SESSIONS

TUESDAY 18TH MARCH - PRE-CONFERENCE DAY - 18/03/2025

Registration and Morning Coffee

08:00 - 09:00

The Tech Transfer Landscape for Bioprocessing

09:00 - 10:30
Tech Transfer

- Overview of the Tech Transfer landscape, specifically in regard to consistently evolving and increasingly complex biologics/advanced therapies
- Key challenges when approaching tech transfer
- CMOs and CDMOs: the importance of choosing the right partner
- Building effective partnership
- Importance of cross-functional teams and clear communication channels

Participants

Laura Buttafoco - Senior Consultant & Founder, Protea

Process Characterization and Optimization Enabling Efficient Continuous Manufacturing Process

09:00 - 09:30
Intensifed and Continuous Manufacturing

- Process improvements to increase productivity
- Process monitoring and control strategy targeting intensified continuous processing

Participants

Vivek Kumar Muthusamy - Process Development Senior Scientist, Amgen

Morning Session

09:00 - 10:00
CDMO Management

- **Overview of the CDMO Landscape for biopharma and biotech**
  - Key players and their capabilities
  - How the market is changing
- **CDMO Selection**
  - Considerations for CDMO selection
  - Framework for selecting the right partner
- **Contractual agreements**
  - Different forms of contracts
  - Setting expectations and fostering a collaborative environment
  - Timelines and opportunities for acceleration
- **Executing a seamless tech transfer**
  - Key challenges and advice

Participants

Shalaka Purohit - Principal Consultant, Suveda Solutions LLC

Single Pass Tangential Flow Filtration for Concentrating Intermediate Process Pools to Mitigate GMP Plant Fit Challenges Associated with High-Titer Batch Processes

09:30 - 10:00
Intensifed and Continuous Manufacturing

Advances in Chinese Hamster Ovary (CHO) cell technologies, cell culture media composition, and bioreactor operating parameters have increased monoclonal antibody titers in the bioreactor greater than 10-fold over the last 20 years. These high-titer batch processes offer increased productivity (mass of biologics produced per unit of time and area) and allow for meeting the growing demand for protein therapeutics. However, fitting the high-titer processes in legacy manufacturing plants, typically designed for low titer processes, can be challenging due to product pool volumes that exceed intermediate hold tank volumetric capacities. A solution to mitigate volume-related challenges is concentrating intermediate product streams *in-line* by single pass tangential flow filtration (SPTFF) to fit within fixed tank assets. This talk will elaborate on various considerations related to developing, characterizing, and scaling up SPTFF processes for *in-line* concentration of the intermediate product streams to fit high titer processes in legacy manufacturing plants. Specifically, the discussion will include how to determine the development goals for the SPTFF process, perform a risk assessment, and identify parameter ranges for robust process performance while minimizing the cost of goods sold (COGS). Results from bench-scale and pilot-scale experiments across different molecules will also be shared, showing the minimal impact of incorporating SPTFF in high-titer batch processes on product quality. Overall, SPTFF provides the tools to address many volume-related facility-fit constraints associated with high-titer processes.

Participants

Claire Tantillo - Process Development Engineer, Regeneron Pharmaceuticals

Scientific Presentation by Sartorius

10:00 - 10:30
Intensifed and Continuous Manufacturing

Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
CDMO Management

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Morning Break

10:30 - 11:00

Tech Transfer for Novel Modalities: Strategies for Success

11:00 - 12:00
Tech Transfer

- Overcoming the unique specific challenges of aseptic injectables and novel therapeutics such as mRNA
- Developing a tailored tech transfer programme
- Importance of a lifecycle approach
- Flexibility for unforeseen issues
- Considerations for regulatory compliance when approaching tech transfer

Participants

Laura Buttafoco - Senior Consultant & Founder, Protea

Roundtable Discussions led by Industry Experts

11:00 - 12:00
Intensifed and Continuous Manufacturing

1. **Control Strategy:** What are the Challenges in Process Control for Continuous Processing and How Can We Overcome These?
2. **The Data Issue:** How Can We Utilize and Effectively Analyse Data to Move Towards Fully Automated Processes?
3. **Future Thinking:** Dreaming Big – Where Do We Want to be in the Next 10 Years?
4. **Business Case for Continuous Bioprocessing:** What Barriers Exist for Implementing Continuous and Intensified Approaches and Do the Benefits Outweigh this?

30 minutes to discuss within groups then feedback main points for 5 minutes.

SESSIONS

TUESDAY 18TH MARCH - PRE-CONFERENCE DAY - 18/03/2025

In-House Manufacturing vs. CDMO: Navigating the Choice for Vector-Based Therapies

11:00 - 11:30
CDMO Management

This session will dive into the decision-making process behind GenVivo's choice to manufacture vector-based immunotherapies in-house rather than partnering with an external manufacturer. We will examine key considerations, including the time and cost implications of establishing an internal manufacturing facility, as well as strategic factors that influence whether to build or outsource production. Attendees will gain practical insights into the complexities of this decision, applicable to companies developing cutting-edge therapies.

Participants

Victor Constantinescu - Executive Director, Business Development and Manufacturing, GenVivo, Inc.

Case Study: Leveraging CDMO Expertise for Complex Manufacturing Needs

11:30 - 12:00
CDMO Management

The majority of innovative ideas and disruptive technologies are nucleated at academic and educational institutions. However, these organizations have limited budget and lack the process development and manufacturing infrastructure, particularly if their advanced products belong to different technological platforms. This gap can be closed by contract development and manufacturing organizations (CDMOs), which remain crucial to new drug process development, manufacturing and commercialization.

The goal of this presentation is to provide the framework for the development of modern biologics through global CDMOs. Two case studies are presented: small molecule-antibody conjugate (SMAC) and chimeric antigen receptor T-cells (CAR-T), which are currently undergoing clinical trials in the immuno-oncology field. Each of these programs required the involvement of five different CDMOs located in different parts of the world due to the unique nature of these drug products. The CDMO selection process includes business documentation, GMP due diligence process, CDMO structure analysis, communication, technical expertise, and establishing a timeline, and a budget. This presentation will cover the key benchmarks in analytical and process development to ensure a successful manufacturing outcome.

Participants

Vadim Klyushnichenko - VP Bio/Pharmaceutical Development & Quality, Calibr-Skaggs Institute for Innovative Medicines

Lunch

12:00 - 13:00

Ensuring Seamless Tech Transfer: Best Practices and Strategies

13:00 - 14:30
Tech Transfer

- Importance of planning and preparation:
- Thorough documentation and knowledge transfer
- Identifying and maintaining critical quality attributes (CQAs) throughout tech transfer
- Collaboration & communication: keys to success
- Approaching risk management to mitigate bottlenecks
- Maintaining product integrity: strategies to ensure consistent product quality during tech transfer and subsequent validation
- Considerations for regulatory compliance during a tech transfer.

Participants

Laura Buttafoco - Senior Consultant & Founder, Protea

Process Intensification of Continuous Ultrafiltration and Diafiltration for Monoclonal Antibodies

13:00 - 13:30
Intensifed and Continuous Manufacturing

Participants

Vishwanath Hebbi - Senior Scientist, Merck & Co., Inc.

Afternoon Session

13:00 - 14:00
CDMO Management

- **Managing ongoing relationship with your CDMO**
  - Having a proactive approach to project management to avoid costly delays
  - Conflict resolution
- **Implementing robust risk management frameworks**
  - Utilize with clear, concise and collaborative communication
- **Fostering a culture of continuous improvement**

Participants

Shalaka Purohit - Principal Consultant, Suveda Solutions LLC

Building an Innovative Integrated Continuous Manufacturing Platform for the Downstream Purification of Biologics

13:30 - 14:00
Intensifed and Continuous Manufacturing

- Creating modular systems to ensure flexibility and scalability of processes;
- Facility considerations for the move to continuous;
- Learning from early successes and failures to improve processes.

Participants

Michael Coolbaugh - Associate Director, Purification Process Development, Sanofi

Spotlight Presentation – Calling all Technology Thought Leaders!

14:00 - 14:30
Intensifed and Continuous Manufacturing

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CDMO Management

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Afternoon Break

14:30 - 15:00

SESSIONS

TUESDAY 18TH MARCH - PRE-CONFERENCE DAY - 18/03/2025

Digital Transformation in Tech Transfer: Leveraging Technology for Success

15:00 - 16:00
Tech Transfer

- Utilizing digital tools for efficient documentation and knowledge sharing during the tech transfer process
- How PAT and other real-time monitoring solutions can be implemented for control during tech transfer
- Leveraging novel digital tools and subsequent outcomes

Participants

Laura Buttafoco - Senior Consultant & Founder, Protea

Round Up Panel - Continuous Manufacturing in Bioprocessing: Future or Fad?

15:00 - 16:00
Intensifed and Continuous Manufacturing

- What barriers are limiting the uptake of continuous manufacturing and how are these being addressed?
- How can you evaluate which processes require an intensified/continuous approach?
- Should companies commit to continuous for sustainability?
- How are emerging technologies assisting?
- How can you move from batch to continuous?
- Where do we want to be in 5/10 years? How can we get there?

Participants

Panellist: Michael Coolbaugh - Associate Director, Purification Process Development, Sanofi

Panellist: Vivek Kumar Muthusamy - Process Development Senior Scientist, Amgen

Panellist: Vishwanath Hebbi - Senior Scientist, Merck & Co., Inc.

Round Up Fireside Chat - Forging Strategic Alliances: Maximizing Value in CDMO Partnerships

15:00 - 16:00
CDMO Management

- How to select the right CDMO partner?
- Establishing clear communication channels and expectations;
- Fostering a collaborative problem-solving approach;
- Best practices for seamless technology transfer.

Participants

Moderator: Shalaka Purohit - Principal Consultant, Suveda Solutions LLC

Panellist: Victor Constantinescu - Executive Director, Business Development and Manufacturing, GenVivo, Inc.

Panellist: Vadim Klyushnichenko - VP Bio/ Pharmaceutical Development & Quality, Calibr-Skaggs Institute for Innovative Medicines

Close of Pre-Conference Day

16:00 - 16:05

SCHEDULE

TUESDAY 18TH MARCH - PRE-CONFERENCE DAY - 18/03/2025

TIME	TECH TRANSFER	INTENSIFED AND CONTINUOUS MANUFACTURING	CDMO MANAGEMENT
08:00	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee
09:00	**09:00** - The Tech Transfer Landscape for Bioprocessing	**09:00** - Process Characterization and Optimization Enabling Efficient Continuous Manufacturing Process **09:30** - Single Pass Tangential Flow Filtration for Concentrating Intermediate Process Pools to Mitigate GMP Plant Fit Challenges Associated with High-Titer Batch Processes	**09:00** - Morning Session
10:00	**10:30** - Morning Break	**10:00** - Scientific Presentation by Sartorius **10:30** - Morning Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Break
11:00	**11:00** - Tech Transfer for Novel Modalities: Strategies for Success	**11:00** - Roundtable Discussions led by Industry Experts	**11:00** - In-House Manufacturing vs. CDMO: Navigating the Choice for Vector-Based Therapies **11:30** - Case Study: Leveraging CDMO Expertise for Complex Manufacturing Needs
12:00	**12:00** - Lunch	**12:00** - Lunch	**12:00** - Lunch
13:00	**13:00** - Ensuring Seamless Tech Transfer: Best Practices and Strategies	**13:00** - Process Intensification of Continuous Ultrafiltration and Diafiltration for Monoclonal Antibodies **13:30** - Building an Innovative Integrated Continuous Manufacturing Platform for the Downstream Purification of Biologics	**13:00** - Afternoon Session
14:00	**14:30** - Afternoon Break	**14:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **14:30** - Afternoon Break	**14:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **14:30** - Afternoon Break
15:00	**15:00** - Digital Transformation in Tech Transfer: Leveraging Technology for Success	**15:00** - Round Up Panel - Continuous Manufacturing in Bioprocessing: Future or Fad?	**15:00** - Round Up Fireside Chat - Forging Strategic Alliances: Maximizing Value in CDMO Partnerships
16:00	**16:00** - Close of Pre-Conference Day	**16:00** - Close of Pre-Conference Day	**16:00** - Close of Pre-Conference Day

SESSIONS

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

Registration and Morning Coffee

08:00 - 09:00

Welcome to BPI West - Chair's Opening of Conference

09:00 - 09:10
Plenary Keynote Sessions

A Practical Roadmap for Implementing Digitalization in Bioprocess Development

09:10 - 09:50
Plenary Keynote Sessions

- Insights and best practices for successful implementation
- Achieving scalable optimization
- Ensuring user adoption

Participants

Ramila Peiris - Global Head of Process Data Management, ML and AI Platform, MSAT, Sanofi

Integrating Continuous Manufacturing - What is the realistic goal and how do we get there?

09:50 - 10:30
Plenary Keynote Sessions

As biopharmaceuticals grow in complexity and demand, the shift from traditional batch processing to integrated continuous manufacturing (ICB) has emerged as a compelling solution to reduce cost, waste and time to launch. However, integrating continuous manufacturing in bioprocessing requires a realistic evaluation of both opportunities and challenges. Key topics include the availability of commercially ready plug-and-play modular technologies, integration of real-time monitoring and development of robust control strategies. By examining the status of ICB implementation and recent innovations, we'll outline a roadmap for adopting continuous bioprocessing practices and suggest actionable steps for industry stakeholders. The goal of this presentation is to provide a practical perspective on what is realistically achievable in the near term and to encourage a collaborative approach to realizing the potential of continuous manufacturing in bioprocessing.

Participants

Veena Warikoo - VP, Global Technical Operations, AstraZeneca

Morning Networking Break

10:30 - 11:15

Chairperson's Remarks: Cell Line Development & Engineering

11:15 - 11:20
Cell Line Development & Engineering

Chairperson's Remarks: Cell Culture & Upstream Processing

11:15 - 11:20
Cell Culture & Upstream Processing

Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0

11:15 - 11:20
Manufacturing Strategy & Digitalization

Chairperson's Remarks: Recovery & Purification

11:15 - 11:20
Recovery & Purification

Chairperson's Remarks: Cell and Gene Therapy Manufacturing

11:15 - 11:20
Cell and Gene Therapy Manufacturing

Dosage compensation of subunit expression in CHO to improve PQA of biologics

11:20 - 11:50
Cell Line Development & Engineering

In CHO cells, the expression levels of heavy chain (HC) and light chain (LC) in monoclonal antibodies (mAb), and the subunits in bispecific antibodies, have a significant impact on productivity and product quality. Studies have shown that the modulation of HC and LC expression levels directly influences antibody productivity and quality. We would like to share our experiences with dosage compensation in the production of biologics.

Participants

Mr Satish Kallappagoudar - Associate Principal Scientist, Merck

Intensification Strategies in Mammalian Cell Culture: Enhancing Efficiency and Yield

11:20 - 11:50
Cell Culture & Upstream Processing

This talk will delve into the intensification strategies being employed in mammalian cell culture to speed up the production process and improve yield. The session will cover techniques such as N-1 perfusion, seed culture optimization, and the use of larger flasks to reduce the number of bioreactors needed. Attendees will gain insights into how these strategies help overcome the physiological limitations of mammalian cell lines and reduce costs and risks associated with large-scale bioreactors.

- Understand the principles and benefits of process intensification.
- Explore different perfusion strategies and their applications.
- Learn about high seeding density techniques and their impact on productivity.
- Gain insights into media improvements for fed-batch and perfusion processes.

Participants

Mr Keshab Rijal - Principal Scientist, Amgen

Streamline Biologics Process Characterization and Control Strategy Development

11:20 - 11:50
Manufacturing Strategy & Digitalization

- Case study

Participants

Lihua Yang - Principal Research Scientist, AbbVie Bioresearch Center, USA

Balancing speed and quality in purification process development and manufacturing for bispecific antibodies

11:20 - 11:50
Recovery & Purification

- A phase-appropriate process development strategy balances overall speed and quality
- Case studies of balancing speed and quality at different clinical phases are reviewed
- Product understanding drives development efficiency and effectiveness for bispecific antibodies

Participants

Jian Ren, Ph.D. - Senior Scientist, AbbVie

SESSIONS

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

Complexities of CGT Manufacturing & Standardizing the Path to Successful Commercialization

11:20 - 11:50
Cell and Gene Therapy Manufacturing

- Spotlight on the complexities of CGT manufacturing;
- How do we address these complexities by standardizing the path to commercialization;
- What innovation and platforms exist to make CGTs more accessible now and in the future?

Participants

Adam Haskett - Senior Director, External Manufacturing, Cargo Therapeutics, USA

Analysis of Host Cell Proteins in AAV Products with ProteoMiner Protein Enrichment Technology

11:50 - 12:20
Cell Line Development & Engineering

HCPs in adeno-associated virus (AAV) products can be effectively enriched by ProtoeMiner beads and the detergent Pluronic F-68 can be simultaneously removed without loss of low-abundance HCPs.

Up to 34-fold increase in the enrichment of HCPs can be achieved by using ProteoMiner beads comparing to direct digestion.

After applying ProtoeMiner beads on AAV products, HCPs at a level as low as 0.1 ng/mL can be detected.

Participants

Hui Xiao - Associate Director, Regeneron

FIRESIDE CHAT: Continuous Vs Fed-Batch The Ongoing Debate

11:50 - 12:20
Cell Culture & Upstream Processing

This session will look at both methods of biologic production and when, how and why to use them? What are the pros and cons to both and are they molecule dependent? Is there a clear winner and what will the future look like?

Participants

Continuous: Ken Lee - Director, Bioprocess Technologies and Engineering, BioPharmaceuticals Development, R&D, AstraZeneca

Fed Batch: Chiali Liu - Senior Director, Drug Substance Development, Teva Pharmaceuticals

Comparability Studies to Support Manufacturing Process Change, Enhancing Product Quality and Accelerating Timeline to Commercial Launch

11:50 - 12:20
Manufacturing Strategy & Digitalization

- During product development and the life cycle of commercial products, process changes are inevitable. Products manufactured using pre- and post- process changes are required to demonstrate comparability per ICH Q5E. A comparability study is a critical tool to ensure the “similarity” of product quality including efficacy, pharmacokinetics, safety and immunogenicity.
- In this presentation, a phase appropriate risk assessment of process change will be introduced, followed by comparability strategy based on the risk assessment. Analytical comparability study tools will be discussed including the analytical comparability plan, comparability criteria, execution, data analysis and presentation. Furthermore, non-clinical and clinical comparability will be briefly discussed if there is any analytical difference which may impact product quality. Two comparability case studies will be presented. The first study is to support a new bioprocess to improve product quality and to facilitate larger scale manufacturing. The second one is to support the use of an early process stability study for establishing commercial shelf-life by leveraging the comparability study for an accelerated program. The agency feedback from multiple markets for the case studies will also be discussed.

Participants

Dr Wenqin Ni - Senior Principal Scientist, Pfizer

Optimizing Early-Stage Recovery for Viral Vectors and Other Novel Modalities

11:50 - 12:20
Recovery & Purification

- Unique purification challenges associated with lentivirus and other emerging viral vectors (RLPs, AAV, etc.);
- Tailored purification strategies for different viral vector types;
- Developing efficient methods for the removal of empty/partial capsids;
- Strategies for dealing with post-translational modifications and heterogeneity in viral vectors.

Participants

Ohnmar Khanal, Ph.D - Downstream Technology Lead, Spark Therapeutics

Scaling Up Manufacturing Processes for Commercial-Level Production

11:50 - 12:20
Cell and Gene Therapy Manufacturing

- How do manufacturers achieve scalability without compromising product quality?
- Increasing batch sizes and maintaining consistency to reduce costs;
- How early is too early to consider strategy for scaling up?
- Strategies to ensure reproducibility, robustness and cell product quality to uphold therapeutic efficacy;
- Harnessing rapid/integrated platforms and process improvements to broaden cell therapy impact;
- Accelerating delivery to patients and catering to increased demand at a clinical and commercial scale.

Participants

Kate Rochlin - Chief Operating Officer, IN8bio

Scientific Presentation by Cytiva

12:20 - 12:50
Cell Line Development & Engineering

Scientific Presentation by CRODA

12:20 - 12:50
Cell Culture & Upstream Processing

Spotlight Presentation – Calling all Technology Thought Leaders!

12:20 - 12:50
Manufacturing Strategy & Digitalization

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Spotlight Presentation – Calling all Technology Thought Leaders!

12:20 - 12:50
Recovery & Purification

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Spotlight Presentation – Calling all Technology Thought Leaders!

12:20 - 12:50
Cell and Gene Therapy Manufacturing

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Lunch & Spex 'Lunch n Learns'

12:50 - 13:55

Chairperson's Remarks: Cell Line Development & Engineering

13:55 - 14:00
Cell Line Development & Engineering

Chairperson's Remarks: Cell Culture & Upstream Processing

13:55 - 14:00
Cell Culture & Upstream Processing

Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0

13:55 - 14:00
Manufacturing Strategy & Digitalization

Chairperson's Remarks: Recovery & Purification

13:55 - 14:00
Recovery & Purification

Chairperson's Remarks: Cell and Gene Therapy Manufacturing

13:55 - 14:00
Cell and Gene Therapy Manufacturing

Achieving Essential Product Quality & Titre for Multispecific Antibodies

14:00 - 14:30
Cell Line Development & Engineering

- Strategies To Balancing Chain Ratio and Assembly Issues To Maximise Formation of Fully Formed Multispecifics;
- Solutions for preventing light chain swapping;
- Analytical techniques to screen and ensure proper chain pairing;
- Case studies on successful mitigation of chain mismatching issues;
- Can transposons give a better ratio?
- Vector design strategies? Promoters? - Explore innovative strategies for optimizing expression vectors, with a focus on chain ratio modulation;
- Keep product impurities to a minimum;
- Strategies to navigate longer timelines and additional assays required for multispecifics;
- How to reduce aggregation of product within the cell? Bioreactor conditions? Engineering?

Participants

Eva Rubio-Marrero - Senior Scientist II, AbbVie

Considerations for Mammalian Cell Culture Media Development for Intensified Fed Batch Processes

14:00 - 14:30
Cell Culture & Upstream Processing

Cell culture media is arguably the most important and valuable component of a bioprocess. While use of commercially available basal and feed media is an option for some enterprises, biotherapeutic innovators must develop their own recipes for a variety of reasons including sourcing/supply chain and process control. While media development in the past has been focused on the application of fed-batch process, a workflow is also needed for designing media that can be used for intensified processes. A case study along with benefits and challenges that can be encountered with intensified bioprocess media development will be presented.

Participants

Mr Neil McCracken, PhD - Principal Research Scientist, Upstream Process Development, Group Leader, Elanco

PANEL DISCUSSION: Navigating the Ever-Changing CDMO Landscape

14:00 - 15:00
Manufacturing Strategy & Digitalization

- How CDMOs have evolved in the last 5 years and what to expect in the coming years;
- Geopolitical uncertainty and its impact on outsourced manufacturing;
- Collaboration to understand the changing needs of pharma and biotech.

Participants

Moderator: Vadim Klyushnichenko - VP Bio/ Pharmaceutical Development & Quality, Calibr-Skaggs Institute for Innovative Medicines

Panellist: Lihua Yang - Principal Research Scientist, AbbVie Bioresearch Center, USA

HCP Challenges in Antibody Manufacturing: A Review of Current Insights and Pathways Forward

14:00 - 14:30
Recovery & Purification

Host-cell proteins (HCPs) can compromise biopharmaceutical products by persisting through purification, leading to polysorbate degradation and reduced stability. This presentation summarizes literature on HCP challenges, provides case studies, and highlights advanced techniques like LC-MS/MS and size-exclusion chromatography. The goal is to develop strategies to control HCP persistence and ensure the stability and safety of biotherapeutic products.

Participants

Younghoon Oh - Senior Scientist, API Protein, Johnson & Johnson Innovative Medicine

How the Joint Audit Model Helps in Cell and Gene Therapy

14:00 - 14:30
Cell and Gene Therapy Manufacturing

Over the past 3 years the joining of cell and gene therapy material quality with the joint auditing model has proven to not only increase safety but also decrease money spent. The joint audit model can partner confidentially C&G organizations together to audit material suppliers, which in turn provides a much more robust audit, and return. This presentation will dive into the joint auditing model and provide case examples on best practices as well as guidance.

Participants

Kendall Feshuk - Senior Manager, Member Development, Rx-360, USA

SESSIONS

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

Utilizing a regulated targeted integration expression system as both a diagnostic tool for difficult to express molecules and as a method to improve specific productivity without affecting cell growth in CHO cell lines

14:30 - 15:00
Cell Line Development & Engineering

Targeted integration (TI) approaches, which involve integration of a transgene into a specific locus in the genome, are increasingly utilized for CHO cell line development (CLD) in recent years. But none of these CLD approaches are suitable for expression of toxic or difficult-to-express molecules, or can help in determining the underlying causes for a poor expression molecule. Here we introduce how a regulated target integration (RTI) system can help determine the underlying causes of low protein expression in an antibody (mAb-A). In addition, we will discuss how using a RTI system can help boost specific productivity and protein expression without negatively impacting cell growth.

Participants

Cynthia Lam - Senior Scientific Researcher, Genentech

Accelerating Process Development Utilizing LC-MS for Enhanced Data Acquisition

14:30 - 15:00
Cell Culture & Upstream Processing

Cell culture process development is often limited by the turnaround time of spent media and of product quality analysis. Additionally, these methods are typically very complex requiring various SMEs to conduct the work. Here, we have assessed the Waters BioAccord instrument for its utility for streamlining these analyses to improve cell culture development timelines.

Participants

Ms Alexandria Triozzi - Technical Development Engineer III, Biogen

Use of Ultrafiltration/Diafiltration for the Processing of Antisense Oligonucleotides

14:30 - 15:00
Recovery & Purification

Ultrafiltration/Diafiltration has been the hallmark for concentration and buffer exchange of protein and peptide-based therapeutics for years. With the emergence of nucleic acid-based therapeutics, UF/DF is often being used to process these new modalities. We examine the capabilities and limitations of UF/DF membranes to process oligonucleotides using antisense oligonucleotides (ASOs) as a model. This presentation will share our experiences with oligonucleotide process development around the use of UF/DF, as well as the development of the oligonucleotide purification platform.

Participants

Jonas Immel-Brown - Scientist - Technical Development, Biogen

Selecting CDMO's for Successful Translation from Lab to Clinic

14:30 - 15:00
Cell and Gene Therapy Manufacturing

- Pointers for evaluating academic/early stage programs before technology transfer to a commercial CDMO;
- Choosing and interacting with an optimal CDMO for streamlining manufacturing protocol development;
- Practical tips to avoid time and cost in early manufacturing planning.

Participants

Lakshman Prakash Balajepalli - Manage QA, Cedars Sinai Biomanufacturing Center, USA

Spotlight Presentation – Calling all Technology Thought Leaders!

15:00 - 15:30
Cell Line Development & Engineering

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Spotlight Presentation – Calling all Technology Thought Leaders!

15:00 - 15:30
Cell Culture & Upstream Processing

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Spotlight Presentation – Calling all Technology Thought Leaders!

15:00 - 15:30
Manufacturing Strategy & Digitalization

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Scientific Presentation by Cytiva

15:00 - 15:30
Recovery & Purification

Scientific Presentation by Single Use Support

15:00 - 15:30
Cell and Gene Therapy Manufacturing

Afternoon Break & Grand Opening of Exhibit Hall

15:30 - 16:30

SESSIONS

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

Improving the Production of a Difficult to Express Protein Using Rational Expression Vector Optimization

16:30 - 17:00
Cell Line Development & Engineering

The demand for production of difficult-to-express (DTE) proteins continues to grow as the diversity of new biotherapeutic protein modalities increase. However, DTE proteins can be challenging for production from cellular systems due to factors such as protein complexity and toxicity. In this study, we used a DTE model molecule to evaluate different strategies aimed at enhancing protein expression and identifying bottlenecks in the biosynthetic process. This engineered model protein involves the assembly of two chains and complex post-translational modifications with product maturation requiring co-expression of a heterologous peptidase. By systematic evaluation of various DNA vector elements and host cells using stable pools, we identified that a combination of 5′ UTR, signal peptide sequence, codon optimization and host cell line significantly enhanced protein expression by 4-fold. Surprisingly, inclusion of a synthetic promoter to reduce the expression of the peptidase not only improved protein titer, but also promoted cell recovery following transfection and single cell cloning, indicating that overexpression of the peptidase was deleterious for the cells. To understand more about the limitations in the expression process for this DTE protein, super-transfection experiments were performed using low and high titer clones. Super-transfection resulted in an increase in transgene copy number and mRNA levels that led to higher protein titers in low-titer clones, but not in high-titer clones, indicating that the bottleneck for expression was post-transcriptional over a certain expression threshold. Investigation using immuno-fluorescent staining and microscopic analysis showed that this DTE molecule exhibits an organelle distribution that suggests a limitation in the protein secretion pathway. Altogether, these findings provide valuable strategies for improving protein expression and offer clues towards unravelling the mechanisms that limit the production of DTE molecules.

Participants

Hui-Lan Hu - Senior Scientist, AstraZeneca

Up Your Efficiency & Quality Game for AAV Production

16:30 - 17:00
Cell Culture & Upstream Processing

- Innovations in HEK293 suspension cell cultures;
- Strategies to maximize AAV production yield;
- Regulatory considerations for CQAs in gene therapy;
- Overcoming challenges in process scale-up and technology transfer.

Participants

Larry Forman - CEO, CHO PLUS

Successful Global Launch with a Risk-based Approach to Tech Transfer

16:30 - 17:00
Manufacturing Strategy & Digitalization

- Identifying and mitigating project, technical, and operational risks
- Ensure consistent product quality and robust processing across manufacturing sites through global integration
- Digitalization of tech transfer workflows and knowledge management

Participants

Mr Jesse Richter - Executive Director, Tech Transfer and Validation - Global Technical Operations, Biopharmaceuticals, AstraZeneca

ROUNDTABLE SESSION: Cracking the Code for Scalable Novel & Complex Modalities

16:30 - 17:30
Recovery & Purification

Novel modalities propose unique challenges for their purification and removal of impurities - how can purification processes be optimized for these novel modalities?

Roundtable groups discussing:

Emerging technologies and approaches utilized for DNA/RNA/mRNA downstream processing

- Scaling these technologies for growth;
- Unique purification challenges and solutions for viral vectors and mRNA;
- Challenges when transitioning from membranes for viral vector/mRNA based therapeutics.

Addressing challenges related to ADC degradation and impurity clearance

- Developing analytical methods for monitoring ADC stability and purity;
- Optimizing conjugation processes to prevent downstream bottlenecks;
- Strategies for managing heterogeneity in ADC products;
- The impact of ADC instability on downstream processing and product quality.

Overcoming issues for purification for Radiopharmaceuticals

- Unique challenges associated with handling and purifying radio-labelled compounds;
- Ensuring the safety and efficacy of radiopharmaceuticals through effective purification;
- Regulatory considerations for the purification of radiopharmaceuticals;
- The role of automation and robotics in radiopharmaceutical purification.

Achieving optimal downstream purity during vaccine development

- Specific purification challenges associated with different vaccine types (e.g., viral, bacterial, subunit);
- Strategies for removing impurities and contaminants from vaccine products;
- The importance of maintaining vaccine stability and potency throughout purification;
- Regulatory requirements for vaccine purity and quality.

30 minute roundtable discussions, 30 mins feedback to group and key takeaways.

Participants

Roundtable Leader: Mr Attila Nagy - Associate Director – Downstream Process Development, National Institute of Health

SESSIONS

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

PANEL DISCUSSION: Preparing for the Future of ATMP Commercialization & Attracting Investment to Avoid Roadblocks

16:30 - 17:30
Cell and Gene Therapy Manufacturing

- Ensuring the commercial sustainability of cell & gene therapies;
- Tackling barriers and identifying opportunities for commercialization;
- Innovative payment models in the US and globally;
- Strategies for attracting investment to ensure smooth transition from bench to bedside.

Participants

Panellist: Adam Haskett - Senior Director, External Manufacturing, Cargo Therapeutics, USA

Panellist: Kate Rochlin - Chief Operating Officer, IN8bio

Panellist: Dan Oliver - CEO and Founder, Rejuvenate Bio, USA

A CHO cell-based simultaneous display and secretion platform for high throughput discovery of bispecific antibodies

17:00 - 17:30
Cell Line Development & Engineering

Bispecific antibody (BsAb) discovery is complex, time-consuming, and costly. The traditional process begins by discovering two sets of monoclonal antibodies (mAbs) targeting different antigens, which are then combined into BsAbs for production and testing. Low screening throughput and multiple transitions in format and production methods often result in failures. To improve efficiency, we developed a CHO cell-based platform that enables simultaneous display and secretion of millions of BsAbs, allowing high-throughput, in-format screening of multiple parameters in CHO cells. This platform significantly increases throughput, reduces costs by over multiple folds, and halves development time.

Participants

Yuansheng Yang - Senior Principle Scientist 1, A*STAR

Enhancing AAV Production: Techniques to Optimize Empty to Full Capsid Ratios

17:00 - 17:30
Cell Culture & Upstream Processing

This talk will explore the critical challenge of optimizing the empty to full capsid ratio in AAV production. By examining various techniques such as plasmid engineering and feed studies, the session will provide insights into improving viral yield and product quality. The discussion will also cover innovative tools and analytical methods for early detection of capsid ratios in crude harvest materials, aiming to streamline the purification process and enhance overall efficiency.

Participants

Mr Stephen Zano - Director, Early Research and Process Development, Sarepta Therapeutics

Tech Talk: Amplifying Your Licensing Message in a Digital World

17:00 - 17:30
Manufacturing Strategy & Digitalization

In today's fast-paced tech landscape, expediting the licensing of innovative technologies is crucial for success. However, many organizations struggle to effectively communicate their offerings to potential licensees. This presentation explores the often-overlooked question: Are we using the right technology to get the word out? We will analyze various outreach methods—from traditional networking to modern digital platforms—and their effectiveness in reaching target audiences. By examining case studies and best practices, we will identify key strategies for leveraging the latest communication tools to enhance visibility and engagement. Attendees will leave with actionable insights on optimizing their technology outreach efforts, ultimately accelerating the licensing process and driving innovation forward. Join us to discover how to align your messaging with the most effective channels to ensure your technology gets the attention it deserves.

Participants

Noman Khan - Associate Director External Engagement, University of Utah

Networking Drinks in Exhibit Hall

17:30 - 19:00

Unwind with a drink in hand, share ideas, and make meaningful connections during the networking drinks reception. Cheers to opportunity as you mingle with industry pros and discover your next big collaboration.

SCHEDULE

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

TIME	PLENARY KEYNOTE SESSIONS	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING
08:00	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee	**08:00** - Registration and Morning Coffee
09:00	**09:00** - Welcome to BPI West - Chair's Opening of Conference **09:10** - A Practical Roadmap for Implementing Digitalization in Bioprocess Development **09:50** - Integrating Continuous Manufacturing - What is the realistic goal and how do we get there?					
10:00	**10:30** - Morning Networking Break	**10:30** - Morning Networking Break	**10:30** - Morning Networking Break	**10:30** - Morning Networking Break	**10:30** - Morning Networking Break	**10:30** - Morning Networking Break
11:00		**11:15** - Chairperson's Remarks: Cell Line Development & Engineering **11:20** - Dosage compensation of subunit expression in CHO to improve PQA of biologics **11:50** - Analysis of Host Cell Proteins in AAV Products with ProteoMiner Protein Enrichment Technology	**11:15** - Chairperson's Remarks: Cell Culture & Upstream Processing **11:20** - Intensification Strategies in Mammalian Cell Culture: Enhancing Efficiency and Yield **11:50** - FIRESIDE CHAT: Continuous Vs Fed-Batch The Ongoing Debate	**11:15** - Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0 **11:20** - Streamline Biologics Process Characterization and Control Strategy Development **11:50** - Comparability Studies to Support Manufacturing Process Change, Enhancing Product Quality and Accelerating Timeline to Commercial Launch	**11:15** - Chairperson's Remarks: Recovery & Purification **11:20** - Balancing speed and quality in purification process development and manufacturing for bispecific antibodies **11:50** - Optimizing Early-Stage Recovery for Viral Vectors and Other Novel Modalities	**11:15** - Chairperson's Remarks: Cell and Gene Therapy Manufacturing **11:20** - Complexities of CGT Manufacturing & Standardizing the Path to Successful Commercialization **11:50** - Scaling Up Manufacturing Processes for Commercial-Level Production

SCHEDULE

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

TIME	PLENARY KEYNOTE SESSIONS	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING
12:00	**12:50** - Lunch & Spex 'Lunch n Learns'	**12:20** - Scientific Presentation by Cytiva **12:50** - Lunch & Spex 'Lunch n Learns'	**12:20** - Scientific Presentation by CRODA **12:50** - Lunch & Spex 'Lunch n Learns'	**12:20** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:50** - Lunch & Spex 'Lunch n Learns'	**12:20** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:50** - Lunch & Spex 'Lunch n Learns'	**12:20** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:50** - Lunch & Spex 'Lunch n Learns'
13:00		**13:55** - Chairperson's Remarks: Cell Line Development & Engineering	**13:55** - Chairperson's Remarks: Cell Culture & Upstream Processing	**13:55** - Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0	**13:55** - Chairperson's Remarks: Recovery & Purification	**13:55** - Chairperson's Remarks: Cell and Gene Therapy Manufacturing
14:00		**14:00** - Achieving Essential Product Quality & Titre for Multispecific Antibodies **14:30** - Utilizing a regulated targeted integration expression system as both a diagnostic tool for difficult to express molecules and as a method to improve specific productivity without affecting cell growth in CHO cell lines	**14:00** - Considerations for Mammalian Cell Culture Media Development for Intensified Fed Batch Processes **14:30** - Accelerating Process Development Utilizing LC-MS for Enhanced Data Acquisition	**14:00** - PANEL DISCUSSION: Navigating the Ever-Changing CDMO Landscape	**14:00** - HCP Challenges in Antibody Manufacturing: A Review of Current Insights and Pathways Forward **14:30** - Use of Ultrafiltration/ Diafiltration for the Processing of Antisense Oligonucleotides	**14:00** - How the Joint Audit Model Helps in Cell and Gene Therapy **14:30** - Selecting CDMO's for Successful Translation from Lab to Clinic
15:00	**15:30** - Afternoon Break & Grand Opening of Exhibit Hall	**15:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **15:30** - Afternoon Break & Grand Opening of Exhibit Hall	**15:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **15:30** - Afternoon Break & Grand Opening of Exhibit Hall	**15:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **15:30** - Afternoon Break & Grand Opening of Exhibit Hall	**15:00** - Scientific Presentation by Cytiva **15:30** - Afternoon Break & Grand Opening of Exhibit Hall	**15:00** - Scientific Presentation by Single Use Support **15:30** - Afternoon Break & Grand Opening of Exhibit Hall
16:00		**16:30** - Improving the Production of a Difficult to Express Protein Using Rational Expression Vector Optimization	**16:30** - Up Your Efficiency & Quality Game for AAV Production	**16:30** - Successful Global Launch with a Risk-based Approach to Tech Transfer	**16:30** - ROUNDTABLE SESSION: Cracking the Code for Scalable Novel & Complex Modalities	**16:30** - PANEL DISCUSSION: Preparing for the Future of ATMP Commercialization & Attracting Investment to Avoid Roadblocks

SCHEDULE

WEDNESDAY 19TH MARCH - MAIN CONFERENCE DAY ONE - 19/03/2025

TIME	PLENARY KEYNOTE SESSIONS	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING
17:00	**17:30** - Networking Drinks in Exhibit Hall	**17:00** - A CHO cell-based simultaneous display and secretion platform for high throughput discovery of bispecific antibodies **17:30** - Networking Drinks in Exhibit Hall	**17:00** - Enhancing AAV Production: Techniques to Optimize Empty to Full Capsid Ratios **17:30** - Networking Drinks in Exhibit Hall	**17:00** - Tech Talk: Amplifying Your Licensing Message in a Digital World **17:30** - Networking Drinks in Exhibit Hall	**17:30** - Networking Drinks in Exhibit Hall	**17:30** - Networking Drinks in Exhibit Hall

SESSIONS

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

Registration and Morning Coffee

08:25 - 08:55

Chairperson's Remarks: Cell Line Development & Engineering

08:55 - 09:00
Cell Line Development & Engineering

Chairperson's Remarks: Cell Culture & Upstream Processing

08:55 - 09:00
Cell Culture & Upstream Processing

Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0

08:55 - 09:00
Manufacturing Strategy & Digitalization

Chairperson's Remarks: Recovery & Purification

08:55 - 09:00
Recovery & Purification

Chairperson's Remarks: Cell and Gene Therapy Manufacturing

08:55 - 09:00
Cell and Gene Therapy Manufacturing

Advances in Machine Learning for Cell Line Development To Predict Better Clones, Reduce Timelines & Experiments

09:00 - 09:30
Cell Line Development & Engineering

- Case Study: ML for Cell Line Selection – how to get enough data?
- Predicting clone performance and stability;
- In silico prediction tools - Predicting product quality issues from candidate sequences;
- Reducing risks and avoiding unviable candidates early;
- Challenges in managing large datasets;
- Tools and methods for data structuring and analysis;
- Case studies on successful implementations;
- Deep Sequencing and AI: Developing algorithms to identify protein characteristics and improve expression in CHO cells.

Participants

Nathan Lewis, PhD - Professor, University of California, San Diego

Development of Two Alternative CHO Culture Harvest Processes using Acid Precipitation and Cationic Flocculation

09:00 - 09:30
Cell Culture & Upstream Processing

Advances in upstream cell culture processes has increased cell densities and productivity but has added challenges to cell clarification. In this case study, extensive work was done to develop a CHO harvest process, but typical harvest methods were unable to meet process scale up needs. Two alternative harvest processes using acid precipitation and cationic flocculation were developed to enable process scale up.

Participants

Victoria Drake Carnein - Upstream Process Development Associate Scientist IV, Alexion AstraZeneca Rare Disease

The Role of Raw Material Development in the Cultivated Meat Industry

09:00 - 09:30
Manufacturing Strategy & Digitalization

The global population is about to reach nearly 10 billion by 2050, accompanied by rising affluence in developing regions. This dual phenomenon poses a formidable challenge in meeting the escalating demand for meat through conventional means. Cultivated meat offers a more sustainable solution to the growing population's increasing hunger for meat.The biopharma industry has a solid foundation for understanding the criticality of raw material quality used in cell culture media and the impact on cell growth and product quality. Raw materials selection is critical in the scaleup, safety and efficacy of therapeutics. Similarly, cultivated meat production requires many of the same raw materials that can impact many critical quality attributes in the cultivated meat industry including edible mass, flavor and nutritional profiles. Where the biopharma industry leverages high-purity and costly raw materials,the cultivated meat industry must develop strategies to lower cost. Food grade materials are a potential solution to make safe products for consumption. This work reviews considerations and strategies of raw materials from initial stages of development through large scale tech transfer to make cultivated meat.

Participants

Brian Wong - Associate Director, Upside Foods

Improved Affinity Tag Self-Removal via Targeted Protein Engineering

09:00 - 09:30
Recovery & Purification

Recombinant affinity tags used in therapeutic protein purification can cause immunogenicity and complicate the downstream processing. Here we rationally re-engineered the Nostoc punctiforme DnaE split-intein (Npu) as an affinity tag system with accelerated self-cleaving for a wider range of target proteins under milder conditions, increasing the utility of tagless protein purification from a single-column process. This engineered system also shows improved tolerance to target protein sequence, pH, buffer composition, and temperature, providing a versatile platform for universal tagless recombinant protein purification.

Participants

Sabat Gonzalez-Serrano - Graduate Research Associate, The Ohio State University

SESSIONS

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

FIRESIDE CHAT: The Need for Continuous Requalification & Support of Cell & Gene Therapy Distribution

09:00 - 10:00
Cell and Gene Therapy Manufacturing

- Looking at recent FDA disclosures and contamination risks;
- What is the industry doing to work on the need for continuous requalification;
- Looking at performance of the equipment and processes and well as transportation and distribution.

Participants

Jose Vidal - Chief Operating Officer, CytoImmune, USA

How Reliable are Chinese Hamster Ovary (CHO) Cell Genome-scale Metabolic Models?

09:30 - 10:00
Cell Line Development & Engineering

Genome-scale metabolic models (GEMs) provide enable the interrogation of cellular metabolism to predict and understand metabolic behavior. Chinese Hamster Ovary (CHO) cell GEMs have been used extensively in bioprocessing applications, yet despite their potential, it is unclear how accurately GEMs can capture both intracellular metabolic states and extracellular phenotypes. In this work, we assess the current CHO cell GEM landscape and evaluate various models and solution methodologies to determine the best approach for meeting process development needs.

Participants

Mr James Morrissey - Postdoctoral Fellow, Vaccine Production Program, NIAID Vaccine Research Centre

Reduce Workload via AI, Machine Learning, and Modeling in Bioprocessing

09:30 - 10:00
Cell Culture & Upstream Processing

- Learn about digital twins and advanced modeling techniques;
- Explore the challenges of data integration across the industry;
- Discover potential applications and benefits of AI in cell culture processes.

Participants

A Representative - From, Takeda

Optimizing Process Development and Clinical Production Efficiency with Continuous Improvement Projects

09:30 - 10:00
Manufacturing Strategy & Digitalization

Continuous Improvement efforts are initiated to enhance process understanding and streamline operations for clinical Drug Substance production at Teva. This presentation will discuss two projects: Compiling and analyzing process performance data of pre-clinical and clinical production, as well as standardizing calculations on material demands for clinical batch production. The background, approaches, and impact of these projects, especially how they contribute to improving process development efficiency and bringing cost saving for clinical production, will be presented.

Participants

Chiali Liu - Senior Director, Drug Substance Development, Teva Pharmaceuticals

Development and evolution of downstream purification platform for inhalable biologics

09:30 - 10:00
Recovery & Purification

Fragmented antibody (fAb) is an emerging format of therapeutics suitable for inhalation delivery thanks to small size and excellent stability. However, the lack of affinity technology (like Protein A for mAbs) had caused significant challenges for downstream process development and often slow down speed-to-clinics. At AZ, we had developed three generations of purification processes for inhalable fAbs. This presentation will share extensive experiences (control of product related impurities, facility fit, and Cost of Good improvement) through multiple case studies and also review the evolutions of the purification platforms

Participants

Haibin Luo, PhD - Director of Downstream Process Development, BioPharmaceutical Development, AstraZeneca

Scientific Presentation by Great Bay Bio

10:00 - 10:30
Cell Line Development & Engineering

Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
Cell Culture & Upstream Processing

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Scientific Presentation by Thermo Fisher

10:00 - 10:30
Manufacturing Strategy & Digitalization

Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
Recovery & Purification

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Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
Cell and Gene Therapy Manufacturing

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Morning Networking Break

10:30 - 11:40

SESSIONS

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

Optimizing Cell Line Development of Bispecific Antibodies by Customized Plasmid Configuration Modulation

11:40 - 12:10
Cell Line Development & Engineering

Developing production cell lines for bispecific antibodies (bsAbs) presents significant challenges due to the additional work required to minimize product quality risks, such as mispairing or aggregation. Each bsAb molecule can display unique impurity profiles when using standard cell line development workflows. Here we have explored an optimized workflow that includes comprehensive expression evaluation to guide plasmid construction. This approach ensures high product quality with just one round of pool development.

Participants

Mr Zheng Zhang - Director, Cell Line Development, BeiGene

Design Experiments to Obtain Desirable Product Quality Attributes for Protein Biologics

11:40 - 12:10
Cell Culture & Upstream Processing

Participants

Mr Jared Dopp - Scientist, Upstream Process Development, Bristol-Myers Squibb

Next-Gen Bioprocessing: Leveraging Industry 4.0 for Smart Biomanufacturing Facilities

11:40 - 12:10
Manufacturing Strategy & Digitalization

In an era where biopharma is evolving rapidly, the integration of Industry 4.0 technologies into biomanufacturing is transforming production efficiency, quality control and scalability. This presentation will explore how smart biomanufacturing facilities are reshaping the industry by utilizing automation, artificial intelligence (AI), machine learning (ML), and real-time data analytics to enhance bioprocessing strategies. Drawing from over two decades of hands-on experience, he will share insights on how Industry 4.0 tools can optimize manufacturing workflows, reduce costs, and accelerate time-to-market for biopharmaceutical products. The talk will also touch upon the challenges in transitioning to smart facilities and how to overcome them by focusing on regulatory compliance and digital transformation strategies.

Participants

Dr Bala Reddy - Fonder & Managing Director, Provis Biolabs Pvt Ltd

PANEL DISCUSSION: Building Strategic Partnerships for Downstream Success

11:40 - 12:40
Recovery & Purification

- CDMO Landscape:
  - Benefits of partnering for facility design, equipment selection, etc.
- Key Selection Criteria:
  - Identifying and prioritizing the important factors to consider when selecting a partner within downstream.
- Approaching Tech Transfer and Best Practices;
- Real-world experiences of successful facility fit-outs and collaborations that have led to improved efficiency, reduced costs, and enhanced product quality.

Participants

Panellist: Ms Shalima Sreenath - Head of Downstream Process Development, Cellibre

KEYNOTE PRESENTATION: Poseida Therapeutics

11:40 - 12:10
Cell and Gene Therapy Manufacturing

Participants

Mr Loren Wagner - Chief Operations Officer, Poseida Therapeutics, USA

High-Throughput Workflows and Automation For High Productivity, Reduced CoG and Time Saving

12:10 - 12:40
Cell Line Development & Engineering

- Examples: High-throughput Cell Line selection;
- High-throughput screening for product quality early in CLD process;
- Automating and accelerating clone selection for complex molecules;
- How has it reduced FTEs and resourcing costs?
- Areas for further automation: cell banking, clone scale-up;
- Key process steps for leveraging automation: transfection and freezing;
- High-throughput solutions for early transfection and freezing of cell lines;
- Integration of automation in handling and storing cell lines.

Participants

A Representative - |, Novartis

Co-Culturing Cell Lines for Efficient Manufacture of Multispecifics

12:10 - 12:40
Cell Culture & Upstream Processing

Participants

Ms Dawn Eriksen-Stapleton - Principal Scientist, Pfizer

BioPharm Manufacturing Optimization with a Factory Digital Twin

12:10 - 12:40
Manufacturing Strategy & Digitalization

- Implementing transformative and disruptive technologies in a GMP environment
- Cross-collaboration between key stakeholders
- Extractable and leachable strategy improvements
- Ensure data quality and integrity

Participants

Joseph Pekny - Professor, Chemical Engineering, Purdue University

Tuning CAR-T Cell Phenotype Through Enhanced Bioprocess Control in Stirred -Tank Bioreactors

12:10 - 12:40
Cell and Gene Therapy Manufacturing

CAR-T cell-based immunotherapies have emerged as a promising tool to treat cancer. However, the impact of critical process parameters (CPP) applied during distinct stages of the cell manufacturing process on CAR-T cell phenotype is still poorly understood. Herein, we propose to tune CPP in stirred-tank bioreactors (STB) as a strategy to shape phenotypic characteristics of CAR-T cells. We outline the process development contribution to significantly improve CAR-T cell yields and, therefore, reduce manufacturing costs, upon optimizing cell culture in closed and automated STB. Unlike static systems, STB provide a homogeneous microenvironment and allow for precise control of culture parameters in real time. By adjusting CPP - such as dissolved oxygen levels and cell activation signalling - at key stages of the CAR-T cell manufacturing process, we can fine-tune cell phenotype. This approach contributes to mitigate patient variability and batch failures associated to manual operations, enhancing process consistency and facilitating a streamlined transition to commercial scale production."

Participants

Manuel Carrondo - Vice-President, Instituto de Biologia Experimental e Tecnológica

Spotlight Presentation – Calling all Technology Thought Leaders!

12:40 - 13:10
Cell Line Development & Engineering

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SESSIONS

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Spotlight Presentation – Calling all Technology Thought Leaders!

12:40 - 13:10
Cell Culture & Upstream Processing

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Spotlight Presentation – Calling all Technology Thought Leaders!

12:40 - 13:10
Manufacturing Strategy & Digitalization

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Spotlight Presentation – Calling all Technology Thought Leaders!

12:40 - 13:10
Recovery & Purification

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Scientific Presentation by Millipore Sigma

12:40 - 13:10
Cell and Gene Therapy Manufacturing

Lunch

13:10 - 14:40

Chairperson's Remarks: Cell Line Development & Engineering

14:40 - 14:45
Cell Line Development & Engineering

Chairperson's Remarks: Cell Culture & Upstream Processing

14:40 - 14:45
Cell Culture & Upstream Processing

Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0

14:40 - 14:45
Manufacturing Strategy & Digitalization

Chairperson's Remarks: Recovery & Purification

14:40 - 14:45
Recovery & Purification

Chairperson's Remarks: Cell and Gene Therapy Manufacturing

14:40 - 14:45
Cell and Gene Therapy Manufacturing

Green Lab Initiatives and Sustainable Practices – How Every Stage can Assist with Carbon Emissions, Water Usage and Waste?

14:45 - 15:15
Cell Line Development & Engineering

- Implementing environmentally friendly practices in CLD;
- Case studies on the impact of green initiatives in biopharmaceutical production;
- Strategies for reducing the environmental footprint of CLD processes.

Participants

Saurabh Sen - Associate Director, Cell Line Development, Genomic Medicine Unit CMC, Sanofi

Optimizing Metabolic Flux in CHO Cells: A Hybrid Approach for Improved Cell Culture Productivity

14:45 - 15:15
Cell Culture & Upstream Processing

Participants

Eliot Boulanger - Co-Founder and CEO, Levacells

Network-Based Scale-Up Data Collection and Analysis for AI Controlled Bioreactor Operations

14:45 - 15:15
Manufacturing Strategy & Digitalization

Scale-up campaigns are resource-intensive, and data is crucial to assessing the performance of a bioprocess technology in the “stressful” scale-up environment. However, scale-up datasets, which currently comprises of mostly numerical data with minimal context, are small (~100s of MBs) and incomplete for the application of AI. Ability to acquire data with context, of not just what works but also what doesn't work, provides a powerful framework for aggregating knowledge for re-use. Aggregating comprehensive scale-up datasets across organism/product classes for applications of AI is too expensive for any one academic or industrial entity. Network-based intra- and inter-companies sharing of scale-up knowledge is key to AI based learning and democratizing opportunities in this field. We are further exploring network-based control of bioreactors to probe biomanufacturing 4.0 level operations.

Participants

Ms Deepti Tanjore - Chief Product Officer, enScale Bio

SESSIONS

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

Challenges and solutions to manufacturing of low viscosity, ultra-high concentration IgG1 drug products: From late downstream process to final fill finish processing.

14:45 - 15:15
Recovery & Purification

The need to formulate higher antibody dose in smaller injection volumes has led to trend in manufacturing of ultra-high concentration antibody formulation. However, the challenges in manufacturing ultra-high concentration antibody formulations have seldom been discussed. These are mainly observed form late downstream unit operations (where antibody gets concentrated) to its final concentration, to final fill finish processing and containerization of the drug product. Present research is focused on challenges practically observed in manufacturing and processing of ultra-high concentration antibody formulations and provides turnkey solutions to these challenges to have consistent and robust manufacturing process. IgG1 has been used as model protein for studying the challenges associated in manufacturing and providing their turnkey solutions. Challenges in late downstream like increased viscosity limiting further concentration can be resolved by used of viscosity modifying agents in the formulation. Replacement of conventionally used 'A' screen membranes with 'D' screen. Using single pass TFF further provide advantage in targeting higher concentrations for IgG1 with lesser shear and aggregation. Bilayer or asymmetric membrane instead of conventional 0.2µm membrane resulted in better flux while filtration of ultra-high concentration IgG1 formulation. In process holding and maximum idle time during filling operation was optimized to <60min based on the nozzle drying time for ultra-high concentration IgG1 formulation. An appropriate control strategy of replacing filling nozzles was proposed for fill finish process of ultra-high concentration IgG1 formulation.

Participants

Dr. Vaibhav Deokar - Principal Scientist, Lupin Limited (Biotech Division)

Controlling Manufacturing Processes in Pre-Commercial & Commercial Autologous Cell & Gene Therapy Products

14:45 - 15:15
Cell and Gene Therapy Manufacturing

- Specific constraint around autologous CGT and rare disease;
- Establishing controls;
- Managing a commercial process.

Participants

Alex Bloom - Chief Technology Officer, AviadoBio, United Kingdom

CLE Toolbox: Optimizing Parental Cell Lines for Better Expression

15:15 - 15:45
Cell Line Development & Engineering

- Next Generation Hosts – what is beyond the GS KO?
- Enhancing Productivity Through Omics;
- KO of HCP proteins to aid in purification;
- Gene identification for improved titre and quality;
- Evolving cell lines through stress adaptation;
- Understanding and leveraging the cell cycle phases (G1 and S1) for productivity gains;
- Modulating transcription, translation, and productivity pathways;
- Case studies on successful cell cycle exploitation;
- Linking omics insights to tangible improvements in product quality and titre.

Participants

Ms Sara Maimouni, PhD - Scientist, Cell Line Development, Sanofi

ADCs: Translating from Bench to Production Scale

15:15 - 15:45
Cell Culture & Upstream Processing

- Scaling up the production process while maintaining product quality and yield requires careful optimization and validation;
- Ensuring consistent product quality during scale-up is critical. This includes maintaining the same glycosylation patterns, folding, and other quality attributes at larger scales;
- Adhering to Guidelines: Meeting the stringent regulatory requirements for the production of ADCs.

Maximizing the Impact of Digital Twins in Bioprocess Development and Manufacturing

15:15 - 15:45
Manufacturing Strategy & Digitalization

In recent years, innovative solutions such as digital twins have emerged to revolutionize the field of bioprocessing. The potential benefits are significant: shorter development timelines, reduced costs, enhanced process understanding across units and scales, and the possibility of autonomous process control. Bioprocessing, one of the most complex engineering fields, presents a unique set of challenges, including managing biological variability and overcoming scale-up limitations. In this presentation, Maximilian will highlight the advantages of digital twins in various stages of bioprocessing, focusing on process performance, quality, and cost-effectiveness. Practical use cases will be discussed, offering insights and actionable strategies for scientists and engineers looking to leverage digital twins in their work.

Participants

Maximilian Krippl - Head of Consulting, Novasign GmbH

PANEL DISCUSSION: Achieving Sustainable Biomanufacturing from Lab to Market: Is Single-Use the Answer?

15:15 - 15:45
Recovery & Purification

- Learning from successful transitions and collaborative projects with CDMOs;
- Exploring future trends and emerging innovations in sustainability;
- Minimizing environmental impact through waste reduction and efficient resource use;
- Cross-team and cross-collaborator synchronicity to achieve EEG goals during bioprocessing.

Addressing the Challenges in Allogeneic CAR-T Manufacturing

15:15 - 15:45
Cell and Gene Therapy Manufacturing

- Autologous vs allogeneic;
- The power of allogeneic therapies;
- Challenges and promises;
- Address open steps and aseptic manufacturing.

Participants

Amy Shaw - Head of Process and Product Development, Cell Therapy Sciences, Takeda, USA

Afternoon Break

15:45 - 16:45

SESSIONS

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

NISTCHO: An open access, living reference material for biomanufacturing

16:45 - 17:15
Cell Line Development & Engineering

There was a need in the biopharmaceutical industry for a Chinese hamster ovary (CHO) cell line expressing a monoclonal antibody. NISTCHO cells express a non-originator version of the NISTmAb, cNISTmAb. Importantly, the cell line is open access with minimal IP constraints to encourage open innovation and pre-competitive research. The properties of the NISTCHO and the cNISTmAb will be presented along with examples of how the community is using the cells.

Participants

Mr Zvi Kelman - Director, Biomolecular Labeling Laboratory, NIST

Comprehensive Modeling of Cell Culture Profile Using Raman Spectroscopy and Machine Learning

16:45 - 17:15
Cell Culture & Upstream Processing

Participants

Mr Hiroki Tanemura - Upstream Cell Culture Process Development, Daiichi Sankyo Co

PANEL DISCUSSION: Technology as a Catalyst to Revolutionize the Future of Biomanufacturing

16:45 - 17:45
Manufacturing Strategy & Digitalization

- Implementing next-generation technologies, including AI/ML-powered tools, for optimized efficiency;
- How can you seamlessly incorporate technologies?
- Where do we think manufacturing technology is heading in the next 5-10 years?

Participants

Panelist: Ms Deepti Tanjore - Chief Product Officer, enScale Bio

Panelist: Maximilian Krippl - Head of Consulting, Novasign GmbH

Panelist: Ramila Peiris - Global Head of Process Data Management, ML and AI Platform, MSAT, Sanofi

Panelist: Semsi Ensari - Sr Director, Process Development, Kite Pharma

Mechanisms and modeling of depth filtration in biopharma

16:45 - 17:15
Recovery & Purification

Depth filtration is widely used in harvest and other steps in biopharmaceutical manufacturing. Although idealized filtration fouling models have been used to infer deposition mechanisms from observed pressure drop data, they ignore deposition along the depth of the filter and are typically used without independently verifying the actual mechanism. We have analyzed pressure drop and turbidity data from clarification of Chinese hamster ovary cell culture fluid on different industrially-relevant depth filters and their constituent layers and used them to validate a mechanistic model for primary depth filtration that accounts for different filtration mechanisms. The mechanisms invoked include sieving, adsorption, and caking, and their respective contributions are assessed as a function of both the structure and depth of the filter and the features of the feed. Direct visualization of spent media provides further context for parameter values and mechanisms used in the model, as do imaging analyses such as X-ray tomography.

Participants

Abraham Lenhoff - Allan P. Colburn Professor, University of Delaware

Innovation Showcase

16:45 - 17:45
Cell and Gene Therapy Manufacturing

Informa is looking for 4 speakers to take part in 4 15-minute short data-led presentations focusing on various innovative approaches in the field of advanced therapies. Topics can include, but aren't limited to:

- The use of AI;
- Precision medicine approaches;
- Live imaging in stem cell analysis;
- Novel human promoters for improved safety and efficacy.

Talk 1: Driving digital innovation for supply chain orchestration in cell and gene therapy

Christian Fuchs, Head of Orchestration and Exceptions Management for Cell & Gene Therapy (CGT) at Roche/Genentech, USA

Talk 2: Therapeutic epigenome editing: safety and quality considerations of a new class of gene-targeted medicines

Houria Bachtarzi, Principal Consultant, Founding Director, BIOCELLGENE Consulting Ltd, UK

Participants

Christian Fuchs - Head of Orchestration and Exceptions Management for Cell & Gene Therapy (CGT), Roche/Genentech, USA

Houria Bachtarzi - Principal Consultant, Founding Director, BIOCELLGENE Consulting Ltd, UK

Chromatin accessibility plays an important epigenetic role on antibody expression from CMV promoter and DNA elements surrounding the CHO TI host landing-pad

17:15 - 17:45
Cell Line Development & Engineering

The impact of epigenetic modifications on monoclonal antibody expression from targeted integration (TI) clones is not well studied. Here we show that unlike clones obtained by the random integration (RI) approach, certain epigenetic modifications such as promoter methylation or histone acetylation/ methylation are not determinant when comparing average and high antibody expressing TI clones. Only chromatin accessibility (ATACseq analysis) positively correlated with higher transcription and titers in TI clones. Therefore, increasing chromatin accessibility may be an effective approach for increasing culture titers in TI cell lines.

Participants

Shahram Misaghi, PhD - Staff Scientist, Genentech, Inc

Increasing Productivity of Difficult-to-Express Proteins

17:15 - 17:45
Cell Culture & Upstream Processing

- Identify key challenges in expressing complex proteins;
- Learn about CLD strategies that can improve productivity;
- Understand media optimization techniques for higher yield;
- Explore the benefits and implementation of perfusion formats.

PAT-Integrated Downstream Processing of Novel Modalities

17:15 - 17:45
Recovery & Purification

Participants

Stefano Menegatti - Associate Professor, North Carolina State University

Outdoor Evening Drinks Reception/Party

17:45 - 19:15

SCHEDULE

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

TIME	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING
08:00	**08:55** - Chairperson's Remarks: Cell Line Development & Engineering **08:25** - Registration and Morning Coffee	**08:55** - Chairperson's Remarks: Cell Culture & Upstream Processing **08:25** - Registration and Morning Coffee	**08:55** - Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0 **08:25** - Registration and Morning Coffee	**08:55** - Chairperson's Remarks: Recovery & Purification **08:25** - Registration and Morning Coffee	**08:55** - Chairperson's Remarks: Cell and Gene Therapy Manufacturing **08:25** - Registration and Morning Coffee
09:00	**09:00** - Advances in Machine Learning for Cell Line Development To Predict Better Clones, Reduce Timelines & Experiments **09:30** - How Reliable are Chinese Hamster Ovary (CHO) Cell Genome-scale Metabolic Models?	**09:00** - Development of Two Alternative CHO Culture Harvest Processes using Acid Precipitation and Cationic Flocculation **09:30** - Reduce Workload via AI, Machine Learning, and Modeling in Bioprocessing	**09:00** - The Role of Raw Material Development in the Cultivated Meat Industry **09:30** - Optimizing Process Development and Clinical Production Efficiency with Continuous Improvement Projects	**09:00** - Improved Affinity Tag Self-Removal via Targeted Protein Engineering **09:30** - Development and evolution of downstream purification platform for inhalable biologics	**09:00** - FIRESIDE CHAT: The Need for Continuous Requalification & Support of Cell & Gene Therapy Distribution
10:00	**10:00** - Scientific Presentation by Great Bay Bio **10:30** - Morning Networking Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Networking Break	**10:00** - Scientific Presentation by Thermo Fisher **10:30** - Morning Networking Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Networking Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Networking Break
11:00	**11:40** - Optimizing Cell Line Development of Bispecific Antibodies by Customized Plasmid Configuration Modulation	**11:40** - Design Experiments to Obtain Desirable Product Quality Attributes for Protein Biologics	**11:40** - Next-Gen Bioprocessing: Leveraging Industry 4.0 for Smart Biomanufacturing Facilities	**11:40** - PANEL DISCUSSION: Building Strategic Partnerships for Downstream Success	**11:40** - KEYNOTE PRESENTATION: Poseida Therapeutics
12:00	**12:10** - High-Throughput Workflows and Automation For High Productivity, Reduced CoG and Time Saving **12:40** - Spotlight Presentation – Calling all Technology Thought Leaders!	**12:10** - Co-Culturing Cell Lines for Efficient Manufacture of Multispecifics **12:40** - Spotlight Presentation – Calling all Technology Thought Leaders!	**12:10** - BioPharm Manufacturing Optimization with a Factory Digital Twin **12:40** - Spotlight Presentation – Calling all Technology Thought Leaders!	**12:40** - Spotlight Presentation – Calling all Technology Thought Leaders!	**12:10** - Tuning CAR-T Cell Phenotype Through Enhanced Bioprocess Control in Stirred -Tank Bioreactors **12:40** - Scientific Presentation by Millipore Sigma
13:00	**13:10** - Lunch	**13:10** - Lunch	**13:10** - Lunch	**13:10** - Lunch	**13:10** - Lunch

SCHEDULE

THURSDAY 20TH MARCH - MAIN CONFERENCE DAY TWO - 20/03/2025

TIME	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING
14:00	**14:40** - Chairperson's Remarks: Cell Line Development & Engineering **14:45** - Green Lab Initiatives and Sustainable Practices – How Every Stage can Assist with Carbon Emissions, Water Usage and Waste?	**14:40** - Chairperson's Remarks: Cell Culture & Upstream Processing **14:45** - Optimizing Metabolic Flux in CHO Cells: A Hybrid Approach for Improved Cell Culture Productivity	**14:40** - Chairperson's Remarks: Manufacturing Strategy & Bioprocessing 4.0 **14:45** - Network-Based Scale-Up Data Collection and Analysis for AI Controlled Bioreactor Operations	**14:40** - Chairperson's Remarks: Recovery & Purification **14:45** - Challenges and solutions to manufacturing of low viscosity, ultra-high concentration IgG1 drug products: From late downstream process to final fill finish processing.	**14:40** - Chairperson's Remarks: Cell and Gene Therapy Manufacturing **14:45** - Controlling Manufacturing Processes in Pre-Commercial & Commercial Autologous Cell & Gene Therapy Products
15:00	**15:15** - CLE Toolbox: Optimizing Parental Cell Lines for Better Expression **15:45** - Afternoon Break	**15:15** - ADCs: Translating from Bench to Production Scale **15:45** - Afternoon Break	**15:15** - Maximizing the Impact of Digital Twins in Bioprocess Development and Manufacturing **15:45** - Afternoon Break	**15:15** - PANEL DISCUSSION: Achieving Sustainable Biomanufacturing from Lab to Market: Is Single-Use the Answer? **15:45** - Afternoon Break	**15:15** - Addressing the Challenges in Allogeneic CAR-T Manufacturing **15:45** - Afternoon Break
16:00	**16:45** - NISTCHO: An open access, living reference material for biomanufacturing	**16:45** - Comprehensive Modeling of Cell Culture Profile Using Raman Spectroscopy and Machine Learning	**16:45** - PANEL DISCUSSION: Technology as a Catalyst to Revolutionize the Future of Biomanufacturing	**16:45** - Mechanisms and modeling of depth filtration in biopharma	**16:45** - Innovation Showcase
17:00	**17:15** - Chromatin accessibility plays an important epigenetic role on antibody expression from CMV promoter and DNA elements surrounding the CHO TI host landing-pad **17:45** - Outdoor Evening Drinks Reception/Party	**17:15** - Increasing Productivity of Difficult-to-Express Proteins **17:45** - Outdoor Evening Drinks Reception/Party	**17:45** - Outdoor Evening Drinks Reception/Party	**17:15** - PAT-Integrated Downstream Processing of Novel Modalities **17:45** - Outdoor Evening Drinks Reception/Party	**17:45** - Outdoor Evening Drinks Reception/Party

SESSIONS

FRIDAY 21ST MARCH - MAIN CONFERENCE DAY THREE - 21/03/2025

Registration and Morning Coffee

08:30 - 08:55

Chairperson's Opening Remarks: Cell Line Development & Engineering

08:55 - 09:00
Cell Line Development & Engineering

Chairperson's Opening Remarks: Cell Culture & Upstream Processing

08:55 - 09:00
Cell Culture & Upstream Processing

Chairperson's Opening Remarks: Manufacturing Strategy & Bioprocessing 4.0

08:55 - 09:00
Manufacturing Strategy & Digitalization

Chairperson's Opening Remarks: Recovery & Purification

08:55 - 09:00
Recovery & Purification

Chairperson's Opening Remarks: Cell and Gene Therapy Manufacturing

08:55 - 09:00
Cell and Gene Therapy Manufacturing

End-to-End Automation Solutions: Doing More with Less to Accelerate Timelines in FIH Clone Screening

09:00 - 09:30
Cell Line Development & Engineering

One of the most time-consuming and tedious aspects of pre-clinical program development is clone screening for a production cell line. Automation tools allow efficient execution of these activities as well as timeline reductions to meet the demands of next generation modalities. Here, we will discuss a toolset that enables end-to-end automation for clone screening timeline optimization and execution.

Participants

Dr Landon Mott - Process Development Principal Scientist, Amgen Inc.

Cost of Goods (CoG) Reduction through Process Optimization

09:00 - 09:30
Cell Culture & Upstream Processing

- Explore strategies to improve yield and titer for CoG reduction;
- Learn about the connection between CoG reduction and sustainability;
- Gain practical examples and insights from industry case studies.

Participants

Frank Ritacco, PhD - Senior Director, Cell Culture Development, Regeneron

Revolutionizing Cell Therapy with Automated Manufacturing and Testing Solutions

09:00 - 09:30
Manufacturing Strategy & Digitalization

This presentation addresses key concerns surrounding the successful implementation of automation in cell therapy manufacturing. It explores strategies for simplifying the integration of cell therapy equipment, both through digital systems and robotics. Additionally, it explains how enhanced integration capabilities improve system robustness while reducing costs and risks for both vendors and customers. The presentation also highlights the importance of balancing standardization with innovation, drawing on historical examples from biotech and other industries to illustrate best practices.

Participants

Semsi Ensari - Sr Director, Process Development, Kite Pharma

Continuous Chromatography in Biomanufacturing: Are We Ready for Full Integration?

09:00 - 09:30
Recovery & Purification

- Managing resin saturation and desaturation cycles when implementing a continuous processing approach within downstream;
- Can upstream and downstream operations be combined for a seamless workflow?
- Utilising PAT for real-time data and process control throughout production;
- Case-study examples and data: how has continuous been implemented and what happened?

Participants

Aishwarya Ramanan - Scientist MSAT Labs & Innovation, Pfizer (Legacy Seagen)

Allogeneic CRISPR Genome Edited CAR-T Cells

09:00 - 09:30
Cell and Gene Therapy Manufacturing

- Case Study

Participants

Justin Skoble - Vice President, Caribou Biosciences, Inc.

Manifestations of CHO Cell Line Instability

09:30 - 10:00
Cell Line Development & Engineering

- Risks of accelerating the CLD timeline;
- Associated methods to perform early screens for stability.

Participants

Allyn Spear - Principal Research Scientist, Cell Line Development Lead, Elanco Animal Health

Next-gen Upstream Process for Our New, Metabolically Engineered, CHO Host

09:30 - 10:00
Cell Culture & Upstream Processing

Participants

Maddie Andres - Scientist, Pfizer

Replacing a Cell Line to Improve Manufacturing of a Clinical Bispecific Antibody

09:30 - 10:00
Manufacturing Strategy & Digitalization

Participants

Mr Neal Schilling - Director – Manufacturing, Compass Therapeutics

SESSIONS

FRIDAY 21ST MARCH - MAIN CONFERENCE DAY THREE - 21/03/2025

Realizing the Potential of Intensified and Continuous Processing in Biomanufacturing

09:30 - 10:00
Recovery & Purification

- Technological hurdles and challenges associated with implementing an intensified or continuous approach:
  - Equipment design
  - Process Control
  - Consistent product quality
- Cost-benefit viability of continuous processing: potential for reduced costs, increased production, expedited time to market
- Regulatory landscape for continuous manufacturing:
  - Navigating approval process
  - Implementing new approach into existing processes effectively
- Case study examples, real world lessons
- Future outlook of continuous in the biopharm industry: driving adoption

Participants

Panelist: Stefano Menegatti - Associate Professor, North Carolina State University

Production of PLVs for Vaccines: Bench to Clinic

09:30 - 10:00
Cell and Gene Therapy Manufacturing

- Case Study

Participants

Jitendra Kumar - Lead Scientist - Chemistry & Process Development, Entos Pharmaceuticals Inc., USA

Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
Cell Line Development & Engineering

Whether you're increasing your company profile, launching a new product or focusing on new business development opportunities, collaborate with us to identify custom solutions to help you reach your goals.

Contact us today to learn more: Partners@informaconnectls.com

Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
Cell Culture & Upstream Processing

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Scientific Presentation by Sartorius

10:00 - 10:30
Recovery & Purification

Spotlight Presentation – Calling all Technology Thought Leaders!

10:00 - 10:30
Cell and Gene Therapy Manufacturing

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Morning Break

10:30 - 11:00

Duplication of a chromosome 2 segment in production CHO cell lines correlates with age-related growth improvement

11:00 - 11:30
Cell Line Development & Engineering

Recombinant CHO cell lines often show improved growth in late generations, but the molecular mechanism is largely unclear. In this study, integrated genomic and transcriptomic profiling was performed on multiple Pfizer cell lines with different CHO host and monoclonal antibodies. We found the duplication of a continuous 50.2 Mbp segment in chromosome 2 (Chr2) correlated with the gain of improved growth phenotype. Yet such chr2 duplication was absent in clones without age-correlated growth change. In-depth mechanistic studies are ongoing to facilitate biomarker-based cell line screening and rational cell line engineering.

Participants

Wei Wei - Senior Principal Scientist, Pfizer

The Role of Automation and Real-Time Analysis in Modern Biologics Manufacturing

11:00 - 11:30
Cell Culture & Upstream Processing

- Advances in automation and real-time analysis for biologics manufacturing;
- Raman spectroscopy and its application in bioreactors
- Real-time protein analysis;
- Case studies on improving efficiency and reducing production timelines.

Participants

Mr Rahul Pradhan - Associate Director, Cell Culture Platform, Sanofi

Future-Proofing ADC Manufacturing: Expanding Capabilities and Capacity

11:00 - 11:30
Manufacturing Strategy & Digitalization

- Optimizing technologies for efficient biomanufacturing of Antibody Drug Conjugates (ADCs)
- Scaling up production for commercial and clinical supply
- Investing in cutting-edge facilities and equipment to meet growing demand
- Developing innovative process improvements for greater flexibility and cost-effectiveness

Participants

A Representative - From, Sutro Biopharma, Inc.

SESSIONS

FRIDAY 21ST MARCH - MAIN CONFERENCE DAY THREE - 21/03/2025

Strategies for Validating Affinity Tag Removal in GMP Bioprocessing

11:00 - 11:30
Recovery & Purification

The use of affinity tags is generally considered a non-starter for the purification of biopharmaceuticals clinical use. New developments in this field, including self-removing tags and optimized protease enzymes, have eliminated some of the technical and economic barriers to these methods. This talk will focus on one major remaining concern, which is how to develop validated release assays for characterizing products that are manufactured using cleavable tags. Several options will be discussed, along with preliminary data on several approaches.

Participants

David Wood - Professor of Chemical and Biomolecular Engineering, Ohio State University

Case Study: A Liver Directed Gene Therapy Program Targeting FGF21

11:00 - 11:30
Cell and Gene Therapy Manufacturing

Participants

Dan Oliver - CEO and Founder, Rejuvenate Bio, USA

Cell line development of a multi-chain bispecific molecule: vector design, selection method and clone screening strategy

11:30 - 12:00
Cell Line Development & Engineering

Balanced chain expression is crucial for achieving high productivity and proper assembly of multi-chain bispecific molecules. In this talk, we will present a case study demonstrating how vector design and selection methods impact the titer of correctly assembled molecules. Additionally, we will discuss clone diversity and single cell cloning strategies.

Participants

Bin Fan, PhD - Director of Biologics, NGM Biopharmaceuticals

Transfection and Cell Culture

11:30 - 12:00
Cell Culture & Upstream Processing

Participants

Yashas Rajendra Ph.D. - Associate Director & Principal Scientist, Denali Therapeutics

High Throughput Platform for Preclinical Cardiotoxicity Screening with hiPSC Derived Heart Tissues

11:30 - 12:00
Manufacturing Strategy & Digitalization

Cardiotoxicity is the leading cause of drug failure during pharmaceutical development. It also significantly impacts medical device and therapeutic development due to the complexity of heart function and the inability of regeneration of heart tissue. Engineered heart tissue (EHT) derived from hiPSCs has become an indispensable research tool in the past decade. With the increasing use of this in vitro testing model for internal decision making at pharmaceutical companies and the recent release of the FDA Modernization Act 2.0, there is an emerging need for scalable platform that can reliably produce and characterize EHTs. To address this issue, a high throughput in vitro testing platform and the associated accessories are developed to fit the industrial standard 96-well plates. With the current collaboration between BU and FDA's CDER, the prototype system will be evaluated and refined according to the FDA framework. Successful technology transfer of this innovation will help the industry and the regulatory to establish a standard guideline in using EHTs for all types of bioprocessing.

Participants

Marshall Ma - Research Fellow, Boston University

From Bottleneck to Breakthrough: Overcoming Downstream Challenges in AAV Gene Therapy Process Development

11:30 - 12:00
Recovery & Purification

Rapid advancement to manufacturing is crucial for AAV gene therapies, yet downstream processes frequently present a significant bottleneck. To address this challenge, MeiraGTx has established a high-throughput toolbox that integrates microscale screening platforms with a novel affinity HPLC method for in-process sample analysis. These high-throughput techniques are supported by automated digital workflows, effectively streamlining and accelerating the process development pipeline.

Participants

Marion Jenny - MSAT Senior Scientist (DSP), MeiraGTx

Direct Permutational Control of Transcription Factor Networks for Precision Cell Differentiation – Reducing Manufacturing Complexity and Duration

11:30 - 12:00
Cell and Gene Therapy Manufacturing

Participants

Nick Timmins - CSO, Syntax Bio

Spotlight Presentation – Calling all Technology Thought Leaders!

12:00 - 12:30
Cell Line Development & Engineering

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Spotlight Presentation – Calling all Technology Thought Leaders!

12:00 - 12:30
Cell Culture & Upstream Processing

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SESSIONS

FRIDAY 21ST MARCH - MAIN CONFERENCE DAY THREE - 21/03/2025

Spotlight Presentation – Calling all Technology Thought Leaders!

12:00 - 12:30
Cell and Gene Therapy Manufacturing

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Lunch

12:30 - 13:30

Closing Keynote 1

13:30 - 14:00
Plenary Keynote Sessions

Closing Keynote 2

14:00 - 14:30
Plenary Keynote Sessions

End of BioProcess International US West 2025

14:30 - 14:35

SCHEDULE

FRIDAY 21ST MARCH - MAIN CONFERENCE DAY THREE - 21/03/2025

TIME	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING	PLENARY KEYNOTE SESSIONS
08:00	**08:55** - Chairperson's Opening Remarks: Cell Line Development & Engineering **08:30** - Registration and Morning Coffee	**08:55** - Chairperson's Opening Remarks: Cell Culture & Upstream Processing **08:30** - Registration and Morning Coffee	**08:55** - Chairperson's Opening Remarks: Manufacturing Strategy & Bioprocessing 4.0 **08:30** - Registration and Morning Coffee	**08:55** - Chairperson's Opening Remarks: Recovery & Purification **08:30** - Registration and Morning Coffee	**08:55** - Chairperson's Opening Remarks: Cell and Gene Therapy Manufacturing **08:30** - Registration and Morning Coffee	**08:30** - Registration and Morning Coffee
09:00	**09:00** - End-to-End Automation Solutions: Doing More with Less to Accelerate Timelines in FIH Clone Screening **09:30** - Manifestations of CHO Cell Line Instability	**09:00** - Cost of Goods (CoG) Reduction through Process Optimization **09:30** - Next-gen Upstream Process for Our New, Metabolically Engineered, CHO Host	**09:00** - Revolutionizing Cell Therapy with Automated Manufacturing and Testing Solutions **09:30** - Replacing a Cell Line to Improve Manufacturing of a Clinical Bispecific Antibody	**09:00** - Continuous Chromatography in Biomanufacturing: Are We Ready for Full Integration? **09:30** - Realizing the Potential of Intensified and Continuous Processing in Biomanufacturing	**09:00** - Allogeneic CRISPR Genome Edited CAR-T Cells **09:30** - Production of PLVs for Vaccines: Bench to Clinic	
10:00	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Break	**10:00** - Scientific Presentation by Sartorius **10:30** - Morning Break	**10:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **10:30** - Morning Break	**10:30** - Morning Break
11:00	**11:00** - Duplication of a chromosome 2 segment in production CHO cell lines correlates with age-related growth improvement **11:30** - Cell line development of a multi-chain bispecific molecule: vector design, selection method and clone screening strategy	**11:00** - The Role of Automation and Real-Time Analysis in Modern Biologics Manufacturing **11:30** - Transfection and Cell Culture	**11:00** - Future-Proofing ADC Manufacturing: Expanding Capabilities and Capacity **11:30** - High Throughput Platform for Preclinical Cardiotoxicity Screening with hiPSC Derived Heart Tissues	**11:00** - Strategies for Validating Affinity Tag Removal in GMP Bioprocessing **11:30** - From Bottleneck to Breakthrough: Overcoming Downstream Challenges in AAV Gene Therapy Process Development	**11:00** - Case Study: A Liver Directed Gene Therapy Program Targeting FGF21 **11:30** - Direct Permutational Control of Transcription Factor Networks for Precision Cell Differentiation – Reducing Manufacturing Complexity and Duration	

SCHEDULE

FRIDAY 21ST MARCH - MAIN CONFERENCE DAY THREE - 21/03/2025

TIME	CELL LINE DEVELOPMENT & ENGINEERING	CELL CULTURE & UPSTREAM PROCESSING	MANUFACTURING STRATEGY & DIGITALIZATION	RECOVERY & PURIFICATION	CELL AND GENE THERAPY MANUFACTURING	PLENARY KEYNOTE SESSIONS
12:00	**12:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:30** - Lunch	**12:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:30** - Lunch	**12:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:30** - Lunch	**12:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:30** - Lunch	**12:00** - Spotlight Presentation – Calling all Technology Thought Leaders! **12:30** - Lunch	**12:30** - Lunch
13:00						**13:30** - Closing Keynote 1
14:00	**14:30** - End of BioProcess International US West 2025	**14:30** - End of BioProcess International US West 2025	**14:30** - End of BioProcess International US West 2025	**14:30** - End of BioProcess International US West 2025	**14:30** - End of BioProcess International US West 2025	**14:00** - Closing Keynote 2 **14:30** - End of BioProcess International US West 2025