August 18–21, 2025 | Boston, MA + Virtual

NEW VENUE! Omni Boston Hotel at the Seaport

Cambridge Healthtech Institute's

17TH ANNUAL BIOPROCESSING SUMMIT

SOLVING TODAY'S CHALLENGES, LEADING TO TOMORROW'S ADVANCES

Register by April 25 and SAVE $500

2025 PROGRAMS

- Stream #1 **UPSTREAM PROCESSING**
- Stream #2 **DOWNSTREAM PROCESSING**
- Stream #3 *New for 2025* **AI AND DIGITALIZATION**
- Stream #4 **ANALYTICAL & QUALITY**
- Stream #5 **GENE THERAPY**
- Stream #6 **CELL THERAPY**
- Stream #7 **RNA AND GENETIC MEDICINES**
- Stream #8 **FORMULATION AND STABILITY**

PLENARY KEYNOTE SPEAKERS

CHAIRPERSON:
Raghavan V. Venkat, PhD
Senior Vice President, Bioprocess Development, AstraZeneca

Lisbet Jensen Young
Vice President & General Manager, AstraZeneca

PLENARY FIRESIDE CHAT

MODERATOR:
Ran Zheng
CEO, Landmark Bio

David Y. H. Chang
CEO, Taiwan Bio-Manufacturing Company (TBMC)

Daniella Kranjac
Founding Partner, Dynamk Capital LLC

Bo Wiinberg, PhD
Chief Business Development Officer, Novo Nordisk Foundation Cellerator

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#CHIBioprocessingSummit

BioprocessingSummit.com

Join a global community of bioprocessing leaders to explore cutting-edge research, share insights, and tackle challenges in R&D, scale-up, quality, and analytics. The Summit features expert-led sessions on emerging bioprocessing strategies, technology advancements, and industry best practices, along with in-depth training seminars and a dynamic exhibit hall. Connect with industry experts, explore AI and machine learning in bioprocessing, and engage in discussions on cell culture, purification, and cell and gene therapy. Expand your expertise and network while driving innovation forward.

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PLENARY KEYNOTE SESSIONS

Monday, August 18, 2025, 4:20 – 5:30 PM

SOLVING TODAY'S CHALLENGES

CHAIRPERSON
Raghavan V. Venkat, PhD, *Senior Vice President, Bioprocess Development, AstraZeneca*

Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies

Lisbet Jensen Young, *Vice President & General Manager, AstraZeneca*

This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

Wednesday, August 20, 2025, 3:50 – 5:00 PM

LEADING TO TOMORROW'S ADVANCES

Plenary Fireside Chat: Innovation and Investment for Biomanufacturing Future Medicines

What are the technologies and innovations shaping the future of biomanufacturing in 2025 and beyond? Join us for an engaging Plenary panel discussion where leading experts from the investment, strategic, and big pharma community will explore upcoming trends, investment opportunities, and modalities into the next decade. How should the bioprocessing industry best prepare?

MODERATOR:

Ran Zheng
CEO, Landmark Bio

PANELISTS:

Daniella Kranjac
Founding Partner, Dynamk Capital LLC

David Y. H. Chang
CEO, Taiwan Bio-Manufacturing Company (TBMC)

Bo Wiinberg, PhD
Chief Business Development Officer, Novo Nordisk Foundation Cellerator

CONFERENCE-AT-A-GLANCE

2025 Conference Programs

	AUGUST 18-19	AUGUST 20-21
Stream #1 **UPSTREAM PROCESSING**	Cell Line Engineering & Development	Cell Culture Optimization & Scale-Up
Stream #2 **DOWNSTREAM PROCESSING**	Intensified & Continuous Bioprocessing	Advances in Purification and Recovery
Stream #3 **AI AND DIGITALIZATION**	Training Seminar ML/AI for Biomanufacturing	Digital Transformation & AI in Bioprocess
Stream #4 **ANALYTICAL & QUALITY**	Accelerating Analytical Development	Next-Gen Analytical Methods
Stream #5 **GENE THERAPY**	Gene Therapy CMC and Analytics	Gene Therapy Manufacturing
Stream #6 **CELL THERAPY**	Cell Therapy CMC and Analytics	Cell Therapy Manufacturing
Stream #7 **RNA AND GENETIC MEDICINES**	RNA Development, CMC & Manufacturing	Gene Therapy Manufacturing
Stream #8 **FORMULATION AND STABILITY**	Formulation, Stability & Delivery	Training Seminar Formulation of Biopharmaceuticals
Training SEMINARS By Cambridge Healthtech Institute	See page 6 for details	See page 6 for details

Training SEMINARS

By Cambridge Healthtech Institute

In-Person Only

Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered, and solutions applied, along with extensive coverage of the academic theory and background. Each Training Seminar offers a mix of formal lecture and interactive discussions and activities to maximize the learning experience. These Training Seminars are led by experienced instructors who will focus on content applicable to your current research and provide important guidance to those new to their fields.

Monday, August 18, 2025 9:45 AM – 3:30 PM
Tuesday, August 19, 2025 8:00 AM – 1:00 PM

TS3A: Introduction to Machine Learning for CMC and Biomanufacturing

Instructor:

Michael Sokolov, PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG

The aim of this training seminar is 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, to identify the important process drivers as well as to forecast the process and product quality behaviour will be presented in lectures. Hands-on coding and brainstorming sessions will be used to solve case studies from the biopharmaceutical industry. After the course the participants will be aware of relevant techniques and literature for bioprocess data analysis and will be able to evaluate different analysis paths for a given problem.

TS9A: Introduction to Bioprocessing: Discovery to Commercialization

Instructors:

Martin Hurley, Managing Director, BioPharma Technical Consulting (BPTC)

Tiffany D. Rau, PhD, Owner, Rau Consulting LLC

The seminar will introduce participants to bioprocessing from a process development, manufacturing and regulatory perspective. The seminar will follow a "molecule" from discovery to commercialization that is produced using mammalian cell culture and the different unit operations will be introduced as well as CMC considerations. In addition, different modalities will be explored with regards to opportunities and challenges in development and production methods such as production of Advanced Therapies (Cell and Gene Therapies). In addition, data and its analysis is a critical component to ensure process understanding and minimize CMC challenges and best practices for data management and new statistical methods and tools will be introduced.

Wednesday, August 20, 2025 8:00 AM – 3:00 PM
Thursday, August 21, 2025 8:00 AM – 12:00 PM

TS7B: 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.

TS8B: Introduction to CMC for Biological Products: Bioprocessing and Analytical

Instructor:

Kevin Zen, PhD, Senior Director, IGM Biosciences

This 2-day training seminar provides a comprehensive overview of the phase-appropriate CMC activities, quality compliance, and regulatory requirement for developing therapeutic biologics. 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, DS/DP release and stability, extended characterization and comparability exercise. Join this interactive training seminar to learn the best practices of CMC activities for the preparation of dossiers. The common CMC pitfalls, queries from health authorities worldwide, and CRL will be exemplified throughout this training class.

TS9B: Comparability and Potency Assays for Advanced Therapies and Biotherapeutics

Instructor:

Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.

Comparability studies following process changes are a critical component of drug development, impacting both CMC (Chemistry, Manufacturing, and Controls) and process development teams significantly. Robust potency assays are crucial not only for these studies but also for process validation and stability testing. This 1.5-day training seminar offers a comprehensive exploration of regulatory science and biological standardization in biologics. The seminar details the nature of potency, highlights the differences in potency assays across biotech and advanced therapies such as cell, gene, and RNA medicines, and discusses the principles of comparability and their varied applications across these modalities.

STREAM #1
UPSTREAM PROCESSING

The biopharmaceutical industry has long chased the holy grail: achieving peak productivity, unwavering quality, and cost-efficiency. The past decade has seen remarkable progress in **upstream processing**, fueled by sophisticated host cell engineering, potent expression cell lines, optimized culturing techniques, and upstream improvements such as perfusion and intensified processing. The next chapter promises a paradigm shift, where intelligence takes center stage. We will witness next-generation platforms such as targeted integration and genetic editing of cell line development, while AI-optimized bioreactor and culture conditions, PAT, digital twins, and machine learning will lead the way to better process understanding, monitoring and control, simulation, and prediction.

Conference Programs

AUGUST 18-19

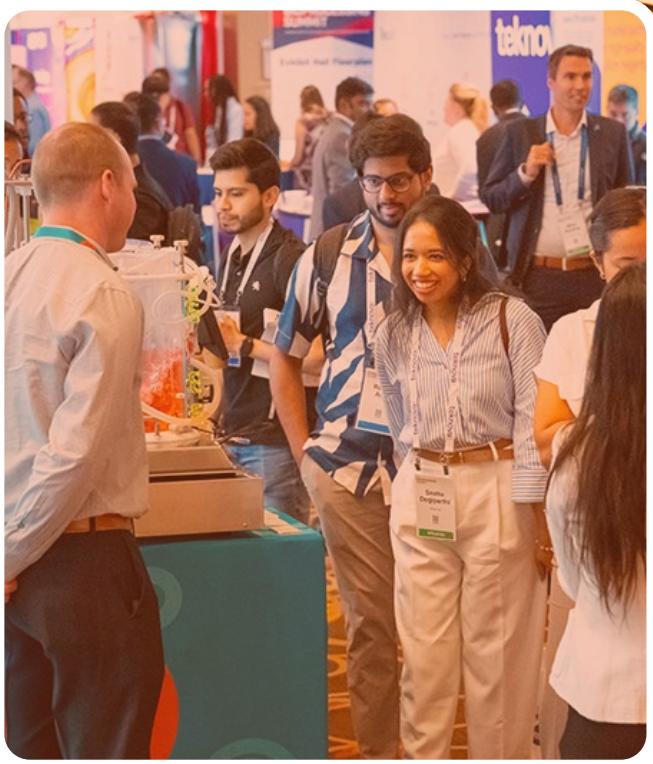
Cell Line Engineering & Development

View Program »

AUGUST 20-21

Cell Culture Optimization & Scale-Up

View Program »



MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

VECTOR DESIGN AND TRANSFECTION

9:40 Chairperson's Remarks
Jolanda Gerritsen, PhD, Director & Lead, Cell Engineering & Sciences, Genmab BV

9:45 Targeted Gene Integration for Robust Performance of Inducible Transcriptional Circuits in CHO Cells
Ioscani Jimenez Del Val, PhD, Lecturer & Assistant Professor, Animal Cell Technology Group, University College Dublin
Linearizer transcriptional circuits enable gradual gene expression in response to inducer molecule concentrations and can be used to enhance the yield and quality of mAbs, multispecifics, and rAAV products. This study compares the impact of random and targeted gene integration on the performance of Linearizer circuits in CHO cells. Our results show that targeted integration delivers optimal linearizer performance by maintaining stoichiometric equivalence of all circuit components.

10:15 CHO Site-Specific Integration System Enables Development of Stable Pools with Comparable Attributes to Clonal Cell Lines
Mam Mboge, PhD, Senior Scientist, Molecular & Cellular Technologies, Biotherapeutics Pharmaceutical Sciences, Pfizer Inc.
The critical step for clinical trials is having regulatory toxicology (RT) material, which depends on the availability of clones. Pfizer's site-specific integration system accelerates medicine development by reducing development times. This study demonstrates that material from non-clonal pools is comparable to clonal cell lines, with no significant trends in performance or differences in product quality. This strategy enables the acceleration of RT studies, thereby saving time without compromising quality.

10:45 In-Room Networking Introductions

11:00 Site-Specific Integration to Streamline Cell-Line Development and Speed to Clinic
Shengyuan Zhao, PhD, Senior Scientist, Process Cell Sciences, BPR&D, Merck & Co.
Traditional cell line development relies on random transgene integration, and its intrinsic variability often requires more time and effort for clone selection and process development. This presentation will describe a site-specific integration approach to accelerate cell line development by targeting integration of transgenes to support high and stable antibody expression.

11:30 Presentation to be Announced

ASIMOV

12:00 pm Luncheon Presentation to be Announced

THOMSON Solutions at Work INSTRUMENT COMPANY

12:30 Session Break

CELL-LINE DEVELOPMENT AND PROTEIN PRODUCTION STRATEGIES

12:50 Chairperson's Remarks
Susan Sharfstein, PhD, Professor of Nanoscale Science and Engineering, University at Albany

12:55 KEYNOTE PRESENTATION: What Does a Cell Need for Efficient Protein Secretion?
Nathan E. Lewis, PhD, GRA Eminent Scholar and Professor, Center for Molecular Medicine Complex, Department of Biochemistry and Molecular Biology, University of Georgia
The protein secretion pathway involves thousands of proteins and enzymes that mediate the synthesis, post-translational modification, and transport of thousands of native secreted and membrane proteins. Here I will present our efforts to catalog all the genes associated in this process in mammalian cells and innovative omics, systems biology, and machine learning techniques to identify components that are essential or can aid in increasing titers for recombinant therapeutic proteins.

1:25 Establishing a New Cell-Line Development Platform through Innovation, Optimization, and Automation
Jolanda Gerritsen, PhD, Director & Lead, Cell Engineering & Sciences, Genmab BV
A new automated cell line technology platform designed to enhance standardization, reduce errors, and ensure stability in CHO cell line development for monoclonal antibodies. This high-throughput system accelerates timelines, delivers stable pools with yields of 3 g/L, and increases the likelihood of achieving monoclonal cell lines with titers of 4–6 g/L cost-effectively.

1:55 Presentation to be Announced

BECKMAN COULTER

2:25 Feasible or Not? Developing an *in vitro* Model for AAV Immunogenicity Assessment
Metewo Selase Enuameh, PhD, Associate Director, Vector Core Cell Line Development, REGENXBIO, Inc.
The development of *in vitro* models and assays for screening gene therapy products early in the drug discovery process, could aid in the discovery of high-quality AAV gene therapy candidates with ameliorated immunogenicity. Using cell line engineering and flow cytometry approaches, we demonstrate the feasibility of developing multiple assays to measure the comparative innate immunogenicity of AAV vectors comprised of different capsids and genomes.

2:55 Exploring Molecular Mechanisms of AAV Production Using RNA Sequencing
Zhe Zhang, PhD, Senior Staff Engineer, PMPD VPC, Regeneron Pharmaceuticals Inc.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

AUTOMATION AND AI IN CELL-LINE DEVELOPMENT

7:55 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

8:00 Artificial Intelligence Approaches to Addressing Manufacturability
Susan Sharfstein, PhD, Professor of Nanoscale Science and Engineering, University at Albany

As increasing numbers of monoclonal antibodies are developed to treat various diseases including cancer, autoimmune, and infectious diseases, there is a need to rapidly identify molecules easily expressed in cultured cells, particularly CHO cells. Using a novel AI approach, we have developed a library of Vhh molecules and assessed their expression in CHO cells to further train our AI tool, allowing us to discover design rules to improve antibody expression.

8:30 End-to-End Automated HTP Platform for Biotherapeutics Discovery
Whitney Liu, PhD, Principal Scientist, Bristol Myers Squibb Co.

High-yield CHO cell lines are essential for biotherapeutics, but traditional CLD platforms are slow and low-throughput. We present an automated high-throughput, transposon-based CLD platform. Integrating chemical transfection, transposase, and CHO cells in 24- or 96-well formats, the platform supports both batch and fed-batch bulk production. Robust monitoring ensures optimal quality, accelerating stable pool generation. Successfully applied to mAbs and complex biologics, this system enhances productivity while reducing CLD timelines.

9:00 Using AI Models to Assess Long-Term Stability of CHO Cells as a Function of Epigenetic Properties
Pedro Seber e Silva, PhD Student, Chemical Engineering, Massachusetts Institute of Technology

Chinese hamster ovary (CHO) cells are the main system for producing biopharmaceuticals, but they suffer from instability, affecting their long-term productivity. We created the first models for predicting long-term CHO cell stability due to epigenetic changes. Multilayer perceptrons are the best-performing models, reaching an F_1 score of 59.1% and a Matthews correlation coefficient of 19.4%. Interpretability studies are used to contribute biological insight and help focus future data collection efforts.

9:30 Efficiency Enhancement in mAb Production: Streamlining Bioprocesses with Peptides to Boost CHO Cell Culture Performance
Zachary Demorest, Director, Technical Marketing, Biopharma Solutions, Evonik Corp.

Conventional media formulations for CHO cell cultivation typically involve dual-feed systems (main feed and alkaline feed) that come with inherent process and quality challenges. With a case study involving two CHO cell lines, we will explore the transition towards a pH-neutral single-feed system using the cQrex tyrosine and cystine peptides. Besides reducing complexity, such a streamlined bioprocess enhances cell culture performance with improved cell growth, viability, and monoclonal antibody titer, contributing to cost efficiency in biomanufacturing.

9:45 Enhancing Genome Editing Capabilities: Unveiling the Advantages of Cas-CLOVER over CRISPR/Cas9
Corey Brizzee, Director, Gene Editing, Demeetra

Cas-CLOVER is an advanced CRISPR/Cas9 alternative offering higher targeted integration efficiency, larger transgene capacity (≥20 kb), and superior FTO. Unlike CRISPR/Cas9 which has low knock-in efficiency and off-target effects, Cas-CLOVER's dimeric system and Clo051 nuclease enhance precision. It achieves 3x higher knock-in rates, making it ideal for cell-line development (CLD) and complex biologics like bi- and tri-specific antibodies

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Breakout Discussions

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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

ADVANCES IN CELL-LINE ENGINEERING: GENE EDITING, OMICS, AND NGS

11:25 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

11:30 Proteomic Approaches to Cell-Line Engineering
Gihoon Lee, PhD, Senior Scientist, Johnson & Johnson Innovative Medicine

This study investigates the role of DYRK1B in lactate metabolism within Chinese Hamster Ovary (CHO) cells experiencing high lactate production, which reduces cell viability and protein synthesis. Utilizing crosslinking and advanced mass spectrometry, we explore DYRK1B's protein interactions to uncover molecular mechanisms linking it to lactate production. Our findings highlight potential pathways for enhancing CHO cell productivity and inform future CHO cell engineering strategies aimed at improving biologics production.

12:00 pm Leveraging Omics-Based and tRNA-Centric Insights into Cellular Stress Response Mechanisms to Enhance Recombinant Protein Production
Shane Byrne, Co-Founder and CSO, Codomax

Codomax has developed the Epi-MAX platform, a systems-level, omics-driven, and tRNA-centric cell line engineering platform, to produce difficult-to-express proteins at scale with retention of biofidelity. The platform

leverages an alternative genetic code in which a cell's tRNA pool is reprogrammed in response to cellular stresses, including those associated with biomanufacturing. Here, I will highlight recent efforts to engineer *Pichia* and CHO cell lines for the enhanced production of difficult-to-express biologics.

12:30 From Single-Cell Cloning to Selection of Top-Performing Cell Lines: A Turnkey Solution for Clonal Cell Line Generation and Screening in Advanced Therapeutics

John Carroll, Sales Manager North America, Sales, CYTENA GmbH

Developing stable, genetically engineered cell lines is a cornerstone of modern biologics production. To streamline this process and enhance the capacity and consistency of laboratories conducting cell line development (CLD) campaigns on a routine basis, CYTENA has introduced the C.STATION—an all-in-one automation solution offering a complete workflow from single-cell cloning to the identification of top-performing cell lines. In this presentation, we will explore the C.STATION's versatile configurations for creating stable cell lines across therapeutic modalities, including monoclonal antibodies and gene-edited iPS cell lines. We will demonstrate its intuitive user interface, which allows scientists to efficiently schedule and manage complex cell culture campaigns, and highlight its comprehensive clonality assurance and data management software suite, ensuring full traceability and regulatory compliance. Unlock the Future of Cell Line Development with C.STATION.

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

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

2:10 Chairperson's Remarks

Mam Mboge, PhD, Senior Scientist, Molecular & Cellular Technologies, Biotherapeutics Pharmaceutical Sciences, Pfizer Inc.

2:15 CHO Host Glycosylation Engineering

SeongCho Dong, PhD, Technical Development Associate Scientist, Genentech Inc.

2:45 Integrating LC-MS-Based Metabolomics and Machine Learning for Enhanced Insights into Bioprocesses

Yudong Sun, PhD, Postdoc Researcher, Merck

A limited understanding of cellular metabolism often restricts rational bioprocess optimization, leading to reliance on empirical methods such as design of experiments (DoE). Analytical methods including mass spectrometry-based metabolomics offers valuable insights into cellular status, highlighting potential metabolic bottlenecks for enhancing productivity and product quality. Method development on targeted metabolomics and machine learning (ML)-based absolute metabolite quantification, and their applications for media optimization and process understanding will be presented.

3:15 Using NGS to Facilitate Cell Line Development

Ying Shen, PhD, Assoc Scientific Fellow, Takeda Pharmaceuticals

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

CELL-LINE DEVELOPMENT STRATEGIES FOR INTENSIFIED/CONTINUOUS PROCESSES

4:25 Chairperson's Remarks

Hussain Nuruddin Dahodwala, PhD, Director, Upstream Process Development, NIIMBL

4:30 Cell Line Development and Selection for Intensified Fed-Batch Processes

Lenneke De Winter, PhD, Head of Cellular R&D, Polpharma Biologics

This presentation explores crucial clone characteristics for successful intensified fed-batch processes. By analyzing various clones' performance in fed-batch and intensified fed-batch mode, we identify key attributes that enhance productivity in intensified conditions. Additionally, we discuss whether selection criteria vary with process mode. Is it necessary to adapt the process mode during clone selection from traditional fed-batch to intensified fed-batch mode to select the most successful clones for further process development?

5:00 Strategies to Support Perfusion/Intensified Fed-Batch Cultures

Hussain Nuruddin Dahodwala, PhD, Director, Upstream Process Development, NIIMBL

Perfusion and intensified cultures reduce costs, shorten production durations, and maximize recombinant productivity. Using NISTCHO, an open-access living standard, we achieved a 3x productivity increase with shorter culture durations through media screening, culture additives, optimized feeds, and seeding/bleeding strategies. Improved specific productivity via N-1 culture and feed strategies highlights their role in cell culture optimization for continuous and intensified processes.

5:30 Close of Cell Line Engineering & Development Conference

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

OPTIMIZING PROCESSES TO MEET NEW AND EXISTING CHALLENGES

7:55 Chairperson's Remarks
Jianfa Ou, PhD, Principal Scientist, Evonik Corporation

8:00 Lessons Learned: Adapting Existing Processes to Established Cell-Culture Platforms
Paul Gramlich, PhD, Director, Process Development, Amgen Inc.
Biopharmaceutical companies routinely rely on manufacturing platforms to accelerate process development. However, when an external asset is internalized, they come with inherently off-platform cell culture processes. This includes cell lines, media, production formats, and process control strategies with which the company may have limited experience. This talk will highlight lessons learned from several recent integrations at Amgen, highlighting both the challenges faced, and solutions.

8:30 Single-Use Faciity Strategy: The Need for Advanced Single-Use Bioreactors and Universal Controllers
Edward Chan, Senior Technical Specialist, Cell Culture and Bioprocess Operations, Genentech Inc.
As the industry continues to develop processes for higher titers and cell densities, there is a growing need for more advanced single-use bioreactors that offer improved mixing, kLa, and CO2 stripping, while minimizing foam. When a new single-use bioreactor is purchased, it usually comes with proprietary controllers, representing a significant capital investment and complicating automation integration. A universal controller helps address these challenges by lowering initial CapEx and integration costs.

9:00 Understanding Product Attribute Shifts in Large-Scale Manufacturing: A Case Study
Gisel Lopez, Senior Research Associate I, Upstream Process Development, Gilead Sciences Inc.
This talk will examine a case study of product attribute shifts observed during biopharmaceutical manufacturing scale-up. We'll analyze different factors including equipment differences, process parameter variations, and raw material inconsistencies that impacted critical quality attributes.

9:30 Presentation to be Announced

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

ENABLING RAPID PROCESS SCALE-UP

10:40 Navigating Platform Constraints during Rapid Scale-Up Process Transfer for Yeast Fermentation Clinical Drug Substance Manufacture
Griffin Thomas, Senior Scientist, Preclinical Development, Vaccines and Advanced Biotechnologies Process R&D, Merck & Co., Inc.
This talk summarizes the challenging dynamic to rapidly develop, scale-up, and transfer novel advanced process controls while maintaining legacy platform constraints of an existing vaccine franchise. Dictated by aggressive timelines, rapid development efforts focused on key unit operations with refined parameter optimization of a *Saccharomyces cerevisiae* fermentation process expressing target protein antigens. This phase-appropriate development strategy was complemented by state-of-the-art scale down systems to enable clinical manufacture at unprecedented speeds.

11:10 Development of Pre-Harvest Treatment Technologies Using pDADMAC and Acidification to Enable Process Scale-Up
Poorvaja Ganesan, Masters in Bioengineering, Associate Scientist III, Upstream Process Development, Alexion AstraZeneca Rare Disease
Recent advances in upstream processes have led to increased cell densities and productivities, resulting in more sub-micron particles that pose challenges to the clarification process. Traditional harvest strategies were inadequate to achieve scale-up needs. Alternative techniques were developed, including acid precipitation prior to harvest and pDADMAC treatment to enhance harvest process performance. Therefore, a combination of centrifugation and a pre-harvest treatment show promise in meeting scale-up requirements.

11:40 Building the Lab of the Future for Protein Production in the Age of AI and Automation
Iman Farasat, PhD, Director, High Throughput Expression, Johnson & Johnson Innovative Medicine
The complexity of mammalian cell culture and the heterogeneity of large molecule products have historically limited the application of robotic automation platforms in production and characterization to mainly either early stages for small-quantity, stage-gate quality material, or later stages for industrializing specific task accomplishments. Here, we discuss our next-generation automation strategy for bridging the gap to prepare large-quantity of high-quality material, solving an essential need for more complex Biologics modalities.

12:10 pm LUNCHEON PRESENTATION: Quality by Digital Design (QbDD): Transforming Bioprocess Lifecycles with Predictive Modeling
Zheng Huang, CoFounder & CTO, Ark Biotech
Computational bioprocess models can enhance predictive decision-making, deepen scientific understanding, and enable Quality by Digital Design (QbDD). This talk will use case studies centered on the application of a single hybrid cell culture model applied across the bioprocess lifecycle. The case studies will illustrate how scientists can leverage simulation to reduce physical experiments, accelerate R&D timelines, de-risk critical decision-making, and improve process robustness.

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

PLATFORM FIT AND HOST-SYSTEM SELECTION

1:25 Chairperson's Remarks
Anne Skaja Robinson, PhD, Trustee Professor, Chemical Engineering, Carnegie Mellon University

1:30 KEYNOTE PRESENTATION: Platform Fit for Non-Platform Molecules
Shuangping Shi, Associate Vice President, Head of Biologics Process Research & Development, Merck & Co.
Merck maintains a drug substance manufacturing platform to seamlessly advance a rich and diverse biologics pipeline. State of the art facilities are built to support the pipeline with consideration of green and sustainability. While adopting the platform approach to enable speed and efficiency, we thoughtfully integrate technological advances to manage the ever-evolving complexity associated with the next generation biologics. Platform fit for the non-platform molecules are discussed in case studies.

2:00 Using a Baculovirus Platform for the Manufacturing of Antigens Aimed at Immune System Modulation
Martin Linhult, PhD, CMC Lead, Diamyd
Diamyd Medical, with our lead product candidate Diamyd (rhGAD65/alum) aimed at immune system modulation, is in phase III clinical development to treat patients with Type 1 Diabetes. We have developed a manufacturing platform for our unique protein antigen therapy and we strongly believe that this platform could be applicable for other projects. The talk will include a discussion around challenges such as establishing comparability during development.

2:30 YOKOGWA's Digital Solutions for Integration of Bioprocess—Accelerate Process Development and Stabilize Manufacturing
Shahzad Khan
Hiroaki Yamanaka, Production Business Development Department, Life Business Headquarters, Yokogawa Electric Corporation
Process Analytical Technology (PAT) in biomanufacturing requires comprehensive data acquisition during cultivation. The data, derived from various sensors and offline analyzers from different vendors, results in non-standard data types communicated through diverse industrial protocols. Managing and standardizing such data in central storage is difficult. Here, we introduce YOKOGAWA's digital solutions, which integrate with existing instruments (inline/online/offline) to automate data collection. This integration enhances reproducibility and stability through automation, speeding up process development and ensuring consistent manufacturing.

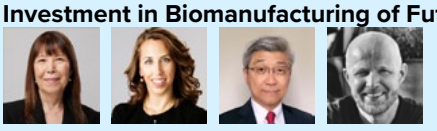
2:45 LSPR Applications for Upstream IgG Monitoring
Erik Martinsson, CEO, ArgusEye AB
The Auga platform can be used for IgG monitoring both in upstream and downstream processes. Due to the linearity range of the Protein-A sensors and versability of the system when it comes to flow rate and sample volume, Auga can be used for IgG quantification based on a calibration curve. To automatize and speed up IgG quantification with the Auga platform, ArgusEye is developing an online system that can be connected to a bioprocess for near real-time monitoring of IgG in cell-free samples.

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
What are the technologies and innovations shaping the future of biomanufacturing in 2025 and beyond? Join us for an engaging plenary panel discussion on "Innovation and Investment in Biomanufacturing of Future Medicine," where leading experts from the investment and strategies community will explore upcoming trends, investment opportunities, and modalities into the next decade. How should the industry best prepare?
Panelists:
Daniella Kranjac, Founding General Partner, Avant Bio LLC
David Y. H. Chang, CEO, Taiwan Bio-Manufacturing Company (TBMC)
Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

MEDIA AND FEED OPTIMIZATION

7:55 Chairperson's Remarks
Martin Linhult, PhD, CMC Lead, Diamyd

8:00 Development and Characterization of Media Supplement to Improve Cell Culture Performance
Jianfa Ou, PhD, Principal Scientist, Evonik Corporation
Cell culture medium serves as a foundational element for robust processes to produce antibodies and various complex biologics. The industry has increasingly sought intensified processes that enhance productivity and simplify operations, all while aiming for lower production costs and improved product quality. To meet these demands, supplements for cell culture media have evolved significantly. In this presentation, we will demonstrate case studies that successfully enhance the CHO cell upstream processes.

8:30 Engineering CHO Cell Growth Conditions to Improve Antibody Production
Anne Skaja Robinson, PhD, Trustee Professor, Chemical Engineering, Carnegie Mellon University
Engineered producer cell lines have led to antibody yield increases driven by an improved understanding of the cellular machinery influencing cell health and protein production. In this study, I will describe the utilization of multiple culture longevity-prolonging strategies (chemical and process-related) to enable up to a three-fold increase in total antibody production as well as three-fold higher cell-specific productivity to further improve yields.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

DIGITAL TOOLS AND AIML-BASED MODELS FOR UPSTREAM DEVELOPMENT

10:30 AI-Driven Advances in Upstream Cell Culture Optimization: Challenges and Opportunities
Shruti G. Vij, PhD, Associate Director, Data Analytics & Modeling, DSAI, Takeda Pharmaceuticals Inc.
There is huge potential in the application of AI/ML such as deviation detection, process understanding and optimization, device control, and recovery to reduce batch failures and improve process outcomes both in development and production. This talk will discuss a practical framework for developing and applying AI/ML in upstream bioprocessing and have an honest conversation about the challenges teams face when trying to adopt these technologies and how to navigate them.

11:00 Leveraging Hybrid and Machine-Learning-Based Models to Build a Robust Upstream Development Toolkit

Craig Allen, Associate Scientist II, Upstream Processing, Alexion Pharmaceuticals, Inc.

We will discuss the potential of custom modelling tools to simplify process development and enable more efficient knowledge transfer between manufacturing processes and scales. We will demonstrate the power of building an *in silico* toolbox that compliments upstream development by enabling more efficient design of experiments and a more robust understanding of our processes.

11:30 From Data to Decisions: Transforming Upstream Processes with Digital Tools

Taha Salim, PhD, Staff Engineer, Regeneron Pharmaceuticals Inc.

In the biopharmaceutical industry, many companies are working towards integration of digital technologies to improve the efficiency and resilience of upstream processdevelopment. This presentation presents custom-built digital tools that transform raw data into actionable insights to enhance process development activities. Two innovative solutions will be showcased: (1) a multivariate analytics tool to help accelerate upstream operations and (2) a model that streamlines data quality analysis, thereby driving smart automation.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

MODELING AND ADVANCED PROCESS CONTROL

1:05 Chairperson's Remarks

Moo Sun Hong, PhD, Assistant Professor, Department of Chemical and Biological Engineering, Seoul National University

1:10 Advanced Process Data Analytics for End-to-End Biopharmaceutical Manufacturing

Moo Sun Hong, PhD, Assistant Professor, Department of Chemical and Biological Engineering, Seoul National University

Selecting optimal data-driven modeling methods and integrating batch and time-series data are key challenges in biopharmaceutical manufacturing. Accurate modeling requires capturing both inter-batch variability and intra-batch dynamics. This presentation describes the application of smart process data analytics software and tensorial methods to industrial end-to-end biomanufacturing datasets for monoclonal antibody production, demonstrating how automated DA/ML tool selection and multiway modeling improve predictive accuracy and process understanding.

1:40 Enhancing Biologics Manufacturing Efficiency through Data Science: Insights from Case Studies

Shyam Panjwani, PhD, Principal Data Scientist, Bayer Healthcare Pharmaceuticals

The biopharmaceutical industry is increasingly turning to data science to optimize manufacturing processes and enhance product quality. This presentation explores two case studies that leverage data science to improve efficiency in biologics manufacturing. The first case study focuses on a cloud-based predictive modeling application designed to enhance the predictability of cell culture processes. The second case study presents a framework for assessing the out-of-specification risk associated with drug product potency.

2:10 Model-Based Optimal Control of Fed-Batch *in vitro* Transcription for RNA Manufacturing

Nathan Stover, PhD Student, Process Engineering, Massachusetts Institute of Technology

While the *in vitro* reaction for RNA synthesis is traditionally performed in a batch mode, fed-batch *in vitro* transcription holds promise to more efficiently use expensive catalysts. We develop and mathematically optimize a mechanistic model for IVT to find feeding policies that maximize RNA production while maintaining key critical quality attributes. Experimental validation demonstrates how these model-based strategies can be used to accelerate process development and optimize costly resources.

2:40 Networking Refreshment Break and Transition into Town Hall Discussion

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 Facilitated Town Hall Discussion

This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?

Lori Ellis, Head of Insights, BioSpace

3:55 Close of Summit

STREAM #2
DOWNSTREAM PROCESSING

The rise of high-potency therapies and complex biologics is pushing the boundaries of downstream processing. The bottleneck is shifting from upstream production to purifying these intricate molecules efficiently and sustainably. Companies are exploring AI-optimized process optimization and continuous manufacturing for higher yield and agility. New materials such as membranes and resins, and innovations in affinity chromatography, microfluidics, rapid cycling, etc., continue to push improvements in the field. Meanwhile, the hunt for greener solutions is on, with the goal of minimizing waste and environmental impact. Join the **Downstream Processing** conferences to witness first-hand the tools and strategies shaping the future of biologics manufacturing.

Conference Programs

AUGUST 18-19

Intensified and Continuous Bioprocessing

View Program »

AUGUST 20-21

Advances in Purification and Recovery

View Program »

MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

INNOVATIONS IN CONTINUOUS PROCESSING OF NOVEL MODALITIES

9:40 Chairperson's Remarks
David W. Wood, PhD, Professor, Chemical & Biomolecular Engineering, The Ohio State University

9:45 KEYNOTE PRESENTATION: Single-Pass Tangential Flow Filtration for Continuous Concentration and Purification of mRNA Therapeutics
Andrew Zydney, PhD, Bayard D. Kunkle Chair & Professor, Chemical Engineering, Pennsylvania State University
Ultrafiltration is widely used for concentration and purification of mRNA, but performance is limited by fouling and mRNA degradation. This talk explores the development of single pass tangential flow filtration (SPTFF) technology for downstream processing of mRNA. SPTFF was successfully demonstrated using both conventional TFF modules and a novel vibratory membrane system with enhanced performance. Stable operation with 10X concentration factors were readily achieved, without any loss of mRNA integrity.

10:15 Advanced Upstream rAAV Process for Scalable Gene Therapy Applications
Nipun Goel, Senior Scientist, Sanofi

10:45 In-Room Networking Introductions

11:00 Computational Modeling for Cost-Effective, Continuous rAAV Production
Francesco Destro, PhD, Postdoctoral Associate, Chemical Engineering, Center for Biomedical Innovation, Massachusetts Institute of Technology
Recombinant adeno-associated virus (rAAV) manufacturing faces significant challenges in scalability and cost-effectiveness, limiting the widespread application of rAAV-based gene therapies. This presentation showcases how computational modeling is a crucial tool for addressing these challenges. A continuous process for rAAV production is designed through mechanistic modeling and process optimization. The digitally designed continuous rAAV manufacturing process is experimentally validated, achieving high-titer rAAV production for 25 days.

11:30 Presentation to be Announced DFE pharma

11:45 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation to be Announced cytiva

12:30 Session Break

INTEGRATED AND INNOVATIVE CONTINUOUS BIOPROCESS STRATEGIES

12:50 Chairperson's Remarks
Jeffrey N. Odum, Strategic Consultant, NCBioSource

12:55 The Future of Biomanufacturing: How Ultra-High Productivity Perfusion & Integrated DSP Drive Speed, Cost Savings, and Just-in-Time Capacity
Christopher Hwang, PhD, Executive Vice President & CTO, Transcenta Therapeutics/HJB
Continuous biomanufacturing significantly increased productivity, enhanced control, cost savings, and sustainability. We implemented a late-stage hybrid continuous platform, achieving >10-fold productivity increase with continuous perfusion reaching 8 g/L-day. We applied robust control, automation, and comprehensive risk assessments to mitigate complexity and risks. Our downstream platform includes single-use continuous ProA capture and an automated flow-through polish system. We will share our strategy, insights, and case study for this successful implementation.

1:25 Fully End-to-End Continuous Production of Recombinant Proteins using *E. coli*
Juergen Mairhofer, CEO & Co-Founder, enGenes Biotech GmbH
Continuous biomanufacturing is transforming recombinant protein production, offering efficiency and scalability. We introduce enGenes-e^{x}press, a growth-decoupled *E. coli* system that is genetically stabilized and mitigates adaptive evolution in a two-stage chemostat. This process enables sustained, high-yield recombinant protein production while reducing operational footprint, CAPEX, and OPEX. By integrating cost-effective solutions with process intensification, enGenes-e^{x}press paves the way for decentralized, scalable biomanufacturing.

1:55 Presentation to be Announced ECOLAB LIFE SCIENCES

2:25 Development of an Innovative Column-Free Continuous Antibody Purification Technology
Tadayoshi Kawasaki, PhD, Director, DRK Bioprocess Technology Consulting, Technical Advisor of Noritake Co., Ltd.
We have developed an innovative antibody capturing technology that efficiently and continuously purifies antibody proteins without using a chromatography column. This system allows continuous capture of monoclonal antibodies directly from cell-containing culture fluid without clarification. This shortens the monoclonal antibody manufacturing process and makes it possible to use single-use for all processes, leading to reduced capital investment.

2:55 Advancing Platform Processes through Intensified Operations and PAT
Terrence Dobrowsky, PhD, Head, Technology Development and Implementation, Takeda Development Center Americas, Inc.
This talk will examine strategies for enhancing bioprocess platforms through process intensification and Process Analytical Technology (PAT) implementation. We'll explore continuous processing approaches, advanced monitoring systems, and real-time quality control methods that maximize efficiency while maintaining product integrity.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center,

increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

SUSTAINABILITY & LIFECYCLE ANALYSIS

7:55 Chairperson's Remarks
Andrew Sinclair, MSc, CEng, FIChemE, FREng, President & Founder, BioPharm Services Ltd.

8:00 Revolutionizing Bioprocess Development: Sustainability Meets Innovation in the Digital Age
Andrew Sinclair, MSc, CEng, FIChemE, FREng, President & Founder, BioPharm Services Ltd.
Early process development is crucial for reducing environmental impact and pursuing sustainable, cost-effective bioprocessing. Traditional metrics like Process Mass Intensity (PMI) are inadequate for predicting energy use and CO2 emissions. A new approach uses early process information to build a digital factory to evaluate cost, building, and process energy. A case study explores strategies for minimizing environmental impact and costs through process intensification, optimization of water usage, and HVAC improvements.

8:30 Reduce Energy Usage for Drug Substance Facilities: Development and Application of Models
Ken Hamilton, Distinguished Engineer, Genentech
This presentation is focused on developing and applying models to evaluate energy usage in bioprocess facilities. We describe the key facility inputs that should be included. Model structure is reviewed. The role of facility equipment type, cleanroom classification and facility size are discussed. Factors that most influence energy usage are discussed. An end-to-end review of facility attributes and those that most contribute to energy usage are discussed.

9:00 Enhancing the Sustainability of Drug Substance Processes through Process Evolution and Facility Fit Modeling
Christopher Furcht, PhD, Director, Biologics Development, Bristol Myers Squibb
"Green by Design" is a strategic imperative to improve environmental sustainability metrics of our manufacturing processes. This effort is particularly important for more complex biologics such as bispecific antibodies, which often have a higher process mass intensity (PMI) than traditional monoclonal antibodies. Here, we demonstrate a combined approach of implementing facility fit modeling and downstream process optimizations to improve process sustainability through decreased water and raw material requirements.

9:30 Integrated mAb Capture and Polishing Steps Using the Octave MCC Platform
Marissa Heino, Commercial Product Manager - Process Solutions, Tosoh Bioscience LLC
The shift from batch to continuous and semi-continuous bioprocessing continues to become more popular in the biopharmaceutical industry, and Multi-Column Chromatography (MCC) plays a crucial role in this conversion. MCC has already been adopted in downstream processing (DSP) for monoclonal antibody (mAb) capture step intensification; however, for some, the end goal is to transition to fully continuous processes to fulfill the industry's economic goals and environmental regulations. Tosoh Bioscience supports this evolution with its Octave MCC platform, which integrates two chromatographic DSP steps within a single 8-column system. This presentation highlights recent achievements in combining a Protein A capture step with a subsequent polishing step to purify high-titer mAb feedstock. We showcase the potential of the Octave to simplify and advance intensified, integrated bioprocessing.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

11:30 Regeneration of Spent Culture Media for Sustainable and Continuous mAb Production via Ion Concentration Polarization
Jongyoon Han, PhD, Professor, Electrical Engineering & Computer Science, Massachusetts Institute of Technology
We have developed a self-recycling perfusion bioreactor that leads to lower cost of goods and reduced environmental impact compared to conventional perfusion manufacturing processes. After harvesting mAbs we process spent media in our waste separation device that utilizes ion concentration polarization to remove ammonia and lactate. Our process allows us to "regenerate" media by replacing depleted nutrients and recycling them into the bioreactor without accumulating inhibitory metabolic waste products.

12:00 pm PANEL DISCUSSION: Fed-Batch vs. Continuous: The Decision Space for Implementation
Moderator: Jeffrey N. Odum, Strategic Consultant, NCBioSource
Faced with making the choice between a traditional fed-batch manufacturing platform and moving to a continuous/perfusion-based process, what are the sourcing decisions that must be addressed? This panel aims to identify critical decision parameters and discuss a decision space model that includes:
- Molecule fit for the process
- Productivity, Yield, and Manufacturability
- Speed to Clinic
- Speed to Market
- Risk Mitigation Strategy

Panelists:
Andrew Sinclair, MSc, CEng, FIChemE, FREng, President & Founder, BioPharm Services Ltd.
Kenneth Lee, PhD, Sr Scientist, Astrazeneca

12:30 Presentation to be Announced

12:45 Presentation to be Announced

PAK BioSolutions

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

DIGITAL TWINS AND PAT FOR CONTINUOUS BIOPROCESSING

2:10 Chairperson's Remarks
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

2:15 Digital Twins for Vial-Based Continuous Lyophilization
Richard D. Braatz, PhD, Edwin R. Gilliland Professor, Massachusetts Institute of Technology
A mechanistic model is presented for continuous lyophilization in which vials are suspended and move continuously through the process. The model predicts the evolution of critical process parameters, including ice/water fraction and concentration of bound water, for the entire process. The model is applied to process design and optimization of continuous lyophilization. The model is made available in MATLAB and Julia as a software package called ContLyo.

2:45 Development of End-to-End Digital Twins for Continuous Bioprocessing
Gabriele Bano, PhD, Head of Process Modeling, Global CMC Development - Data Sciences, Sanofi
In this talk, we discuss the development of a comprehensive modeling strategy for a continuous downstream process for monoclonal and multi-specific antibodies. The modeling framework includes (i) an end-to-end systems model for process design, optimization, and what-if analysis; (ii) residence-time distribution models; (iii) multivariate statistical process monitoring models for real-time process monitoring, and (iv) advanced process control. A demonstration of the modeling capability is provided for a multi-specific antibody.

3:15 Automation, Capacity, and Product Learnings from GMP Integrated Continuous Downstream Manufacturing Process
Jill Paddock, Principal Scientist, Bioprocess Development, Pfizer Inc.
The iSKID downstream process runs continuous protein A capture with periodic cycles of continuous low pH inactivation, anion exchange chromatography and single pass TTF into a collection vessel across several days from a perfusion bioreactor. Key learnings gathered from GMP manufacture of three different products include automation improvements for enhanced productivity, diversion control strategies, and process impurity clearance. These learnings help further optimize iSKID integration within the clinical manufacturing facility.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

CELL-LINE DEVELOPMENT STRATEGIES FOR INTENSIFIED/CONTINUOUS PROCESSES

4:25 Chairperson's Remarks
Hussain Nuruddin Dahodwala, PhD, Director, Upstream Process Development, NIIMBL

4:30 Cell Line Development and Selection for Intensified Fed-Batch Processes
Lenneke De Winter, PhD, Head of Cellular R&D, Polpharma Biologics
This presentation explores crucial clone characteristics for successful intensified fed-batch processes. By analyzing various clones' performance in fed-batch and intensified fed-batch mode, we identify key attributes that enhance productivity in intensified conditions. Additionally, we discuss whether selection criteria vary with process mode. Is it necessary to adapt the process mode during clone selection from traditional fed-batch to intensified fed-batch mode to select the most successful clones for further process development?

5:00 Strategies to Support Perfusion/Intensified Fed-Batch Cultures
Hussain Nuruddin Dahodwala, PhD, Director, Upstream Process Development, NIIMBL
Perfusion and intensified cultures reduce costs, shorten production durations, and maximize recombinant productivity. Using NISTCHO, an open-access living standard, we achieved a 3x productivity increase with shorter culture durations through media screening, culture additives, optimized feeds, and seeding/bleeding strategies. Improved specific productivity via N-1 culture and feed strategies highlights their role in cell culture optimization for continuous and intensified processes.

5:30 Close of Intensified and Continuous Bioprocessing Conference

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

OPTIMIZATION AND ACCELERATION OF DOWNSTREAM PROCESSES

7:55 Chairperson's Remarks
Richard D. Braatz, PhD, Edwin R. Gilliland Professor, Massachusetts Institute of Technology

8:00 KEYNOTE PRESENTATION: Purifying mRNA Therapeutics: We Need A Paradigm Shift
Georges Belfort, PhD, Institute Professor, Chemical & Biological Engineering, Rensselaer Polytechnic Institute
Purification of ssRNA vaccines has saved lives, but small amounts of impurities leak through with purified ssRNA causing immunogenetic responses but not death. Here, we (i) show that convective membrane processes outperform chromatographic diffusive processes, (ii) discover, graft and test our patented affinity peptide membranes that selectively bind to ssRNA or dsRNA, and (iii) present the first results on our patented cost-effective ligand-less multimodal approach to purify ssRNA from dsRNA.

8:30 From Seed to Drug Substance: Acceleration of Manufacturing Process to One Week
Jennifer Reid, PhD, Senior Scientist, Vaccine Drug Substance Development, Sanofi
End-to-end drug substance manufacturing was accelerated to five days; thawing seed on Day 1 and producing drug substance on Day 5. Unit operations were tailored to accelerate the entire cycle with in-line PAT, advanced process control, and automated overnight processing. Manual intervention was reduced and limited to day-time hours. Accelerated processing is not cost prohibitive and has wide ranging application in accelerating manufacture of microbial enzymes and proteins, vaccines, and other biologics.

9:00 Optimization and Scale-Up of a Capture Chromatography Step for pDNA Purification
Baley Reeves, PhD, Interim Director, National Center for Therapeutics Manufacturing (NCTM)
An anion exchange-based capture chromatography step for pDNA purification was developed and optimized at small (5mL) scale on the AKTA Avant system. Different chromatography supports were evaluated for clearance of host cell impurities, including host cell RNA. In addition, buffer solutions were optimized to maximize pDNA purity. Finally, the optimized process was scaled up to manufacturing scale using the AKTA Process skid (30L load).

9:30 Presentation to be Announced

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

ADVANCES IN CHROMATOGRAPHY, NOVEL RESINS, AND ALTERNATIVE APPROACHES

10:40 Capacity Versus Speed in Chromatography and Advanced Chromatography
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University
The old physical problem worsens with the large new modalities such as viral gene therapy vectors, where binding capacity is lost due to required channel or pore size. Rules will be presented to find the best compromise with beads, fibers, and monoliths. The biophysical properties relevant to adsorption and resolution of chromatography will be compared to antibodies and an outlook will be given on whether a platform process is possible.

11:10 Novel Agarose-Based Chromatography Resin with Enhanced Downstream Purification Efficiency, Offering a Scalable and Cost-Effective Solution for Improving the Performance of Bioprocessing Workflows
Luca Mazzaferro, PhD, Postdoctoral Associate, Chemical Engineering, Massachusetts Institute of Technology
Chromatography resins play a critical role in optimizing downstream purification, directly impacting yield, purity, scalability, and cost. Our chromatography resin manufacturing platform enables a bespoke approach to resin design, tailoring particle size, mass transfer properties, and binding capacity to specific separation needs. By engineering resins for enhanced performance and scalability, we deliver a cost-effective solution that improves purification efficiencies across diverse bioprocessing workflows, enabling higher throughput and reduced processing costs.

11:40 High Throughput Chromatographic Screening Using Microfluidic Devices
Stefano Menegatti, PhD, Associate Professor, Chemical & Biomolecular Engineering, North Carolina State University
We present a micro-chromatographic device for rapid development of methods for protein and gene therapy purification. The device houses multiple parallel columns and a dilution architecture that provides independent control of (1) load ratio, (2) formulation of binding, washing, and elution buffers, and (3) format of the elution step. The device is connected online to UV/fluorescence spectrophotometry and light-scattering detectors. Studies on mAb and viral vector purification are discussed.

12:10 pm Luncheon Presentation to be Announced

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

1:25 Chairperson's Remarks
Jian Ren, PhD, Principal Scientist, AbbVie

1:30 Exploring Metal-Ion Affinity Aggregation for His-Tagged Virus-Like Particle Purification: Beyond Nickel-Based Methods
Khai Wooi Jason Lee, PhD, Senior Lecturer, School of Biosciences, Taylors University
Virus-like particles (VLPs) are valuable for nanobiotechnology and vaccines due to their virus-like structure and immunogenicity. We previously developed a nickel-based affinity aggregation method for efficient VLP purification. Here, we evaluate alternative metals (zinc, calcium, iron, copper, cobalt) for metal-ion affinity aggregation, achieving >50% recovery and >90% purity. Using DLS, TEM, and ITC, we elucidate metal-histidine interactions, optimizing low-toxicity alternatives for scalable, sustainable VLP purification.

2:00 Small-Scale Model Development for Ultrafiltration/ Diafiltration (UF/DF): Detecting, Understanding, and Accounting for Differences Between the Bench and the Manufacturing Facility
Krishn Patel, Sr Research Assoc, Purification Dev, Sanofi
To develop a process control strategy for the production of safe and effective biologics, experiments are performed at small scale to provide operating ranges to the manufacturing site. In this case study, we share a challenge encountered during the qualification of a small-scale UF/DF, describe the subsequent root cause investigation, and explain how the model was updated to ensure it was fit for purpose.

2:30 Sponsored Presentation *(Opportunity Available)*

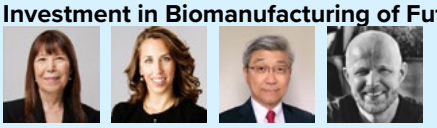
3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

FORMULATRIX

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
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Panelists:
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David Y. H. Chang, CEO, Taiwan Bio-Manufacturing Company (TBMC)
Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

DOWNSTREAM PURIFICATION OF NOVEL/COMPLEX MOLECULES

7:55 Chairperson's Remarks
Stefano Menegatti, PhD, Associate Professor, Chemical & Biomolecular Engineering, North Carolina State University

8:00 Process Development and Manufacturing of Cysteine Linked Antibody-Drug Conjugates—Control of Product Heterogeneity
Guy De Roo, PhD, Principal Scientist, Byondis B V
An overview of different ADC platforms used at Byondis will be presented together with challenges encountered and solutions found during development and processing. Challenges to control heterogeneity will be discussed and strategies for ADC manufacturing will be presented, as well as strategies for improvement of future processes.

8:30 Utilization of Activated Carbon for FDRI Removal in ADCs
Brandon Coyle, PhD, Senior Research Scientist II, Gilead Sciences Inc.
As the ADC landscape becomes more complex, FDRIs can become increasingly difficult to remove through UF/DF. As a result, scientists have been relying on other traditional biologics methods for purification such as chromatography to achieve this task. This can add significant cost and time to the ADC production. This presentation focuses on a novel purification that utilizes activated carbon for removal of FDRI to change the model for ADC purification.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

10:30 Practical Aggregates Removal Strategies in Bispecific Antibody Purification
Wei Zhang, PhD, Principal Scientist & DSP Group Head, Downstream Processing, Bioprocessing Technology Institute
Bispecific antibodies are highly aggregation prone and difficult to be removed. This presentation will discuss effective ways to remove aggregates in both bind-elute and flow-through modes chromatography. We will also demonstrate how to mitigate chromatography induced aggregation by mixed-mode chromatography.

11:00 Enhancing Aggregate Reduction Using Anion Exchange Hybrid Filter in an Immunocytokine Diabody Fusion Protein Purification Process
Jian Ren, PhD, Principal Scientist, AbbVie
- Unique aggregation challenge was presented by a diabody fusion protein.
- Anion exchange hybrid filter (Emphaze AEX) showed significant aggregate reduction.
- ~ 25 % aggregate reduction at harvest clarification step.
- Aggregate binding mechanism was elucidated to be primarily electrostatic interaction.

11:30 Purification Process Development and Manufacturing of a Novel tsAb for Tumor Therapy
Yanhuai (Richard) Ding, PhD, Senior Director, CMC DS/DP, EvolveImmune Therapeutics
This presentation will demonstrate that the developed process is scalable with high yield, high efficiency, and robust biosafety, and that the purified product meets product safety, quality, identity, potency for phase I clinical support. Some challenges and solutions associated with process capacity, impurity removal, and biosafety will be discussed.

12:00 pm Luncheon Presentation to be Announced

GORE

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

DOWNSTREAM PROCESSING OF VIRAL VECTORS

1:05 Chairperson's Remarks
Meisam Bakhshayeshi, PhD, Senior Director, Process Development, Obsidian Therapeutics

1:10 Virus Filtration Development for Adeno-Associated Virus-Based Gene Therapy Products
Namila Fnu, PhD, Scientist, Downstream Process Development, Spark Therapeutics Inc.
This talk will address the unique challenges in developing effective virus filtration strategies for rAAV gene therapy products. We'll examine the role of virus filtration in enhancing viral clearance robustness and its increasing regulatory emphasis in AAV manufacturing. Key topics include evaluating

commercially available virus filters for AAV manufacturing, assessing their throughput and process yield, and demonstrating robust clearance of model viruses like Adenovirus type 5 and Simian virus 40.

1:40 Challenges and Process Development for Purification of Gene Therapy Vector AAV

Xue Mi, PhD, Senior Scientist I, Purification Process Development, Abbvie Bioresearch Center

Adeno-associated virus (AAV) is highly inefficient at packaging its genome, with up to 90% of the formed AAV capsids being empty. The upstream process requires cell lysis to achieve a manufacturable viral titer, which generates significantly more impurity burdens than the therapeutic protein production process. A purification process involving harvest clarification, ultrafiltration/diafiltration, affinity chromatography for AAV capture, and anion exchange chromatography for AAV polishing was developed for different serotypes.

2:10 Development of a Universal and Scalable Adeno-Associated Virus Capture Step Using Steric Exclusion Chromatography

Juan Carlos Rosario, PhD, Senior Principal Scientist, Purification & Virology Development, Eli Lilly & Company

Adeno-associated viruses (AAV) are among the leading vectors for gene therapy. The purification of AAV remains a bottleneck as it typically requires multiple individual process steps, often resulting in product loss and high costs. Current downstream processes are usually serotype-specific and rely primarily on expensive affinity resins. To address these limitations, we developed a serotype-independent capture method using steric exclusion chromatography that can be combined with a subsequent empty separation step.

2:40 Networking Refreshment Break and Transition into Town Hall Discussion

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 Facilitated Town Hall Discussion

This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?

Lori Ellis, Head of Insights, BioSpace

3:55 Close of Summit

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

STREAM #3
AI AND DIGITALIZATION

The **AI and Digitalization** stream delves into cutting-edge bioprocess innovation, exploring two critical themes: Automating Analytical Development and Digital Transformation & AI in Bioprocess. The first conference tackles transitioning from manual methods to agile, data-driven automation, offering enhanced speed and precision. The second dives deep into harnessing AI and machine learning, empowering researchers to predict, optimize, and accelerate process development and manufacturing. This Stream equips you with the tools and insights to propel your process to the next generation, leaving behind time-consuming traditional methods and ushering in a new era of data-driven bioprocess revolution. Don't miss this opportunity to network, learn, and shape the future of biomanufacturing!

Conference Programs

AUGUST 18-19

Training Seminar

ML/AI for Biomanufacturing

View Program »

AUGUST 20-21

Digital Transformation & AI in Bioprocess

View Program »

Training SEMINARS
By Cambridge Healthtech Institute

Introduction to Machine Learning for CMC and Biomanufacturing

AUGUST 18-19
All Times EDT

Monday, August 18, 2025 9:45 am - 3:30 pm | Tuesday, August 19, 2025 8:00 am - 1:00 pm

The aim of this seminar is 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, to identify the important process drivers as well as to forecast the process and product quality behaviour will be presented in lectures. Hands-on coding and brainstorming sessions will be used to solve case studies from the biopharmaceuticalindustry. After the course the participants will be aware of relevant techniques and literature for bioprocess data analysis and will be able to evaluate different analysis paths for a given problem.

Topics to be covered include:

- Learn from more than 10 years of experience on many 100s of process data sets analyzed
- Toolbox of key methods for bioprocess data analysis
- Introduction to multivariate methods
- Introduction to machine learning methods
- Introduction to hybrid process modeling
- Industrial examples for USP and DSP
- Model-based process understanding and design
- Model-based process monitoring and control
- Transfer learning across molecules and scales
- Digital twins

Instructor Biography:

Michael Sokolov, *PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG*

Dr. Michael Sokolov is co-founder and COO of DataHow AG, a spin-off company from ETH Zurich specialized on process data analytics and modeling with a particular focus on the biopharmaceutical and chemical domains. He also holds a lecturer position for statistics for chemical engineers at ETH.

> The conference is a great platform to connect with opinion leaders and outstanding industry peers in-person and to learn about the newest advancements.
>
> *— Angela L., Sanofi*

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

THE DIGITAL CONTINUUM IN CMC AND BIOPROCESSING

7:55 Chairperson's Remarks
Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria

8:00 CMC Development Digital Continuum
Dana I. Filoti, PhD, Associate Director of Scientific Architecture, Development Sciences Data and Digital Strategy, Abbvie
Analytical and formulation data is foundational to CMC Development. Recording CMC development data in a user-friendly manner and having a standardized way to capture analytical results, register formulations, process parameters, batches, and samples unlocks efficiency gains and ensures data is easily accessible in the future. In this presentation we discuss AbbVie's CMC data digital journey towards connecting analytical and formulation results to their respective study.

8:30 Automated End-to-End Data Paradigm for Biologics Bioprocess Development
Yi Li, PhD, Principal Scientist, Process Development, Amgen Inc.
Modern biologics process development often involves extensive data from upstream and downstream operations. Our end-to-end automated solution unifies these diverse data streams into a single digital workflow, eliminating manual merges, reducing errors, and accelerating decision-making. By leveraging a cloud-based data ecosystem that harmonizes, validates, and visualizes process information, researchers gain immediate insights and can adopt advanced analytics and machine learning for enhanced efficiency and process robustness.

9:00 KEYNOTE PRESENTATION: Beyond Digital: Harnessing the Power of Data and AI to Revolutionize Bioprocessing
Cenk Undey, PhD, Independent Consultant, Formerly Roche/Genentech
Harnessing data and AI in bioprocessing goes beyond traditional digital methods by leveraging advanced analytics, machine learning, and automation to optimize production. These technologies enable real-time monitoring, predictive modeling, and adaptive control, enhancing efficiency, scalability, and product quality. This data-driven approach revolutionizes biomanufacturing by accelerating innovation and reducing costs.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

THE DIGITAL APPROACH TO DOWNSTREAM PROCESSING

10:40 A Digital-First Approach to Downstream Bioprocessing
Laura Pereira-Diaz, PhD, Digital CMC Scientist, Takeda
This presentation explores the integration of digital modeling and simulations as a starting point for downstream bioprocessing, focusing on a proof of concept for cation exchange chromatography. This represents a shift toward Quality by Digital Design (QbDD), leading to enhanced process efficiency and increase productivity through computational models and real-time data, demonstrating the future state of our *in silico* first approach.

11:10 Transforming Downstream Processes: From Paper to Digital with an In-House LIMS
Brian R. Lowry, PhD, Principal Research Scientist II, Purification, Abbvie
Michail Vlysidis, PhD, Senior Engineer, AbbVie
Our digital transformation efforts have successfully extended the reach of our internally developed Laboratory Information Management System (LIMS)—originally used in upstream processes—into downstream operations. This talk will explore the evolution of our workflows from traditional paper and Excel-based methods to an integrated digital system. Attendees will gain insights into how the novel implementation of our LIMS facilitates more informed decision-making, driving improved outcomes and innovation in our downstream processes.

11:40 Optimal Control of Startup for a Continuous Filtration/ Diafiltration Unit
Anastasia Nikolakopoulou, PhD, Senior Data Scientist, Process Simulation and Control, Sanofi

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

THE FUTURE OF DIGITALIZATION

1:25 Chairperson's Remarks
Irene Rombel, PhD, CEO & Co-Founder, BioCurie Inc.

1:30 Pharma 4.0 MTP Plug and Produce Standard—Implementation Guidance
Scott Clark, Principal, ElevateOps4.0
As the life sciences industry moves toward greater flexibility, scalability, and efficiency, the Module Type Package (MTP) standard is emerging as a key enabler of modular automation, Plug & Produce integration, and advanced data orchestration. By showcasing diverse use cases, this guide provides practical insights into how MTP can reduce deployment time, improve interoperability, simplify process change agility, democratize data, and streamline compliance in regulated manufacturing environments.

2:00 PANEL DISCUSSION: Future of Digital Transformation and AI in Bioprocessing
Moderator: Irene Rombel, PhD, CEO & Co-Founder, BioCurie Inc.
The future of digital transformation and AI in bioprocessing lies in advanced automation, real-time data analytics, and intelligent decision-making. This panel brings together industry experts for an interactive discussion on what we can do to drive the future forward.
Panelists:
Christian Airiau, PhD, Global Head, Data Sciences, CMC, R&D, Sanofi
Richard D. Braatz, PhD, Edwin R. Gilliland Professor, Massachusetts Institute of Technology
Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria

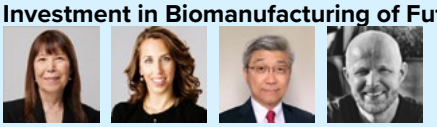
2:30 Sponsored Presentation *(Opportunity Available)*

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
What are the technologies and innovations shaping the future of biomanufacturing in 2025 and beyond? Join us for an engaging plenary panel discussion on "Innovation and Investment in Biomanufacturing of Future Medicine," where leading experts from the investment and strategies community will explore upcoming trends, investment opportunities, and modalities into the next decade. How should the industry best prepare?

Panelists:
Daniella Kranjac, Founding General Partner, Avant Bio LLC
David Y. H. Chang, CEO, Taiwan Bio-Manufacturing Company (TBMC)
Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

DIGITAL TWINS AND AI IMPLEMENTATIONS AND CHALLENGES

7:55 Chairperson's Remarks
Christian Airiau, PhD, Global Head, Data Sciences, CMC, R&D, Sanofi

8:00 Digital Twin Calibration and Optimal Control for Biomanufacturing Processes
Wei Xie, PhD, Assistant Professor, Mechanical & Industrial Engineering, Northeastern University
Digital twin calibration and optimal control in biomanufacturing involve creating and refining virtual models that replicate real-world bioprocesses. Calibration ensures the digital twin accurately reflects experimental data, while optimal control leverages this model to enhance process efficiency, stability, and product quality. This approach enables real-time monitoring, predictive adjustments, and improved decision-making in biomanufacturing.

8:30 Digital Twins for Application from mAbs to Viral Vectors Reducing Experimental Effort in the Lab
Mark Duerkop, CEO, Novasign GmbH
Digital twins streamline bioprocessing by creating virtual models that simulate monoclonal antibody (mAb) and viral vector production, reducing the need for extensive lab experiments. These models enable real-time optimization, predictive insights, and process control, improving efficiency and scalability. By minimizing experimental effort, digital twins accelerate development timelines and enhance biomanufacturing precision.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY BREAKOUT: Addressing Workforce Gaps: Cross-Sector Collaboration, Targeted Training Programs, and Global Talent Mobility
Jason Beckwith, PhD, Professor, School of Business, University of Dundee

- *Cross-Sector Collaboration:* Foster partnerships between academia, industry, and government to align skills development with bioprocessing needs.
- *Targeted Training Programs*: Develop specialized education and upskilling initiatives to equip workers with the latest digital and AI-driven biomanufacturing skills.
- *Global Talent Mobility:* Streamline policies and initiatives to attract and retain skilled professionals worldwide, ensuring a diverse and adaptable workforce.

DIGITAL TWINS IMPLEMENTATIONS AND CHALLENGES CONTINUED

10:30 Real-Time Release Solutions by Integration of End-to-End Digital Twins
Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria
Real Time Release is a clear business case; however, there are hardly any solutions in place so far. This contribution shows how end-to-end digital twins can be embedded in real time environment cocurrently with the actual batch. Digital Twin predictions can be directly fed into the electronic batch record and the OOS probability is therewith minimized. This solution can also be used to target CPV and continuous optimization.

11:00 Hybrid Modeling Approaches for Biopharmaceutical Drug Substance Development
Samira Beyramysoltan, PhD, Senior Scientist, Modeling and Simulation, GSK
The development of robust models for process optimization is a critical aspect of enhancing efficiency, reducing costs, and ensuring consistency in manufacturing processes. This presentation will address how Hybrid Model approaches used to extract the missing relationships that cannot be captured by the mechanistic model in downstream and upstream process.

11:30 The Bumpy Road to Implementation: Why There Isn't More AI in Manufacturing, and How to Reroute the Course
Myra Coufal, PhD, Director, Process Development, Amgen Inc.
Ever had a great AI/ML solution that was technically feasible but didn't make it to implementation? You are not alone, let's talk. We will discuss hurdles that are often overlooked until it is too late, and approaches to overcome them. We will recommend under-valued areas for AI/ML solutions. Brought to you as confessions from someone who has been on the AI/ML development side and on the manufacturing receiving side.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

MODELING AND ADVANCED PROCESS CONTROL

1:05 Chairperson's Remarks
Moo Sun Hong, PhD, Assistant Professor, Department of Chemical and Biological Engineering, Seoul National University

1:10 Advanced Process Data Analytics for End-to-End Biopharmaceutical Manufacturing
Moo Sun Hong, PhD, Assistant Professor, Department of Chemical and Biological Engineering, Seoul National University
Selecting optimal data-driven modeling methods and integrating batch and time-series data are key challenges in biopharmaceutical manufacturing. Accurate modeling requires capturing both inter-batch variability and intra-batch dynamics. This presentation describes the application of smart process data analytics software and tensorial methods to industrial end-to-end biomanufacturing datasets for monoclonal antibody production, demonstrating how automated DA/ML tool selection and multiway modeling improve predictive accuracy and process understanding.

1:40 Enhancing Biologics Manufacturing Efficiency through Data Science: Insights from Case Studies
Shyam Panjwani, PhD, Principal Data Scientist, Bayer Healthcare Pharmaceuticals
The biopharmaceutical industry is increasingly turning to data science to optimize manufacturing processes and enhance product quality. This presentation explores two case studies that leverage data science to improve efficiency in biologics manufacturing. The first case study focuses on a cloud-based predictive modeling application designed to enhance the predictability of cell culture processes. The second case study presents a framework for assessing the out-of-specification risk associated with drug product potency.

2:10 Model-Based Optimal Control of Fed-Batch *in vitro* Transcription for RNA Manufacturing
Nathan Stover, PhD Student, Process Engineering, Massachusetts Institute of Technology
While the *in vitro* reaction for RNA synthesis is traditionally performed in a batch mode, fed-batch *in vitro* transcription holds promise to more efficiently use expensive catalysts. We develop and mathematically optimize a mechanistic model for IVT to find feeding policies that maximize RNA production while maintaining key critical quality attributes. Experimental validation demonstrates how these model-based strategies can be used to accelerate process development and optimize costly resources.

2:40 Networking Refreshment Break and Transition into Town Hall Discussion

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 Facilitated Town Hall Discussion
This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?
Lori Ellis, Head of Insights, BioSpace

3:55 Close of Summit

> The Bioprocessing Summit brings together expert scientists and cutting edge technologies in biomanufacturing and fertile ground for networking with key partners.
>
> *—Martin L., National Research Council Canada*

STREAM #4
ANALYTICAL & QUALITY

At the 2025 Bioprocessing Summit, the **Analytical and Quality Stream** dives into the evolving landscape of biotherapeutic development, emphasizing innovations that enhance analytical precision and efficiency. This stream spans topics from automation and predictive modeling to next-generation tools like MS, NGS, and CRISPR technologies. Attendees will gain practical knowledge on navigating phase transitions, characterizing complex biologics, and overcoming common workflow bottlenecks. With a strong focus on digital transformation through AI, data integration, and automation, the stream reflects the dynamic interplay between cutting-edge methods and real-world applications in analytical science.

Conference Programs

AUGUST 18-19

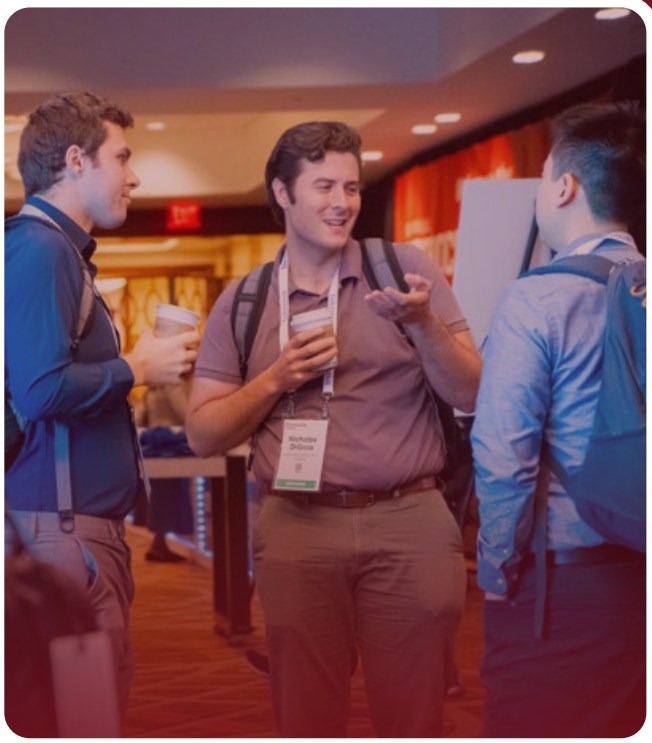
Accelerating Analytical Development

View Program »

AUGUST 20-21

Next Generation Analytical Methods

View Program »



Accelerating Analytical Development

Applying New Technologies to Optimize the Speed and Efficiency of Biotherapeutic Development

AUGUST 18-19
All Times EDT

MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

DIGITALIZATION AND AI TO OPTIMIZE ANALYTICAL DEVELOPMENT

9:40 Chairperson's Remarks
Meng Xu, PhD, Senior Scientist, Lab Automation, Merck

9:45 Integrating Data in an Automation Center
Ajuna Azad, PhD, Senior Data Strategy Officer, DTU Bioengineering
Efficient data integration is crucial for advancing automation centers in life sciences. Efforts at DTU Arena for Life Science Automation (DALSA) and DTU Bioengineering focus on automating data capture, managing the data lifecycle, and ensuring compliance with FAIR principles. Key processes include handling retrospective data and standardizing data processing through reproducible pipelines. These practices accelerate scientific discovery and enhance automated labs, highlighting their transformative impact on biotech research and development.

10:15 Development and Application of Mechanistic Models Based on Historical Data
Francesco Destro, PhD, Postdoctoral Associate, Chemical Engineering, Center for Biomedical Innovation, Massachusetts Institute of Technology
Mechanistic models condense complex information into quantitative and interpretable frameworks, which can guide experimental designs for model refinement and process optimization. This presentation discusses how mechanistic models built from historical data can be used to speed up analytical development. A case study on recombinant adeno-associated virus manufacturing showcases how robust mechanistic models can be developed even from sparse experimental datasets that comprise data from a diverse array of analytical tools.

10:45 In Room Networking Introductions

11:00 FEATURED PRESENTATION: Recent Advances in Machine Learning for High-Concentration Antibody Viscosity Prediction
Pin-Kuang Lai, PhD, Assistant Professor, Chemical Engineering and Materials Science, Stevens Institute of Technology
Over the past five years, machine learning for predicting high-concentration antibody viscosity has experienced significant breakthroughs. In this talk, I will review key developments in data collection, feature selection, algorithm design, model validation, and deployment. By integrating diverse datasets with advanced machine learning methods, these innovations yield improved predictions that enhance high-concentration antibody formulation and reduce experimental burdens—ultimately accelerating analytical development for subcutaneous injection.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

AUTOMATION AND MULTIPLEXING

12:50 Chairperson's Remarks
Kanwal Gill, PhD, Principal Scientist, Pharmaceutical R&D, Pfizer Inc.

12:55 Automated High-Throughput Method for the Quantitation of Glucose Tetrasaccharide in Human Plasma
Avraham Rosenberg, MS, Senior Scientist, Analytical Chemistry, Regeneron
Pompe disease, a lysosomal storage disorder, is characterized by glycogen accumulation in tissues, leading to elevated levels of glucose tetrasaccharide (Glc4) in biological fluids. In this study, we developed and validated a high-throughput assay for the quantification of Glc4 in human plasma. This method offers a robust, efficient, and non-invasive tool for clinical monitoring Pompe disease, facilitating the assessment of enzyme replacement therapy efficacy.

1:25 Enhancing Analytical and QC Testing for Biologics Using Modular Automation System and Semi-Automation Approach
Meng Xu, PhD, Senior Scientist, Lab Automation, Merck
Biologics pose unique challenges in analysis due to high protein concentrations and viscosity, making manual liquid handling inadequate. Implementing modular automation systems, like Hamilton Microlab Prep and Andrew Alliance Robot, enhances productivity and turnaround times in biologics development. These platforms facilitate medium-to-high-throughput testing for key assays, including Ligand binding ELISA and enzymatic activity assays, streamlining workflows and improving accuracy in both research and quality control settings.

1:55 Sponsored Presentation *(Opportunity Available)*

2:25 From Bottlenecks to Breakthroughs: Transforming mRNA Drug-Product Development via Automated Analytical Solutions
Kanwal Gill, PhD, Principal Scientist, Pharmaceutical R&D, Pfizer Inc.
Recent advances in mRNA therapeutics development have driven automation of critical analytical methods. Through systematic development, we automated RiboGreen using robotic liquid handling, then integrated Fragment Analysis into a single automated workflow. Concurrently, we implemented Stunner for rapid UV-Vis based mRNA quantification. This three-pronged automation strategy has revolutionized traditional bottlenecks, enabling high-throughput analysis while maintaining exceptional precision (<2% RSD) and reliability.

2:55 Addressing Challenges of Miniaturization in the Automation of rAAV Quantification by qPCR
Kelly Dube, Senior Research Associate, Ultragenyx
A variety of automated liquid handling systems exist, many differing in price, size, ease of use, and quality. This talk focuses on the development of the Echo 525 Liquid Handler for qPCR after experiencing difficulties with an alternative liquid handling instrument. The challenges experienced with both the alternative liquid handler and the Echo 525 will be addressed, along with the methods used to develop the final automated qPCR method.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

MITIGATING RISK

7:55 Chairperson's Remarks
Xiaoyang Zheng, PhD, Scientific Fellow, Global Manufacturing Science & Global Quality, Takeda

8:00 Turning Diverse Analytical Data into Actionable Knowledge for Enzymatically Driven Polysorbate Degradation Risk Assessment and Control in Biotherapeutic Protein Formulations
Alex Dow, PhD, Associate Principal Scientist, Merck & Co., Inc.
Polysorbate degradation in biotherapeutic protein formulations poses significant challenges toward long-term stability. Various assays have been developed for assessing degradation risk. While multiple data sets enhance understanding, they can complicate interpretation. Three case studies are presented to demonstrate how different assays align in evaluating enzymatically-driven polysorbate degradation, categorized into risk informing, characterization, and extended characterization. This framework offers guidance for future work in addressing polysorbate degradation.

8:30 Accelerating Analytical Development: Implementing Platform Approaches and Embracing Smart Risks
Tilen Praper, PhD, Associate Director, Process Analytical Science, Novartis Pharmaceuticals
Novartis has a broad and diversified portfolio of biologics, where analytics play a vital role in technical development. This presentation highlights strategic approaches to enhance efficiency and speed in analytics, including process standardization, platform implementation, and smart risk adoption (e.g., predictive stability). These elements aim to streamline analytical development, expedite overall progress, and ensure robust support for our biotherapeutic pipeline.

9:00 Transfer Strategies (Interphase, between Sites, Development to QC/GMP, to/from CDMO)
Xiaoyang Zheng, PhD, Scientific Fellow, Global Manufacturing Science & Global Quality, Takeda
This presentation will explore strategies for optimizing method transfer processes and provide insights on transferring methods as intended. Key focus areas will include the challenges associated with method transfer, thorough risk assessment to identify potential pitfalls and mitigate risks early, practical considerations for sample size rationale calculation, and best practices to ensure seamless execution. Case studies will be shared to illustrate successful method transfers, including lessons learned.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

11:30 Evaluating Parameters Influencing Recovery and Stability of Low-Dose In-Use Formulations
Zahra Ghassemi, PhD, Senior Scientist, Dosage Form Design & Development, AstraZeneca
This presentation will address the challenges of maintaining product stability and recovery under in-use conditions for novel modalities administered at low doses. It will discuss the impact of formulation parameters and factors influencing low-dose compatibility on product safety and efficacy, using a case study to illustrate the crucial role of surface area to volume ratio and total surface area in the recovery at low concentrations.

12:00 pm KEYNOTE PRESENTATION: Aligned Control Strategy Proportions and Staging Opportunities—Concept and Execution Roadmap for an Enhanced and Integrated Analytical Control Strategy
Stephan O. Krause, PhD, Executive Director Analytical Quality, BMS Cell Therapies
Using case studies, the implementation of an enhanced, AI-capable, analytical control strategy is provided. The benefits of standardizing and proportioning variation/bias targets for CQA-impacting analytical control strategy elements are illustrated. "Staging" and change opportunities are aligned with typical product lifecycle steps. It will be shown how we should effectively track and control allocated variation/bias proportions throughout product development, technology transfer and commercial operations.

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

STRATEGIES AND SOLUTIONS

2:10 Chairperson's Remarks
Byung Chul Kim, PhD, Principal Scientist, Protein Biochemistry, Regeneron Pharmaceuticals

2:15 Analysis of the Structure of 14 Therapeutic Antibodies Using Circular Dichroism Spectroscopy
Tim Dafforn, PhD, Professor, Biotechnology, University of Birmingham
Using 14 therapeutic mAbs, we have carried out the largest assessment of the use of CD data biotherapeutic structural analysis. We have identified the optimum data analytics approach to deconvoluting CD data from mAbs and

show how a small regions of CD spectral data are important in detecting mAbs mis-folding. These data, combined with our other work on inline CD measurement show CD has utility for next generation PAT.

2:45 Optimizing Critical Reagents: A Key Strategy when Accelerating Analytical Development of Potency Release Assays
Byung Chul Kim, PhD, Principal Scientist, Protein Biochemistry, Regeneron Pharmaceuticals
At Regeneron, we ensure high-quality reagents through comprehensive biophysical and biochemical characterization. This work highlights the characterization and optimization of two critical reagents using SDS-PAGE, Mass spectroscopy, Analytical Ultracentrifugation, Biacore and SEC-MS, linking their purity and structural integrity to bioassay performance. These case studies underscore the importance of high-quality reagents for consistent and robust potency assay development.

3:15 Product-Specific Host-Cell ELISA Assays
Jonathan Sun, Scientist, Assay Development, Sanofi
Host Cell Protein (HCP) assays play a key role during process development, characterization, and to support the analytical control strategy. The transition from a generic or platform ELISA to a process specific method can be challenge for in licensed or accelerated programs. A case study will be presented describing the strategy used for establishing a suitable project specific host cell protein assay to support late-stage program.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

4:30 Strategies and Tools to Improve Bioassay Consistency
Xiaolei Zhuang, PhD, Scientific Liaison, Global Biologics, USP
USP has a set of general chapters to guide bioassay work, from development to validation and even assay maintenance throughout the method's life cycle. For bioassay development, a stepwise approach should be taken.

5:00 SoloVPE as a Substitute for LC-UV for at-Line Determination of Oligonucleotide Crude Concentration
Tai Nguyen, Scientist, Biogen
The concentration of crude oligonucleotide products is an in-process control that needs to be determined after synthesis before proceeding with the purification process. We evaluated SoloVPE as an alternative to LC-UV. Because SoloVPE is a test that can be performed on the manufacturing floor, it enabled generation of the data in a fraction of the time, thus allowing for faster and continuous processing of the material from synthesis into purification.

5:30 Novel Applications of Mass Photometry in Early R&D for Innovative Biotherapeutic Modalities
Fabian Soltermann, PhD, Principal Scientist, Biomedical Research, Novartis
We discuss the deployment of mass photometry in early R&D for innovative biotherapeutic modalities, exploring a range of use-cases and novel applications to show how increased robustness and reproducibility paves the way for routine analysis with minute sample amounts. Our discussion will elucidate the potential of mass photometry in giving biologically meaningful insights and more reproducible reads, all of which contribute significantly to the development, optimization, and QC of biologics.

6:00 Close of Accelerating Analytical Development Conference

> "The Bioprocess Summit hosted by CII is my favorite biomanufacturing show. The event is well organized and well attended, with excellent technical content from leading biotherapeutic companies sharing relevant findings. It is a great place to meet new people in the industry and catch up with longtime friends."
>
> *—Scott Z., VP of Sales and Business Development, Chromatan, Inc.*

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

STRATEGIES AND METHODS FOR EMERGING MODALITIES

7:55 Chairperson's Remarks
Hao Liu, PhD, Senior Advisor, BioProduct Development, Eli Lilly & Co.

8:00 New Methods to Develop Binding ELISAs for Multispecifics
Theresa O'Brien, Scientist, Sanofi
Residual Protein A is a process related impurity that needs monitoring, due to potential safety considerations. A new Protein A resin was introduced into the process which uses a new commercially available ELISA (kit 1). Challenges during qualification using kit 1, led to the use of a well-established Protein A commercial kit 2. This presentation will focus on the challenges observed transitioning between the two commercial Protein A ELISA kits.

8:30 KEYNOTE PRESENTATION: Characterization of Co-Formulations and Therapeutic Cocktails
Paul Dalby, PhD, Professor, Biochemical Engineering; Co-Director, Future Targeted Healthcare Manufacturing Hub, University College London
Protein formulation challenges remain for high-protein concentrations, new molecular entities, and co-formulated bioactives. Understanding aggregation mechanisms will inform formulation strategies and the design of better predictive algorithms. Higher order structure analyses and simulations have revealed the protein aggregation mechanisms, including for previously unexpected stabilization in a highly stable, high-concentration antibody Fab fragment. The impact of the same Fab in IgG1 and bispecific antibody co-formulations has also been explored.

9:00 Best Practices for Bioanalysis of ADCs
John "Jack" Kellie, PhD, Group Director, Integrated Bioanalysis, AstraZeneca
ADC bioanalysis strategies are shared for pre-clinical ADC studies. Total antibody and total ADC quantitation by digestion approaches are accompanied by free payload quantitation for determination of PK concentration, efficacy, and safety. Intact mass analyses of ADCs from in-life studies are also leveraged to calculate *in vivo* DAR. Presented here are current MS methods for pre-clinical ADC bioanalytical support, including hybrid immunocapture MS formats and payload quantitation.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

MS APPLICATIONS AND TECHNOLOGIES

10:40 Implementation of Intact Multi-Attribute Method (iMAM) for Characterization and Quality Control of Therapeutic Antibody-Oligonucleotide Conjugates
Hao Liu, PhD, Senior Advisor, BioProduct Development, Eli Lilly & Co.
The Intact Multi-Attribute Method (iMAM) is a powerful analytical approach for characterizing and ensuring the quality of therapeutic antibody-oligonucleotide conjugates (ARCs). This presentation explores the implementation of iMAM in biopharmaceutical development, highlighting its ability to provide detailed structural insights, monitor product consistency, and support quality control. By integrating high-resolution mass spectrometry, iMAM enhances the detection of critical quality attributes, offering a robust alternative to traditional assays for ARC characterization.

11:10 MS for the Characterization of Glycoproteins
Yunlong Zhao, PhD, Principal Scientist, Analytical Chemistry, Regeneron Pharmaceuticals
Mass spectrometry (MS) plays a crucial role in the characterization of glycoproteins, providing detailed insights into glycosylation patterns, site occupancy, and structural heterogeneity. In biologic drug development, MS enables high-resolution analysis of glycan structures, essential for ensuring product consistency, efficacy, and safety. This presentation will explore advanced MS techniques, including glycopeptide mapping and intact glycoprotein analysis, highlighting their applications in regulatory compliance and quality control of therapeutic glycoproteins.

11:40 MS Applications for Novel Modalities
Cydney M. Martell, PhD Candidate, Pharmacology, Northwestern University
Predicting protein aggregation remains difficult, limiting their use for biotechnology and therapeutic applications. We aim to design aggregation-resistance by collecting and learning from large, experimentally validated datasets. I quantified aggregation after thermal and pH stress for thousands of small protein domains using mass spectrometry. I'm developing machine learning models to predict aggregation from protein features. Through iterative experiments and design, I will refine my model to achieve unprecedented aggregation-resistance.

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

CHARACTERIZATION OF NUCLEIC ACID PRODUCTS

1:25 Chairperson's Remarks
Juan Perilla, PhD, Assistant Professor, Chemistry & Biochemistry, University of Delaware

1:30 Next-Generation Sequencing as a Platform Method for Identity & Multivalent Ratio Release Testing of Nucleic-Acid Products
Lawrence C. Thompson, PhD, Associate Research Fellow, Analytical R&D, Pfizer Inc.
This talk will discuss the development of a platform of next generation sequencing ID/ratio method from early data showing proof of concept work and the path to GMP for all instrumentation and the bioinformatics which culminated in completion of method qualification.

2:00 Methods for Quality Assurance of Oligo Raw Materials
Xiaolei Zhuang, PhD, Scientific Liaison, Global Biologics, USP
Phosphoramidites are the building blocks currently used to manufacture therapeutic oligonucleotides. USP has been exploring new opportunities to develop standards for phosphoramidite, including DNA, RNA, MOE amidites, and impurities amidites. A multi-center collaborative study extensively characterized USP standards, suitable for use as reference standards for raw materials in oligonucleotide-related products.

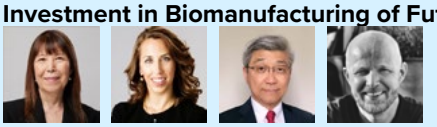
2:30 Sponsored Presentation *(Opportunity Available)*

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
What are the technologies and innovations shaping the future of biomanufacturing in 2025 and beyond? Join us for an engaging plenary panel discussion on "Innovation and Investment in Biomanufacturing of Future Medicine," where leading experts from the investment and strategies community will explore upcoming trends, investment opportunities, and modalities into the next decade. How should the industry best prepare?

Panelists:
Daniella Kranjac, Founding General Partner, Avant Bio LLC
David Y. H. Chang, CEO, Taiwan Bio-Manufacturing Company (TBMC)
Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

CHARACTERIZATION OF GENE AND CELL THERAPIES

7:55 Chairperson's Remarks
Sarah Richer, PhD, Director, BioProduct Research & Development, Eli Lilly and Company

8:00 Mass-Spec Methods for Characterization of AAVs
Frank Sobott, PhD, Professor, Biomolecular Mass Spectrometry, University of Leeds
In this contribution we show how native mass spectrometry in the Megadalton range can be used to accurately measure masses of recombinant AAV particles of varying compositions. We discuss approaches to increase mass resolving power and deconvolution of signals on commercial instruments such as the Thermo Scientific Orbitrap Exactive UHMR using charge detection and charge-shifting solution additives. We are also discussing characterization of AAV topology and cargo release.

8:30 Novel High-Throughput Multiplex MSD Method for Characterizing rAAV Genome Integrity
Xushan Wang, Director, Eli Lilly and Company
rAAV genomes comprises a heterogeneous population within AAV particles. These particles contain the intact genome but also include numerous truncated species, which likely lack functionality and may induce adverse effects. Viral genome titer methods do not accurately reflect this heterogeneity and there are no reliable quantitative methods. We have developed a novel high-throughput RNA-DNA hybrid method for quantitating the intact and truncated rAAV genomes. A much-needed advancement for the field.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

10:30 Learnings from Simulations of Whole Intact Viruses
Juan Perilla, PhD, Assistant Professor, Chemistry & Biochemistry, University of Delaware
Full-scale molecular dynamics simulations of viral capsids provide a well-established platform for high spatial and temporal resolution analysis of capsid mechanoelastic properties. These simulations provide accurate molecular views that are successfully validated against multiple experimental techniques. Altogether, our results suggest that the HIV-1 capsid is a robust container with finely tuned viscoelastic properties that allow it to adapt to a range of geometries during cytoplasmic and nuclear trafficking.

11:00 Characterization and Quantitation of Baculoviral DNA in rAAV Vectors Produced in Sf9 Cells by Multiplex Digital PCR
Sarah Richer, PhD, Director, BioProduct Research & Development, Eli Lilly and Company
rAAV vectors can be produced in various cell types, including the baculovirus/Sf9 system, which introduce residual DNA impurities. We characterized and quantified baculoviral (BV) DNA and determine the mechanism for introduction of these impurities. This demonstrates important features of the BV plasmid design including antibiotic resistance gene location, questions the need for stuffer DNA, indicates selective packaging, and highlights important aspects for design of residual BV DNA quantitative methods.

11:30 Identification and Quantification of Phosphorothioate Stereoisomers in sgRNA Using LC Ion-Mobility Mass Spectrometry
Yue Su, Scientist, Regeneron
In CRISPR/Cas9 genome editing system, phosphorothioate (PS) modifications in single-guide RNA (sgRNA) introduce chiral centers, creating complex isomers. This study presents a novel approach using endonuclease digestion and ion pairing reversed-phase liquid chromatography with cyclic ion mobility mass spectrometry (IPRP-LC/cIMS) to differentiate and quantify PS-induced isomers. This method, rigorously evaluated, also investigates the conversion kinetics from PS to phosphodiester (PO) impurities under oxidative stress, offering insights into PS stability.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

PROBLEMS AND SOLUTIONS

1:05 Chairperson's Remarks
Therese Herling, PhD, Postdoctoral Researcher, Chemistry, University of Cambridge

1:10 Non-Specificity Fingerprints for Clinical-Stage Antibodies in Solution

Therese Herling, PhD, Postdoctoral Researcher, Chemistry, University of Cambridge

Non-specific interactions are a key developability parameter during monoclonal antibody discovery and development. However, the underlying physicochemical parameters remain poorly understood. Here, we employ microfluidic technologies to generate non-specificity fingerprints for a panel of clinical-stage antibodies in solution, providing quantitative data on the underlying physical chemistry. Based on our findings, we propose a quantitative non-specificity score, which can be integrated in the development workflow for biological therapeutics and protein engineering.

1:40 Dielectrophoretic Analysis of Single Cells Using Novel Designs of Microfluidic Cytometers

Michael Butler, PhD, Principal Investigator, Cell Technology, National Institute for Bioprocessing Research & Training (NIBRT)

Dielectrophoresis (DEP) is a valuable technique for single-cell analysis in a population of mammalian cells. Using a selected frequency, viable and non-viable cells can be distinguished by their differential trajectory in a microfluidic cytometer. DEP analysis can also be used to measure changes in cytoplasmic conductivity or changes in membrane structure. DEP is a label-free technique and can identify early changes in metabolism that occur toward the end of bioprocesses.

2:10 Accelerating Cell Line Development: Balancing Speed and Depth through Tiered Analytical Workflows

Gong Cheng, PhD, Head, Analytical Sciences, Asimov Inc.

This presentation introduces a tiered, high-throughput analytical workflow designed to optimize Cell CLD by balancing speed and depth in early-stage screening. It will cover the integration of high-throughput assays, automated purification, and in-depth characterizations to efficiently evaluate pools and clones while ensuring product identity and integrity. Emphasis will be placed on overcoming challenges with complex formats like bispecifics and surrobodies, and streamlining clone selection based on critical quality attributes (CQAs).

2:40 Networking Refreshment Break and Transition into Town Hall Discussion

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 Facilitated Town Hall Discussion

This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?

Lori Ellis, Head of Insights, BioSpace

3:55 Close of Summit

> The Bioprocessing Summit is one of the few "must-attend" industry events of the year. If you want to remain at the cutting edge of industry advancements, this is the place to be.
>
> *—Dr. Ben L., Black Diamond*

STREAM #5
GENE THERAPY

The **Gene Therapy** stream focuses on the critical challenges facing the analysis, characterization, quality control and manufacture of gene therapies for clinical and commercial supply, viral and non-viral-based. Split across two back-to-back tracks, Gene Therapy CMC and Analytics, and Gene Therapy Manufacturing, topics include product and process characterization, CMC, upstream development, molecular biology, potency assays, comparability, emerging analytical technologies, impurities, quality control, comparability, process development, purification, formulation, scale-up and commercial manufacturing.

Conference Programs

AUGUST 18-19

Gene Therapy CMC and Analytics

View Program »

AUGUST 20-21

Gene Therapy Manufacturing

View Program »

MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

COMMERCIALIZING AND INCREASING ACCESS TO GENE THERAPIES

9:40 Chairperson's Remarks
Susan D'Costa, PhD, CTO, Genezen

9:45 KEYNOTE PANEL DISCUSSION: Commercializing Gene Therapies: Balancing Innovation with Patient Access
Moderator: Susan D'Costa, PhD, CTO, Genezen
Panelists:
Jay Newman, Individual Consultant, Former Head, US Commercial, Spark Therapeutics
Phillip Ramsey, Senior Vice President, Technical Operations, Sangamo Therapeutics
Rachel Salzman, DVM, Founder, The Stop ALD Foundation; CEO, Armatus Bio

10:45 In-Room Networking Introductions

METHOD DEVELOPMENT AND VALIDATION OF AAV

11:00 Method Development and Validation of AAV
Veronica Bonazza, Quality Control Site Head, Sangamo
How the QbD approach is critical in developing and validating methods. Which are the common methods used in AAV Gene Therapy for releasing and stability of the clinical products, which ones are evaluated as Critical Attributes and Regulatory requirements? Which is the relationship between Analytical Development and Quality Control in developing robust methods for late phase approvals and which are the common issues at different stages?

11:30 Presentation to be Announced

11:45 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

GENE THERAPY POTENCY STRATEGIES

12:50 Chairperson's Remarks
Aisleen McColl-Carboni, PhD, Senior Director, Analytical Development, Sarepta

12:55 Gene Therapy Potency Methods: CMC Strategy, Development, Optimization, and Performance Monitoring
Lyndi Rice, PhD, Head, Gene Therapy Analytical Technologies, BioMarin
Potency is a critical quality attribute that can be difficult to measure via a robust analytical method. CMC strategies for development, optimization, and implementation will be discussed. Case studies will be used to demonstrate method validation and transfer strategies, including method remediation, method health and performance monitoring, and reference standard and assay control implementation and bridging.

1:25 Development of a Potency Assurance Strategy to Replace Functional Potency
Peter Z. Webster, Senior Scientist, Analytical Development, Solid Biosciences Inc.

1:55 Presentation to be Announced

REFERENCE STANDARDS AND RAW MATERIALS

2:25 United States Pharmacopeia Standards for AAV Testing
Anthony Blaszczyk, PhD, Senior Scientist, Global Biologics, US Pharmacopeia
Reference standards are a critical component for analytical method development, as they help ensure consistent method performance. Well-characterized gene therapy reference standards, specifically for adeno-associated virus (AAV), have been difficult to reliably source. The USP has recently developed reference materials that support AAV stakeholders from raw material qualification through product release, including AAV standards for empty/full assessment, capsid titer, genomic titer, residual plasmid quantification, endonuclease activity, and plasmid topology.

2:55 Characterisation of Vector Reference Standards: Orthogonal Methods
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.
Establishing the accuracy of a method for any new active substance is a challenge because *de facto* there is no established reference standard. The use of orthogonal methods (different measurement principle) helps to confirm a measured value is reliable. This talk will use some literature examples to discuss the challenges.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

CAPSID ANALYSIS TO DETERMINE STRUCTURE/ FUNCTION

7:55 Chairperson's Remarks
Xiaohui Lu, PhD, Director, Analytical Development, Ultragenyx Pharmaceutical

8:00 Structural Changes of AAV Based on Genome Content
Caryn L. Heldt, PhD, Professor, Chemical Engineering, Michigan Technological University
As the application of viral gene therapy matures, the quantification and analysis of empty and full AAV particles is also maturing. Using an atomic force microscope (AFM), we are studying the difference in capsid surface chemistry to help delineate an additional method to separate full and empty capsids besides anion exchange chromatography. Potential structural differences that explain these surface chemistry changes will be explored.

8:30 The Behavior of Modified AAV Capsids in CE-Based Techniques
Chelsey Mattison, Scientist, Novartis
Non-wild type AAVs are engineered AAVs that improve the targeting efficiency, safety, and specificity for therapeutic applications. The behavior of modified AAVs in CE-based techniques was investigated using labchip, CE-UV, and other techniques. The study revealed the presence of temperature-dependent aggregate peaks that failed to migrate according to their expected size. These anomalous migration patterns were observed across varying conditions, suggesting the resulting electropherogram contained artifact peaks.

9:00 Orthogonal Characterization for AAV Full/Empty and Particle Titer
Jin Park, PhD, Associate Director, Ultragenyx
Several analytical methods were evaluated to determine the level of DNA encapsulation in rAAV8, rAAV9, and HU37. The methods included SV-AUC (Sedimentation Velocity-Analytical Ultracentrifugation), Mass Photometry, SEC-MALS (Size-Exclusion Chromatography with Multi-Angle Light Scattering), CDMS (Charge Detection Mass Spectrometry, Waters), and ES-DMA (Electrospray-Differential Mobility Analysis, Nano Engineering). The advantages and limitations of each method will be discussed.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

11:30 Analytical Comparability Following Analytical and Process Changes
Santoshkumar L. Khatwani, PhD, Director, Analytical Development, Sangamo Therapeutics
This presentation outlines the development of AAV manufacturing processes and concurrent advancements in analytical methods. It highlights the crucial role of product characterization in ensuring analytical comparability and details a risk-based approach to demonstrate comparability through statistical analysis aligned with established acceptance criteria. These strategies are vital for maintaining consistent product quality, meeting regulatory standards, and supporting the effective development of AAV-based therapies.

ANALYTICAL STRATEGIES DURING LATE-STAGE DEVELOPMENT

12:00 pm PANEL DISCUSSION: Analytical Strategies for Late-Stage Candidates
Moderator: Xiaohui Lu, PhD, Director, Analytical Development, Ultragenyx Pharmaceutical
Panelists:
Lyndi Rice, PhD, Head, Gene Therapy Analytical Technologies, BioMarin
Aisleen McColl-Carboni, PhD, Senior Director, Analytical Development, Sarepta
Santoshkumar L. Khatwani, PhD, Director, Analytical Development, Sangamo Therapeutics

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

2:10 Chairperson's Remarks
DingJiang Dean Liu, PhD, Senior Director, Formulation Development, Regeneron Pharmaceuticals Inc.

NEXT-GENERATION SEQUENCING FOR VIRAL VECTORS

2:15 Development of NGS Method for rAAV Characterization
Esko A. Kautto, Bioinformatics Scientist II, Forge Biologics
High-quality rAAV products depend on rigorous assessment of genome integrity and sequence identity, from initial plasmid constructs to cGMP manufacturing. A long-read sequencing-based approach enables robust and adaptable characterization at multiple development stages, allowing early identification of plasmid irregularities and detection of problems with rAAV lots that could impact product safety or efficacy. This method supports proactive quality management throughout the development and manufacturing lifecycle.

DEGRADATION PATHWAYS FOR AAV

2:45 Insight into the Degradation Pathways of an AAV9
Chen Zhou, PhD, Principal Research Scientist, Biologics Drug Product Development, AbbVie Bioresearch Center
Recombinant AAV vectors are a favored option for *in vivo* gene therapy, currently involved in hundreds of clinical trials aimed at treating various genetic diseases. In an effort to develop formulations using a model AAV9 encoding GFP, we explored its degradation pathways under specific stressed conditions. This presentation will offer insights into the mechanisms responsible for the degradation and potency loss of AAV9.

3:15 Degradation Pathway of AAV

Jefferson S. Plegaria, PhD, Senior Scientist, Drug Product Development, Spark Therapeutics Inc.

Adeno-associated virus (AAV) is widely used in gene therapy, but its degradation mechanisms remain unclear. This study identifies two degradation pathways using capillary gel electrophoresis: encapsidated DNA degradation at acidic pH and DNA ejection at basic pH. Furthermore, potency loss strongly correlates with encapsidated DNA degradation rather than genome titer or full capsid percentage. These findings highlight the importance of maintaining DNA integrity in AAV-based gene therapy development and manufacturing.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

FORMULATION AND STABILITY FOR AAV

4:30 Development and Qualification of AAV Stability Indicating Methods

Wen Shi, PhD, Regeneron

To determine the stability of AAV drug substance and drug product, a comprehensive panel of analytical methods should be established and validated. We have investigated several novel analytical techniques for monitoring the percentage of full capsids and the sizing purity to support formulation research stability studies. These methods were qualified on a fit-for-purpose basis following ICH guidelines with additional forced degradation studies performed to determine the stability indicating capability.

5:00 Formulation and Stability

Jonathan Wert, Senior Scientist, Formulation Development, Regeneron Pharmaceuticals Inc.

AAV2 is widely used for gene therapy products treating ocular diseases, which require formulations with high vector genome (vg) titers due to limited injection volume. However, AAV2 showed low thermal stability and high propensity to aggregate. In this study, we systematically evaluated the impact of formulation components including pH, stabilizers, and surfactants. We successfully identified a formulation design space for achieving stable high titer AAV2 formulations suitable for preclinical studies.

5:30 Close of Gene Therapy CMC and Analytics Conference

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

OPTIMIZING VIRAL VECTOR PRODUCTION

7:55 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

8:00 Development of a Commercial Manufacturing Process for RGX-202, a Systemically Delivered AAV8 for the Treatment of Duchenne Muscular Dystrophy
Don Startt, Executive Director, Upstream Process Development and Project Development Lead, REGENXBIO Inc.
This presentation outlines the development of a commercial manufacturing process for RGX-202, a systemically delivered AAV8 vector targeting Duchenne Muscular Dystrophy. It will cover the scale-up from laboratory to commercial production, focusing on optimizing both upstream and downstream processes to ensure high yield, purity, and efficiency. Advances in downstream processing, including improvements in purification and recovery methods, will be discussed in the context of enhancing scalability and maintaining product consistency.

8:30 Innovations in Upstream Process Development and Optimization for Gene Therapy Manufacturing
Marissa Stanvick, Director, Upstream Viral Vector Product Development, Alexion, AstraZeneca Rare Disease

9:00 Advances in Gene Therapy Process Development
Shamik S. Sharma, PhD, Senior Director, Process Development, Voyager Therapeutics Inc.
To accelerate timelines post-candidate nomination, process development may commence prior to this milestone, sometimes on more than one candidate. In this presentation we share one such case study regarding process development for an AAV gene therapy using a novel capsid, that led to a successful manufacturing campaign. We will discuss team strategy while managing uncertainty along with lessons learned to accelerate manufacturing timelines.

9:30 Presentation to be Announced

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

PROCESS OPTIMIZATION AND COMPARABILITY

10:40 Upstream Process Optimization: Using Design of Experiments (DoE) to Create Scalable Manufacturing Processes and Improve rAAV Yields and Quality
Danielle Sexton, PhD, Associate Director, Process Development, Forge Biologics
Increasing yields is one of gene therapy's greatest challenges—and addressing this helps to make gene therapy more accessible to broader patient populations. This talk will explore strategies used to improve yield and the empty to full particle (E/F) ratio by leveraging design of experiments (DoE) to systematically evaluate transfection parameters including total DNA, plasmid ratios, complexation time, transfection reagent, and enhancers.

11:10 The Impact of CQAs' Determination on Successful Manufacturing
Nesredin A. Mussa, PhD, President, Dynamica Biologics
Critical Quality Attributes (CQAs) are key characteristics of a drug product that must be maintained within specified limits to ensure the product's safety, efficacy, and quality. Appropriate CQAs set the tone of manufacturing development. We discuss the role and significance of CQAs in robust manufacturing development for gene therapy. By testing appropriate CQAs early in the development process, the risk of unexpected quality issues and potential safety incidences are reduced.

11:40 KEYNOTE PRESENTATION: Comparability Studies Following Process Change
Scott A. Jeffers, PhD, CTO, Gensight Biologics
Comparability studies for gene therapy manufacturing are critical when process or CDMO changes occur. These studies require comprehensive analytical characterization to demonstrate product equivalence across critical quality attributes, including physicochemical properties, biological potency, and vector integrity. Regulatory agencies primarily evaluate substantial scientific evidence to ensure no clinically meaningful differences emerge.

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

INCREASING YIELD

1:25 Chairperson's Remarks
Seth Levy, PhD, Director, Bioprocess Development, Modalis Therapeutics

1:30 Optimizing Producer Cell Line Performance through High-Throughput Screening Techniques
Amit Mathur, PhD, Senior Scientist, Genomic Medicine Unit, Sanofi
This presentation will discuss the application of high-throughput screening in generation-of-producer cell lines for AAV production at Sanofi. It will highlight the technologies which contribute to building a robust and efficient producer cell line generation platform, improving throughput, reproducibility, and scalability.

2:00 Process Development for Complementing Suspension-Adapted A549 Cell Line for High Titer RCA-Free Adenoviral Vector
Martin Loignon, PhD, Team Leader, Cell Engineering, National Research Council Canada
Adenovirus is one attractive viral vector for gene therapy and therapeutic vaccines. We have engineered A-549 adenoviral vector complementing cells for the production of E1-deleted adenoviral vectors and developed bioprocesses in cell suspension yielding free of replication-competent adenovirus. We have tested several production modes and increased initial titers in batch mode from mid 109 vp/mL up to 7,0 x 1010vp/mL in a bioreactor perfusion culture at the 3 L scale.

2:30 Integrated AAV Capture and Polishing via ChromaTan BioRMB—A Continuous, Column-Free Chromatography Platform

Oleg Shinkazh, Founder & CEO, ChromaTan Inc
BioRMB is a column-free steady-state purification platform tailored for sensitive modalities such as gene therapies, vaccines, mRNA, and antibody constructs. In this work we will present capture purification data for two AAV serotypes, as well as preliminary findings on a novel real-time PAT technique. This PAT application will monitor AAV whole capsid titer and empty-full ratio analysis by integrating Real-Time Multi Angle Light Scattering (rtMALS) into BioRMB continuous purification.

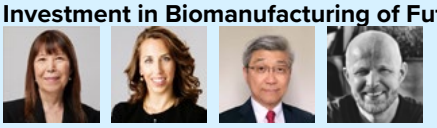
3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

FORMULATRIX®

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
What are the technologies and innovations shaping the future of biomanufacturing in 2025 and beyond? Join us for an engaging plenary panel discussion on "Innovation and Investment in Biomanufacturing of Future Medicine," where leading experts from the investment and strategies community will explore upcoming trends, investment opportunities, and modalities into the next decade. How should the industry best prepare?
Panelists:
Daniella Kranjac, Founding General Partner, Avant Bio LLC
David Y. H. Chang, CEO, Taiwan Bio-Manufacturing Company (TBMC)
Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

ADVANCES IN VIRAL VECTOR PRODUCTION

7:55 Chairperson's Remarks
Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics

8:00 CRISPR Screen Reveals Modifiers of rAAV Production
Emily O'Driscoll, Student, Shalem Lab, Raymond G. Perelman Center for Cellular and Molecular Therapeutics, The Children's Hospital of Philadelphia
We performed a genome-wide CRISPR-based knockout screen to identify genes that can be targeted in human embryonic kidney (HEK) 293 producer cells to modulate rAAV production. We discovered that the knockout of a group of heparan sulfate biosynthesis genes previously implicated in rAAV infectivity decreased rAAV production. Additionally, we identified several vesicular trafficking proteins for which knockout in HEK 293 cells increased rAAV yields.

8:30 Elucidating Key Factors Impacting the Robustness of Cell Revival from Cryopreservation
Connor Shank, Senior Research Associate I, GT Research & Tech Ops, Ultragenyx Pharmaceutical Inc.
Cryopreservation is an essential part of cell-based biomanufacturing. At Ultragenyx, we utilize HeLa cell lines to produce recombinant AAV gene therapy products. We observed several MCB and WCB with poor thaw recovery (viability % and cell density) and initiated an investigation of cell-banking, transfer & handling, and thawing procedures. Cell banking density, freeze/thaw cycles, media, and transfer durations, amongst other factors, were shown to have significant impact on thaw recovery.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

DOWNSTREAM PROCESSING OF VIRAL VECTORS

10:30 Downstream Process Optimization and Scale-Up for rAAV Production
Keerthana Subramanian, Senior Scientist, Process Development, Forge Biologics
Efficient purification processes are needed for the increasing number of recombinant adeno-associated virus (rAAV) therapies. Impurities such as host cell proteins and empty capsids copurify with rAAV and should be reduced during manufacturing. Optimization strategies in downstream purification and supporting data for improved vector purity and recovery will be presented in this talk. The process ensures production of high-quality rAAV for clinical use and is scalable from 1L to 1000L.

11:00 AAV Polishing Technology Development
Jessica Chia-Yun Sun, PhD, Senior Director, AAV Downstream Development, Alexion Pharmaceuticals Inc.
This presentation will focus on the latest advancements in AAV polishing technology, crucial for enhancing the purity and potency of adeno-associated virus (AAV) vectors used in gene therapy. It will cover innovative methods for downstream processing, including chromatography and filtration techniques that effectively remove impurities and improve vector yield. The session will also discuss the impact of these technologies on the overall quality and scalability of AAV production.

11:30 Downstream Platform Processes across HEK Transfection and Pinnacle PCL—Challenges and Considerations
Mukesh Mayani, PhD, P.Eng, Senior Director, Purification Development at Global CMC Development, Ultragenyx Gene Therapy
This presentation explores the downstream platform process across HEK transfection and Pinnacle PCL cell line platforms, focusing on key differences in process for AAV vector manufacturing. We will discuss purification process differences, impurity removal, and viral clearance strategy for reproducible vector manufacturing intended for clinical and commercial use. Key considerations to address challenges will be discussed, offering insights for advancing AAV GT vector manufacturing.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

DOWNSTREAM PROCESSING OF VIRAL VECTORS

1:05 Chairperson's Remarks
Meisam Bakhshayeshi, PhD, Senior Director, Process Development, Obsidian Therapeutics

1:10 Virus Filtration Development for Adeno-Associated Virus-Based Gene Therapy Products
Namila Fnu, PhD, Scientist, Downstream Process Development, Spark Therapeutics Inc.
This talk will address the unique challenges in developing effective virus filtration strategies for rAAV gene therapy products. We'll examine the role of virus filtration in enhancing viral clearance robustness and its increasing regulatory emphasis in AAV manufacturing. Key topics include evaluating commercially available virus filters for AAV manufacturing, assessing their throughput and process yield, and demonstrating robust clearance of model viruses like Adenovirus type 5 and Simian virus 40.

1:40 Challenges and Process Development for Purification of Gene Therapy Vector AAV
Xue Mi, PhD, Senior Scientist I, Purification Process Development, Abbvie Bioresearch Center
Adeno-associated virus (AAV) is highly inefficient at packaging its genome, with up to 90% of the formed AAV capsids being empty. The upstream process requires cell lysis to achieve a manufacturable viral titer, which generates significantly more impurity burdens than the therapeutic protein production process. A purification process involving harvest clarification, ultrafiltration/diafiltration, affinity chromatography for AAV capture, and anion exchange chromatography for AAV polishing was developed for different serotypes.

2:10 Development of a Universal and Scalable Adeno-Associated Virus Capture Step Using Steric Exclusion Chromatography
Juan Carlos Rosario, PhD, Senior Principal Scientist, Purification & Virology Development, Eli Lilly & Company
Adeno-associated viruses (AAV) are among the leading vectors for gene therapy. The purification of AAV remains a bottleneck as it typically requires multiple individual process steps, often resulting in product loss and high costs. Current downstream processes are usually serotype-specific and rely primarily on expensive affinity resins. To address these limitations, we developed a serotype-independent capture method using steric exclusion chromatography that can be combined with a subsequent empty separation step.

2:40 Networking Refreshment Break and Transition into Town Hall Discussion

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 Facilitated Town Hall Discussion
This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?
Lori Ellis, Head of Insights, BioSpace

3:55 Close of Summit

> 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*

STREAM #6
CELL THERAPY

The **Cell Therapy** stream explores the critical challenges facing the manufacture, analysis and quality of cell-based therapies across clinical and commercial development. Featuring two back-to-back conferences, Cell Therapy CMC and Analytics, and Cell Therapy Manufacturing, topics include product and process characterization, CMC strategies, decentralized manufacturing, autologous and allogeneic manufacturing strategies, automation, the role of AI, scale-up and supply of CAR Ts and next-generation cell therapies such as NK cells, TILs, iPSCs, gamma deltas, and TCR-based therapies.

Conference Programs

AUGUST 18-19

Cell Therapy CMC and Analytics

View Program »

AUGUST 20-21

Cell Therapy Manufacturing

View Program »

MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

CMC STRATEGIES AND STANDARDS FOR CELL THERAPIES

9:40 Chairperson's Remarks
Scott R. Burger, Principal, Advanced Cell & Gene Therapy LLC

9:45 Standards and Reference Materials to Support Cell-Therapy Characterization and Testing
Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology
Cellular therapy products (CTPs) require high quality, robust, and validated analytical methods. In recent years, several NIST-led ISO standards have been developed that address common testing needs for CTPs including cell characterization and count—and current efforts aim to develop a cell viability standard. Here, we describe the recently published and upcoming standards and the cell-counting COMET application, and give practical examples for the development of fit-for-purpose analytical methods.

10:15 Raw Material Considerations for Cell Therapies
Diana Colleluori, PhD, MBA, Principal CMC Consultant, CMC Analytical, Biologics Consulting Group
The development of a robust manufacturing process for cell therapy products is a difficult strategy to navigate during the early stages. With the development of a solid manufacturing process comes the use of many raw materials to take your starting materials through to drug products. Common challenges and considerations will be discussed for assuring a successful manufacturing process that aligns with regulatory expectations.

10:45 In-Room Networking Introductions

11:00 Qualifying and Validating Cell Counting and Viability Methods: Practical Considerations
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.
This presentation will discuss various types of method qualifications, beginning with the exploratory work needed to refine validation strategies. It will cover the execution of qualification studies that validate and fine-tune these approaches, followed by the practical implementation of the methods. The discussion will conclude with best practices for accurately reporting the results, ensuring compliance and reliability in the application of these methods.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

RAPID STERILITY TESTING AND NOVEL ANALYTICAL TECHNOLOGIES

12:50 Chairperson's Remarks
William E. Janssen, PhD, Principal, WEJ Cell & Gene Therapy Consulting Services LLC

12:55 KEYNOTE PRESENTATION: USP's Evolving Position on the Use of Rapid Microbial Methods for the Detection of Microbiological Contamination
Huiping Tu, PhD, Senior Principal Scientist, Microbiology, Global Biologics, USP
The classic microbial tests are unsuitable for products with a short life, limited supply, and urgent needs, and which may be infused into patients before the completion of the test. RMMs as alternative to compendial methods has the advantage of reduced testing time, advanced technologies and possible automation, increased sensitivity, and accuracy. In this presentation we will share with you USP's evolving position on use of RMMs.

1:25 Rapid Sterility Testing
Scott R. Burger, Principal, Advanced Cell & Gene Therapy LLC
Automated blood culture and PCR-based methods have marked limitations for rapid sterility testing of CGT products. This presentation will discuss novel rapid sterility testing technologies, including a matrix-independent method capable of detecting microbial growth and identifying even slowest-growing bacteria and fungi in <72 hours, and most species within 24 hours, with high sensitivity (LOD <5 CFU) even in the presence of high cell concentrations.

1:55 Sponsored Presentation *(Opportunity Available)*

2:25 Flow Cytometry QC
Ruud Hulspas, PhD, Technical Director, Process Development, Dana-Farber Cancer Institute
Flow cytometry has become an essential tool in QC of advanced cell therapies while challenges in reproducibility remain. These challenges do not solely reside in laboratory-designed assays but instrument setup, qualification, and standardization still hold obstacles to overcome. We address a number of these challenges and obstacles within the context of the latest CLSI guidelines on Validation of Assays Performed by Flow Cytometry.

2:55 Statistical Considerations for Development and Validation of Novel Analytical Methods
William E. Janssen, PhD, Principal, WEJ Cell & Gene Therapy Consulting Services LLC
Analytics are essential parts of CGT CMC design. Analytic methods must demonstrate product sterility, identity, strength, and purity. Quality attributes for analytic methods require high specificity for the product, low limits of detection for impurities and contaminants, and high accuracy and precision. Validation of analytics must demonstrate consistent reproducibility. This requires sufficient repeated measures using consistent controls followed by statistical analysis to document confidence intervals for each analytic method.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies

Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

POTENCY ASSAYS FOR CELL THERAPIES

7:55 Chairperson's Remarks
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.

8:00 Enhancing Potency-Assay Strategy for CGT
Kelly Bowen, PhD, Senior Scientist, Analytical and Process Development, KSQ Therapeutics Inc.
The potency pathway for cell therapy includes developing assays early, tech transfer to QC, and lifecycle management. Regulatory agencies promote a risk-based approach for potency assay development. This presentation outlines key strategies for developing robust and accurate potency assays that meet regulatory standards, such as defining potential potency-related attributes from the start and implementing strong QC measures to ensure consistent therapeutic performance.

8:30 Potency-Assay Development: Evolution of Assay Design to Correspond with an Evolving Product
Christopher Rold, PhD, Vice President, Vector Development and Quality Control, Adicet Bio
Designing potency assays in early stages of product development poses multiple challenges. An unclear idea of the product's mechanism of action, inevitable changes in manufacturing during development and scale-up, assay format, choice of product attribute for readout, choice of method for data interpretation—these hurdles will arise with program advancement. How should developers approach potency assay and assurance strategy development in a manner that will evolve with the product?

9:00 Development and Standardization of Cell-Based Potency Assays for Product Characterization
Helen Sarantis, PhD, Associate Director, A&QC, BlueRock Therapeutics
Cell-based assays are commonly used to characterize cell therapy products, typically as part of a potency matrix approach. While these assays provide useful and often critical information about product functional attributes, they come with challenges including variability across operators, reagent lots, instruments, and laboratories. This presentation will focus on elements to consider when designing cell-based potency assays and relevant performance assessments, in order to support clinical product understanding.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

NEXT-GEN ANALYTICS FOR CELL THERAPIES

11:30 CMC Strategies for TCR-T Cell Therapies
Kim (Qiaoqiao) Shi, PhD, Principal Scientist, Assay Development, Affini-T Therapeutics Inc.

12:00 pm Enhancing Cell-Therapy Development: The Role of Characterization Assays in Production and Product Understanding
Jie Wei, PhD, Director, Bioanalytical Sciences, tr1x Bio
This presentation will explore the critical role of characterization assays in the development of cell therapies. It will discuss how these assays enhance understanding of product attributes and production processes, leading to improved therapeutic efficacy and safety.

12:30 Using Immunoprecipitation and Mass-Spectrometry to Analyze Cell-Surface Proteins
Nicolle Serrano SantoDomingo, Senior Scientist, Novartis
Analyzing surface proteins reveals therapeutic insights, yet their small presence in cell proteomes poses challenges. Workflows targeting surface proteins could revolutionize cancer immunotherapy. CAR T cells connect the immune system to tumors by recognizing cancer antigens. Despite similar expression levels, CAR constructs exhibit differences. Developing methods to characterize CAR-associated proteins and PTMs is crucial. Our approach involves immunoprecipitation of the CAR from cell surfaces followed by LC-MS analysis to provide insights.

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

LIPID NANOPARTICLES FOR *IN VIVO* ENGINEERING AND DELIVERY

2:10 Chairperson's Remarks
Bo Yan, PhD, Director, Analytical Research & Development, Beam Therapeutics

2:15 Physiochemical and Biophysical Characterization of Base Editing Drug Substances and Drug Products
Bo Yan, PhD, Director, Analytical Research & Development, Beam Therapeutics
Base editing *ex vivo* and *in vivo* therapies has emerged as a groundbreaking approach with the potential to offer curative solutions for unmet medical needs. I will summarize the contributions of analytical tools in the development of cell- and gene-editing therapy with base-editing technology. I will highlight phase-appropriate considerations for characterization assays and GMP QC release assays for novel modalities (i.e., gRNA, mRNA, lipid nanoparticles, and edited cells).

2:45 CMC Challenges for Prime-Edited Therapies

Luis Santos, PhD, Senior Director, Non-Viral Delivery, mRNA & LNP Product Development, Prime Medicine Inc.

This presentation will address the unique chemistry, manufacturing, and controls (CMC) challenges associated with prime-edited therapies. It will explore the intricacies of developing and scaling up prime editing platforms, focusing on aspects such as product design, delivery systems, and manufacturing processes. The session will also discuss regulatory hurdles, strategies for ensuring product consistency and purity, and the critical role of CMC in advancing prime-edited therapies towards clinical application.

3:15 Advances in Lipid Nanoparticles Analytics

Wei-Chiang Chen, PhD, Associate Director, BioProcess Analytics, Genomic Medicine Unit, Sanofi

This presentation will explore the latest advancements in the analytical methods used to evaluate lipid nanoparticles (LNPs). It will cover a range of cutting-edge techniques that improve the characterization and understanding of LNPs, focusing on their application in drug-delivery systems. Key topics will include the development of more precise and efficient analytical tools, their impact on quality control, and their role in enhancing the overall development process of LNPs.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

NEXT-GENERATION SEQUENCING FOR EXTENDED CHARACTERIZATION

4:30 Next-Generation Sequencing (NGS) for Extended Characterization of Cell Therapies: Enhancing Product and Process Characterization

Wenjie Yao, PhD, Staff Scientist, Cell Therapy Analytical Development, Bayer US LLC

This presentation will discuss the application of Next-Generation Sequencing (NGS) in the extended characterization of cell therapies. It will focus on how NGS technologies enhance both product and process understanding, providing detailed insights into genetic stability, cell purity, and function. The session will highlight the benefits of NGS in ensuring product consistency and optimizing manufacturing processes, thereby advancing the development and effectiveness of cell-based therapies.

IABS FOCUS SESSION: NEXT-GENERATION SEQUENCING FOR ADVENTITIOUS AGENT TESTING

5:00 Implementing NGS for Adventitious Agent Testing for Biotherapeutics and Advanced Therapies

Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.

Ben Clarke, PhD, Senior Scientist, USP

This session will discuss the implementation of next-generation sequencing (NGS) for adventitious agent testing for biotherapeutics and advanced therapies, based on the latest work from the International Alliance for Biological Standardization (IABS). It will cover the advantages of NGS over traditional methods, including its sensitivity, specificity, and ability to detect a broad range of contaminants.

5:30 Close of Cell Therapy CMC and Analytics Conference

> 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*

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

COMMERCIALIZING CELL THERAPIES

7:55 Chairperson's Remarks
Zhimei Du, PhD, CSO, BlueSphere Bio

8:00 Meeting the Challenge of Manufacturing at Scale, Cost-Effectively, and Consistently: Case Studies
Michael Orrico, Executive in Residence, Commercialization Strategy, Advanced Regenerative Manufacturing Institute ARMI
The Advanced Regenerative Manufacturing Institute's (ARMI) mission is to advance cell- & tissue-based therapy manufacturing to be scalable, affordable, and accessible for patients. ARMI will present its progress and that of its members in overcoming the overlooked challenges of scalability and cost-efficiency that have perennially limited commercialization. Presentation will include case studies from actual production of cell therapy products in a GMP-compliant environment including cost-effectiveness, process repeatability, and control strategies.

8:30 KEYNOTE PRESENTATION: Considerations for Process Development (CAR T Drug Product and Lentiviral Vector) in Autologous Cell Therapy for Commercial Manufacturing
Ravi Bhatia, Scientific Director, Cell Technology, Johnson & Johnson Pharmaceutical R&D
The commercial success of an autologous cell therapy product is intricately linked to a robust manufacturing process. This presentation will delve into the considerations for CAR T drug product and lentiviral-vector process development, focusing on ensuring process control, managing costs of goods sold (COGs), and achieving scalability to meet commercial demand.

9:00 FEATURED PRESENTATION: Developing First-in-Class Allogeneic off-the-Shelf TCR-T
Zhimei Du, PhD, CSO, BlueSphere Bio
TCR-T cell therapy offers high target specificity with reduced toxicity compared to mAbs and CAR T. However, its autologous nature poses significant challenges in scalability, cost, and accessibility. Converting TCR-T to an allogeneic process presents additional complexities. This presentation examines key hurdles in developing allogeneic TCR-T therapies and explores strategies to overcome manufacturing and commercialization barriers, ultimately expanding patient access and the therapeutic potential of TCR-based immunotherapies.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

FROM BENCHSIDE TO PATIENT, POINT-OF-CARE MANUFACTURING

10:40 Translation of Novel Cell Therapies from Bench to Clinical Trial
Carolyn M. Lutzko, PhD, Scientific Director, Dana-Farber Cancer Institute
This presentation will examine the translation of novel cell therapies from laboratory research to clinical trials. It will focus on key phases including process optimization, scale-up challenges, and regulatory compliance. The discussion will emphasize the critical steps involved in moving from experimental protocols to standardized clinical applications, ensuring safety and efficacy.

11:10 Translating Cell Therapies from Academia to GMP
Stephen Sawyer, PhD, Associate Professor, Wake Forest Institute for Regenerative Medicine, Wake Forest University School of Medicine
This presentation will discuss the transition of cell therapies from academic research to Good Manufacturing Practice (GMP) compliant production. It will cover critical aspects such as process standardization, scalability, and compliance with regulatory frameworks. The session will emphasize the importance of integrating quality assurance throughout development to meet GMP standards. Strategies for effective collaboration between academic institutions and manufacturing facilities to ensure smooth translation will also be explored.

POINT-OF-CARE MANUFACTURING

11:40 Point-of-Care Manufacturing: Challenges and Benefits
Yongping Wang, MD, PhD, Director, Cell Based Therapy Lab, Children's Hospital of Philadelphia
Point-of-Care (POC) manufacturing carries substantial challenges for academic hospitals but also tremendous benefits. Initial investments include not only expensive cGMP infrastructure but also highly trained staff and sophisticated analytical capabilities. Once overcome, however, POC manufacturing simplifies logistics, reduces cost, and most importantly, increases access for patients, which should be the ultimate goal for these exciting, novel therapies. Regulatory advances can also help democratize this approach.

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

REDUCING COSTS IN CELL-THERAPY MANUFACTURING

1:25 Chairperson's Remarks
Michael Orrico, Executive in Residence, Commercialization Strategy, Advanced Regenerative Manufacturing Institute ARMI

1:30 From Manual to Machine: The Shifting Landscape of Cell-Therapy Automation
Peter Walters, Fellow of Advanced Therapies, CRB
As cell therapy scales, automation remains both a challenge and a necessity. This presentation explores the evolving strategies used to streamline manufacturing, from modular systems to fully integrated platforms. Attendees will gain insight into the diverse approaches taken, key hurdles faced, and how automation may shape the future of this rapidly growing field.

2:00 Efficient Technology Transfer of Cell Therapies
Sean Marnane, Director, External Manufacturing and MSAT, Be Biopharma Inc.
Through precision engineering, we can create B cells designed to produce specific therapeutic proteins needed for a specific disease. Engineered B cells are expanded and then, by changing culture conditions, they are differentiated into plasma cells that secrete the desired therapeutic protein. All of these steps have been optimized for scale-up and clinical manufacturing. This talk will detail some of the tech-transfer challenges involved in working with these therapies.

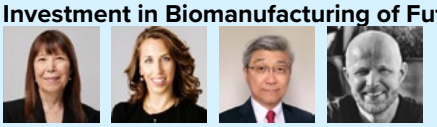
2:30 Presentation to be Announced

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
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Panelists:
Daniella Kranjac, Founding General Partner, Avant Bio LLC
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Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

LATEST MARKET TRENDS AND REGULATIONS

7:55 Chairperson's Remarks
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.

8:00 Cell & Gene-Therapy Manufacturing Demand: Forecasting in an Uncertain Landscape
Michael D. Jacobson, PhD, Managing Partner, Cambridge Biostrategy Associates LLC
We developed a comprehensive and detailed bottom-up model to forecast therapeutic cell, vector, and nucleic acid manufacturing demand in cell and gene therapy for clinical-trial and commercial-production markets. Using global pipeline data, historical trends, probability weighted phase-progression, and disease epidemiology in major markets, our model predicts industry trends and accounts for uncertainty by modeling outcomes under different scenarios and assumptions.

8:30 FDA Updates: Frequently Asked Questions—Developing Potential Cellular and Gene Therapy Products
Scott R. Burger, Principal, Advanced Cell & Gene Therapy LLC
This presentation will summarize CGT-related FDA guidance documents released over the last year. These include a draft guidance on "Frequently Asked Questions—Developing Potential Cellular and Gene Therapy Products," which features FDA's answers to 36 questions about interactions with FDA, and CMC, nonclinical, and clinical aspects of product development. Six January 2025 guidance documents on reducing risk of transmission of infectious diseases will also be discussed.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

OPTIMIZING IPSC MANUFACTURING

10:30 Cell-Therapy Product Manufacturing Considerations
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.
Cell-based products are defined as autologous, allogeneic, or xenogeneic cells that have been expanded, selected, or otherwise altered in biological characteristics *ex vivo*. Due to the complexity of these therapies, the reproducible and consistent manufacturing of cell-based products remains challenging. I will provide insight to address common manufacturing challenges that include phase-appropriate product and process development focusing on key principles of CGMPs, QbD approach, and risk assessment.

11:00 Addressing cGMP Bottlenecks in Unmodified and Genetically Modified Cell-Therapy Manufacturing to Accelerate Clinical Translation
Dhruv Sareen, PhD, Executive Director of the Biomanufacturing Center, Cedars-Sinai Medical Center; Director, iPSC Core; Associate Professor, Board of Governors Regenerative Medicine Institute (BOG-RMI)

11:30 Navigating Bioprocessing Hurdles in a PSC-Derived NK Cell Production Platform
Allen Qiang Feng, PhD, Founder and CSO, HebeCell Corp.
HebeCell's proprietary protoNK platform is a first-in-class scalable technology for manufacturing PSC-NK cells. PSC-derived cell products are often made in small batch sizes. NK cells are notoriously sensitive to cryopreservation. The final product has a short shelf life. These presented significant challenges to the bioprocessing. In my presentation, I will highlight our solutions to address these challenges and produce NKs with cytotoxic potency to achieve better clinical outcome.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

1:05 Chairperson's Remarks
Dominic Clarke, Vice President of Technical Operations, IntegriCell; PDM Committee Chair, ISCT

1:10 Towards Industry 4.0: Development of a Smart Bioprocessing Platform for Autologous Cell Therapy
Patrick Statham, PhD, Bioprocessing Scientist, Technology & Process Innovation, Cell & Gene Therapy Catapult
Using a TIL manufacturing process as a model, we adapted a static baseline process into a dynamic system capable of integration with analytical soft sensors such as Raman spectroscopy. Metabolomic profiling of spent media identified ~50 metabolites with a significant effect on cell expansion; these were investigated in a large DoE, the results of which provide an improved understanding of these CPP effects on cell expansion and T cell reactivity.

SPECIAL ISCT SESSION: PAT AND AI/ML TO SUPPORT CELL THERAPY MANUFACTURING

1:40 **PANEL DISCUSSION: ISCT Focus Session: PAT and AI/ML to Support Cell-Therapy Manufacturing**
Moderator: Dominic Clarke, Vice President of Technical Operations, IntegriCell; PDM Committee Chair, ISCT
Panelists:
Dalip Sethi, PhD, Co-Chair, PAAD Working Group, ISCT, and Cell Therapy Technologies & North America, Terumo BCT Inc.
Shannon Eaker, PhD, Member, PAAD Working Group, ISCT; CTO, Xcell Biosciences
Renee A. Hart, Member, PAAD Working Group, ISCT; President, LumaCyte

2:40 **Networking Refreshment Break and Transition into Town Hall Discussion**

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 **Facilitated Town Hall Discussion**
This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?
Lori Ellis, Head of Insights, BioSpace

3:55 **Close of Summit**

STREAM #7
RNA AND GENETIC MEDICINES

RNA and genetic medicines have undergone transformative evolution in recent years following major advancements in LNPs, mRNA, oligonucleotides, viral vectors, and a trend towards in vivo engineering and delivery. The **RNA and Genetic Medicines** stream delves into the technical challenges associated with bringing these innovative technologies from early-stage development to commercial success. Topics include CMC strategies, raw materials, platform development, analytical support, purity and quality control, plus scalable approaches to production, purification, formulation, and delivery. Be prepared for the next generation of biotherapeutics.

Conference Programs

AUGUST 18-19

RNA Development, CMC & Manufacturing

View Program »

AUGUST 20-21

Gene Therapy Manufacturing

View Program »

RNA Development, CMC, and Manufacturing

Analyzing, Scaling and Delivering RNA Medicines Using High-Quality Lipid Nanoparticles

AUGUST 18-19
All Times EDT

MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

CMC AND ANALYTICS OF RNA-BASED MEDICINES

9:40 Chairperson's Remarks
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant, Y-Chem Consulting LLC

9:45 Quality of Materials for RNA-Based Products
Mo Heidaran, PhD, Chief Regulatory Scientist, Cellx Inc.
RNA-based products are revolutionizing the field of advanced therapies, including the development of prophylactic vaccines, cancer vaccines, and genome-editing products. In this presentation, I briefly introduce various product types under investigation and provide guidance on the quality of materials used in the manufacturing of different product classes.

10:15 Impurities—Process Controls and Ensuring Quality
Sarita Kattel, PhD, Principal Scientist, US Pharmacopeia
The quality and purity of mRNA are critical for vaccine and therapeutic safety. As new technologies emerge, bridging analytical methods, especially in impurity detection, remains challenging. Comprehensive characterization is essential for identifying impurities like dsRNA and residual DNA. USP is developing documentary and physical standards which support the mRNA product lifecycle. This presentation explores evolving mRNA analytics and opportunities to enhance impurity detection and improve product reliability.

10:45 In-Room Networking Introductions

11:00 Analytical Testing of Self-Amplifying mRNA for Regulatory CMC Submissions
Rohit Mahajan, PhD, Vice President, Head of Analytical Development and Quality Control, Arcturus Therapeutics Inc.
This presentation will delve into the analytical testing methodologies critical for the regulatory CMC submissions of self-amplifying mRNA therapies. It will cover the development of robust analytical strategies to assess the quality, potency, and stability of these mRNA constructs. Key challenges such as assay validation, sensitivity optimization, and meeting regulatory standards will be discussed, alongside case studies highlighting successful CMC documentation for approval processes.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

QUALITY AND CONTROL OF GENOMIC MEDICINES

12:50 Chairperson's Remarks
Lawrence C. Thompson, PhD, Associate Research Fellow, Analytical R&D, Pfizer Inc.

12:55 Hollistic Analytical Control Strategy for mRNA Therapeutics
Siddharth Bhoraskar, PhD, Senior Scientist, Beam Therapeutics

1:25 Novel Lipid Excipient Strategies for mRNA Lipid Nanoparticles
Roger H. Pak, PhD, Research Fellow, BTx Pharm R&D, Pfizer Inc.
Lipid nanoparticle (LNP) technology for mRNA delivery has gained much interest in recent years. These LNPs are typically formulated with lipids that may be categorized as non-compendial novel excipients in regulatory filings. The chemistry, manufacturing, and controls (CMC) challenges to developing these novel lipid excipients—and strategies to address them—will be discussed in this presentation.

1:55 Sponsored Presentation *(Opportunity Available)*

2:25 CMC Challenges and Opportunities in Gene Editing: Navigating Cost, Scale, and Innovation
Christopher Ladd Effio, PhD, Director, Gene Editing CMC, Ionis Pharmaceuticals Inc.
Gene editing therapeutics face unique CMC challenges, from raw material sourcing to scalable, cost-effective manufacturing. This talk explores key CMC considerations, comparing gene editing to oligonucleotide therapies. Topics include manufacturing challenges for pDNA, mRNA, and LNPs, analytical hurdles in mRNA, gRNA, and LNP characterization, and strategies for outsourcing, tech transfer, and CDMO engagement, focusing on integrating innovation with practical manufacturing solutions.

2:55 PANEL DISCUSSION: Platform Development, CMC Strategies, and Raw Materials
Moderator: Lawrence C. Thompson, PhD, Associate Research Fellow, Analytical R&D, Pfizer Inc.
Panelists:
Rohit Mahajan, PhD, Vice President, Head of Analytical Development and Quality Control, Arcturus Therapeutics Inc.
Luis Santos, PhD, Senior Director, Non-Viral Delivery, mRNA & LNP Product Development, Prime Medicine Inc.
Marie Lea Berkowitz, Manager, GCMC Vaccines Regulatory Affairs, Pfizer Inc.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

PROCESS DEVELOPMENT AND PURIFICATION

7:55 Chairperson's Remarks
Craig Martin, PhD, Professor, Chemistry, University of Massachusetts, Amherst

8:00 Purification of mRNA and How AI Can Accelerate Process Development
Carme Pons Royo, PhD, Postdoctoral Associate, Massachusetts Institute of Technology
mRNA-based therapeutics are advancing, but downstream processing remains challenging due to low yields and high costs. We present an integrated, continuous manufacturing process for mRNA purification using precipitation-based methods, followed by continuous flow filtration. In these processes, the 3D structure of precipitates is crucial for recovery and dissolution. To address this, we introduce an AI-driven high-throughput image analysis system to screen and characterize precipitates and precipitation conditions, optimizing filterability.

8:30 A Scalable Continuous-Flow RNA Manufacturing Platform Using Functionally Co-Immobilized Enzyme and DNA
Craig Martin, PhD, Professor, Chemistry, University of Massachusetts, Amherst
Current RNA manufacturing generates dsRNA impurities that must be removed, along with enzyme(s) and DNA, in purification. Functional co-immobilization of enzyme and DNA to a solid support prevents the formation of dsRNA, and eliminates costly purification. This allows a single-use chip, continuous flow reactor from NTPs to highly pure RNA of any length. New analytics allow for real-time quality and yield optimizations in long continuous production runs at all scales.

9:00 KEYNOTE PRESENTATION: Tailoring mRNA Processes and Purification for Diverse Applications
Qian Ruan, PhD, Senior Vice President, Tech Operations and Manufacturing, Arcturus Therapeutics, Inc.
The rapid development of COVID vaccines has established a foundation for mRNA assay and process development, GMP production, and path for commercialization. Companies are now expanding mRNA technology to therapeutic applications, including personalized cancer vaccines. While the unit operations for mRNA development are similar, the Fit-for-Purpose scaling can greatly affect outcomes. This presentation will explore how to tailor processes for various applications with mRNA technology.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

10:45 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

OLIGONUCLEOTIDES, SIRNAs

11:30 Preparation of Anti-Sense Oligonucleotide (ASO) via Hybrid Synthesis
Jiabao Zhang, PhD, Scientist I, Biogen
ASO Hybrid Synthesis Strategy was developed as new ASO preparation platform which was enabled by novel resin. With this approach, protected oligonucleotide fragments are prepared through solid-phase synthesis followed by liquid-phase synthesis assembly. The Hybrid ASO Synthesis Strategy reduces LPOS production cycle time significantly and facilitates the use of LPOS material to support early-stage clinical studies.

12:00 pm Synthesis of Linear DNA Using a Programmable PCR via Flow Chemistry
Hyungseok Kim, PhD, Postdoctoral Associate, Massachusetts Institute of Technology
In vitro transcription is an RNA synthesis step used in non-viral gene therapy, including mRNA or CRISPR gRNA, where linearized DNA serves as a template for the enzymatic reaction. Conventional methods for preparing the DNA template have required large-scale microbial cultivation, plasmid purification, and linearization using additional restriction enzymes. In this talk, we present a novel method for DNA preparation using continuous, programmable PCR amplification enabled by flow chemistry.

12:30 Sponsored Presentation *(Opportunity Available)*

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

LIPID NANOPARTICLES FOR *IN VIVO* ENGINEERING AND DELIVERY

2:10 Chairperson's Remarks
Bo Yan, PhD, Director, Analytical Research & Development, Beam Therapeutics

2:15 Physiochemical and Biophysical Characterization of Base Editing Drug Substances and Drug Products
Bo Yan, PhD, Director, Analytical Research & Development, Beam Therapeutics
Base editing *ex vivo* and *in vivo* therapies has emerged as a groundbreaking approach with the potential to offer curative solutions for unmet medical needs. I will summarize the contributions of analytical tools in the development of cell- and gene-editing therapy with base-editing technology. I will highlight phase-appropriate considerations for characterization assays and GMP QC release assays for novel modalities (i.e., gRNA, mRNA, lipid nanoparticles, and edited cells).

2:45 CMC Challenges for Prime-Edited Therapies
Luis Santos, PhD, Senior Director, Non-Viral Delivery, mRNA & LNP Product Development, Prime Medicine Inc.
This presentation will address the unique chemistry, manufacturing, and controls (CMC) challenges associated with prime-edited therapies. It will explore the intricacies of developing and scaling up prime editing platforms, focusing on aspects such as product design, delivery systems, and manufacturing processes. The session will also discuss regulatory hurdles, strategies for ensuring product consistency and purity, and the critical role of CMC in advancing prime-edited therapies towards clinical application.

3:15 Advances in Lipid Nanoparticles Analytics
Wei-Chiang Chen, PhD, Associate Director, BioProcess Analytics, Genomic Medicine Unit, Sanofi
This presentation will explore the latest advancements in the analytical methods used to evaluate lipid nanoparticles (LNPs). It will cover a range of cutting-edge techniques that improve the characterization and understanding of LNPs, focusing on their application in drug-delivery systems. Key topics will include the development of more precise and efficient analytical tools, their impact on quality control, and their role in enhancing the overall development process of LNPs.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

PROCESS MODELING FOR LNP PROCESS DEVELOPMENT AND FORMULATION

4:30 Early LNP Development Considerations and Challenges
Yuefei Shen, PhD, Principal Scientist, CMC Drug Product Development, Sanofi
Compared to intramuscular vaccine delivery, intravenous (i.v.) delivery of a LNP formulation for gene therapy shows unique challenges. An LNP formulation for gene therapy via i.v. may require different lipid and formulation design. Here, we will discuss the considerations and challenges in early LNP development and impact on tissue targeting for NVGT.

5:00 Towards a Mechanistic Model of Lipid Nanoparticle Production
Pavan Inguva, PhD, Massachusetts Institute of Technology
Lipid nanoparticles (LNPs) are a versatile and effective platform for delivering nucleic acid therapeutics, as demonstrated by the COVID-19 vaccines. Despite a conceptually straightforward manufacturing process, challenges in understanding LNP formation and scale-up persist. This presentation outlines a multiscale mechanistic modeling framework, leveraging thermodynamic and phase-field models to predict properties, study RNA encapsulation, and optimize processes. Links between the model(s) and product quality, process control, and optimization are discussed.

5:15 Application of Digital Tools to LNP Formulation and Process Development
Umang Khamar, PhD, Scientist, Sanofi
This presentation will discuss the role of digital technologies in enhancing the development of lipid nanoparticle (LNP) formulations. It will focus on the integration of computational tools, data analytics, and machine learning to refine LNP design and manufacturing processes. It will examine how these technologies contribute to improved efficiency, scalability, and precision, ultimately facilitating faster and more reliable production cycles for advanced therapeutic delivery systems.

5:30 Close of RNA Development, CMC, and Manufacturing Conference

> This event allows participant to cover the biologic field from proteins, to cell gene therapy to AVV to mRNA all at the same time
>
> *— Khaled Y., Yamout Chem Consulting, LLC*

WEDNESDAY, AUGUST 20

7:30 am Registration and Morning Coffee

OPTIMIZING VIRAL VECTOR PRODUCTION

7:55 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

8:00 Development of a Commercial Manufacturing Process for RGX-202, a Systemically Delivered AAV8 for the Treatment of Duchenne Muscular Dystrophy
Don Startt, Executive Director, Upstream Process Development and Project Development Lead, REGENXBIO Inc.
This presentation outlines the development of a commercial manufacturing process for RGX-202, a systemically delivered AAV8 vector targeting Duchenne Muscular Dystrophy. It will cover the scale-up from laboratory to commercial production, focusing on optimizing both upstream and downstream processes to ensure high yield, purity, and efficiency. Advances in downstream processing, including improvements in purification and recovery methods, will be discussed in the context of enhancing scalability and maintaining product consistency.

8:30 Innovations in Upstream Process Development and Optimization for Gene Therapy Manufacturing
Marissa Stanvick, Director, Upstream Viral Vector Product Development, Alexion, AstraZeneca Rare Disease

9:00 Advances in Gene Therapy Process Development
Shamik S. Sharma, PhD, Senior Director, Process Development, Voyager Therapeutics Inc.
To accelerate timelines post-candidate nomination, process development may commence prior to this milestone, sometimes on more than one candidate. In this presentation we share one such case study regarding process development for an AAV gene therapy using a novel capsid, that led to a successful manufacturing campaign. We will discuss team strategy while managing uncertainty along with lessons learned to accelerate manufacturing timelines.

9:30 Presentation to be Announced

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

PROCESS OPTIMIZATION AND COMPARABILITY

10:40 Upstream Process Optimization: Using Design of Experiments (DoE) to Create Scalable Manufacturing Processes and Improve rAAV Yields and Quality
Danielle Sexton, PhD, Associate Director, Process Development, Forge Biologics
Increasing yields is one of gene therapy's greatest challenges—and addressing this helps to make gene therapy more accessible to broader patient populations. This talk will explore strategies used to improve yield and the empty to full particle (E/F) ratio by leveraging design of experiments (DoE) to systematically evaluate transfection parameters including total DNA, plasmid ratios, complexation time, transfection reagent, and enhancers.

11:10 The Impact of CQAs' Determination on Successful Manufacturing
Nesredin A. Mussa, PhD, President, Dynamica Biologics
Critical Quality Attributes (CQAs) are key characteristics of a drug product that must be maintained within specified limits to ensure the product's safety, efficacy, and quality. Appropriate CQAs set the tone of manufacturing development. We discuss the role and significance of CQAs in robust manufacturing development for gene therapy. By testing appropriate CQAs early in the development process, the risk of unexpected quality issues and potential safety incidences are reduced.

11:40 KEYNOTE PRESENTATION: Comparability Studies Following Process Change
Scott A. Jeffers, PhD, CTO, Gensight Biologics
Comparability studies for gene therapy manufacturing are critical when process or CDMO changes occur. These studies require comprehensive analytical characterization to demonstrate product equivalence across critical quality attributes, including physicochemical properties, biological potency, and vector integrity. Regulatory agencies primarily evaluate substantial scientific evidence to ensure no clinically meaningful differences emerge.

12:10 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:40 Refreshment Break in the Exhibit Hall with Poster Viewing

INCREASING YIELD

1:25 Chairperson's Remarks
Seth Levy, PhD, Director, Bioprocess Development, Modalis Therapeutics

1:30 Optimizing Producer Cell Line Performance through High-Throughput Screening Techniques
Amit Mathur, PhD, Senior Scientist, Genomic Medicine Unit, Sanofi
This presentation will discuss the application of high-throughput screening in generation-of-producer cell lines for AAV production at Sanofi. It will highlight the technologies which contribute to building a robust and efficient producer cell line generation platform, improving throughput, reproducibility, and scalability.

2:00 Process Development for Complementing Suspension-Adapted A549 Cell Line for High Titer RCA-Free Adenoviral Vector
Martin Loignon, PhD, Team Leader, Cell Engineering, National Research Council Canada
Adenovirus is one attractive viral vector for gene therapy and therapeutic vaccines. We have engineered A-549 adenoviral vector complementing cells for the production of E1-deleted adenoviral vectors and developed bioprocesses in cell suspension yielding free of replication-competent adenovirus. We have tested several production modes and increased initial titers in batch mode from mid 109 vp/mL up to 7,0 x 1010vp/mL in a bioreactor perfusion culture at the 3 L scale.

2:30 Integrated AAV Capture and Polishing via ChromaTan BioRMB—A Continuous, Column-Free Chromatography Platform

Oleg Shinkazh, Founder & CEO, ChromaTan Inc
BioRMB is a column-free steady-state purification platform tailored for sensitive modalities such as gene therapies, vaccines, mRNA, and antibody constructs. In this work we will present capture purification data for two AAV serotypes, as well as preliminary findings on a novel real-time PAT technique. This PAT application will monitor AAV whole capsid titer and empty-full ratio analysis by integrating Real-Time Multi Angle Light Scattering (rtMALS) into BioRMB continuous purification.

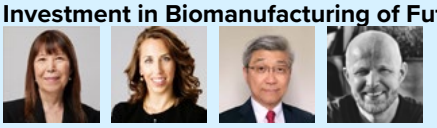
3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

FORMULATRIX®

PLENARY KEYNOTE SESSION: LEADING TO TOMORROW'S ADVANCES

3:50 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:00 PLENARY PANEL DISCUSSION: Innovation and Investment in Biomanufacturing of Future Medicine



Moderator: Ran Zheng, CEO, Landmark Bio
What are the technologies and innovations shaping the future of biomanufacturing in 2025 and beyond? Join us for an engaging plenary panel discussion on "Innovation and Investment in Biomanufacturing of Future Medicine," where leading experts from the investment and strategies community will explore upcoming trends, investment opportunities, and modalities into the next decade. How should the industry best prepare?
Panelists:
Daniella Kranjac, Founding General Partner, Avant Bio LLC
David Y. H. Chang, CEO, Taiwan Bio-Manufacturing Company (TBMC)
Bo Wiinberg, PhD, Chief Business Development Officer, Novo Nordisk Foundation Cellerator

5:00 Networking Reception in the Exhibit Hall with Poster Viewing

6:00 Close of Day

THURSDAY, AUGUST 21

7:30 am Registration and Morning Coffee

ADVANCES IN VIRAL VECTOR PRODUCTION

7:55 Chairperson's Remarks
Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics

8:00 CRISPR Screen Reveals Modifiers of rAAV Production
Emily O'Driscoll, Student, Shalem Lab, Raymond G. Perelman Center for Cellular and Molecular Therapeutics, The Children's Hospital of Philadelphia
We performed a genome-wide CRISPR-based knockout screen to identify genes that can be targeted in human embryonic kidney (HEK) 293 producer cells to modulate rAAV production. We discovered that the knockout of a group of heparan sulfate biosynthesis genes previously implicated in rAAV infectivity decreased rAAV production. Additionally, we identified several vesicular trafficking proteins for which knockout in HEK 293 cells increased rAAV yields.

8:30 Elucidating Key Factors Impacting the Robustness of Cell Revival from Cryopreservation
Connor Shank, Senior Research Associate I, GT Research & Tech Ops, Ultragenyx Pharmaceutical Inc.
Cryopreservation is an essential part of cell-based biomanufacturing. At Ultragenyx, we utilize HeLa cell lines to produce recombinant AAV gene therapy products. We observed several MCB and WCB with poor thaw recovery (viability % and cell density) and initiated an investigation of cell-banking, transfer & handling, and thawing procedures. Cell banking density, freeze/thaw cycles, media, and transfer durations, amongst other factors, were shown to have significant impact on thaw recovery.

9:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

9:30 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

DOWNSTREAM PROCESSING OF VIRAL VECTORS

10:30 Downstream Process Optimization and Scale-Up for rAAV Production
Keerthana Subramanian, Senior Scientist, Process Development, Forge Biologics
Efficient purification processes are needed for the increasing number of recombinant adeno-associated virus (rAAV) therapies. Impurities such as host cell proteins and empty capsids copurify with rAAV and should be reduced during manufacturing. Optimization strategies in downstream purification and supporting data for improved vector purity and recovery will be presented in this talk. The process ensures production of high-quality rAAV for clinical use and is scalable from 1L to 1000L.

11:00 AAV Polishing Technology Development
Jessica Chia-Yun Sun, PhD, Senior Director, AAV Downstream Development, Alexion Pharmaceuticals Inc.
This presentation will focus on the latest advancements in AAV polishing technology, crucial for enhancing the purity and potency of adeno-associated virus (AAV) vectors used in gene therapy. It will cover innovative methods for downstream processing, including chromatography and filtration techniques that effectively remove impurities and improve vector yield. The session will also discuss the impact of these technologies on the overall quality and scalability of AAV production.

11:30 Downstream Platform Processes across HEK Transfection and Pinnacle PCL—Challenges and Considerations
Mukesh Mayani, PhD, P.Eng, Senior Director, Purification Development at Global CMC Development, Ultragenyx Gene Therapy
This presentation explores the downstream platform process across HEK transfection and Pinnacle PCL cell line platforms, focusing on key differences in process for AAV vector manufacturing. We will discuss purification process differences, impurity removal, and viral clearance strategy for reproducible vector manufacturing intended for clinical and commercial use. Key considerations to address challenges will be discussed, offering insights for advancing AAV GT vector manufacturing.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Refreshment Break in the Exhibit Hall with Poster Viewing

DOWNSTREAM PROCESSING OF VIRAL VECTORS

1:05 Chairperson's Remarks
Meisam Bakhshayeshi, PhD, Senior Director, Process Development, Obsidian Therapeutics

1:10 Virus Filtration Development for Adeno-Associated Virus-Based Gene Therapy Products

Namila Fnu, PhD, Scientist, Downstream Process Development, Spark Therapeutics Inc.

This talk will address the unique challenges in developing effective virus filtration strategies for rAAV gene therapy products. We'll examine the role of virus filtration in enhancing viral clearance robustness and its increasing regulatory emphasis in AAV manufacturing. Key topics include evaluating commercially available virus filters for AAV manufacturing, assessing their throughput and process yield, and demonstrating robust clearance of model viruses like Adenovirus type 5 and Simian virus 40.

1:40 Challenges and Process Development for Purification of Gene Therapy Vector AAV

Xue Mi, PhD, Senior Scientist I, Purification Process Development, Abbvie Bioresearch Center

Adeno-associated virus (AAV) is highly inefficient at packaging its genome, with up to 90% of the formed AAV capsids being empty. The upstream process requires cell lysis to achieve a manufacturable viral titer, which generates significantly more impurity burdens than the therapeutic protein production process. A purification process involving harvest clarification, ultrafiltration/diafiltration, affinity chromatography for AAV capture, and anion exchange chromatography for AAV polishing was developed for different serotypes.

2:10 Development of a Universal and Scalable Adeno-Associated Virus Capture Step Using Steric Exclusion Chromatography

Juan Carlos Rosario, PhD, Senior Principal Scientist, Purification & Virology Development, Eli Lilly & Company

Adeno-associated viruses (AAV) are among the leading vectors for gene therapy. The purification of AAV remains a bottleneck as it typically requires multiple individual process steps, often resulting in product loss and high costs. Current downstream processes are usually serotype-specific and rely primarily on expensive affinity resins. To address these limitations, we developed a serotype-independent capture method using steric exclusion chromatography that can be combined with a subsequent empty separation step.

2:40 Networking Refreshment Break and Transition into Town Hall Discussion

FACILITATED TOWN HALL DISCUSSION: AI & DIGITAL TRANSFORMATION IN BIOPROCESSING—OPPORTUNITIES VERSUS REALITIES?

2:55 Facilitated Town Hall Discussion

This Town Hall offers delegates the opportunity to participate in an interactive discussion on important themes that were explored during the conference. The Town Hall will have hosts to facilitate the conversation, and all are welcome to participate, share views and best practices, and ask questions of colleagues.

AI & Digital Transformation in Bioprocessing—Opportunities versus Realities?
Lori Ellis, Head of Insights, BioSpace

3:55 Close of Summit

> "I'm always impressed by the high-quality talks and informative discussions at Bioprocessing Summit."
>
> *— Jian R., PhD, Principal Scientist, AbbVie*

STREAM #8
FORMULATION & STABILITY

The **Formulation and Stability** stream brings together experts in formulation, analytical sciences, drug delivery and process science to share expertise and foster collaborations. This conference stream will deliver practical insights and in-depth case studies on formulation, analytical and AI/ML-driven strategies for high-concentration protein formulations in the production of traditional and novel biotherapeutics. Methods for predicting protein instabilities and strategies for impurity detection will also be explored.

Conference Programs

AUGUST 18-19

Formulation, Stability & Delivery

View Program »

AUGUST 20-21

Training Seminar

Formulation of Biopharmaceuticals

View Program »

MONDAY, AUGUST 18

8:00 am Registration Open and Morning Coffee

OPTIMIZING FORMULATION AND CO-FORMULATION DEVELOPMENT

9:40 Chairperson's Opening Remarks
Danny Chou, PhD, President and Founder, Compassion BioSolution, LLC

9:45 Identification of Dominant Factors Leading to High Viscosity in Antibodies by Application of Automated DoE Excipient Screening
Alejandro D'Aquino, PhD, Principal Investigator, GSK
Development of patient-centric medicines is a current trend in pharmaceuticals. These novel presentations are based on concentrated liquid formulations of antibodies integrated with a device. High viscosity can cause manufacturing and device compatibility issues. A design of experiments approach was used to screen combinations of four excipients targeting different viscosity mechanisms. This method successfully reduced viscosity of antibody formulations (=150 mg/mL) to optimal levels and identified dominant viscosity mechanisms.

10:15 Co-Formulation of Antibodies and Peptides: Challenges and Strategies
Steven Cottle, Senior Advisor, Biotherapeutic Discovery and Research, Eli Lilly & Company
This talk will focus on the challenges of co-formulating antibodies and peptides as well as strategies to address those challenges. Discussion points will include formulation, biophysical characterization, and analytical method development. Two case studies will be used to demonstrate these points.

10:45 In-Room Networking Introductions

11:00 Advancements in Automated Biologics Formulation Screening to Meet a Dynamic Pipeline
Alex Vouga, PhD, Automation Investigator, Drug Product Development, GSK
While automated workflows have been used for years to accelerate and expand biologic formulation screening, ever-increasing protein therapeutic concentrations demand innovative and agile automated solutions to manage high material viscosity, sample loss, and equipment failure. Here, we introduce tools and strategies designed to enhance the flexibility of automation to ensure we can effectively meet evolving demands of a dynamic pipeline.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

IMPURITIES AND HOST CELL PROTEINS (HCPs)

12:50 Chairperson's Remarks
Erika Friedl, PhD, Senior Quality Expert, Haematology, Cell and Gene Therapy, Paul Ehrlich Institute

12:55 HCP Impurities and Regulatory Challenges
Erika Friedl, PhD, Senior Quality Expert, Haematology, Cell and Gene Therapy, Paul Ehrlich Institute
Process-related impurities can severely impact product quality and patient safety. A wide range of different problematic HCPs are known which need to be controlled to ensure the quality, efficacy, and safety of the pharmaceutical product. HCP-specific guidelines should be followed when developing appropriate methods and techniques for HCP characterization, specification setting, and life-cycle control. Overcoming regulatory challenges while using possible flexibilities will be discussed based on case studies.

1:25 Site-Specific Polyclonal Antibody Immobilization as a Platform for Targeted Capture and Deep Characterization of Complex Host Cell Proteins
Leo Wang, PhD, Senior Scientist, Takeda
Effective removal and characterization of problematic host cell proteins (HCPs) are critical in biotherapeutic manufacturing. Using site-specific immobilization of polyclonal antibodies as a versatile platform, we selectively captured CHO-derived phospholipase B-like 2 (PLBL2), a challenging HCP. Coupled with advanced mass spectrometry, this approach unveiled previously unknown proteoforms, including multiple charge and size variants. Our method provides a powerful framework broadly applicable for enhancing purification strategies across diverse biotherapeutics.

1:55 Presentation to be Announced

CYGNUS TECHNOLOGIES
part of Maraval LifeSciences

2:25 Harness Biotherapeutic Impurities from Early Development to Commercial
Kevin Zen, PhD, Senior Director, IGM Biosciences
The potential impurities of biological therapeutics originated from cell bank, raw material, upstream culture, downstream bioprocess, fill finish, container closure, and product degradation. This presentation will exemplify the product and process impurities from manufacturing process and share the phase-appropriate control strategies to ensure the process is under control and the product is safe and efficacious.

LEVERAGING AI IN BIOPROCESSING DEVELOPMENT

2:55 GV20-0251 mAb Product: From AI Discovery to Accelerated CMC Development
Jie Chen, MD, Chief Technical Operations & Quality Officer, GV20 Therapeutics
GV20-0251, a first-in-class human monoclonal antibody against IGSF8, was discovered through GV20 proprietary AI platform that predicted both target and antibody sequences. The antibody exhibits excellent performance in antibody platform process with over 36-month stability. We will also present the identification and resolution of a particulate matter challenge during drug-product manufacturing. In this presentation GV20-0251 showcases how AI-driven discovery can accelerate bioprocessing development.

3:25 Networking Refreshment Break and Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: SOLVING TODAY'S CHALLENGES

4:20 Organizer's Remarks
Daniel Barry, Senior Conference Director, Cambridge Healthtech Institute

4:25 Chairperson's Remarks
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

4:30 Increasing mAb Output Ten-Fold while Reducing Natural Resources through Digitalization and New Technologies

Lisbet Jensen Young, Vice President & General Manager, AstraZeneca
This presentation will give insights into the latest sustainability strategies at AstraZeneca and the unique opportunities they provide the leadership of a mAb drug substance manufacturing center, increasing output ten-fold. It will take you through the approaches using digital in the value stream, partnering with suppliers in capacity expansions, and deployment of new technologies.

5:10 One-on-One Interview, with Audience Q&A
Lisbet Jensen Young, Vice President & General Manager, AstraZeneca

Interviewed By:
Raghavan V. Venkat, PhD, Senior Vice President, Bioprocess Development, AstraZeneca

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Close of Day

TUESDAY, AUGUST 19

7:30 am Registration and Morning Coffee

PREVENTING AND MITIGATING PROTEIN AGGREGATION

7:55 Chairperson's Remarks
Christina Vessely, PhD, Senior Consultant, CMC Analytics & Formulation Development, Biologics Consulting Group, Inc.

8:00 Flow-Induced Aggregation Assays for Developing Protein Formulations
Vishal Toprani, PhD, Director, Formulation and Drug Product Development, Upstream Bio
The development of therapeutic proteins, including monoclonal antibodies, has been accelerated through advanced formulation platforms and protein stability assessments. This presentation will focus on the use of a low-volume Extensional Flow Device (EFD), which subjects proteins to an extensional flow field commonly encountered in manufacturing processes. The EFD provides an alternative method for probing protein aggregation, supporting the screening of formulation additives and the development of more robust formulations.

8:30 Polysorbate Degradation across Shelf Life: Mitigation and Justification
Christina Vessely, PhD, Senior Consultant, CMC Analytics & Formulation Development, Biologics Consulting Group, Inc.
Polysorbates are widely used in biopharmaceutical formulations to prevent aggregation due to interfacial stress. These excipients are susceptible to degradation via oxidation and enzymatic hydrolysis during storage, potentially leading to the formation of subvisible particles and loss of protection from surface-induced aggregation. This presentation is focused on strategies for mitigating degradation, confirming which levels of intact polysorbate are required to protect the product and justifying acceptance criteria to regulators.

ADVANCED DELIVERY METHODS

9:00 Solving PEGylation's Growing Challenges with a Next-Gen Polymer Conjugate Platform
Soumen Saha, PhD, Senior Research Scientist, Duke University
As PEGylated therapeutics face growing concerns of anti-PEG antibodies—present in up to 60% of the population—our novel POEGMA platform offers a breakthrough solution. Built on a brush-like oligoethylene structure, it eliminates PEG antigenicity while improving PEG's beneficial traits. With minimal immunogenicity and enhanced stability, POEGMA shows strong potential in therapeutic development. Early R&D and preclinical data will be presented. Join us to explore how POEGMA can unlock new therapeutic innovation potential.

9:30 Presentation to be Announced

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

BREAKOUT DISCUSSIONS

10:45 Breakout Discussions
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 Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

OVERCOMING MANUFACTURING AND STABILITY CHALLENGES

11:30 Overcoming Hurdles: Development and Manufacturing Challenges of Antibody-Drug Conjugates (ADCs)
Purbasa Patnaik, Associate Director, Formulation & Drug Product Development, Exelixis
Currently, ADCs are among the most rapidly advancing cancer treatments due to their precision in delivering powerful cytotoxic agents directly to tumor cells, minimizing unwanted side effects. Despite their recent achievements, ADCs present various technical and manufacturing hurdles. This presentation will delve into the challenges faced by CMC in the development and production of ADC drug products, as well as potential solutions.

12:00 pm Challenges in Manufacturing of High-Concentration Antibody Formulation and Solutions to Mitigate Them
Vaibhav Deokar, Principal Scientist, Formulation Development, Biotechnology Division, Lupin Ltd.
Challenges in manufacturing high-concentration antibody formulations are between late downstream operations to containerization. Late downstream challenges, like increased viscosity limiting concentration, are resolved by using viscosity-modifying agents. Using 'D' screen or single-pass TFF further provides an advantage in targeting higher concentrations with lesser shear. Using 0.5µm/0.2µm asymmetric membrane results in better flux during filtration. Control strategy for filling nozzles and periodic fill weight check resolves issues with filling.

12:30 Presentation to be Announced

1:00 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:30 Refreshment Break in the Exhibit Hall with Poster Viewing

NOVEL BIOTHERAPEUTICS: FORMULATION, STABILITY, AND DELIVERY

2:10 Chairperson's Remarks
Marilia Barros, PhD, Principal Scientist, Regeneron Pharmaceuticals

2:15 KEYNOTE PRESENTATION: Formulation & Process Development Considerations for Nonviral Gene Delivery
Amey Bandekar, PhD, Associate Director, Drug Product Development, Sanofi
In development of LNP drug product, the choice of lipid components and manufacturing technology is the key factor. The lipid matrix can be modulated to maneuver biodistribution to the target site. The manufacturing technology can have significant impact on biophysical characteristics, colloidal stability, and efficacy. This study describes the key considerations for designing LNP formulations, impact of different manufacturing parameters, and scale-up considerations to enable successful LNP drug product.

2:45 Unveiling AAV Adsorption at Interfaces across Drug-Development Stages Using QCMD
Yasmin Van Cura, Senior Associate Scientist, Formulation Development, Regeneron Pharmaceuticals
AAV-based therapies encounter interfacial stress during manufacturing, storage, and administration, often resulting in adsorption loss, aggregation, and vector leakage compromising therapeutic safety and efficacy. Quartz crystal microbalance with dissipation monitoring (QCM-D) was employed to characterize AAV adsorption behavior at critical interfaces and evaluate material compatibility between different serotypes. The results can help guide formulation development and material selection for manufacturing and dose administration during drug-product development.

3:15 Single-Particle and Single-Cell Microscopy to Advance Our Understanding, Development, and Quality Control of mRNA-LNP Vaccines and Therapeutics
Sabrina Leslie, PhD, Associate Professor, Department of Physics, The University of British Columbia
I will present CLiC (Convex Lens-induced Confinement), a unique single-particle imaging platform for measuring the size, mRNA-payload, and dynamics of nanoparticles in controlled, cell-like conditions. This platform enables imaging of particles in solution and during reagent-exchange to emulate manufacturing and cellular dynamics, with and without fluorescent labels. We aim to correlate multi-scale data with clinical results, advancing our understanding of vaccine effectiveness and enabling rational design and optimization.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

4:30 Drug Product Development Strategies for AAV Gene Therapies
Tuna Yucel, PhD, Senior Scientist, Biologics Drug Product Development & Manufacturing, Sanofi
This presentation will discuss key considerations and risk mitigation strategies for the development of AAV gene therapy products. Challenges around formulation and process development of deep-frozen AAV products, along with ultra-cold supply-chain considerations will be covered. Case studies will be shared with the goal to engage with the broader gene-therapy R&D community and facilitate information exchange.

5:00 Case Study from Oruka Therapeutics
Rajiv Panwar, PhD, Vice President, CMC, Oruka Therapeutics

5:30 Close of Formulation, Stability, and Delivery Conference

> This event may be smaller compared to other events, but the quality of research presented combined with access to strategic partners and good decision makers makes this a standout event.
>
> *— Brian B., Chief Commercial Officer, Tozaro*

Training SEMINARS
By Cambridge Healthtech Institute

Formulation, Development, and Manufacturing of Biopharmaceutical Drug Products

AUGUST 20-21
All Times EDT

Wednesday, August 20, 2025 8:00 am - 3:00 pm | Thursday, August 21, 2025 8:00 am - 12:00 pm

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.

Topics to be Covered Include:

- Introduction to the role of formulation development in the biopharmaceutical industry
- Mechanisms for physical degradation of proteins and strategies for prevention and management
- Mechanisms for chemical degradation of proteins and strategies to prevent chemical degradation in protein formulations
- Overview of analytical methods for monitoring protein structure and degradation, including analysis and management of impurities such as sub-visible and visible particles
- Biophysical characterization of proteins and its role in protein formulation development
- Global strategy for rational development of stable protein formulations
- Case studies in biopharmaceutical formulation development, including high/low concentration antibody formulations and delivery device integration to create combination products
- The role of advanced technologies in the detection and management of protein aggregation during formulation/device development and bioprocessing
- Challenges in the development and manufacture of protein drug products, including strategies for overcoming these challenges
- Regulatory aspects of biologics formulation development, including regulatory guidance, process and product impurities, extractables and leachables, and more
- Exploration of novel excipients and how to implement these into the regulatory process
- Leveraging AI and ML to enhance formulation, stability and delivery methods
- Detection, identification, analysis, control, removal, risk assessment and regulation of impurities and Host Cell Proteins (HCPs)
- How to apply the concept of DoE and QbD in the development of protein formulations

Instructor Biography:

Danny Chou, *PhD, President and Founder, Compassion BioSolution, LLC*

Dr. Danny K. Chou is a biopharmaceutical industry veteran with expertise in biopharmaceutical characterization, formulation development, and emerging technologies for protein aggregate/subvisible particle analysis. Currently, Dr. Chou is the Founder and President of Compassion BioSolution, a biopharmaceutical consultancy and Contract Development Service provider that serves clients throughout the world. Dr. Chou has over 20 years of experience in the pharmaceutical industry, both as a pharmacist and pharmaceutical scientist. Over the past 15 years he has led the development of formulations for numerous therapeutic modalities ranging from peptides, growth factors, mAbs, ADCs, and bispecific antibodies. Prior to starting Compassion BioSolution, Dr. Chou was a Senior Scientist and Group Leader at Gilead Sciences, where he successfully built up state-of-the-art analytical capabilities for the company and converted IV formulations of monoclonal antibodies to high concentration formulations that are more stable and can be easily administered by subcutaneous injection. Prior to this, Danny was employed by Genzyme and Amgen, where he played critical roles in drug product process development, manufacturing technical support, and pharmaceutical development. Since founding Compassion BioSolution, Danny has developed stable pharmaceutical dosage form for clients ranging from small start-up biopharmaceutical companies to Fortune 500 pharmaceutical companies. Danny received his PhD from the University of Colorado Center for Pharmaceutical Biotechnology under a NIH Fellowship and his PharmD from the University of Florida.

Sponsorship Programs

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.

Podium Presentations

Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific program, breakfast, or lunch. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CII. Lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly! Sign on early to secure your talk.

One-on-One Meetings

CHI will set up 6-8 in-person meetings during the conference, based on your selections from the advance registration list. Our staff will handle invites, confirmations and reminders, and walk the guest over to the meeting area. This package also includes a meeting space at the venue, complimentary main-conference registrations, branding, an 8'x10' exhibit space, and more.

Invitation-Only Dinner/Hospitality Suite

Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending the invitations, to venue suggestions, CII will deliver your prospects and help you make the most of this invaluable opportunity.

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional Sponsorship & Branding Opportunities Include:

- Exhibit Hall Networking Reception
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- Product Launch Promo
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- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Padfolios and More...

For more information regarding exhibits and sponsorship, please contact:

Companies A-K

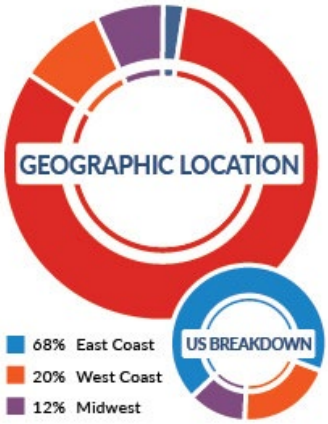
Phillip Zakim-Yacouby
Sr. Business Development Manager
(781) 247-1815
philzy@cambridgeinnovationinstitute.com

Companies L-Z

Aimee Croke
Sr. Business Development Manager
(781) 292-0777
acroke@cambridgeinnovationinstitute.com

2024 Attendee Demographics

- 61% Biotech
- 20% Pharma
- 6% Academic
- 5% Financial
- 3% Services
- 2% Government
- 2% Healthcare
- 1% CRO



- 68% East Coast
- 20% West Coast
- 12% Midwest

- 83% USA
- 9% Asia
- 7% Europe
- 1% Rest of World

- 48% Scientist/Technologist
- 15% Director
- 12% Sales & Marketing
- 11% Manager
- 10% Executive
- 2% Professor
- 2% Assistant

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