing Analytical Development** stream addresses this necessity by examining the latest breakthroughs in both predictive analytics and experimental methodology. Attendees will explore strategies for optimizing method development through digital paradigms before transitioning into the practical application of automated assay systems and ultra-sensitive characterization tools. By focusing on the integration of "dry-lab" insights and "wet-lab" innovations, this stream provides essential guidance for streamlining workflows and ensuring the highest standards of product quality and robustness.

Conference Programs

AUGUST 10

Training Seminar: Introduction to CMC for Biological Products: Bioprocessing and Analytical

View Program »

AUGUST 11-12

Analytical Intelligence

View Program »

AUGUST 12-13

Next-Generation Analytical Methods

View Program »

Introduction to CMC for Biological Products: Bioprocessing and Analytical

**Training Seminars will be offered in person only*

Training SEMINARS
By Cambridge Healthtech Institute

Monday, August 10
8:30 am – 4:20 pm

TS4A: Introduction to CMC for Biotherapeutic Products: Bioprocessing and Analytical

INSTRUCTOR:
Kevin Zen, PhD, Principal Consultant, Biologics CMC Consulting

This 1-day training seminar provides a comprehensive overview of the phase-appropriate CMC activities for biotherapeutic products and introduces the brand new CTD Quality guidance (2026). The curriculum is meticulously designed to cover not only bioprocessing activities such as cell line development, process development, qualification and manufacturing, but also analytical activities such as analytical development, validation, reference standard qualification, rational formulation, specifications, QC release and stability, extended characterization and comparability exercise. Join this interactive educational class to learn how to execute CMC activities and how to prepare eCTD Module 2.3 and Module 3 Quality for regulatory submission. The common CMC pitfalls, queries from health authorities worldwide, and Complete Response Letters (CRLs) will be exemplified throughout this training class.

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Monday, August 10

4:20 pm **Networking Refreshment Break and Transition to Plenary Keynote**

PLENARY KEYNOTE SESSION

5:00 **PANEL DISCUSSION: Manufacturing Complex Modalities**




Moderator: Ran Zheng, Former CEO, Landmark Bio
As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
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Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 **Welcome Reception in the Exhibit Hall with Poster Viewing**

Tuesday, August 11

7:30 am **Registration and Morning Coffee**

8:15 **Organizer's Welcome Remarks**

OPTIMIZING PREDICTIVE ANALYTICS

8:20 **Chairperson's Opening Remarks**
Kedric Milholland, PhD, Senior Scientist, Biologics Drug Product Development, AbbVie Inc.

8:25 **Accelerating Biologics Development with Predictive Stability Modeling**
Dan (Cassie) Liu, Principal Statistician, Bristol Myers Squibb
Predictive stability modeling is revolutionizing biologic drug shelf-life evaluation by providing accurate long-term stability forecasts based on relevant short-term data. Several practical applications will be presented. The integration of scientific rigor and statistical robustness in these models supports critical CMC decision-making, optimizes stability filing strategies, and accelerates the development timeline for new biologic therapies.

8:55 **High-Throughput Surrogate for Viscosity and Aggregation**
Pin-Kuang Lai, PhD, Assistant Professor, Chemical Engineering and Materials Science, Stevens Institute of Technology
High-concentration monoclonal antibody (mAb) formulations are limited by viscosity driven by protein–protein interactions, yet early risk assessment lacks high-throughput tools. We developed a high-throughput SAXS workflow to detect self-association at dilute concentrations. Across 22 mAbs in histidine buffer (pH 6.0), low-q structure factor transitions below 10 mg/mL predicted viscosity at 150 mg/mL, correctly classifying 21/22 antibodies. This scalable, sample-efficient approach enables early developability screening and model validation.

9:25 **Use of Bayesian Optimization for Analytical Method Development**
Rose Yin, PhD, Senior Scientist, Merck
Ensuring consistent enzyme performance is crucial in regulated drug process development. Traditional optimization methods, such as OFAT and DoE, can be resource-intensive and biased. Here, we used Bayesian Optimization (BO) to rapidly optimize a ligase enzyme activity assay used in process development. The optimized assay achieved improved performance and reduced experimental workload compared to OFAT. In addition, the model produced accurate robustness predictions and interpretable parameter insights for method transfer.

9:55 **Presentation to be Announced**

10:25 **Coffee Break in the Exhibit Hall with Poster Viewing**

11:05 **Unlocking the Capabilities of Microfluidic Electrophoresis for the Development of Protein-Based Therapeutics Using Predictive Analytics**
Jenna Rutberg, Researcher, Biomedical Engineering, Brown University
Microfluidic electrophoresis is a powerful characterization technique for both novel protein-based therapeutics and protein biomarkers. We will discuss innovative methods that use both size-based and charge-based automated microfluidic electrophoresis to analyze different types of proteins and how this translates to the drug discovery and development process. We will also discuss how our predictive analysis method can be used for reagent manufacturing protocols for microfluidics applications.

11:35 **Implementing a Combined Wet Lab and Dry Lab Initiative to Optimize Developability Studies**
Kedric Milholland, PhD, Senior Scientist, Biologics Drug Product Development, AbbVie Inc.
Developability of biotherapeutics usually involves several stages of preclinical experiments to inform the manufacturability, stability, formulation, and delivery of a biotherapeutic. Over the past two years, data-capture systems have been deployed at AbbVie for pipeline use, with the benefit of enabling collection of AI/ML ready datasets. Using these tools and high-throughput screening assays, we are collecting developability data on thousands of IgG1 mAbs to enable correlative and predictive modeling.

12:05 pm **Multimodal ML Framework to Predict Antibody Viscosity**
Krishna D. Bharadwaj Anapindi, PhD, Senior Scientist, Biology, Gilead Sciences Inc.
High-concentration therapeutic antibody development is constrained by viscosity and limited experimental throughput, motivating *in silico* screening. A multimodal feature learning (MMF) approach combines conventional MOE protein descriptors with protein large-language-model embeddings to improve viscosity prediction while enabling feature interpretability. Across regression and classification benchmarks (including internal data), MMF shows improved performance versus prior models and supports automated high-throughput candidate triage.

12:35 **Transition to Lunch**

12:45 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 **Refreshment Break in the Exhibit Hall with Poster Viewing**

DIGITAL TOOLS FOR ANALYSIS AND INTERPRETATION OF COMPLEX RESULTS

2:00 **Chairperson's Remarks**
Dan (Cassie) Liu, Principal Statistician, Bristol Myers Squibb

2:05 **Advances in Mechanistic and ML-Driven Modeling for Supporting Analytical Technologies in Gene-Therapy Manufacturing**
Francesco Destro, PhD, Principal Engineer, BioCurie; Researcher, Chemical Engineering, Center for Biomedical Innovation, Massachusetts Institute of Technology
This presentation highlights how mechanistic modeling and machine learning can enhance analytical technologies in recombinant adeno-associated virus (rAAV) manufacturing. Case studies showcase models built from diverse analytical datasets that accelerate analytical development and translate analytical insights into effective process control. Additionally, a novel real-time titer quantification approach leveraging single-cell measurements and machine learning is demonstrated across a range of rAAV constructs.

2:35 **Pattern Recognition across Methods, Modalities, Stages, and Time**
Michael Butler, PhD, Principal Investigator, Cell Technology, National Institute for Bioprocessing Research & Training (NIBRT)
Genetic changes of the spike protein of SARS-CoV-2 virus variants during the COVID pandemic were mapped by amino acid sequencing. Such changes in these variants were also reflected by changes in the glycan profile and these changes are reflected in the evolutionary path of the virus. Robust and sensitive methods of glycan structural determination were developed to enable this type of analysis and will be discussed in this presentation.

ANALYTICS FOR PROCESS MODELING

3:05 **Amino Acid Analysis Combined with Process Modeling to Identify Ideal Media Compositions**
Mark Duerkop, CEO, Novasign GmbH
This presentation explores how amino acid analysis, integrated with multivariate process modeling, can clarify the relationship between media composition and product quality in biosimilar development. Emphasis will be placed on linking critical material attributes and critical process parameters to measurable quality attributes. Attendees will gain insight into how high-quality analytical data can drive data-informed media optimization and strengthen comparability assessments throughout development.

3:35 **Sponsored Presentation** *(Opportunity Available)*

4:05 **Refreshment Break in the Exhibit Hall with Poster Viewing**

EXPANDING DATA CAPTURE AND ACCESS

4:40 **Keynote Presentation: From Data Rich to Decision Ready: Building the Computational and AI Infrastructure for Next-Generation Analytical Development**
Francis Poulin, PhD, Vice President, Analytical Sciences, Sail Biomedicines
Pharmaceutical companies developing biologics generate more analytical data than ever, yet the gap between data generation and actionable insight remains wide. This keynote addresses the organizational, technological, and scientific challenges of connecting big data platforms, computational modeling, and machine learning workflows into a coherent analytical development ecosystem. Attendees will leave with a practical perspective on where to invest, what to prioritize, and what capabilities to build in-house versus through partnerships.

5:10 **Digital in Biotherapeutics at AbbVie: A Ten-Year Retrospective Shaping Our Future Vision**
Sukru Kaymakcalan, Director, R&D Information Research, AbbVie, Inc.
Digital transformation, the accelerating pace of scientific and technological advancement and increasingly sophisticated analytics and computational methods are putting intense pressure on delivering digital solutions in biotherapeutics research and development. We'll discuss AbbVie's work in this space over the last decade to share lessons learned, discuss challenges and opportunities, and share our vision of a digitally enabled and data-driven biotherapeutics organization to meet the challenges of tomorrow's biopharma landscape.

5:40 **Interactive Breakout Discussions**
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

6:30 **Close of Day**

Wednesday, August 12

8:00 am **Registration and Morning Coffee**

PROBLEMS AND SOLUTIONS

8:30 **Chairperson's Remarks**
Rozaleen Dash, PhD, Senior Research Scientist, DBT Center of Excellence for Biopharmaceutical Technology, Indian Institute of Technology

8:35 **Strategies for Adapting Experimentalists to Digital Tools and New R&D Paradigms**
Bo Zhai, PhD, Principal Scientist, Analytical Method Development, Janssen
In biopharmaceutical development, accurately tracking cell-line selection and sample lineage is crucial for maintaining product quality and meeting regulatory requirements. Implementing a digital system that records cell line genealogy and connects analytical results to stage-specific samples from cell-line screening ensures traceability and upholds data integrity. This approach aligns with FAIR data principles and facilitates informed decision-making throughout cell-line development and analysis.

9:05 **Cytokine Bioassays to AI Prediction: Assessing Immunogenicity of mAb Charge Variants and Aggregates**
Rozaleen Dash, PhD, Senior Research Scientist, DBT Center of Excellence for Biopharmaceutical Technology, Indian Institute of Technology
Biotherapeutic monoclonal antibodies exhibit charge variants and aggregates that can modulate immunogenic risk. This study integrates functional cytokine release assays with mechanistic and deep learning models to assess immune activation potential. Charge variants of trastuzumab and aggregates of rituximab and infliximab showed distinct cytokine signatures, enabling predictive modeling of cytokine-mediated immunogenicity to support safer biologic development.

9:35 **Sponsored Presentation** *(Opportunity Available)*

10:05 **Coffee Break in the Exhibit Hall with Poster Viewing**

ProteinBioSolutions

10:45 **Single-Cell RNA Sequencing Identifies Cellular Heterogeneity Impacting Product Formation in CHO Perfusion Culture**
Sean Engels, PhD, Senior Scientist, Process Research and Development Enabling Technologies, Merck
Cells grown in perfusion culture are assumed to be in a pseudo steady state; however, changes in productivity and product quality are often observed, and the contributing factors are not yet identified. Here, we use single-cell RNA sequencing to show how the evolution of heterogeneous cell populations in perfusion culture contribute to inconsistencies in monoclonal antibody production. These data are used to drive process improvements for improved robustness.

11:15 ***In silico* Models to Speed-Up and De-Risk Biologics Developability and Formulation Development**
Andrea Arsiccio, PhD, Senior Scientist & Team Lead, In Silico, Coriolis Pharma Research GmbH
In silico computations play an increasing role in drug development, but platforms combining multiple models and comprehensively evaluating therapeutic proteins' developability are currently lacking. This presentation covers this gap, showing how different models, spanning structure prediction, bioinformatics, machine learning, and molecular dynamics, can be combined within an automated platform to speed up and de-risk candidate selection, lead characterization, and formulation development. Relevant case studies will be presented.

11:45 **Transition to Lunch**

11:50 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Close of Analytical Intelligence Conference**

Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

CHALLENGES AND GAPS FOR NOVEL BIOTHERAPEUTICS

1:00 **Chairperson's Remarks**
Megan Sharma, PhD, Principal Scientist, Johnson & Johnson Innovative Medicine

1:05 **Integrative Biophysical Characterization for Advanced Modalities in Biotherapeutic Discovery**
David Boggs, PhD, Senior Scientist, AbbVie

An increasingly complex landscape of antigen targets and therapeutic modalities demands the coordinated use of advanced tools for robust characterization. We present an integrated toolkit for biophysical characterization to support the discovery and development of novel biotherapeutics and genetic medicines. By combining light-scattering techniques with single-particle analysis, we deliver deep insights and drive innovation across antibody-antigen, lipid-nanoparticle, and virus-like particle platforms.

1:35 **Identification of HMW Artifacts Induced by Reducing Agents in CE-SDS Analysis and Their Removal via Post-Reduction Alkylation**
Yannan Lin, PhD, Senior Scientist, Merck

R CE-SDS analysis of a novel biologic product using BME reported a surprisingly higher level of HMW than native SEC and NR CE-SDS. Further investigation revealed that these HMW species were BME-induced artifacts, with their abundance strongly dependent on BME concentration. By evaluating alternative reducing agents via a variety of analytical characterizations, post-reduction alkylation has been identified as a key step to eliminate these artifacts and enable accurate quantification.

2:05 **Buoyant Mass Reveals Distinct T Cell States Predictive of Checkpoint Response**
Jiaquan Yu, PhD, Research Scientist, Massachusetts Institute of Technology

In our under-review work, we demonstrate that resting CD8 T cells exhibit a bimodal buoyant-mass distribution—measured label-free by a Suspended Microchannel Resonator (SMR)—that defines an intrinsic immune-fitness axis. This rapid, <20-minute assay accurately stratified checkpoint-therapy response in a neoadjuvant melanoma cohort (AUC 0.88), outperforming tumor mutational burden. Mechanistically, "light" cells are exhaustion-prone, while "heavy" cells are biosynthetically primed, offering a novel phenotypic readout for drug discovery and clinical stratification.

2:35 **Bridging Across Analytical Methods for Therapeutic Proteins and Novel Modalities**
Diane McCarthy, PhD, Vice President, Global Biologics, US Pharmacopeia

Analytical methods continue to evolve rapidly to meet the evolving needs of new therapeutic modalities. Emerging analytical platforms often utilize different measurement principles, making direct comparison difficult and leading to lack of concordance. Bridging between methods requires comparative studies and a well characterized reference material or control. This talk will outline considerations for design and analysis of such studies using case studies from the mAb and AAV gene therapy fields.

3:05 **Single-Particle and Single-Cell Microscopy to Increase the Sensitivity of Characterizing Multivalent Cargo Nanoparticles**
Sabrina Leslie, PhD, Associate Professor, Physics, The University of British Columbia

The heterogeneity of mRNA lipid nanoparticles (LNPs) must be taken into account in order to rigorously correlate microscopic biophysical properties to therapeutic function (ACS Nano, 2026). For the first time, we demonstrate an in-solution, all-optical, high-throughput method to measure LNP size, mRNA payload, interaction kinetics, and intraparticle structure (how mRNA is arranged) of vaccine nanoparticles as a function of formulation parameters, in correlation with cryo-electron microscopy of these particles.

3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

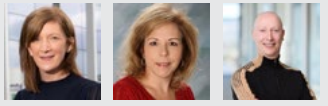
PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK

4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**



Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

EXPANDING AND OPTIMIZING MS ANALYTICS

8:00 **Chairperson's Remarks**
Chris M. Chumsae, PhD, Director, Analytical Development, Bristol-Myers Squibb

8:05 **Subunit Characterization of Therapeutic Proteins by CE-SDS and cIEF-UV/MS**
Megan Sharma, PhD, Principal Scientist, Johnson & Johnson Innovative Medicine

Sodium dodecyl sulfate capillary electrophoresis (CE-SDS) and capillary isoelectric focusing (cIEF) are assays that provide information on purity (CE-SDS) and charge distribution (cIEF-UV/MS) of protein therapeutics. Subunit digests of therapeutic antibodies which cut above and below the hinge can provide further insight into product purity and location of post-translational modifications (PTMs). This research developed procedures for the analysis of antibodies using these techniques for identification and localization of PTMs.

8:35 **HTP MS Chemical Liability Screen**
Xiaohua Liu, PhD, Principal Scientist, Sanofi

Early identification of chemical liabilities is essential for advancing developable biologic candidates without delaying timelines. We present a high-throughput MS-screening platform that overcomes peptide-mapping bottlenecks through an innovative acquisition strategy and automated data processing, delivering a 100-fold increase in throughput. This workflow enables early, comprehensive PTM characterization and generates high-density datasets to support ML/AI-driven antibody engineering.

9:05 **Fit-for-Purpose Characterization Strategies for Comprehensive Assessment of Novel Modalities**
Chris M. Chumsae, PhD, Director, Analytical Development, Bristol-Myers Squibb

Novel biologic modalities introduce new analytical challenges that require flexible and carefully designed characterization strategies. This presentation will discuss how fit-for-purpose analytical approaches can be applied to enable comprehensive assessment of emerging therapeutic formats. Topics will include selecting appropriate analytical techniques, aligning characterization depth with development phase, and leveraging complementary methods to build a robust understanding of molecular attributes that influence quality, stability, and biological activity.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:15 **MS-Based Glycolipid Analysis in Biotherapeutic R&D for Alpha-Gal Syndrome (AGS) and Melanoma Tumors**
Ying Sheng, PhD, Senior Scientist, Analytical Chemistry, Regeneron Pharmaceuticals Inc.
Alpha-gal epitopes on glycolipids and glycoproteins are central to Alpha-Gal Syndrome (AGS), yet their distribution in experimental reagents is poorly defined. We performed LC–FLR–MS glycome profiling of rabbit red-blood cells, developing a unified glycan-release workflow to quantify alpha-gal across glycolipids and N-linked glycoproteins. Over 64% of alpha-gal–containing glycans originated from glycolipids, with 2.24-fold higher mass-spectrometric responses, establishing glycolipids as the predominant alpha-gal source.

10:45 **Simple, Tunable Online Glycopeptide Enrichment for LC-MS Glycoproteomics and Therapeutic Protein Characterization**
Yunlong Zhao, PhD, Senior Principal Scientist, Analytical Chemistry, Regeneron Pharmaceuticals
Comprehensive analysis of glycosylation is essential for biologic characterization but remains analytical challenging due to microheterogeneity and low abundance of glycopeptides. This presentation introduces an online enrichment approach that integrates with LC–MS workflows for glycopeptide mapping and glycoproteomics. The discussion will focus on how this new method increases analytical sensitivity, expands glycopeptide coverage, and enables more efficient characterization of glycosylation profiles in therapeutic proteins and other complex matrices.

11:15 **KEYNOTE PRESENTATION: Emerging Methods for Studying Protein-Protein and Antibody-Ligand Interactions**
Christian Bleiholder, PhD, Professor, Chemistry and Biochemistry, Florida State University
Understanding protein–protein and antibody–ligand interactions is essential for advancing the discovery and development of biotherapeutics. This presentation will highlight emerging ion-mobility/mass-spectrometry approaches designed to characterize these interactions with improved structural and conformational resolution. The speaker will discuss how these technologies provide deeper insight into binding affinity, kinetics, and interaction mechanisms, supporting improved characterization of therapeutic antibodies and other biologics while helping researchers address increasingly complex analytical challenges.

11:45 **Sponsored Presentation** *(Opportunity Available)*

12:15 pm **Transition to Lunch**

12:20 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 **Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing**

AUTOMATION STRATEGIES

1:30 **Chairperson's Remarks**
Lusheng Fan, PhD, Senior Scientist, mRNA Center of Excellence, Sanofi

1:35 **Implementing Assay-Automation Systems**
Lusheng Fan, PhD, Senior Scientist, mRNA Center of Excellence, Sanofi
Characterization of drug substance and drug product is a critical component of mRNA vaccine development and manufacturing. Traditionally, in-process and release testing have relied heavily on manual methods, which can limit throughput and introduce analyst-to-analyst variability. To address these challenges, we developed and implemented automated versions of two key assays: a dsRNA ELISA for quantifying dsRNA impurities, and a RiboGreen assay for assessing mRNA content and encapsulation efficiency.

2:05 **Ultrasensitive nHDX-MS for High-Throughput Epitope Mapping and Analysis of Challenging Protein-Ligand and Protein-Protein Interactions**
Malvina Papanastasiou, PhD, Group Leader & Research Scientist, Proteomics Platform, Broad Institute
We recently developed an automated, ultra-sensitive platform (nHDX-MS) for high-throughput screening of protein interactions (Raval et al., MCP 2026). By operating at fmol-level sensitivity, it enables structural characterization of challenging targets like membrane proteins and transcription factors, even using lower-purity material. The system excels at epitope mapping and identifying low-affinity interactions previously limited by protein yields. This fully automated pipeline transforms complex analysis into a scalable discovery tool.

2:35 **Slope Spectroscopy: The Fast Track to Reliable Protein Quantification**
Veronika Matoša, PhD, Analytical Method Expert, Novartis
Accurate concentration determination is a critical enabler across biological drug development and the full product lifecycle. This study benchmarks slope spectroscopy (UV SoloVPE) against orthogonal Protein A affinity chromatography, focusing on method variability and bias. Statistical analysis shows markedly lower variability and significantly faster turnaround for slope spectroscopy. These performance gains deliver higher accuracy and faster reporting, positioning slope spectroscopy as a compelling technology for routine concentration determination.

3:05 **Identifying Preferred Sites of mRNA Degradation Using Nanopore Sequencing**
Zdravko Ivanov, PhD Candidate, Formulation and Stability Group, National Institute for Bioprocessing Research and Training (NIBRT)
Traditional analytical methods often struggle to capture the mRNA degradation with sufficient resolution. This study explores direct nanopore sequencing as a high-resolution method for monitoring mRNA integrity in solution. By enabling direct, long-read characterization, the approach provides deeper insights into the preferred "hot spots" for degradation. The results demonstrate how nanopore technology can be applied for the design and development of robust mRNA-based therapeutics.

3:35 **Close of Summit**

STREAM #5
GENE THERAPY, RNA, AND LNPs

The Gene Therapy, RNA, and LNPs stream delivers an integrated look at CMC, analytics, formulation, and manufacturing for RNA, lipid nanoparticles, and viral vectors across early through late development. The program begins with RNA and LNP Production and Formulation, covering RNA quality, impurity analysis, scale-up and purification, LNP production, and stability strategies. Next, the Gene Therapy CMC and Analytics meeting advances discussions on emerging CMC challenges, in vivo CAR T, product and process characterization, assay development, formulation, stability, and the unique requirements of N-of-1 manufacturing. The stream concludes with the Gene Therapy Manufacturing conference, focusing on late-stage readiness, upstream and downstream processing, novel capsid and vector production, and recovery and purification of viral vectors. Collectively, these sessions equip attendees with the technical and regulatory insights needed to accelerate development and prepare for commercial-scale manufacturing.

Conference Programs

AUGUST 10

Symposium: RNA and LNP Production and Formulation — View Program »

AUGUST 11-12

Gene Therapy CMC & Analytics — View Program »

AUGUST 12-13

Gene Therapy Manufacturing — View Program »

Monday, August 10

7:30 am **Registration Open and Morning Coffee**

8:30 **Organizer's Welcome Remarks**

8:35 **Chairperson's Remarks**
Lawrence C. Thompson, PhD, Associate Research Fellow, Analytical R&D, Pfizer Inc.

CMC AND ANALYTICS OF RNA MEDICINES

8:40 **Supporting Quality across the mRNA Product Lifecycle: From Raw Materials to CQA Assessment**
Sarita Kattel, Principal Scientist, US Pharmacopeia
The rapid growth of mRNA therapeutics highlights the need for consistent, science-based quality standards to support raw-material testing, manufacturing, and release testing. USP is developing an integrated framework of documentary and physical standards to support reliability, comparability, and regulatory confidence throughout the mRNA–LNP lifecycle. This presentation will discuss key considerations for raw-material quality and outline emerging USP standards that help ensure the development of high-quality mRNA therapeutics.

9:10 **Leveraging Next-Generation Sequencing to Examine saRNA Replication and Host Response**
Sage Rohrer, PhD, Postdoctoral Fellow, Analytical R&D, Pfizer
Self-amplifying RNA (saRNA) is a promising biotherapeutics research area due to the low dosage requirements compared to non-replicating mRNA. Upon saRNA entry into a host cell, the alphavirus-derived replicase is translated by host machinery and the replicase complex amplifies the antigen sequence of interest. We are leveraging NGS approaches to deeply characterize each stage of saRNA replication and host response. These methods may ultimately facilitate regulatory documentation and saRNA design.

9:40 **Technology Advancement and Quality of mRNA**
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant, Y-Chem Consulting LLC
There have been numerous advancements in technologies to generate raw materials and analytical methods for the analysis and characterization of mRNA to advance and improve the quality of mRNA products. To understand how these advancements in these technologies impact the quality of mRNA, we will present and discuss some of these technologies and present case studies on how these advancements impact the quality of mRNA products.

PERSONALIZED AND INDIVIDUALIZED RNA MANUFACTURING

10:10 **FEATURED PRESENTATION: GIVE: Distributed RNA Manufacturing and QC to Scale Personalized and Individualized Genetic Medicines**
John E. Schiel, PhD, Program Manager, Scalable Solutions, ARPA-H
Manufacturing genetic medicines for personalized and individualized (P/I) care is constrained by centralized, complex, and costly production models. The Genetic Medicines and Individualized Manufacturing for Everyone (GIVE) program will enable a distributed, multi-site, multi-product biomanufacturing network for RNA-based genetic medicines, integrating advanced automated RNA manufacturing with rapid, near-point-of-manufacture QC. GIVE aims to push the limits of throughput, footprint, and digital control to, expand access to next-generation P/I therapies.

10:40 **Presentation to be Announced** UNCHAINED LABS

11:10 **Networking Coffee Break**

11:25 **PANEL DISCUSSION: CMC and Quality of RNA-Based Medicines**
Moderator: Lawrence C. Thompson, PhD, Associate Research Fellow, Analytical R&D, Pfizer Inc.
Panelists:
Wei-Chiang Chen, PhD, Associate Director, BioProcess Analytics, Genomic Medicine Unit, Sanofi
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant, Y-Chem Consulting LLC

LNPs FOR RNA, IN VIVO CAR T, AND GENE EDITING

11:55 **KEYNOTE PRESENTATION: LNP Platform Enabling *in vivo* CAR T—Update from Stylus Medicine**
Srinivas Chollangi, PhD, Executive Director, CMC Tech Ops, Stylus Medicine
Stylus Medicine is developing transformative *in vivo* genetic medicines to unlock cures. Stylus combines engineered recombinases with non-viral delivery to specifically encode therapeutics. The company's approach is versatile and modular, with potential therapeutic application across oncology, autoimmune, genetic diseases, and beyond.

12:25 pm **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:55 **Session Break**

1:30 **Chairperson's Remarks**
Yuefei Shen, PhD, Associate Director, CMC Drug Product Development, Sanofi

1:35 **LNP Development**
Xin Jin, PhD, Scientist, Biological Drug Product Development, Sanofi
This presentation will provide an insight into critical considerations in lipid nanoparticle (LNP) drug product development. The discussion will cover LNP formulation strategies, buffer system optimization, manufacturing process development, and container closure system considerations to ensure product quality and stability.

2:05 **Building Scalable Platforms for Targeted LNPs: From Process Development to Manufacturing Readiness**
Ratnesh Joshi, Associate Director, Downstream Process Development, Editas Medicine
This presentation focuses on the transition of LNP manufacturing from early-stage process development to full-scale GMP production. It covers practical scale-up challenges, lessons learned from case studies, and strategies for standardizing platforms across binder modalities.

2:35 **Sponsored Presentation** *(Opportunity Available)*

3:05 **Networking Refreshment Break**

LNP PRODUCTION, QUALITY AND FORMULATION

3:20 **Development and Mechanistic Understanding of Ligand-Targeted mRNA LNP Vaccines**
Daryl Drummond, CSO, Akagera Medicines, Inc.
Akagera Medicines has developed a highly efficient ligand-targeted mRNA LNP vaccine platform composed of a novel biodegradable ionizable cationic lipid with rapid *in vitro* and *in vivo* degradation kinetics combined with rapid uptake and expression by antigen presenting cells. Here, we describe the mechanistic understanding of how these LNPs perform, as well as their production, physical characterization, and stability.

3:35 **Seamless Scale-Up of Bleb-Like mRNA-Loaded Lipid Nanoparticles**
Aniket Pradip Udepurkar, Postdoctoral Associate, Department of Chemical Engineering, Massachusetts Institute of Technology
A major bottleneck in translating mRNA therapies to market is the seamless scale-up from bench to manufacturing. We present a "size- and morphology-control" technique to produce bleb-like mRNA-LNPs that scales from microfluidic systems to manufacturing-relevant turbulent mixers, while preserving critical quality attributes and efficacy—enabling both personalized medicines and large-scale vaccine production.

3:50 **Exploring Non-Lipid-Based Nanoparticles to Expand Delivery and Storage Options to Improve Patient Accessibility**
Kinkini Roy, PhD, Associate Director, Drug Product Development, Aviceda Therapeutics
This presentation will explore emerging non-lipid nanoparticle technologies designed to expand delivery strategies for nucleic acid therapeutics and other advanced modalities. The session will examine how alternative nanoparticle systems may address current

limitations in stability, storage, and distribution. By highlighting advances in formulation and delivery design, the talk will consider how new platforms could broaden therapeutic reach and improve patient accessibility across diverse healthcare settings.

4:05 **Insights into Lipid-Nanoparticle Formulation and Production**

Cedric Devos, PhD, Postdoctoral Associate, Chemical Engineering, Massachusetts Institute of Technology

Lipid-nanoparticles are highly sensitive to processing conditions, making it difficult to consistently achieve target quality attributes. This talk will identify the origins of this sensitivity and show how a mechanistic insight into LNP self-assembly can be leveraged to build more robust processes that selectively tune specific quality attributes. This rational approach also enables predictive manufacturing through both mechanistic modeling and data-driven approaches.

4:20 **Networking Refreshment Break and Transition to Plenary Keynote**

PLENARY KEYNOTE SESSION

5:00 **PANEL DISCUSSION: Manufacturing Complex Modalities**




Moderator: Ran Zheng, Former CEO, Landmark Bio

As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
Melissa J. Moore, PhD, Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics
Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 **Welcome Reception in the Exhibit Hall with Poster Viewing**

7:00 **Close of RNA and LNP Production and Formulation Symposium**

> I thought the meeting was the best I've seen it and there was tremendous engagement in the cell and gene therapy sessions, which I loved to see.
>
> *— Patrick H., PhD, Associate Professor, Pediatrics; Chief & Director, Cellular Therapy Program, Children's National Hospital*

Monday, August 10

4:20 pm Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

5:00 PANEL DISCUSSION: Manufacturing Complex Modalities




Moderator: Ran Zheng, Former CEO, Landmark Bio

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Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

Tuesday, August 11

7:30 am Registration and Morning Coffee

8:15 Organizer's Welcome Remarks

CMC FOR *IN VIVO* CAR T

8:20 Chairperson's Remarks
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.

8:25 KEYNOTE PRESENTATION: CMC for *in vivo* CAR T Manufacturing: Opportunities, Challenges, and the Road Ahead
Nripen Singh, PhD, Executive Director and Site Head, Process Development, TRD CGT, Novartis

In vivo CAR T manufacturing represents a potential paradigm shift by eliminating patient-specific *ex vivo* manufacturing and enabling scalable, off-the-shelf therapies. The platform offers a promising alternative approach, but its success will be largely determined by Chemistry, Manufacturing, and Control (CMC) readiness. This talk evaluates CMC for *in vivo* CAR T production through a CMC lens, focusing on consistency, scalability, formulation stability, analytical control, and comparability.

8:55 CMC and Analytical Challenges in *in vivo* CAR T
James Richardson, PhD, Senior Director, In Vivo Analytical Development, Kite Pharma

The clinical use of *in vivo* lentiviral vectors requires considering the vector as final drug product, creating new analytical expectations. Legacy assays developed for *ex vivo* applications may not adequately characterize quality, potency, and safety, particularly as alternative envelope glycoproteins are introduced for tissue targeting. This presentation highlights key analytical gaps, regulatory drivers, and emerging strategies to enable robust characterization and clinical translation.

9:25 Special Consideration for *in vivo* CAR T Products
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.

There has been a notable shift from traditional *ex vivo* CAR T manufacturing toward strategies designed to engineer CAR T cells directly *in vivo*. The primary driver of this transition is the complexity, cost, and logistical burden associated with autologous CAR T production, from leukapheresis and individualized manufacturing to release testing and chain-of-identity management. I will discuss the major regulatory considerations that distinguish these products from cell therapies.

9:55 Presentation to be Announced

Bionova Scientific an Asahi Kasei company

10:25 Coffee Break in the Exhibit Hall with Poster Viewing

11:05 USP Standards for Analytical Testing of Lentiviral Vectors
Anthony Blaszczyk, PhD, Senior Scientist, Global Biologics, US Pharmacopeia

Lentiviral vectors are essential tools for *ex vivo* applications such as CAR T and are also being developed for *in vivo* therapies. Their size and complex structure make characterization challenging. USP has developed LVV standards for vector copy number quantification, residual HEK293 DNA quantification, and physicochemical characterization to support robust analytics. This talk will demonstrate how these tools can help streamline workflows and strengthen confidence in the quality of LVVs.

11:35 PANEL DISCUSSION: *In vivo* CAR T: CMC Considerations for LV and RNA-Based Platforms
Moderator: Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.

Do current analytical and quality paradigms designed for *ex vivo* cell therapies adequately apply to LV and RNA based *in vivo* platforms, or is a fundamentally different control strategy required . Will RNA-based delivery ultimately outcompete LV for *in vivo* CAR T by offering simpler manufacturing, transient expression, and lower integration risk, or will durability and redosing challenges limit its clinical impact.

Panelists:
Nripen Singh, PhD, Executive Director and Site Head, Process Development, TRD CGT, Novartis
James Richardson, PhD, Senior Director, In Vivo Analytical Development, Kite Pharma
Srinivas Chollangi, PhD, Executive Director, CMC Tech Ops, Stylus Medicine

CMC, CONTROL, AND ANALYTICAL STRATEGIES

12:05 pm The Hidden Link between CMC Decisions and Patient Access in Gene Therapy
Scott A. Jeffers, PhD, CTO, Gensight Biologics

This presentation will explore how pricing and access challenges in gene therapy are often rooted not in reimbursement, but in early CMC, manufacturing, and analytical strategy. It will discuss how process design, platform selection, and control approaches influence cost of goods, supply resilience, and commercial viability. Drawing on industry experience, the session will consider practical levers available during development to improve affordability, scalability, and long-term patient access without compromising quality.

12:35 Transition to Lunch

12:45 Luncheon Presentation to be Announced

chemometec

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks
Scott A. Jeffers, PhD, CTO, Gensight Biologics

2:05 Accelerated CMC Development for AAV Product
Santoshkumar L. Khatwani, PhD, Director, Analytical Development, Sangamo Therapeutics

This presentation will focus on strategies for a late-stage AAV program for accelerated CMC development in support of the approval pathway. A case study and some data will be presented.

2:35 CMC and Analytical Strategy—Case Study from Alexion
William Lee, Research Associate, AAV Analytical Method Development, Alexion-AstraZeneca Rare Disease

Novel capsids modify wildtype adeno-associated virus (AAVs) serotypes to improve efficacy and tissue specificity. This is often done with the placement of inserts onto the capsid. However, complex capsids require advanced analytics to properly characterize and assess lot-to-lot variability of manufactured batches. Here, several analytical methods focusing on the abundance, polydispersity, and function of the insert are used to elucidate attributes that may impact the quality of the final product.

3:05 Potency Assay Development—A Case Study from Sensorium
Christine Le Bec, PhD, Head, CMC Gene Therapy, Sensorion

This presentation examines the unique manufacturing complexities

of dual AAV vector systems including vector design, co-packaging efficiency, and ensuring balanced expression of both halves. It highlights key control strategies for process optimization, analytical characterization, and product consistency. Emphasis is placed on developing robust, scalable workflows to maintain quality and regulatory compliance in dual-vector gene-therapy manufacturing.

3:35 **Presentation to be Announced**

4:05 **Refreshment Break in the Exhibit Hall with Poster Viewing**

PERSONALIZED AND INDIVIDUALIZED GENETIC MEDICINES: N-OF-1 MANUFACTURING

4:40 **Scaling Personalized CRISPR Therapy: Regulatory, Manufacturing, and Platform Strategies**
Kok-Seong Lim, PhD, Independent Consultant; Member, USP Biologics—Cell and Gene Therapy Expert Committee
In 2025, Baby KJ became the world's first patient to receive personalized CRISPR therapy in just six months. The critical next step is translating this breakthrough into scalable, cost-effective standard care for thousands with rare genetic diseases. This presentation explores the strategic and technical foundations for building scalable gene-editing platforms, examines regulatory innovations that enable rapid deployment, and discusses how industry is reshaping the economics of personalized CRISPR therapy.

5:10 **PANEL DISCUSSION: Personalized and Individualized Genetic Medicines: N-of-1 Manufacturing**
Moderator: Susan D'Costa, PhD, CTO, Genezen
Regulatory expectations and emerging guidance for demonstrating comparability, control, and product-specific quality in highly personalized manufacturing runs.Strategies for designing ultra-flexible manufacturing platforms that can pivot from batch to batch while maintaining GMP compliance for individualized therapies. The evolving role of the patient as a central "input" to manufacturing. Approaches to supply-chain orchestration for N-of-1, including scheduling, raw-material readiness, and minimizing vein-to-vein variability.
Panelists:
John E. Schiel, PhD, Program Manager, Scalable Solutions, ARPA-H
Chris Williams, Co-Lead, Viral Vector, NIIMBL

5:40 **Interactive Breakout Discussions**
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

6:30 **Close of Day**

WEDNESDAY, AUGUST 12

8:00 am **Registration and Morning Coffee**

BIOPHYSICAL CHARACTERIZATION, DRUG PRODUCT

8:30 **Chairperson's Remarks**
Santoshkumar L. Khatwani, PhD, Director, Analytical Development, Sangamo Therapeutics

8:35 **Standardizing AAV Quality Control: USP and Solutions for Robust Gene-Therapy Analytics**
Ben Clarke, PhD, Senior Scientist, USP
There are tremendous advancements happening in quality control for adeno-associated virus (AAV) therapies, including innovations in analytical methods for impurities, titer, and capsid content. To support emerging best practices, USP is collaborating with stakeholders and expert volunteers in developing <1067> and a growing set of standards, reference materials, and other tools to support quality strategies. Attendees will learn how to integrate these resources into a robust analytical quality-control strategy.

9:05 **AAV Stress Study and CQA Assessment**
Jill Bradley-Graham, PhD, Scientist, BioAnalytics Characterization, Sanofi Genzyme
Adeno-associated virus vectors must maintain stability and product quality throughout development and manufacturing. This presentation will explore how stress studies can be used to understand potential degradation pathways and inform critical quality attribute assessment for AAV therapies.

9:35 **Biophysical Characterization of Lentivirus for *in vivo* CAR T**
Kristen Kellar, Research Scientist, Kite Pharma
Lentiviral vectors are widely used in *ex vivo* and *in vivo* cell and gene therapies. Manufacturing generates lentiviral particles alongside heterogeneous membrane-bound species with similar properties, creating analytical challenges. Monitoring particle concentration, size, charge, and protein content across production, purification, formulation, and storage provides critical data to inform process decisions. This presentation highlights the use of multiple orthogonal analytical techniques, including DLS, NTA, and flow virometry, to characterize lentiviral vectors.

10:05 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:45 **The Journey to Qualifying an Infectivity Assay, TCID50, for AAVs**
Chin Ying Angela Shiu, Process Development Engineer, Preclinical Manufacturing and Process Development, Regeneron Pharmaceuticals Inc.
This presentation will explore the development and qualification of TCID50 as an infectivity assay for AAV programs, highlighting its role in supporting process development, analytical characterization, and product quality assessment. It will discuss key considerations in assay design, variability, robustness, and comparability, as well as broader lessons learned when implementing functional assays in a regulated environment. The session will offer practical insights for teams advancing viral-vector analytics.

11:15 **Formulation Development of Adeno-Associated Virus-Based Gene Therapies**
Kaushal Jerajani, PhD, Scientist II, Genomic Medicine, Alexion AstraZeneca Rare Diseases

11:45 **Transition to Lunch**

11:50 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Close of Gene Therapy CMC & Analytics Conference**

Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

NEXT-GENERATION VECTORS, CAPSIDS, PLASMIDS

1:00 **Chairperson's Remarks**
Johannes C.M. Van Der Loo, PhD, Director Clinical Vector Core, Perelman Center for Cellular & Molecular Therapeutics, Children's Hospital of Philadelphia

1:05 **Advancing AAV Manufacturing with a Next-Generation Plasmid Platform**
Matt Edwards, Vice President, Process Science, Affinia Therapeutics
This work presents a next-generation plasmid platform engineered to enhance the efficiency, robustness, and scalability of AAV production. By integrating optimized genetic elements with a modular design, the platform increases vector yield and quality while reducing process complexity. This streamlined approach enables more reliable performance across manufacturing scales and offers a transformative solution to meet the growing demand for high-quality AAV therapeutics.

1:35 **KEYNOTE PRESENTATION: Directed Evolution of New AAV Vectors for Clinical Gene Therapy**
David V. Schaffer, PhD, Hubbard Howe Jr. Distinguished Professor, Chemical & Biomolecular Engineering, University of California Berkeley
Adeno-associated virus (AAV) is utilized in numerous FDA-approved therapies, though low delivery efficiency limits the success of natural serotypes. For over two decades, we have been implementing directed evolution to engineer highly optimized, next-generation AAV variants for efficient and targeted delivery. The resulting variants have been effective in both animal models and in numerous human clinical trials to date, and results from both will be discussed.

2:05 **Manufacturing Novel Capsids and Vectors—Case Study from Apertura**
Jorge Santiago-Ortiz, Vice President, CMC & Regulatory Affairs, Apertura Gene Therapy
This presentation will highlight CMC and bioprocessing considerations for advancing a next-generation AAV capsid designed for intravenous delivery to the brain. Using case studies, the talk will explore process development, analytical strategies, and manufacturing approaches supporting novel vector platforms. Broader themes around scalability, product quality, and preparing emerging AAV technologies for clinical manufacturing. as programs move toward first-in-human studies in 2026, will also be discussed.

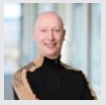
2:35 **Advances in Gene-Therapy Process Development: Case Study From Sangamo**
Phillip Ramsey, Senior Vice President, Technical Operations, Sangamo Therapeutics
This presentation will explore the evolving landscape of genome-editing therapeutics and the key considerations required to advance these products toward the clinic. As diverse editing platforms emerge, developers must address challenges spanning design, delivery, manufacturing, and regulatory strategy. The talk will discuss common development considerations and highlight approaches used to evaluate risk, support product characterization, and align CMC strategies with the unique requirements of genome-editing modalities.

3:05 **Sponsored Presentation** *(Opportunity Available)*

3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

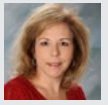
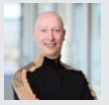
PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK



4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences
Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**

Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

MIDSTREAM OPERATIONS: POSITIONING FOR DOWNSTREAM SUCCESS

8:00 **Chairperson's Remarks**
Sarwat Khattak, PhD, Head of Cell Culture and Cell Line Development, Biogen

8:05 **Mid-Stream Bioprocessing of Gene Therapy Vectors: Setting the Stage for Successful Purification**
Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University
Midstream bioprocessing critically determines the recovery and purity of gene therapy products. This presentation examines how midstream decisions (harvest timing, depth filtration, tangential-flow filtration) set the stage for successful purification. We discuss the impact of midstream processing on chromatographic operations and the resulting quality attributes of adeno-associated virus, lentivirus, and adenovirus. Leveraging process optimization frameworks, we demonstrate how midstream excellence enables robust purification workflows that ensure therapeutic efficacy and safety.

8:35 **Optimization of the Harvest Process for AAV-Based Gene Therapy Manufacturing**
Yixuan Ming, PhD, Downstream Process Development Scientist, Technology Development, Genentech Inc.
This study evaluates alternative nucleases/methods for the harvest of AAV vectors after upstream production. By analyzing the impact of various nucleases/methods under diverse conditions, we assessed process performance, product quality, and downstream Cost of Goods (CoG). Our findings provide critical insights for optimizing the harvest process, balancing robust process with economic efficiency in gene therapy manufacturing.

9:05 **Optimizing an AAV Harvest Process Development of a Mixing Scale-Down Model for Enhanced Filtration Performance**
Yaozhong Zhang, PhD, Senior Scientist, Purification Process Development, Genomic Medicine CMC, Sanofi Group
In Sanofi's AAV manufacturing platform, the harvest process typically involves a flocculation step, where mixing plays a critical role. Developing a robust mixing scale-down model is essential. Floc formation dynamics were characterized in real time using EasyViewer technology. The developed scale-down model demonstrated excellent predictive performance. Implementation of the optimized flocculation conditions resulted in a two-fold increase in depth filter throughput.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

DOWNSTREAM PROCESSING OF VIRAL VECTORS

10:15 **Chairperson's Remarks**
Caryn L. Heldt, PhD, Professor, Chemical Engineering, Michigan Technological University

10:16 **FEATURED PRESENTATION: Innovations in Downstream AAV Purification**
Stephen Soltys, PhD, Chief Manufacturing Officer, Primera Genotech
Is it possible to level the playing field for process development of AAV gene therapies? If we could standardize AAV purification the way that plasmids or even monoclonal biologics are manufactured, we could focus our attention more toward addressing the real problem of AAV gene therapies. In this presentation, optimized purification methods, from lysis to empty full separation, will be discussed.

10:45 **Quantum Cascade Laser-MidIR (QCL-MIDIR) for Real-Time Monitoring of Capsid Concentration and Empty/Non-Empty Percentage of Adeno-Associated Viral Particles**
Juan Carlos Rosario, MSChE, Senior Principal Scientist, Purification & Virology Development, Eli Lilly & Company
AAV vectors are critical for gene therapy, but production faces challenges from empty or partially filled capsids that reduce therapeutic efficacy. Current analytical methods are slow, costly, and low-throughput. This study presents an in-line quantum cascade laser mid-infrared spectroscopy (QCL-MIDIR) platform with Partial Least Squares Regression (PLSR) models to characterize AAV9 particles, predicting concentration and capsid-filling status with a detection limit of 9.79E12 cp/mL and down to 18.4% non-empty capsids.

OPTIMIZING VIRAL VECTOR PROCESS DEVELOPMENT

11:15 **Optimizing AAV Upstream Process Development**
Klaudia Szymczak, PhD, Senior Engineer, Upstream Viral Vector Product Development, Alexion

11:45 **Sponsored Presentation** *(Opportunity Available)*

12:15 pm **Transition to Lunch**

12:20 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 **Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing**

1:30 **Chairperson's Remarks**
Nick DiGioia, CMC Leadership, Alexion Genomic Medicines

1:35 **Challenges in Manufacturing Lentiviral Vectors for *in vivo* Gene Therapy**
Robert Tona, MS, Scientist, In Vivo Process Development, Kite Pharma
Lentiviral vectors (LVs) are widely used for *ex vivo* CAR T cell therapy, but patient-specific manufacturing is complex and costly. Recently, LVs engineered to transduce T cells *in vivo* following intravenous administration have entered clinical studies as off-the-shelf products. LVs used intravenously require higher purity standards. Accordingly, we present process-development efforts to reduce residual DNA and optimize yields, emphasizing impurity–LV interactions critical for robust manufacturing.

2:05 **Transfection Complex Acid Quenching**
Louis Coplan, Process Development Engineer II, Regeneron Pharmaceuticals Inc.
Manufacturing AAV vectors via transient transfection of HEK293 cells depends on timely delivery of transfection complexes to bioreactors. We found plasmid–reagent complex size, which changes with incubation, influences productivity overall. To address this constraint, we developed a method to arrest complex growth at the optimal size, enabling storage up to 2 days with less than 20% change in vector genome titer and less than 5% change in full capsids.

2:35 **Gene-Therapy rAAV Clinical Manufacturing: Readiness and Challenges**
An-Vy Tran, Gene Therapy Process Engineering Lead, Clinical Manufacturing, UCB Inc.
Gene therapy is shifting our perspective on disease treatment with a single-dose life-changing administration. Seamless design, execution, tech transfer, and finetuning of a multi-product clinical facility is one of the key challenges in the field. The ultimate goal is to bring rapidly and with the highest compliance.

3:05 **Late-Stage Manufacturing and Process Characterization: Preparing for Commercialization**
Sumit Dutta, Associate Director, Process Development, Upstream, Forge Biologics
Advancing rAAV gene-therapy programs to commercialization demands robust, well-characterized manufacturing processes aligned with regulatory expectations. This talk will present a platform-driven CMC framework integrating comprehensive process mapping and associated risk assessments (e.g., FMEA), scale-down models, and process characterization studies utilizing DoEs—to understand the design space, determine CPPs, and define a reliable control strategy that supports regulatory submission and commercial readiness.

3:35 **Close of Summit**

STREAM #6
CELL THERAPY: *EX VIVO* AND *IN VIVO*

The Cell Therapy stream brings together cell therapy technical experts to collectively address the standards, strategies, and technologies driving robust development, testing, and production of cell-based therapies. The Cell Therapy Analytics program delves into regulatory guidance, CMC pitfalls, potency assay development, raw material characterization, and analytical innovations such as rapid release testing, flow cytometry, NGS, and mass spectrometry. The CMC and Manufacturing program spotlights automation, decentralized and point-of-care models, off-the-shelf platforms such as allogeneic and in vivo CAR T , cost reduction, digital and AI-driven modernization, and manufacturing for next-generation cell therapies. Case studies throughout provide actionable insight into scalable, compliant, and patient-focused cell therapy manufacturing.

Conference Programs

AUGUST 10

Symposium: Cell Therapy Analytics — View Program »

AUGUST 11-12

Gene Therapy CMC & Analytics — View Program »

AUGUST 12-13

Cell Therapy CMC & Manufacturing — View Program »

Monday, August 10

7:30 am **Registration Open and Morning Coffee**

8:30 **Organizer's Welcome Remarks**

ANALYTICS AND QUALITY CONTROL

8:35 **Chairperson's Remarks**
Richa Tyagi, PhD, Director, Advanced Therapies Characterization, Johnson & Johnson

8:40 **KEYNOTE PRESENTATION: Concept and Execution for an Enhanced Analytical Control Strategy Development and Execution for Autologous Cell Therapies**
Stephan O. Krause, PhD, Executive Director Analytical Quality, BMS Cell Therapies
This presentation will illustrate an enhanced analytical strategy execution roadmap with a focus on method performance optimization and automation throughout product development and commercialization. After reviewing two critical guiding principles and an execution "roadmap," we will deep-dive into an integrated and enhanced analytical development program and state-of-control process. Short case studies will be reviewed to illustrate the practical application of the guiding principles and the associated benefits.

9:10 **PANEL DISCUSSION: Latest Challenges in Cell Therapy Analytics**
Moderator: Richa Tyagi, PhD, Director, Advanced Therapies Characterization, Johnson & Johnson
Panelists:
Stephan O. Krause, PhD, Executive Director Analytical Quality, BMS Cell Therapies
Yu Qian, PhD, Director, Head, Cell Therapy Analytical Development, Novartis
Jigesha Dholakia, Director, CMC Analytical Strategy, DA01 Analytical Workstream Lead, Bayer US LLC

9:40 **Modernizing Microbial Testing: Updates on Rapid Microbiological Methods, and the Introduction of USP**
Huiping Tu, PhD, Senior Principal Scientist, Microbiology, USP
Mycoplasma testing is critical for ensuring the quality of biotechnological products and cell-based materials, yet traditional methods are constrained by long turnaround times and operational demands. USP <77> introduces nucleic acid amplification tests (NATs) for the rapid, qualitative mycoplasma detection and provides risk-based guidance on assay controls, validation, and comparability. This presentation highlights USP's evolving position on Modern Microbiological Methods (M3) and the development of GC <77>.

10:10 **Rapid Sterility Testing for Cell Therapies**
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.
This presentation will explore rapid sterility testing strategies tailored to cell-therapy development and manufacturing. It will highlight the unique time, logistics, and product release pressures associated with living medicines, and consider how faster microbial detection approaches may support quality, safety, and timely patient access. Broader themes may include method selection, implementation challenges, regulatory considerations, and the evolving role of rapid testing within advanced-therapy control strategies.

10:40 **Sponsored Presentation** *(Opportunity Available)*

11:10 **Networking Coffee Break**

11:25 **Cell Characterization Standardization and PAT Considerations for Cell Therapies**
Melis Kant, PhD, Biochemist, Biomaterials Group, NIST
Cell characterization and testing are critical for bioprocess monitoring in biopharmaceuticals and cell-based therapies. Standards are urgently needed to establish common practices, interoperability, and translation in cell-based biotechnologies. Here, we will describe the current standards infrastructure for cell characterization. In addition, we will discuss recent trends in process analytical technologies for cell-therapies, including label-free, real-time monitoring, and metabolomic approaches.

11:55 **Accelerating Cell-Therapy Development with High-Throughput Automation**
Ronnie Lum, PhD, Director, Analytical & Quality Control, BlueRock Therapeutics LP
To accelerate cell-therapy development and scalability, there is an urgent need to accelerate processing times, increase throughput, reduce cell material requirements for testing, and enhance assay robustness. This presentation will review BlueRock's approach to achieve this goal: the development of a suite of plate-based assays to characterize our cell therapy products, adaptation to liquid handling platforms, and the development of automated workflows for hands-free operability.

12:25 pm **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:55 **Session Break**

POTENCY ASSAYS, PRODUCT, AND PROCESS CHARACTERIZATION

1:30 **Chairperson's Remarks**
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.

1:35 **Validation of Potency Assays in Cell Therapy**
Divya Ravirala, PhD, Director, CMC Analytical Development, Immatics Biotechnologies GmbH
Potency is a critical quality attribute for cell- and gene-therapy products and is essential for product release and licensure. Establishing scientifically sound, mechanism-based, and phase-appropriate potency strategies remains a key consideration through clinical development and commercialization. We present a structured, risk-based approach to potency-assay development and validation to ensure functional consistency, support pivotal clinical trials, and enable successful licensure of cell-therapy products.

2:05 **Navigating Phase-Appropriate Method Transfers and Validation**
Jigesha Dholakia, Director, CMC Analytical Strategy, DA01 Analytical Workstream Lead, Bayer US LLC
As Bayer and BlueRock advance towards Commercial Readiness following the RMAT designation from the FDA, the concept of phase-appropriateness becomes increasingly important. We are transitioning into late-phase development and ensure process comparability, it is essential to ensure that our assays effectively capture the Critical Quality Attributes (CQAs), whether during release or through extended characterization.

2:35 **Development of a Single Cell ddPCR Method for Measure of Transfection Efficiency for mRNA Engineered Cell Therapies**
Damian Marshall, PhD, Vice President, Analytical Development, Resolution Therapeutics
This presentation will showcase a novel single-cell digital droplet PCR (SC-ddPCR) method to characterize an autologous mRNA-modified macrophage therapy for the treatment of end-stage liver disease. Offering single-molecule sensitivity, the assay accurately quantifies transfected subpopulations within the drug products. The workflow's robustness and precision ensure it is highly effective for routine batch release within a GMP-QC environment, bridging the gap between high-resolution analysis and, manufacturing scalability.

3:05 **Networking Refreshment Break**

3:20 **Integrating Drug Product Characterization and MoA Understanding to Inform a Robust Potency Assay Strategy**
Kelly Bowen, MS, Senior Scientist, Analytical and Process Development, KSQ Therapeutics Inc.
Developing a robust potency strategy for cell therapy products requires a deep, integrated understanding of product characteristics and MoA. This talk will highlight practical considerations for early-stage programs, including how to balance exploratory analytics with regulatory expectations, how to use characterization data to select surrogate or functional readouts, and how to evolve potency strategies as products advance toward clinical development.

3:50 **Flow Cytometry in QC of Advanced Cell Therapy**
Ruud Hulspas, PhD, Director, Process Development, Dana-Farber Cancer Institute
Most cell-based therapeutic products utilize flow cytometry as part of quality control (QC). The CLSI guidance document, H62, addresses validation of flow cytometry methods but is primarily focused on translational and clinical applications. Led by the International Alliance for Biological Standardization (IABS), guidelines are being developed, specifically for flow cytometry in QC for cell-therapy manufacturing. This presentation discusses key aspects of flow cytometry that demand extra attention in these guidelines.

4:20 **Networking Refreshment Break and Transition to Plenary Keynote**

PLENARY KEYNOTE SESSION

5:00 **PANEL DISCUSSION: Manufacturing Complex Modalities**




Moderator: Ran Zheng, Former CEO, Landmark Bio
As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
Melissa J. Moore, PhD, Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics
Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 **Welcome Reception in the Exhibit Hall with Poster Viewing**

7:00 **Close of Cell Therapy Analytics Symposium**

Monday, August 10

4:20 pm Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION

5:00 PANEL DISCUSSION: Manufacturing Complex Modalities

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Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing

Tuesday, August 11

7:30 am Registration and Morning Coffee

8:15 Organizer's Welcome Remarks

CMC FOR *IN VIVO* CAR T

8:20 Chairperson's Remarks
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.

8:25 KEYNOTE PRESENTATION: CMC for *in vivo* CAR T Manufacturing: Opportunities, Challenges, and the Road Ahead
Nripen Singh, PhD, Executive Director and Site Head, Process Development, TRD CGT, Novartis
In vivo CAR T manufacturing represents a potential paradigm shift by eliminating patient-specific *ex vivo* manufacturing and enabling scalable, off-the-shelf therapies. The platform offers a promising alternative approach, but its success will be largely determined by Chemistry, Manufacturing, and Control (CMC) readiness. This talk evaluates CMC for *in vivo* CAR T production through a CMC lens, focusing on consistency, scalability, formulation stability, analytical control, and comparability.

8:55 CMC and Analytical Challenges in *in vivo* CAR T
James Richardson, PhD, Senior Director, In Vivo Analytical Development, Kite Pharma
The clinical use of *in vivo* lentiviral vectors requires considering the vector as final drug product, creating new analytical expectations. Legacy assays developed for *ex vivo* applications may not adequately characterize quality, potency, and safety, particularly as alternative envelope glycoproteins are introduced for tissue targeting. This presentation highlights key analytical gaps, regulatory drivers, and emerging strategies to enable robust characterization and clinical translation.

9:25 Special Consideration for *in vivo* CAR T Products
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.
There has been a notable shift from traditional *ex vivo* CAR T manufacturing toward strategies designed to engineer CAR T cells directly *in vivo*. The primary driver of this transition is the complexity, cost, and logistical burden associated with autologous CAR T production, from leukapheresis and individualized manufacturing to release testing and chain-of-identity management. I will discuss the major regulatory considerations that distinguish these products from cell therapies.

9:55 Presentation to be Announced

10:25 Coffee Break in the Exhibit Hall with Poster Viewing

11:05 USP Standards for Analytical Testing of Lentiviral Vectors
Anthony Blaszczyk, PhD, Senior Scientist, Global Biologics, US Pharmacopeia
Lentiviral vectors are essential tools for *ex vivo* applications such as CAR T and are also being developed for *in vivo* therapies. Their size and complex structure make characterization challenging. USP has developed LVV standards for vector copy number quantification, residual HEK293 DNA quantification, and physicochemical characterization to support robust analytics. This talk will demonstrate how these tools can help streamline workflows and strengthen confidence in the quality of LVVs.

11:35 PANEL DISCUSSION: *In vivo* CAR T: CMC Considerations for LV and RNA-Based Platforms
Moderator: Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.
Do current analytical and quality paradigms designed for *ex vivo* cell therapies adequately apply to LV and RNA based *in vivo* platforms, or is a fundamentally different control strategy required . Will RNA-based delivery ultimately outcompete LV for *in vivo* CAR T by offering simpler manufacturing, transient expression, and lower integration risk, or will durability and redosing challenges limit its clinical impact.
Panelists:
Nripen Singh, PhD, Executive Director and Site Head, Process Development, TRD CGT, Novartis
James Richardson, PhD, Senior Director, In Vivo Analytical Development, Kite Pharma
Srinivas Chollangi, PhD, Executive Director, CMC Tech Ops, Stylus Medicine

CMC, CONTROL, AND ANALYTICAL STRATEGIES

12:05 pm The Hidden Link between CMC Decisions and Patient Access in Gene Therapy
Scott A. Jeffers, PhD, CTO, Gensight Biologics
This presentation will explore how pricing and access challenges in gene therapy are often rooted not in reimbursement, but in early CMC, manufacturing, and analytical strategy. It will discuss how process design, platform selection, and control approaches influence cost of goods, supply resilience, and commercial viability. Drawing on industry experience, the session will consider practical levers available during development to improve affordability, scalability, and long-term patient access without compromising quality.

12:35 Transition to Lunch

12:45 Luncheon Presentation to be Announced

1:15 Refreshment Break in the Exhibit Hall with Poster Viewing

2:00 Chairperson's Remarks
Scott A. Jeffers, PhD, CTO, Gensight Biologics

2:05 Accelerated CMC Development for AAV Product
Santoshkumar L. Khatwani, PhD, Director, Analytical Development, Sangamo Therapeutics
This presentation will focus on strategies for a late-stage AAV program for accelerated CMC development in support of the approval pathway. A case study and some data will be presented.

2:35 CMC and Analytical Strategy—Case Study from Alexion
William Lee, Research Associate, AAV Analytical Method Development, Alexion-AstraZeneca Rare Disease
Novel capsids modify wildtype adeno-associated virus (AAVs) serotypes to improve efficacy and tissue specificity. This is often done with the placement of inserts onto the capsid. However, complex capsids require advanced analytics to properly characterize and assess lot-to-lot variability of manufactured batches. Here, several analytical methods focusing on the abundance, polydispersity, and function of the insert are used to elucidate attributes that may impact the quality of the final product.

3:05 Potency Assay Development—A Case Study from Sensorium
Christine Le Bec, PhD, Head, CMC Gene Therapy, Sensorion
This presentation examines the unique manufacturing complexities

of dual AAV vector systems including vector design, co-packaging efficiency, and ensuring balanced expression of both halves. It highlights key control strategies for process optimization, analytical characterization, and product consistency. Emphasis is placed on developing robust, scalable workflows to maintain quality and regulatory compliance in dual-vector gene-therapy manufacturing.

3:35 **Presentation to be Announced**

4:05 **Refreshment Break in the Exhibit Hall with Poster Viewing**

PERSONALIZED AND INDIVIDUALIZED GENETIC MEDICINES: N-OF-1 MANUFACTURING

4:40 **Scaling Personalized CRISPR Therapy: Regulatory, Manufacturing, and Platform Strategies**
Kok-Seong Lim, PhD, Independent Consultant; Member, USP Biologics—Cell and Gene Therapy Expert Committee
In 2025, Baby KJ became the world's first patient to receive personalized CRISPR therapy in just six months. The critical next step is translating this breakthrough into scalable, cost-effective standard care for thousands with rare genetic diseases. This presentation explores the strategic and technical foundations for building scalable gene-editing platforms, examines regulatory innovations that enable rapid deployment, and discusses how industry is reshaping the economics of personalized CRISPR therapy.

5:10 **PANEL DISCUSSION: Personalized and Individualized Genetic Medicines: N-of-1 Manufacturing**
Moderator: Susan D'Costa, PhD, CTO, Genezen
Regulatory expectations and emerging guidance for demonstrating comparability, control, and product-specific quality in highly personalized manufacturing runs.Strategies for designing ultra-flexible manufacturing platforms that can pivot from batch to batch while maintaining GMP compliance for individualized therapies. The evolving role of the patient as a central "input" to manufacturing. Approaches to supply-chain orchestration for N-of-1, including scheduling, raw-material readiness, and minimizing vein-to-vein variability.
Panelists:
John E. Schiel, PhD, Program Manager, Scalable Solutions, ARPA-H
Chris Williams, Co-Lead, Viral Vector, NIIMBL

5:40 **Interactive Breakout Discussions**
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

6:30 **Close of Day**

WEDNESDAY, AUGUST 12

8:00 am **Registration and Morning Coffee**

BIOPHYSICAL CHARACTERIZATION, DRUG PRODUCT

8:30 **Chairperson's Remarks**
Santoshkumar L. Khatwani, PhD, Director, Analytical Development, Sangamo Therapeutics

8:35 **Standardizing AAV Quality Control: USP and Solutions for Robust Gene-Therapy Analytics**
Ben Clarke, PhD, Senior Scientist, USP
There are tremendous advancements happening in quality control for adeno-associated virus (AAV) therapies, including innovations in analytical methods for impurities, titer, and capsid content. To support emerging best practices, USP is collaborating with stakeholders and expert volunteers in developing <1067> and a growing set of standards, reference materials, and other tools to support quality strategies. Attendees will learn how to integrate these resources into a robust analytical quality-control strategy.

9:05 **AAV Stress Study and CQA Assessment**
Jill Bradley-Graham, PhD, Scientist, BioAnalytics Characterization, Sanofi Genzyme
Adeno-associated virus vectors must maintain stability and product quality throughout development and manufacturing. This presentation will explore how stress studies can be used to understand potential degradation pathways and inform critical quality attribute assessment for AAV therapies.

9:35 **Biophysical Characterization of Lentivirus for *in vivo* CAR T**
Kristen Kellar, Research Scientist, Kite Pharma
Lentiviral vectors are widely used in *ex vivo* and *in vivo* cell and gene therapies. Manufacturing generates lentiviral particles alongside heterogeneous membrane-bound species with similar properties, creating analytical challenges. Monitoring particle concentration, size, charge, and protein content across production, purification, formulation, and storage provides critical data to inform process decisions. This presentation highlights the use of multiple orthogonal analytical techniques, including DLS, NTA, and flow virometry, to characterize lentiviral vectors.

10:05 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:45 **The Journey to Qualifying an Infectivity Assay, TCID50, for AAVs**
Chin Ying Angela Shiu, Process Development Engineer, Preclinical Manufacturing and Process Development, Regeneron Pharmaceuticals Inc.
This presentation will explore the development and qualification of TCID50 as an infectivity assay for AAV programs, highlighting its role in supporting process development, analytical characterization, and product quality assessment. It will discuss key considerations in assay design, variability, robustness, and comparability, as well as broader lessons learned when implementing functional assays in a regulated environment. The session will offer practical insights for teams advancing viral-vector analytics.

11:15 **Formulation Development of Adeno-Associated Virus-Based Gene Therapies**
Kaushal Jerajani, PhD, Scientist II, Genomic Medicine, Alexion AstraZeneca Rare Diseases

11:45 **Transition to Lunch**

11:50 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Close of Gene Therapy CMC & Analytics Conference**

Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

ADVANCES IN CELL THERAPY MANUFACTURING

1:00 **Chairperson's Remarks**
Ravi Bhatia, Scientific Director, API - Cell and Gene Therapy, Johnson & Johnson Pharmaceutical R&D

1:05 **Fully Automated and Closed Stem-Cell Expansion and Differentiation at a Commercial Scale**
Wonjong Si, Director, Cell Therapy Process Development, Bayer US LLC

This presentation explores the benefits of fully automating and closing stem-cell expansion and differentiation processes. We highlight our innovative system, featuring automated thawing, media exchange, and passaging, along with a confluency estimator algorithm. Additionally, we introduce predictive modeling for stem cell differentiation capability, aiming to enhance consistency and reduce variability, ultimately revolutionizing applications in regenerative medicine.

1:35 **KEYNOTE PRESENTATION: Scaling CAR T: Lessons from a Commercial Manufacturing Launch**
Xavier J. De Mollerat Du Jeu, PhD, Global Head Automation and Innovation, Cell Therapy Manufacturing, Legend Biotech Co.

- Lessons learned from the operational and manufacturing journey of CARVYKTI
- Challenges encountered and how they shaped decision-making
- Key takeaways for advancing CAR T production and delivery

2:05 **Allogeneic Cell-Therapy Manufacturing**
Sreedhar Thirumala, PhD, Director, Process Development, Genentech

Allogeneic CAR T therapies offer off-the-shelf access but present unique CMC challenges. This presentation will discuss donor selection; non-viral gene editing; and current limitations in isolation, expansion, and purification technologies. We will also address fill finish, dose control, cryopreservation, and distribution considerations needed to enable a scalable and compliant manufacturing strategy.

2:35 **From Genome Engineering to GMP: Enabling Scalable Allogeneic CAR T-Cell–Therapy Manufacturing**
Justin Skoble, PhD, Vice President, Tech Operations, Caribou Biosciences, Inc.

Caribou's patented chRDNA (CRISPR hybrid RNA-DNA) technology enables superior specificity and precision that drives complex genome editing, including multiplex gene knockout and insertion, while maintaining genomic integrity. chRDNA genome-editing technology is used to armor allogeneic cell therapies with checkpoint disruption and immune cloaking to enhance anti-tumor activity. Allogeneic, or off-the-shelf, CAR T cell therapies have the potential to provide broad access and rapid treatment for patients with hematologic malignancies.

3:05 **Sponsored Presentation** *(Opportunity Available)*

3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

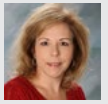
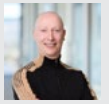
PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK

4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**

Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

MANUFACTURING COMPLEX CELL THERAPIES

8:00 **Chairperson's Remarks**
Patrick J. Hanley, PhD, Associate Professor, Pediatrics; Chief & Director, Cellular Therapy Program, Children's National Hospital

8:05 **Low-Cost Cell-Therapy Manufacturing—A Case Study from Satellite Bio**
Julie Morse, Vice President, Technical Operations, Satellite Bio

Satellite Biosciences has developed a low-cost cell therapy designed to treat patients with severe liver disease. Our breakthrough technology expands primary hepatocytes sourced from donor liver tissue into a cryopreserved, off-the-shelf therapy for on-demand clinical use. To support commercial viability, Satellite has focused on driving down cost of goods by conducting multiple design-of-experiments (DOE) studies, establishing a scalable manufacturing process, and building centralized manufacturing capabilities.

8:35 **Optimizing Cell-Therapy Manufacturing—Case Study from Resolution**
Steven J. Howe, PhD, Vice President, Process Development, Resolution Therapeutics

9:05 **Advancing the Supply Chain for Cell-Based Products: ARMI's Landscape Assessment and Emerging Roadmap**
Juan J. Carmona, PhD, Senior Director, Clinical & Scientific Affairs, Advanced Regenerative Manufacturing Institute ARMI
Patricia Seymour, Managing Director, BioProcess Technology Group, BDO US

The healthcare system is rapidly evolving as cell-based products are approved, scaled, and ready for distribution. Now, their supply chain must catch up. The Advanced Regenerative Manufacturing Institute, Inc. (ARMI) is advancing this supply chain with funding support from the U.S. DOC (EDA award number 01-79-15303). During this presentation, ARMI will share findings from their initial landscape analysis and the emerging roadmap that will drive this industry's next steps.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

SUPPORTING THE DELIVERY OF CELL THERAPIES TO PATIENTS

10:15 **Supporting Translation and Commercialization of Cell and Gene Therapies**
Patrick J. Hanley, PhD, Associate Professor, Pediatrics; Chief & Director, Cellular Therapy Program, Children's National Hospital

The role of cell processing labs has evolved since the approval of the first CAR T cell, Kymriah, in 2017. Here, we will discuss how our program supports investigator-initiated clinical trials and prepares these products for eventual commercialization, while also supporting stem-cell transplants and commercial gene-therapy products such as Kymriah, Lyfgenia, and Casgevy.

10:45 **Process Development of Emerging CAR T Formats—Case Study from Mass General Maus Lab**
Magdi Elsallab, PhD, Director, Process Development, Cellular Immunotherapy Program, Mass General Hospital

Chimeric antigen receptor (CAR) T cell therapy has transformed the treatment landscape for hematologic malignancies, yet widespread adoption remains constrained by complex, time-intensive, and resource-heavy manufacturing processes. This talk will provide an

in-depth overview of process-development strategies and recent advances that have enabled the clinical success of CAR T products while highlighting key bottlenecks that limit scalability, affordability, and global access.

11:15 **Overcoming Challenges of Cell-Therapy Program Establishment for Phase I Trials**
Tatyana Matveeva, PhD, Director of cGMP Cell Production Operations, Neurosurgery, Massachusetts General Hospital
Neurodegenerative conditions are prevalent diseases with severe economic-, personal-, and healthcare-expense consequences. Cell-replacement therapies have offered a route to functional recovery, but clinical cell manufacturing frequently requires distributed production and oversight associated with substantial financial burden. We describe our in-hospital cGMP-cell–manufacturing facility with adjacent quality control and in direct proximity to patients—and demonstrate the challenges of developing a compliant and all-inclusive program at cost.

11:45 **Sponsored Presentation** *(Opportunity Available)*

12:15 pm **Transition to Lunch**

12:20 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 **Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing**

DRUG PRODUCT, PARTICLES, AND PRODUCT QUALITY

1:30 **Chairperson's Remarks**
Bharathi Vellalore, PhD, Senior Manager, Drug Product Development and Delivery, Johnson & Johnson Innovative Medicine

1:35 **Drug Product and Delivery of Cell Therapies**
Vidyashankara Iyer, PhD, Director, AstraZeneca
Cell therapies introduce unique drug product and delivery challenges that differ substantially from traditional biologics. This presentation will explore strategies to develop robust drug-product formulations, optimize storage and handling, and enable reliable administration at the point of care.

2:05 **Visible Particulates in Cell-Containing Products**
Diana Colleluori, PhD, MBA, Principal CMC Consultant, CMC Analytical, Biologics Consulting Group
There are unique challenges to processing and testing cell-containing products that cannot be terminally sterilized. FDA guidance and USP chapters related to visible particulates will be discussed. Lessons learned using a real-life CGT case study will be presented.

DATA, AI/ ML IN CELL THERAPY MANUFACTURING

2:35 **Cell-Therapy Manufacturing Analytics**
Prasid Dasgupta, Process Statistical Analytics Lead, Advanced Therapies Supply Chain, Johnson & Johnson Innovative Medicine
Data, AI, and digitalization are redefining cell-therapy manufacturing by improving process visibility, strengthening control strategies, and enabling real-time monitoring. Integrated data systems, machine learning, and digital twins help manage variability, enhance CPV, and streamline deviation detection. This talk will highlight practical examples showing how digital maturity supports scalable, consistent, and compliant production of CAR T and other advanced therapies.

3:05 **PANEL DISCUSSION: Real-World Application of AI/ML in Cell Therapy from Manufacturing to Regulatory**
Co-Moderators:
Dominic Clarke, Vice President of Technical Operations, IntegriCell; PDM Committee Chair, ISCT
Dalip Sethi, PhD, Co-Chair, PAAD Working Group, ISCT; Commercial Lead, Cell Therapy Technologies, North America, Terumo BCT Inc.
How AI and machine learning are being applied across cell therapy manufacturing to improve process development, optimize production workflows, and enhance product consistency. The role of digital tools and data integration in enabling real-time monitoring, predictive analytics, and smarter decision-making across development and manufacturing operations.

3:35 **Close of Summit**

STREAM #7 *New*
CONJUGATES, OLIGOS, AND PEPTIDES

This stream explores the latest CMC developments in ADCs, novel conjugates, oligonucleotides, and peptides, bringing together experts in bioprocessing, process chemistry, and analytical development to address shared challenges in complex molecule manufacturing. Part One provides a focused examination of CMC strategies for ADCs and next-generation conjugates, covering advances in conjugation chemistry, analytical control, formulation, safety, and scale-up. Part Two delves into oligonucleotide and peptide CMC, analysis, and manufacturing, highlighting synthetic, hybrid, and recombinant production platforms, including delivery and formulation. Part Three showcases innovations in recovery and purification for complex modalities, emphasizing emerging separation technologies, adaptable purification strategies, and methods to improve yield and product quality across diverse molecular formats.

Conference Programs

AUGUST 10

Symposium: CMC for ADC & Next-Generation Conjugates — View Program »

AUGUST 11-12

Oligonucleotide and Peptide CMC and Manufacturing — View Program »

AUGUST 12-13

Advances in Purification & Recovery — View Program »

Monday, August 10

7:30 am **Registration Open and Morning Coffee**

8:30 **Organizer's Welcome Remarks**

CMC CHALLENGES AND COMPLEXITIES

8:35 **Chairperson's Remarks**
Rakesh Dixit, PhD, DABT, CEO & President, Bionavigen Oncology, LLC; CSO, TMAB Therapeutics, Regio Biosciences

8:40 **Overcoming Analytical and CMC Complexities**
Michael H. Xie, PhD, Vice President, Analytics; Head, Bioassay and Analytical Development, Shanghai Henlius Biotech, Inc.

Antibody–drug conjugates (ADCs) present unique analytical and CMC challenges due to their structural complexity, heterogeneous drug-to-antibody ratios, and sensitive linker–payload chemistries. This talk explores emerging strategies to address these hurdles across development and manufacturing. Experts will discuss advanced analytical tools, improved characterization methods, and integrated CMC approaches that support product consistency, regulatory expectations, and scalable production, ultimately accelerating the path from early development to reliable commercial manufacturing.

9:10 **From Clinical to Commercial: De-Risking CMC and Manufacturing for ADCs and Next-Generation Conjugates**
Wasfi Alazzam, PhD, Founder, OmniBioPro

This presentation addresses scalable process design, analytical control, and regulatory readiness, helping teams bridge early development to launch. By integrating quality by design, robust supply strategies, and platform approaches, the program reduces technical uncertainty, accelerates timelines, and improves reproducibility, enabling confident commercialization of complex, high-value therapeutics across global networks and evolving modalities worldwide adoption.

9:40 **KEYNOTE PRESENTATION: ADCs & CMC: The Complexity Remains—Do Next-Gen Conjugates Enable Streamlining?**
Olivier J. Marcq, PhD, Senior Vice President, CMC, Tubulis GmbH

Clinical-stage or commercial ADC production processes and new conjugation technologies will be compared in terms of process/supply-chain complexity. We will consider highly interesting new approaches for continuous manufacturing and potential hindrance to adoption. Tubulis's Tubutecan technology's behavior across multiple programs and scales, and insights on the stability of ADCs generated with this DAR 8.0 enabling technology currently in the clinic, will be discussed.

10:10 **An Integrated CMC Platform for Rapid Development of Novel ADCs Based on TMALIN (Tumor-Microenvironment-Activable-Linker)**
Weichang Zhou, PhD, CTO, MediLink Therapeutics

An integrated CMC platform accelerates development of novel TMALIN-based ADCs from DNA to commercialization. TMALIN features cleavable linkers for high solubility and anti-aggregation, enabling >99% purity (homogeneous DAR=8) and high *in vitro/in vivo* stability. ADCs cleave extracellularly (tumor microenvironment) and intracellularly (lysosomes). This platform encompasses end-to-end capabilities for linker-payload, antibody, conjugation, and drug product development, manufacturing, and release.

10:40 **Sponsored Presentation** *(Opportunity Available)*

11:10 **Networking Coffee Break**

SAFETY, COST & SUSTAINABILITY CONSIDERATIONS FOR MANUFACTURING

11:25 **From Molecule to Facility: Predictive Modeling for ADC Cost and Sustainability**
Andrew Sinclair, MSc, CEng, FIChemE, FREng, President & Founder, BioPharm Services Ltd.

ADC manufacturing costs run 5–10× higher than conventional mAbs, driven by drug-linker expense, cytotoxic containment, and fragmented supply chains—yet standard metrics like PMI miss critical factors including energy and Scope 3 emissions. This talk demonstrates how early-stage digital facility modeling, combining limited process data with AI-conditioned databases, enables end-to-end ADC process optimization before capital is committed, delivering dramatic reductions in COGS, waste, and carbon intensity.

11:55 **Safety and Efficacy for ADCs—Addressing Challenges of Safety for Large-Scale Manufacturing**
Rakesh Dixit, PhD, DABT, CEO & President, Bionavigen Oncology, LLC; CSO, TMAB Therapeutics, Regio Biosciences

Manufacturing deviations can significantly affect the drug-antibody ratio (DAR), free payload levels, and overall product stability. Critical quality attributes (CQAs) associated with clinical outcomes are careful control of free payload levels during release and throughout shelf life, and consistent management of process parameters from conjugation to fill-finish, regardless of scale. This presentation will outline an integrated approach that encompasses process design, analytical controls, stability monitoring, and occupational safety.

12:25 pm **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:55 **Session Break**

ENSURING EFFICACY AND MANUFACTURABILITY OF ADCs

1:30 **Chairperson's Remarks**
Weichang Zhou, PhD, CTO, MediLink Therapeutics

1:35 **The Evolving Landscape of Antibody-Drug Conjugates (ADCs) Technology and the Identification of Its Therapeutic Platform**
Robert Dream, PhD, Managing Director, HDR Co. LLC

Antibody–drug conjugate (ADC) manufacturing is a complex, multi-step biopharmaceutical process that combines biologics production with highly potent small-molecule chemistry. ADCs are targeted cancer therapies composed of three key components: a monoclonal antibody (mAb), a cytotoxic payload, and a chemical linker that connects them. The manufacturing process must ensure safety, precision, reproducibility, and regulatory compliance due to the extreme potency of the payloads involved.

2:05 **From First Conjugate to First Patient: Building ADCs that Translate**
Benjamin Hutchins, PhD, Principle, Strategic CMC and Technical Operations, First Principles CMC

Antibody–drug conjugate development requires seamless integration of discovery, design, and translational strategy to move efficiently from the first conjugate to first-in-human studies. This talk will explore how optimized target selection, linker–payload design, and early developability assessments can improve clinical translation. Speakers will discuss preclinical models, analytical insights, and CMC considerations that help predict safety, efficacy, and manufacturability, enabling teams to build ADCs with a clearer and faster path to patients.

2:35 **Sponsored Presentation** *(Opportunity Available)*

3:05 **Networking Refreshment Break**

3:20 **On-Column Capping of ThiomAb**
Kai Ni, PhD, Bioprocess Engineer, Downstream, Takeda Development Center Americas, Inc.

Cysteine-engineered mAbs (ThiomAbs) enable site-specific ADC conjugation but introduce reactive free thiols that drive variable Cys/GSH capping with charge heterogeneity and uncapped free thiol with stability risk. Here we developed an on-column capping strategy during affinity chromatography by immobilizing antibodies and selectively masking engineered thiols under optimized redox conditions to reduce capping heterogeneity at engineered cysteines, thereby reducing analytical complexity and improving process control.

3:50 **Ensuring Efficacy and Manufacturability of Antibody–Drug Conjugates: Bridging Discovery and Scalable Production**
Sunny Zhou, PhD, Professor, Chemistry & Chemical Biology, Northeastern University

Antibody–drug conjugates (ADCs) represent a powerful class of targeted therapeutics, combining the specificity of monoclonal antibodies with the potency of cytotoxic payloads. However, translating ADCs from discovery to commercial manufacturing requires careful optimization of conjugation chemistry, stability, and process scalability. This talk will discuss strategies to ensure both therapeutic efficacy and manufacturability of ADCs, including

control of drug–antibody ratio (DAR), linker stability, analytical characterization, and robust manufacturing processes.

4:20 **Networking Refreshment Break and Transition to Plenary Keynote**

PLENARY KEYNOTE SESSION

5:00 **PANEL DISCUSSION: Manufacturing Complex Modalities**

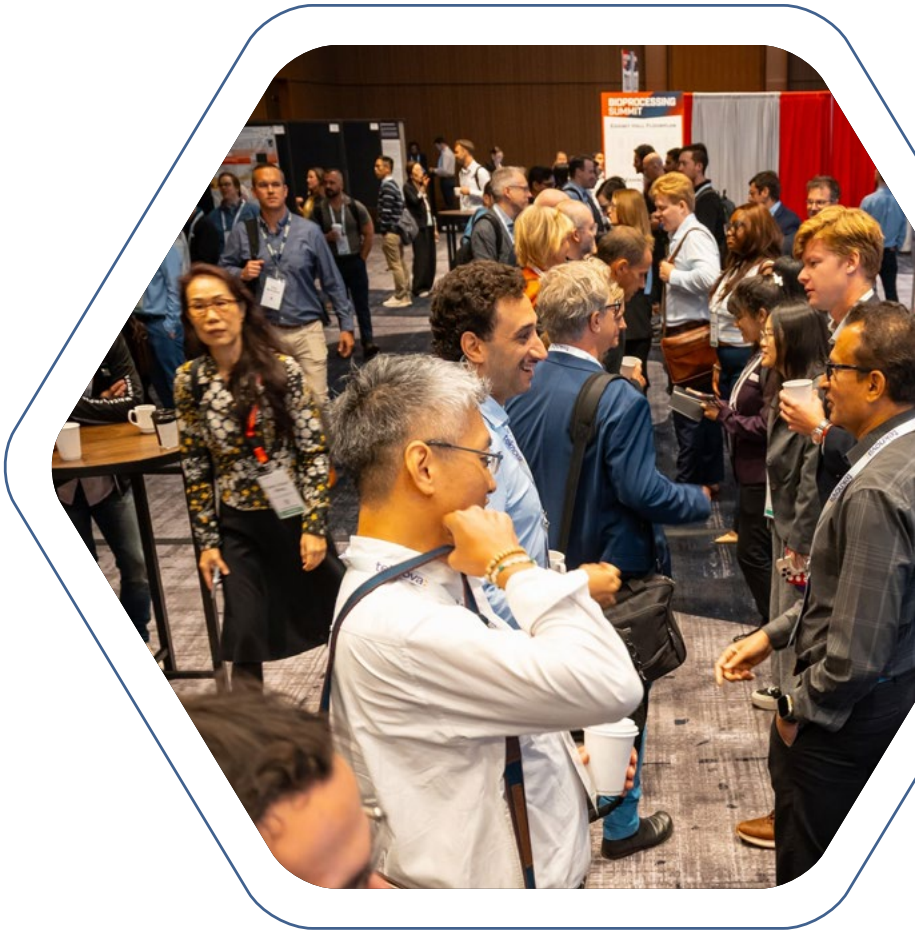



Moderator: Ran Zheng, Former CEO, Landmark Bio
As biologics move toward increasingly complex formats such as multi specific antibodies, conjugated biologics, and *de novo* designed proteins, new challenges are emerging across CMC, bioprocessing, and manufacturing. This plenary discussion will explore how advances in AI/ ML, molecular design, and new chemistries are enabling a new generation of innovative biologics, and the capabilities required to translate these increasingly complex molecules from discovery through to commercially viable manufacturing.

Panelists:
Melissa J. Moore, PhD, Chair, Board of Directors, Waterfall Scientific; Board Member, Tessera Therapeutics
Jennitte L. Stevens, PhD, Chief Technical Operations Officer, insitro
Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 **Welcome Reception in the Exhibit Hall with Poster Viewing**

7:00 **Close of CMC for ADC & Next-Generation Conjugates Symposium**



Monday, August 10

4:20 pm **Networking Refreshment Break and Transition to Plenary Keynote**

PLENARY KEYNOTE SESSION

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Weichang Zhou, PhD, CTO, MediLink Therapeutics

6:00 **Welcome Reception in the Exhibit Hall with Poster Viewing**

Tuesday, August 11

7:30 am **Registration and Morning Coffee**

8:15 **Organizer's Welcome Remarks**

CMC FOR COMPLEX OLIGONUCLEOTIDES

8:20 **Chairperson's Remarks**
Haripada Maity, PhD, Head, R&D, Oligonucleotides, Cipla

8:25 **Quality Frameworks for Oligonucleotides and Peptides: USP Standards Supporting CMC and Manufacturing**
Diane McCarthy, PhD, Vice President, Global Biologics, US Pharmacopeia
This presentation will outline the quality frameworks for therapeutic oligonucleotides and peptides, emphasizing how public standards strengthen CMC development and manufacturing. Challenges in impurity control, starting-material characterization, and analytical consistency across product lifecycles will be discussed. Updates will also be provided on new and upcoming USP-documentary and physical-reference standards that provide robust tools to help support regulatory expectations, enhance process control, and advance reliable, high-quality manufacturing.

8:55 **CMC Strategies for Oligonucleotide Drug Products: Overcoming ATMP Licensing, Administration, and Viscosity Challenges**
Andrei Hutanu, PhD, Senior Scientist, ten23 health
This presentation explores the unique challenges in CMC development for oligonucleotide drug products, including navigating ATMP manufacturing licenses, optimizing specialized routes of administration, and managing high-formulation viscosity. Practical strategies to streamline development, ensure regulatory compliance, and enable patient-centric delivery will be discussed. Insights also highlight common pitfalls and offer guidance for efficient oligonucleotide product development and manufacturing.

9:25 **KEYNOTE PRESENTATION: A Phase-Appropriate CMC Strategy for Synthetic Oligonucleotide Therapeutics**
Bao Zhong Cai, PhD, Vice President, Oligonucleotide CMC, GondolaBio
Synthetic oligonucleotide therapeutics, including antisense oligonucleotides (ASOs), siRNAs, and conjugated oligonucleotide modalities, present unique Chemistry, Manufacturing, and Controls (CMC) challenges due to their solid-phase synthesis, diverse chemical modifications, and complex impurity profiles. Implementing a phase-appropriate CMC strategy is critical to balancing development speed with increasing product and process understanding across clinical stages. This presentation outlines a risk-based framework for developing phase-appropriate CMC strategies and highlights selected case studies.

9:55 **Sponsored Presentation** *(Opportunity Available)*

10:25 **Coffee Break in the Exhibit Hall with Poster Viewing**

AOCs, PEPTIDE CONJUGATES, SIRNAs

11:05 **Novel Approaches to the Manufacturing of AOCs and Oligo-Peptide Conjugates**
Robert Dream, PhD, Managing Director, HDR Co. LLC
The manufacturing of AOCs has emerged as a critical area of innovation in the development of targeted therapeutics and diagnostic tools. This novel approach is aimed at improving the efficiency, specificity, and scalability of conjugation strategies, addressing key challenges such as site-selective modification, linker stability, and product homogeneity by integrating advanced bioconjugation chemistries, optimized purification protocols, and automation-friendly workflows.

11:35 **CMC and Process Development for Clinical siRNA Molecules**
Debasis Patra, PhD, MBA, Senior Vice President, CMC, OliX Pharmaceuticals
RNA interference has emerged as a powerful modality for modulating gene expression and addressing diseases with limited therapeutic options. This presentation will highlight advances in RNAi platform technologies designed to improve delivery, stability, and target engagement across multiple disease areas. Emphasis will also be placed on the CMC, manufacturing, and analytical considerations required to translate RNAi candidates from discovery through clinical development, supporting scalable production and consistent product quality.

12:05 pm **Designing GMP Facilities for Oligonucleotide and Peptide Manufacturing**
Jim Love, Director, Oligo & Peptide Technology, CRB Group
This presentation will explore GMP facilities for oligonucleotide and peptide drug substance manufacturing. Drawing on industry benchmarks and project experience, the talk will examine facility strategies for SPOS synthesis as organizations scale operations to support clinical development. It will also discuss cost drivers, automation, solvent management, and regulatory compliance, while highlighting emerging technologies such as enzymatic ligation and *de novo* enzymatic synthesis and their impact on facility design and investment.

12:35 **Transition to Lunch**

12:45 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 **Refreshment Break in the Exhibit Hall with Poster Viewing**

2:00 **Chairperson's Remarks**
Robert Dream, PhD, Managing Director, HDR Co. LLC

PROCESS DEVELOPMENT OF ASOs

2:05 **CMC and Process Development of Complex ASOs**
Satya Kuchimanchi, PhD, Senior Vice President, Technical Operations, CMC, Camp4 Therapeutics Inc.
Many genetic diseases result from insufficient protein expression. CAMP4 is developing antisense oligonucleotides designed to upregulate gene expression and restore healthy protein levels using insights from the RAP Platform. This presentation will highlight the discovery strategy alongside key CMC considerations, including oligonucleotide design, manufacturability, analytical characterization, and quality attributes required to advance ASO therapeutics that increase gene expression into clinical development.

2:35 **Challenges and Strategies of 2'-NMA Chemistry in Oligonucleotide-Synthesis Process Development**
David Cho, Scientist I, ASO Process Development, Biogen
ASOs with unique n-methylacetamide (NMA)-modified chemical backbones can potentially improve efficacy, allowing patients with long-interval dosing. However, NMA chemistry is not straightforward and comes with many challenges that are unique to this moiety. In this presentation, the challenges associated with NMA ASOs will be discussed along with the developmental work to optimize the process. Moreover, a next-generation starting material will be discussed for ASOs with NMA chemistry.

3:05 **Enhancing Control of Endotoxins during Oligonucleotide Purification**
Sanjeev Jeyabalan, Engineer II, Technical Development, Biogen
Endotoxins are glycolipids shed from gram-negative bacterial membranes. Regulatory agencies require stringent control of endotoxins in drug substance and product with tighter control for intrathecally administered drugs. Conventional endotoxin removal relies on positively charged filters that bind negatively charged endotoxins. However, these approaches are incompatible with highly anionic antisense oligonucleotides, causing yield loss. Here, we demonstrate a hydrophobic-interaction–based separation strategy that removes endotoxins from ASOs while preserving high product recovery.

3:35 **Sponsored Presentation** *(Opportunity Available)*

4:05 **Refreshment Break in the Exhibit Hall with Poster Viewing**

PERSONALIZED AND INDIVIDUALIZED GENETIC MEDICINES: N-OF-1 MANUFACTURING

4:40 **Scaling Personalized CRISPR Therapy: Regulatory, Manufacturing, and Platform Strategies**
Kok-Seong Lim, PhD, Independent Consultant; Member, USP Biologics—Cell and Gene Therapy Expert Committee
In 2025, Baby KJ became the world's first patient to receive personalized CRISPR therapy in just six months. The critical next step is translating this breakthrough into scalable, cost-effective standard care for thousands with rare genetic diseases. This presentation explores the strategic and technical foundations for building scalable gene-editing platforms, examines regulatory innovations that enable rapid deployment, and discusses how industry is reshaping the economics of personalized CRISPR therapy.

5:10 **PANEL DISCUSSION: Personalized and Individualized Genetic Medicines: N-of-1 Manufacturing**
Moderator: Susan D'Costa, PhD, CTO, Genezen
Regulatory expectations and emerging guidance for demonstrating comparability, control, and product-specific quality in highly personalized manufacturing runs.Strategies for designing ultra-flexible manufacturing platforms that can pivot from batch to batch while maintaining GMP compliance for individualized therapies. The evolving role of the patient as a central "input" to manufacturing. Approaches to supply-chain orchestration for N-of-1, including scheduling, raw-material readiness, and minimizing vein-to-vein variability.
Panelists:
John E. Schiel, PhD, Program Manager, Scalable Solutions, ARPA-H
Chris Williams, Co-Lead, Viral Vector, NIIMBL

5:40 **Interactive Breakout Discussions**
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

6:30 **Close of Day**

Wednesday, August 12

8:00 am **Registration and Morning Coffee**

PEPTIDE MANUFACTURING AND FORMULATION

8:30 **Chairperson's Remarks**
Nico Lingg, PhD, Senior Scientist & Area Lead, Health Biotechnology, ACIB

8:35 **Biopharmaceuticals Manufacturing for Peptides, Lifestyle, and Longevity Medicines**
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University
This presentation explores longevity and lifestyle medicines as a growing market, focusing on challenges in large-scale biopharmaceutical manufacturing and cost-reduction strategies. It highlights advances in peptide bioprocessing and beyond, examining whether these innovations can meet rising market demands for longevity biopharmaceuticals. Emphasis is placed on optimizing production efficiency and scalability to align with consumer expectations for effective, accessible, lifestyle and longevity therapies.

9:05 **A Platform Approach to Disulfide-Bonded Peptide Production: Advancing Microbial Manufacturing with CASPON Technology**
Nico Lingg, PhD, Senior Scientist & Area Lead, Health Biotechnology, ACIB
Recombinant production of disulfide-bonded peptides in *Escherichia coli* is a scalable alternative to chemical synthesis but is often constrained by proteolysis and complex downstream processing. CASPON technology enables high-titer soluble expression, affinity capture, and precise tag removal within a platform framework. Combined with outer membrane engineering to facilitate peptide release, this approach simplifies recovery, reduces development timelines, and supports robust, industrial-scale manufacturing of biopharmaceutical peptides.

9:35 **Sponsored Presentation** *(Opportunity Available)*

10:05 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:45 **Biomanufacturing Therapeutic Peptides at Scale with an Expanded Genetic Code**
Robert Salmon, PhD, Head, Bioprocess, Constructive Bio
Today's peptide therapeutics increasingly rely on chemistries beyond the 20 canonical amino acids to achieve exceptional pharmacological functions. Their manufacture relies on chemical methods, generating on average 13,000 kg of waste per kg of peptide, of which >50% is organic solvents. This talk will demonstrate how genetic-code expansion enables the scalable biomanufacture of peptides and proteins that incorporate multiple non-canonical amino acids, in a reprogrammed *E. coli* host.

11:15 **Peptide-Peptide Interaction Studies in Co-Formulations**
Yingmei Gu, Advisor, Eli Lilly and Company
Peptide co-formulation represents a strategic approach to simultaneously modulating complementary biological pathways while reducing injection burden for patients. Successful development requires an understanding of interactions of the co-formulated products to identify potential challenges in the formulation development. This presentation focuses on the thought process of studying peptide interactions in co-formulations using biophysical techniques.

11:45 **Transition to Lunch**

11:50 **Luncheon Presentation** *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Close of Oligonucleotide and Peptide CMC and Manufacturing Conference**

Wednesday, August 12

12:20 pm **Refreshment Break in the Exhibit Hall with Poster Viewing**

12:30 **Registration Open**

MECHANISTIC MODELING, AUTOMATION & PROCESS OPTIMIZATION

1:00 **Chairpeson's Remarks**
Khushdeep Mangat, PhD, Associate Director, GMU Purification Process Development, Sanofi Group

1:05 **Applied Automation and Mechanistic Modeling for Purification Development of Challenging Molecules under Accelerated Timelines**
Scott H. Altern, PhD, Senior Scientist I, AbbVie Inc.
This talk presents a case study in the practical application of automation and mechanistic chromatography modeling in early-stage (FIH) purification process development. High-throughput screening and modeling are used in conjuction to support PD and subsequent tech transfer of a cation-exchange polishing step for an mAb with high aggregate burden. Overall, the proposed workflow allowed for timeline acceleration, process improvement, and de-risked tech transfer, enabling the toxicology study to support IND.

1:35 **Enabling Process Characterization Activities via Mechanistic Modeling of Chromatography for a Protein-A Capture Step**
Spyridon Konstantinidis, PhD, Principal Scientist, Merck
Bioprocessing 4.0 leverages digital tools including mechanistic chromatography modelling to enhance process understanding. We developed Protein A capture and cation exchange polishing models, calibrated with linear gradient and step elution experiments under varying load conditions. These models were used in a digital workflow to determine proven acceptable ranges of process parameters and rank them. Comparison with experimental process characterization shows models can effectively guide and accelerate process characterization campaigns.

2:05 **Utilizing Advanced Modeling Techniques for Investigating and Optimizing Buffer Exchange in Ultrafiltration/Diafiltration (UF/DF) Processes**
Chadakarn Sirasitthichoke, PhD, Senior Process Engineer, MS&T Systems and Engineering, Bristol Myers Squibb Co.
Adequate mixing and buffer exchange during ultrafiltration/diafiltration (UF/DF) are critical for robust downstream bioprocess performance, particularly when mechanical agitation is constrained by equipment or operating limits. In this study, computational fluid dynamics (CFD) modeling was applied to evaluate hydrodynamics, mixing efficiency, and buffer exchange performance in a large-scale UF/DF vessel operated without active agitation during diafiltration.

2:35 **3D Imaging for Enhancing Design of 3D-Printed Chromatography Columns**
Thomas F. Johnson, PhD, Lecturer, Biochemical Engineering, University College London
3D-printed chromatography columns provide advantages over conventional packed bed resins, in particular, control over the multiscale structure that can be tailored to the needs of the separation. However, possible disparities between design and fabricated columns lessens this benefit. We apply 3D imaging to evaluate and compare printed structures to original CAD files to refine the design process, creating more effective separation capabilities for emergent biological products.

3:05 **Presentation to be Announced**

CYGNUS TECHNOLOGIES
part of Maraval LifeSciences

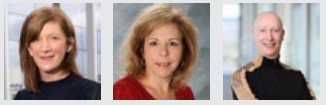
3:35 **Refreshment Break in the Exhibit Hall with Poster Viewing**

PLENARY KEYNOTE SESSION

4:20 **Chairperson's Remarks**
Susan Hynes, Global Head of Quality, GSK

4:25 **The Correct Way to Bring Digitalization and AI into Biopharmaceutical Quality**
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences
Digitalizing quality systems and artificial intelligence could revolutionize the way we work in quality. However, it needs careful planning and execution to gain the maximum benefits to the business. Appropriate use cases, change management, training, and streamlining processes before you digitalize is essential—adding complexity just results in digital complexity. In addition, the implementation of AI must follow GxP principles in what is currently a vague regulatory framework.

4:55 **Fireside Chat with Audience Q&A**



Moderator: Susan Hynes, Global Head of Quality, GSK
Panelists:
Lynn Bottone, Senior Vice President, Quality Operations, Environment Health & Safety, Pfizer Inc.
Anthony R. Mire-Sluis, PhD, Senior Vice President, Global Quality, Gilead Sciences

5:15 **Networking Reception in the Exhibit Hall with Poster Viewing**

6:15 **Close of Day**

Thursday, August 13

7:30 am **Registration and Morning Coffee**

CHROMATOGRAPHY PLATFORM DEVELOPMENT & INNOVATION

8:00 **Chairperson's Remarks**
Ronit Ghosh, PhD, Senior Scientist II, Biologics Purification Development (Operation Science and Technology), Abbvie Bioresearch Center

8:05 **KEYNOTE PRESENTATION: Next-Generation Cation Exchange Chromatography Platform Process Development for Biologics Purification**
Lihua Yang, PhD, Senior Prinicpal Research Scientist, BioProcess Purification Development, AbbVie, Inc.
This study evaluated five cation exchange (CEX) resins using three mAbs to identify optimal resins and develop a CEX process with superior dynamic binding capacity (DBC), impurity clearance, recovery yield, and robustness. In addition to experimental approaches, a mechanistic model was utilized to streamline the programming process as well as offering the potential to significantly reduce or even replace labor-intensive laboratory experiments in future process development.

8:35 **Chromatographic Control of dsRNA Impurities Using a Mixed Mode Method with Platform Potential**
Sabeen Nadir, Scientist, Pfizer Inc.
In vitro transcription enables large-scale mRNA production but generates difficult-to-remove double-stranded RNA (dsRNA) impurities. Existing chromatographic approaches for dsRNA removal are limited by scalability and manufacturing cost. We report a mixed-mode PrimaS monolith chromatography method that selectively clears dsRNA from 1–10 kb mRNA under RNA-compatible conditions, preserving integrity. Up to eightfold clearance of linear and structured dsRNA was achieved, supporting its potential as a platform purification solution.

9:05 **Hydrophobic Interaction Chromatography (HIC) as an Innovative Platform for High Purity and Yield ASO Manufacturing**
Juan P. Cueva, Scientist, Bioprocess Development, Biogen
This presentation introduces Hydrophobic Interaction Chromatography (HIC) as a powerful, aqueous alternative to traditional anion exchange and reverse-phase methods for ASO purification. We demonstrate how retaining the 5' hydrophobic blocking group enables a high dynamic binding capacity, allowing for an efficient bind-and-elute process. Our data highlights a systematic optimization of salt types and stepwise gradients to achieve >90% product yield with superior resolution of failure sequences and process-related impurities.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

VIRAL VECTOR & EXTRACELLULAR VESICLE PURIFICATION

10:15 Enhancing Sanitization for AVB Sepharose Resin in AAV Vector Purification
Albert Kao, Senior Scientist, Purification Development, Genentech, Inc.
This talk shares an enhanced pre-use sanitization strategy for AVB Sepharose resin in adeno-associated virus (AAV) production. By evaluating various alcohol, acid, and NaOH combinations against environmental microbial contaminants and assessing the identified combination in AAV resin re-use studies, we offer a solution that enhances microbial control without compromising resin performance or product quality.

10:45 Adeno-Associated Viral Vector Stability during Affinity Chromatography with Camelid Ligands
Lukas Bongers, PhD Student, Gene Therapy Technical R&D, Roche Diagnostics GmbH
The presented dataset characterizes the impact of affinity chromatography process conditions on quality attributes of AAVs. We can thereby provide information to support a decision for or against direct loading after harvest versus prior concentration by TFF and add to the general understanding of AAVs as a product and the potential influence of proess conditions on yield losses, aggregation, and transduction efficiency.

11:15 Chromatin Removal by Fibrous Chromatographic Media Enables Safer, Large-Scale EV Production
Tomas Mesurado, PhD Student, Acib GmbH
We have developed a scalable, enzyme-free, closed workflow using fibrous chromatographic media before tangential flow filtration (TFF) to selectively remove extracellular chromatin (DNA/histones) from extracellular vesicle (EV) preparations. This strategy prevents proinflammatory responses while preserving EV yield and identity. Moreover, the use of fibrous chromatographic media improves purity, safety, and manufacturability, de-risking late-stage development and enabling GMP-compliant, large-scale EV production.

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Transition to Lunch

12:20 Luncheon Presentation to be Announced GORE

12:50 Refreshment Break in the Exhibit Hall with Last Chance for Poster Viewing

PURIFICATION OF COMPLEX & EMERGING MODALITIES

1:30 Chairperson's Remarks
Lihua Yang, PhD, Senior Prinicpal Research Scientist, BioProcess Purification Development, AbbVie, Inc.

1:35 Low Molecular Weight (LMW) Species Control in Bispecific Antibody Purification Process
Lingling Xia, PhD, Principal Research Scientist I, Purification Process Development—ADC, PDS&T-BDL, AbbVie Inc.
In biologics manufacturing, product-related impurities must be managed through a comprehensive strategy aligned with ICH Q6B guidelines. The emergence of new biologic modalities, such as bispecific antibodies, transpacific antibodies, and DVDs, has increased the complexity of impurity control due to the unique molecular structures and expanded impurity spectrum. This presentation focuses on low molecular weight species and discusses control strategies developed through downstream purification process optimization for those novel modalities.

2:05 Application of MabSelect SuRe 70 to Improve Capture Purification of a Bispecific Antibody for Phase I Manufacturing
Nicholas Delatorre, Principal Scientist, CMC, Third Arc Bio
We present the evaluation and optimization of MabSelect SuRe 70 for capture purification of a bispecific antibody in comparison with an alternative Protein A resin. MabSelect SuRe 70 demonstrated higher dynamic binding capacity, improved specific product recovery, and increased monomer purity. Further process improvements were achieved through optimization of elution conditions to enhance resolution and host cell protein (HCP) clearance.

2:35 Purification Process Development and Manufacturing of a Novel tsAb for Tumor Therapy
Yanhuai (Richard) Ding, PhD, Senior Director, CMC DS/DP, EvolveImmune Therapeutics
This talk discusses purification process development strategies for a novel trispecific antibody (tsAb) intended for tumor therapy. It will highlight approaches to optimize downstream processing and support efficient, scalable manufacturing of complex antibody formats.

3:05 Purification and Analytical Strategies to Overcome Production Challenges for Hexameric IgGs
Rujin Cheng, PhD, Principal Scientist, Biotherapeutics, ImmunEdge
Hexameric IgGs are a class of complex biologics that offers unique pharmacokinetics and pharmacodynamic properties due to their high valency, molecular weight, or hydrodynamic radius. Despite their attractive profile for certain therapeutic indications, technical challenges in purification and analytics hinder their broader application. This talk aims to demystify some of the challenges by providing comprehensive molecule analysis/illustration and a couple of successful examples where key problems are identified and resolved.

3:35 Close of Summit

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CII offers comprehensive packages that can be customized to your budget and objectives. Sponsorship allows you to achieve your goals before, during, and long after the event. Packages may include presentations, exhibit space, and branding, as well as the use of delegate lists. Signing on early will maximize your exposure to qualified decision-makers and drive traffic to your website in the coming months.

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For more information regarding exhibits and sponsorship, please contact:

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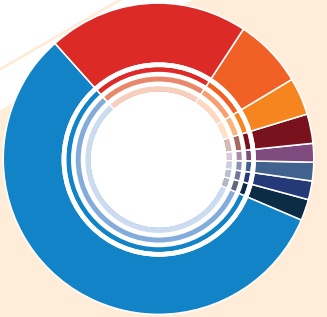
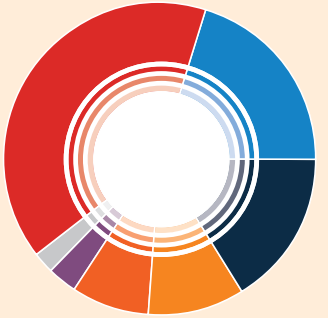
2025 ATTENDEE DEMOGRAPHICS

COMPANY TYPE



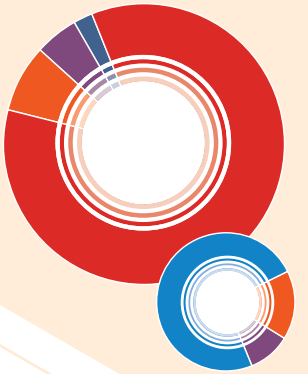
- 60% Biotech
- 22% Pharma
- 7% Academic
- 4% Services
- 3% Healthcare
- 1% Financial
- 1% Press
- 1% Societies
- 1% Other

DELEGATE TITLE



- 40% Scientist/Technologist
- 20% Sales & Marketing
- 16% Director
- 10% Executive
- 8% Manager
- 3% Professor
- 2% Assistant

GEOGRAPHIC LOCATION



- 88% USA
- 8% Asia
- 3% Europe
- 1% Rest of World

US BREAKDOWN

- 74% East Coast
- 16% West Coast
- 10% Midwest

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