Cambridge Healthtech Institute's
8th ANNUAL

BIOPROCESSING SUMMIT EUROPE

Solving Today's Challenges, Leading to Tomorrow's Advances

18–20 MARCH 2025 InterContinental Barcelona, Spain + Virtual (CET)

Register Early for **MAXIMUM SAVINGS!**

2025 PROGRAMS

Stream 1 UPSTREAM
- Cell Culture and Cell Line - 1
- Cell Culture and Cell Line - 2

Stream 2 DOWNSTREAM
- Recovery and Purification - 1
- Recovery and Purification - 2

Stream 3 GENE THERAPY
- Gene Therapy CMC and Analytics
- Gene Therapy Manufacturing

Stream 4 CELL THERAPY
- Cell Therapy CMC and Manuf.
- Gene Therapy Manufacturing

Stream 5 INTENSIFIED AND CONTINUOUS PROCESSING
- Cell Culture and Cell Line - 1
- Intensified and Cont. Processing

Stream 6 ANALYTICAL AND QUALITY
- Analytical Development
- Next-Gen Analytical Methods

Stream 7 *NEW* MODELLING AND DIGITALISATION
- Modelling and Developability
- AI and Process Control

PLENARY KEYNOTE PRESENTERS

CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD
Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD
Scientific Director, Process Development, Amgen Inc.

PREMIER SPONSOR AsahiKASEI BIOPROCESS

BioprocessingEurope.com

About Bioprocessing Summit Europe

Bioprocessing Summit Europe brings together 750+ upstream, downstream, bioproduction, and analytical professionals from industry and academia to advance the manufacture, quality, and control of next-generation biologics and genetic therapies.

This 3-day, 14-track meeting has quickly become a premier event in the European bioprocessing calendar and focuses on the latest innovations in bioprocess R&D as well as the practical solutions to enhance efficiency, speed, and cost in biomanufacturing.

New for 2025, we are excited to add a new conference stream on process modelling and digitalisation, alongside expanded content on ML/AI, advanced process control, developability, cell culture, downstream processing, analytics, and the latest in cell, gene, and RNA therapies.

CONTENTS

3 Sponsors & Media Partners
4 Keynote Addresses
5 Conference-at-a-Glance
6 Stream 1 Upstream
11 Stream 2 Downstream
16 Stream 3 Gene Therapy
21 Stream 4 Cell Therapy
26 Stream 5 Intensified and Continuous Processing
31 Stream 6 Analytics & Formulation
36 Stream 7 *NEW!* Modelling and Digitalisation
41 Sponsorship Opportunities
42 Venue & Poster Information
43 Pricing & Registration Options

2025 Sponsors

PREMIER SPONSOR

AsahiKASEI BIOPROCESS

CORPORATE SPONSORS

908devices · ADVANCED INSTRUMENTS · ANALYSISMODE A.I. Laboratory Simulators · ATUM

BECKMAN COULTER Life Sciences · BIO-RAD · CLADE · CYGNUS TECHNOLOGIES part of Maravai LifeSciences

CYTENA A BICO COMPANY · cytiva · ECOLAB LIFE SCIENCES · eppendorf · GORE

halo labs · HAMILTON · JSR Micro MATERIALS INNOVATION · PathoQuest

Pfanstiehl · REFEYN WEIGHING MOLECULES WITH LIGHT · SARTORIUS · synTQ by Optimal · TOSOH

CORPORATE SUPPORT SPONSORS

Ashland always solving · FORMULATRIX · FyoniBio · gator · LEVITRONIX

nova biomedical · Roche · securecell · ThermoFisher SCIENTIFIC · YOKOGAWA

2025 Media Partners

LEAD SPONSORING PUBLICATIONS

BIOLOGICS INSIGHTS · BioIT World · GEN Genetic Engineering & Biotechnology News · Mary Ann Liebert, Inc. publishers

SPONSORING PUBLICATION

DDN EXPLORING DRUG DISCOVERY AND DEVELOPMENT

WEB PARTNER

Gene Therapy Net

SUPPORTING ASSOCIATION

MABDESIGN

PLENARY KEYNOTE PRESENTERS

Wednesday, 19 March at 11:15

ADAPTING TO GLOBAL BIOPROCESSING DEMANDS AND EVOLVING PIPELINES

CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

BIOGRAPHIES

Christian Hunzinger, PhD

Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Christian is Senior Director, CMC Development Proteins, ADCs & Chemical Entities at BioNTech SE. Christian holds a PhD in Biology from the University of Mainz, Germany. He has 25 years of experience in biotech and pharmaceutical industry with a broad technical expertise ranging from early target and biomarker discovery up to late-stage CMC development and commercial manufacturing of protein-based biologics. Prior to joining BioNTech, Christian worked in various positions at Rentschler Biopharma SE, Merck KGaA, and ProteoSys AG.

Oliver Kaltenbrunner, PhD

Scientific Director, Process Development, Amgen Inc.

Oliver Kaltenbrunner is a Scientific Director of Amgen Process Development and has extensive experience leading the advancement of clinical and commercial processes through their development cycle. Roles have focused on commercial and clinical process support, process optimisation, process economics, multi-site engineering strategies, process transfer, and validation support. Currently, he leads a Manufacturing Technologies group, overseeing the introduction of new technologies into GMP manufacturing of therapeutic biologics.

TRACK KEYNOTE AND FEATURED SPEAKERS

Stream 1: Upstream

Krist V. Gernaey, PhD
Professor, Chemical & Biochemical Engineering, Technical University of Denmark

Jorgen B. Magnus, PhD
Professor & Chair, Biochemical Engineering, RWTH Aachen University

Stream 2: Downstream

Gisela M. Ferreira, PhD
Senior Director, AstraZeneca

Marcel Ottens, PhD
Professor, Biotechnology, Delft University of Technology

Stream 3: Gene Therapy

Advait V. Badkar, PhD
Executive Director & Head, Nanoparticle Development, Pfizer Inc.

Ana Sofia Coroadinha, PhD
Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

Stream 4: Cell Therapy

Paula Alves, PhD
CEO, iBET

Vered Caplan, CEO
Octomera and Orgenesis

Stream 5: Intensified and Continuous Processing

Lara Fernandez-Cerezo, PhD
Associate Principal Scientist, Merck

Richard D. Braatz, PhD
Edwin R. Gilliland Professor, Massachusetts Institute of Technology

Stream 6: Analytical and Quality

Elena Dominguez Vega, PhD
Assistant Professor, Center for Proteomics and Metabolomics, Leiden University Medical Center

Dan Bach Kristensen, PhD
Scientific Director, Symphogen

Stream 7: Modelling and Digitalisation

Peter Neubauer, PhD
Lab Head, Bioprocess Engineering, TU Berlin

Bettina Knapp, PhD
Lab Head, Upstream Development, Boehringer Ingelheim

"This event connects scientists from academia and industry all over the world and allows you to connect and share ideas along with showcasing all novel technologies related to the field of bioproduction."

Sofia Zaichick, PhD, University of Pennsylvania

CONFERENCE-AT-A-GLANCE

	TUESDAY 18 MARCH - WEDNESDAY 19 MARCH	WEDNESDAY 19 MARCH - THURSDAY 20 MARCH
Stream 1 **UPSTREAM**	Cell Culture and Cell Line Engineering - Part 1	Cell Culture and Cell Line Engineering - Part 2
Stream 2 **DOWNSTREAM**	Advances in Recovery and Purification - Part 1	Advances in Recovery and Purification - Part 2
Stream 3 **GENE THERAPY**	Gene Therapy CMC and Analytics	Gene Therapy Manufacturing
Stream 4 **CELL THERAPY**	Cell Therapy CMC and Manufacturing	Gene Therapy Manufacturing
Stream 5 **INTENSIFIED AND CONTINUOUS PROCESSING**	Cell Culture and Cell Line Engineering - Part 1	Intensified and Continuous Processing
Stream 6 **ANALYTICAL & QUALITY**	Accelerating Analytical Development	Next-Generation Analytical Methods
NEW! Stream 7 **MODELLING AND DIGITALISATION**	Process Modelling and Developability	AI and Process Control

“I’ve really appreciated the quality of the talks, and the focus on the science. The organization of the meeting was flawless. I’ll encourage my team members to join next year.”

Nic Preyat, PhD, UCB Pharma

18-19 MARCH 2025

Cell Culture and Cell Line Engineering - Part 1

VIEW PROGRAM »»

19-20 MARCH 2025

Cell Culture and Cell Line Engineering - Part 2

VIEW PROGRAM »»

Stream 1 UPSTREAM

The Upstream Processing stream explores advanced technologies for enhancing cell cultivation and engineering in biopharmaceutical development. Topics include targeted integration, metabolic design, high-throughput screening, and gene editing for cell line development. The stream highlights machine learning applications in upstream processing, addressing chemometrics, process optimisation, and cell line performance prediction. It also covers sustainability improvements, perfusion bioreactor optimisation, and solutions for emerging modalities, showcasing innovations driving efficiency in biotherapeutic production.

Cambridge Healthtech Institute's 8th Annual

18–19 MARCH 2025 ALL TIMES CET

Cell Culture and Cell Line Engineering – Part 1

Advancing Upstream Strategies for Process Efficiency

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

CHEMOMETRICS & MODELLING

8:25 Chairperson's Remarks
Mark Duerkop, CEO, Novasign GmbH

8:30 Deep Learning for Optimisation of Protein Expression
Diego A. Oyarzun, PhD, Reader in Computational Biology, Informatics Forum, University of Edinburgh
Deep learning is a promising approach for building sequence-to-expression models for strain optimisation. But these need large, costly data sets that create steep entry barriers for many laboratories. In this talk, I will discuss data requirements and how they impact predictive accuracy, alongside training strategies for improved prediction of protein expression in new regions of the sequence space. These results provide guidelines for balancing data cost/quality in predictive strain design.

9:00 How to Develop and What to Expect from Predictive Process Models
Michael Sokolov, PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG
This presentation will delve into strategies for developing accurate predictive models from limited and yet complex data, the necessary data inputs, and the potential challenges faced during implementation. Based on many industrial use cases, attendees will gain insights into how these models can forecast performance, reduce variability, and streamline manufacturing, improving both efficiency and product quality in biologic drug development.

9:30 Presentation to be Announced

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

10:45 Automated Knowledge Generation, Valorisation, and Exchange Strategies Reshape Bioprocess Development
Peter Neubauer, PhD, Lab Head, Bioprocess Engineering, TU Berlin
Complex self-driving intelligent experiments for bioprocess development are only possible by integrating all aspects of cell cultivation, analytics, and modelling into a comprehensive framework and steered by an effective Workflow Management System. This is realised in the KIWI-biolab and its opportunities for process optimisation and collaboration are demonstrated by a number of developmental projects. The strict implementation of such fully automated approaches promotes the application of FAIR principles.

11:15 Digital Twin–Enhanced Process Development: Success Stories from mAbs, C&CT, and Continuous Processing
Mark Duerkop, CEO, Novasign GmbH
The application of modelling tools in bioprocess development and manufacturing has garnered considerable interest. But what does it really take to develop digital bioprocess twins? This talk dives into key topics such as the business impact of process modelling, experimental design strategies, tailored modelling approaches, accelerated process development, seamless scale-up, and the real-time use of models for monitoring and control. These principles will be demonstrated through several industrial case studies.

11:45 Physics-Informed Artificial Intelligence: A Groundbreaking Technology in the Biopharmaceutical Industry
Ignasi Bofarull-Manzano, CMC Data Scientist, Mechanical Engineering, RWTH Aachen University
While AI's transformative power is well recognised across industries, its potential in pharmaceutical bioprocessing remains underexploited due to limited data. In 2019, Raissi et al. introduced Physics-Informed Neural Networks (PINNs), creating a new paradigm by integrating deep learning with first-principles laws. This method enables the use of AI even with scarce data, presenting a groundbreaking chance to revolutionise biopharmaceutical processes by cutting costs and accelerating the time-to-market for new therapies.

12:15 Fast-Track Your Way to Process Understanding and Control—A Case Study on How to Simplify PAT Implementation
Milla Neffling, Senior Manager, Bioprocess Applications, Marketing, 908 Devices Inc.

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

PROCESS EFFICIENCY

13:45 Chairperson's Remarks
Philip Probert, PhD, Technology Lead, CPI, United Kingdom

13:50 Increasing Process Efficiency in mAb Production through Perfusion-Based Approaches
Jan Ott, Researcher, Biotechnology and Cell Cultivation Technique, Zurich University of Applied Sciences
Increasing demand and the approval of biosimilars are forcing biopharmaceutical manufacturers to make their processes more efficient. Perfusion processes play an important role in this so-called process intensification. In this presentation, an overview of possible applications of the perfusion mode in the upstream process of antibody productions will be given and case studies from the cell culture lab of the ZHAW will be presented.

14:20 Cell Factory Robustness and Burden-Driven Production
Peter Rugbjerg, PhD, Lecturer, Chalmers University; CSO and Founder, Enduro
Bioproduction at manufacturing scale can be limited by cellular variation. Using synthetic biology, it is possible to addict cells to product formation. Such technology efficiently selects for production in the bioreactor by coupling cell growth to high-level production using essential genes linked to product biosensors. We will present cases and ways of diagnosis in diverse microorganisms, including *E. coli*, *Bacillus*, and yeast.

14:50 KEYNOTE PRESENTATION: Industry 4.0 Implementation in Biomanufacturing: Models and Data Collection
Krist V. Gernaey, PhD, Professor, Chemical & Biochemical Engineering, Technical University of Denmark
Industry 4.0 can potentially transform biomanufacturing, and digital twins play an important role. However, the digital twin is useless without data. The focus is on different modelling approaches for obtaining a digital twin, and on the challenges related to collecting informative data on a biomanufacturing process. Issues of model validation are highlighted, and the need for improved data collection is presented and illustrated with application examples.

15:20 Sponsored Presentation *(Opportunity Available)*

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

SUSTAINABILITY IMPROVEMENTS

16:20 Transforming Biologics Medicines Manufacturing: Technical Barriers and Solutions for a Sustainable Future
Philip Probert, PhD, Technology Lead, CPI, United Kingdom
With the UKNHS setting ambitious targets to be net zero by 2045, there is an increasing impetus for manufacturers to prioritise sustainability. This presentation describes the challenges to be addressed and the innovations being adopted, including energy efficiency improvements, waste reduction strategies, and

Cell Culture and Cell Line Engineering - Part 1

Advancing Upstream Strategies for Process Efficiency

resource optimisation. Solutions discussed will provide pathways to greener processes, demonstrating how sustainability and productivity can coexist in the biologics manufacturing landscape, shaping a more responsible future.

16:50 Potential of the Diversity of Single-Use Bioreactors in Upstream Processing: Cell Physiology and Sustainability Considerations

Stefan Junne, PhD, Associate Professor, Bioscience and Engineering, Aalborg University

Single-use equipment offers various strategies of power input and gas mass transfer. This variety is often not used—as, for a long time, geometrical similarity was one of the most important criteria for applicants. This parameter is, however, not relevant for achieving an optimal cell viability and additionally the maximum sustainability and cost efficiency. This talk aims to present strategies for suitable hybrid bioreactor application under consideration of these parameters.

17:20 "Organised Stress" and Tricks for Robust and Productive Intensified Process

Bassem Ben Yahia, PhD, Senior Scientist, Upstream Process Sciences, UCB Pharmaceuticals, S.A.

This research work is focussed on intensified processes with high seeding density inoculated from seed bioreactor in fed-batch mode using Chinese Hamster Ovary cells. The impact of the feeding strategy and specific power input (P/V) in the seed bioreactor and on the production step with two different cell lines (CL1 and CL2) producing two different monoclonal antibodies was investigated and the "organised stress" concept is introduced.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

UPSTREAM PROCESSING FOR EMERGING MODALITIES

8:25 Chairperson's Remarks

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria

8:30 Process Development for Production of Complex or Difficult-to-Express Proteins

Martin Bertschinger, PhD, Director, Drug Substance Development, Ichnos Sciences

The increased complexity of bi and multispecific formats makes these molecules difficult to express compared to standard mAbs. This session explores a holistic approach to overcoming these challenges, featuring techniques such as signal peptide optimisation, vector design, and cell line selection. Attendees will learn how these strategies have successfully increased expression levels and titres of BEAT and TREAT antibodies by up to 10-fold, reaching titres as high as 11 g/L.

9:00 Cell Engineering and Cell-Line Development Challenges for Emerging Modalities

Zorica Dragic, PhD, Executive Director, Cell Line Screening and Development, Novartis Pharma AG

Emerging therapeutic modalities present unique challenges in cell engineering and cell line development. I will present innovative strategies to address these complexities, focused on genetic optimisation of expression systems and overcoming hurdles specific to novel biologics. Attendees will gain insights into the advanced techniques designed to improve productivity, stability, and quality when working with cutting-edge modalities in biologic drug development.

9:30 Digital Applications to Robustify Bioprocessing despite Starting-Material Variability

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria

Process development focusses on quality-by-design principles and is often focused on CQA to CPP relationships. However, in many bioprocesses, such as bioeconomy or CGT processes, the effect of raw material attributes is the main source for variation. This contribution proposes digital tools to make the process more robust despite raw material variability using PAT, random effect modelling using linear mixed models, and MIMO feedback control tools.

10:00 Presentation to be Announced

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Presentation to be Announced

12:45 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

14:00 Close of Cell Culture and Cell Line Engineering - Part 1 Conference

Cambridge Healthtech Institute's 8th Annual

19–20 MARCH 2025 ALL TIMES CET

Cell Culture and Cell Line Engineering – Part 2

New Strategies for Enhanced Quality and Emerging Modalities

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

EMERGING TECHNOLOGIES FOR CLD

14:15 Chairperson's Remarks
Michael Butler, PhD, Principal Investigator, Cell Technology, National Institute for Bioprocessing Research & Training (NIBRT)

14:20 Finding the Right Clone: CLD Platform Optimisation
Katarzyna Sobkowiak, PhD, Scientist, Biotech Development Center, Merck KGaA
In recent years, more advanced molecule formats, like bispecific asymmetric monoclonal antibodies, have become more prevalent in the biopharmaceutic industry. They pose new challenges in cell line development projects, requiring the development of new screening methods to increase the chances of generating clones with good productivity and quality attributes. We have developed new approaches in early pools and clones' screening to increase the chance of obtaining clones with desired attributes.

14:50 Genomic Barcoding for Clonal Diversity Monitoring in Targeted-Integration CHO Cell Lines
Niels Bauer, Researcher, Genomic Medicine, Roche
To understand the source of interclonal heterogeneity during targeted integration (TI)-based CHO antibody producer cell-line development, we developed a cellular genomic barcoding strategy. This technology provided novel insights about clone diversity during stable cell-line selection on pool level, enabled an imaging-independent monoclonality assessment after single-cell cloning, and eventually improved hit-picking of antibody producer clones by monitoring of cellular lineages during the cell-line development (CLD) process.

15:20 Gene Editing for the Purification of a Large Multiprotein Complex
Arnaud Poterszman, PhD, Research Director, Integrated Structural Biology, IGBMC
Macromolecular complexes are cornerstones of most, if not all, biological processes in cells. We will illustrate how the CRISPR/Cas9 editing technology can be used for gene tagging in order to introduce affinity tags and facilitate the purification of proteins/macromolecular assemblies expressed in physiological conditions. We will also discuss tagging proteins with fluorescent reporters in view of imaging and functional proteomics applications.

15:50 C.STATION: End-to-End Automation for Generating Stable Cell Lines for the Development of Advanced Therapeutics
CYTENA A BICO COMPANY
Speaker to be Announced, CYTENA
Revolutionize cell line development (CLD) workflows with CYTENA's C.STATION. This turnkey automated solution offers efficient single cell isolation, documented clonality assurance, high-producer/high-quality clone enrichment, increased throughput, process consistency, and improved data traceability and integrity. It is tailored and configured with the best-in-class instruments and software for monoclonal antibody development, viral vector production, and iPSCs for cell therapy.

16:05 Sponsored Presentation *(Opportunity Available)*

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Advances in the Pipeline for the Production and Characterisation of Therapeutic Proteins Using Cell-Free Synthesis
Takanori Kigawa, PhD, Senior Scientist, RIKEN Center for Biosystems Dynamics Research
We have established and utilised a protein-production pipeline based on cell-free synthesis that can accelerate the production of therapeutic proteins, including cytokines, antibodies, and membrane proteins. Using this pipeline, microgram to milligram quantities of multiple proteins can be produced simultaneously using automated processes, greatly accelerating the production of therapeutic protein candidates for characterisation by analytical methods including NMR. This presentation will highlight the progress of the pipeline.

17:30 Tastes like Chicken, Because It Is: Insights from the Cultivated Meat Industry
Kalle Johnson, Senior Director, Cell Culture Media, UPSIDE Foods
Rising affluence in developing regions, combined with a population predicted to hit 10 billion by 2050, poses a challenge in producing meat through conventional means. Cultivated meat offers solutions for a sustainable food supply. We explore an industry overview, the many measures to ensure food product safety, how the nutrients contained in culture media impact cost, and the implications of bioprocessing at immense scales compared to traditional biotherapeutics.

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

Cambridge Healthtech Institute's 8th Annual

19–20 MARCH 2025 ALL TIMES CET

Cell Culture and Cell Line Engineering – Part 2

New Strategies for Enhanced Quality and Emerging Modalities

18:30 Close of Day

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

PROCESS MONITORING AND CONTROL

8:25 Chairperson's Remarks

Zach Pang, PhD, Group Leader, Bioprocess Data Integration, A*STAR

8:30 To Model or Not to Model: When Are Models Really Useful?

Bettina Knapp, PhD, Lab Head, Upstream Development, Boehringer Ingelheim

Cell culture development in biopharmaceuticals uses models to optimise processes and understand complex systems. Defining a model's purpose is crucial, as is starting with good data. Embracing model thinking across all disciplines enhances understanding and effective use of models. Despite challenges, effective modelling can lead to faster, better, and more sustainable processes.

9:00 Non-Invasive Methods for Monitoring Bioprocesses

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

Bio-capacitance has become a standard online method to measure growth in cell-based biomanufacturing. The method offers rapid, continuous monitoring without manual sampling. However, there are noted deviations at the inflection point beyond exponential growth compared to standard staining methods such as trypan blue. This can be explained by different measurement criteria that can be exploited to gain a good understanding of the metabolic changes that arise during the bioprocess.

9:30 KEYNOTE PRESENTATION: Using the Oxygen Transfer Rate as a Basis for Scale-Up of Cell Culture

Jorgen B. Magnus, PhD, Professor & Chair, Biochemical Engineering, RWTH Aachen University

Using the Respiration Activity Monitoring System developed at the RWTH University of Aachen, the oxygen transfer rate can be measured very accurately in deep well plates, shake flasks, and stirred tank bioreactors. Thus, the state of the cell culture can be understood at different scales without the need to take samples. This information, in combination with calculations of volumetric power input and maximum energy dissipation, is used for scale-up.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

DIGITAL APPLICATIONS IN CELL CULTURE AND CLD

11:10 Accelerating Design of New Upstream Bioprocesses with Digital Twins: A Case Study on AAV Production

Inês A. Isidro, PhD, Head of Biosystems and Data Science, iBET

Digital twins can significantly transform bioprocess design. We present a case study on AAV production in insect cells, where digital simulation was used to design a new fed-batch operation. This demonstrates how digital twins can be leveraged for new gene and cell therapy products, which often have limited accumulated data and serotype/donor-specific variability, to unlock faster and more efficient bioprocess development.

11:40 Computational Approach to Accelerate Culture Media Optimisation for New Modalities

Zach Pang, PhD, Group Leader, Bioprocess Data Integration, A*STAR

The current workflow involves experimental DOE to determine the optimal culture media formulation. A paradigm shift is underway in the optimisation of culture media, wherein a modelling approach can be employed to accelerate culture media optimisation. I will introduce a computational approach involving genome-scale metabolic modelling and model-guided DoE approach, and how this workflow can help the industry, particularly for new modalities, to accelerate culture media design and optimisation.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

PROBLEMS AND SOLUTIONS

13:25 Chairperson's Remarks

Joaquim Vives, PhD, Head of Production, Advanced Therapies, Banc de Sang i Teixits

13:30 Strategies for Developing Stable CHO Cell Lines for High-Yield mAb Production

Hafsa Boulenouar, PhD, Postdoctoral Researcher, Medicine and Pharmacy, Mohammed V University of Rabat

Trastuzumab (Herceptin) is a key treatment for HER2-positive breast cancer. The aim of this study was to develop a stable CHO cell line with high trastuzumab production using a transposon-based vector, suspension culture, and eGFP/FACS selection. The T1A7 clone, selected from over 1500 clones, reached 4.24 g/L in 7 days. This efficient workflow provides a cost-effective approach to monoclonal antibody production suitable for R&D laboratories, including those in developing countries.

14:00 Engineered CHO Cell Lines for Improved Bioprocess Development

Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

Using genome-scale cell-line engineering, we have generated a large collection of engineered CHO cell lines for the production of the next generations of biologics. The cell lines are engineered for prolonged fed-batch productions, removal of lactate secretion, tailored and improved glycosylation, and removal of contaminating host cell proteins. Using these cell lines, we have demonstrated production of recombinant proteins with tailored glycans, lactate-free bioprocesses, and improved product quality.

14:30 Critical Quality Attributes of Single-Use Stirred Tank Bioreactors versus Planar Culture Systems

Joaquim Vives, PhD, Head of Production, Advanced Therapies, Banc de Sang i Teixits

This presentation will focus on the development and validation of Good Manufacturing Practice-compliant 3D-culture methods using microcarriers and single-use stirred-tank bioreactors for expanding mesenchymal stromal cells (MSCs). Our results showed comparable yields and quality between 3D and 2D cultures, with high cell viability, consistent immunophenotype, and intact multipotency and immunopotency. These processes support scalable, clinical-grade MSC production for use in allogeneic advanced therapies.

15:00 Close of Summit

18-19 MARCH 2025

Advances in Recovery and Purification - Part 1

VIEW PROGRAM »»

19-20 MARCH 2025

Advances in Recovery and Purification - Part 2

VIEW PROGRAM »»

Stream 2 DOWNSTREAM

The Downstream Processing stream brings together leading industry and academic experts to explore the latest advancements in the capture, recovery, and purification of biotherapeutics, across a range of modalities and development phases. Taking place across 3 days, topics include: latest developments in chromatography, resins, digitalisation and process modelling, automation, continuous processing, PAT and digital twins, high-throughput process development (HTPD), innovative membranes, removing impurities, and emerging novel purification techniques.

Cambridge Healthtech Institute's 8th Annual

18–19 MARCH 2025 ALL TIMES CET

Advances in Recovery and Purification - Part 1

Process Optimisation, Continuous Processing, and Novel Capture Technologies

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

MULTISPECIFICS AND ANTIBODY-DRUG CONJUGATES

8:25 Chairperson's Remarks

David O'Connell, PhD, Associate Professor, School of Biomolecular & Biomedical Science, University College Dublin

8:30 CMC Feasibility Assessment of Multispecific Lead Candidates

Bastian Franke, PhD, Associate Director and Group Leader, Downstream Processing, Numab Therapeutics AG

Multispecific antibody-based therapeutics are complex biologics that require comprehensive CMC feasibility assessments to assess developability, minimise manufacturing risks, and ensure product quality, safety, and efficacy throughout the manufacturing process. This presentation will highlight key experiments and risk mitigation strategies for multispecific lead molecules at Numab Therapeutics, with the focus on upstream and downstream platform feasibility, stability studies, biophysical characterisation, and formulation approaches.

9:00 Accelerating Preclinical CMC through Innovation & Optimisation

Rick Hibbert, PhD, Vice President, Head of CMC Science and Technologies, Genmab BV

Rapid preclinical CMC processes are essential for accelerating antibody therapies to meet urgent medical needs. This presentation highlights innovative strategies to streamline CMC processes, including cell line technologies, automation, and data-driven approaches. With greater efficiency, shorter timelines, and consistent product quality, Genmab is optimising the development pipeline for its antibody, DuoBody, and ADC-based therapies.

9:30 Presentation to be Announced

GORE

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

10:45 FEATURED PRESENTATION: Efficient Process Development of Site-Specific Antibody-Drug Conjugates

Michel H.M. Eppink, PhD, Senior Director, Downstream Processing, Byondis BV

Antibody Drug Conjugates (ADCs) are biotherapeutic medicines consisting of a drug (chemotherapeutic agent), a (non-)cleavable linker, and a monoclonal antibody. The current progress on the development of the reduction/conjugation and purification processes for the next-generation ADCs will be explained using single-use materials and lean processes. Moreover, characterisation of the ADCs with physicochemical/biochemical studies and the challenges to handle cytotoxic payloads will be presented.

ADVANCES IN RECOVERY AND PURIFICATION

11:15 Bringing PrA EBA Back to the Future

Curtis Phippen, PhD, Senior Scientist, Downstream Process, UCB Biopharma

Primary recovery of mammalian antibodies includes multiple steps; reducing this number can prevent product loss, save time, and reduce water usage and costs. Expanded Bed Adsorption (EBA) was developed for this purpose, though low titres and large volumes limited its effectiveness. We've brought EBA back to the future via a specialised PrA resin and method. With our setup, =50g of product per litre resin captured directly from bioreactor feedstreams.

11:45 Self-Removing Tags for Protein Purification—A New Production Platform for Tagless Proteins

Philipp Amsler, Principal Scientist I, Protein Production, Novartis Biomedical Research

Affinity tags are an essential tool for drug discovery and development. A potentially required proteolytic tag cleavage and removal requires additional processing steps and sourcing of complex raw materials. Self-removing affinity tag systems based on split inteins display a promising option for research applications but also large-scale manufacturing. We evaluated three different solution providers' tags and resins by testing diverse proteins expressed in different production hosts.

12:15 Presentation to be Announced

Pfanstiehl

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

CONTINUOUS DOWNSTREAM PROCESSING AND VIRAL FILTRATION

13:45 Chairperson's Remarks

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, University of Natural Resources and Life Sciences (BOKU)

13:50 KEYNOTE PRESENTATION: Virus Clearance Strategies in Continuous Processing

Gisela M. Ferreira, PhD, Senior Director, AstraZeneca

Viral safety is a critical quality attribute in biopharmaceuticals. These products are increasingly using continuous manufacturing approaches for improved productivity and cost reduction. This presentation describes two virus inactivation strategies using detergent which are suitable and advantageous to continuous manufacturing. The content will leverage prior knowledge and concepts of viral clearance to support continuous virus inactivation. Testing strategies and controls, data, GMP considerations, and preliminary regulatory feedback will be discussed.

14:20 Residence Time Distribution of Batch and Continuous Viral Filtration

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, University of Natural Resources and Life Sciences (BOKU)

The residence-time distribution is an important parameter to assess the performance of an integrated process. It shows how fast the process is in steady state and how process disturbance propagates. Understanding the RTD also helps to design efficient processes. Examples will be provided.

14:50 Optimisation of Continuous Capture Chromatography Processes

Matthias Wiendahl, Principal Scientist, Biopharm API Support, Novo Nordisk AS

Continuous capture chromatography (cSMB) can be used for capturing monoclonal antibodies offering higher resin utilisation, higher productivity, and lower buffer consumption than traditional single column capture processes. The design of cSMB processes is more challenging than the design of batch processes, so we have developed an iterative solution using different flow rates and different breakthrough curves as inputs which results in significantly higher productivities compared to the standard approach.

15:20 Intensification & Integration: Recent Advances and Continuous Improvement in Octave Multi-Column Chromatography

TOSOH

Speaker to be Announced, Tosoh Bioscience

15:35 Sponsored Presentation *(Opportunity Available)*

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

Cambridge Healthtech Institute's 8th Annual

18–19 MARCH 2025 ALL TIMES CET

Advances in Recovery and Purification - Part 1

Process Optimisation, Continuous Processing, and Novel Capture Technologies

PROCESS INTENSIFICATION

16:20 Building the Future of Bioprocessing: A Strategic Roadmap for Intensification, Innovation, and Sustainable Growth

Andrew Falconbridge, Senior Biotech Innovation Consultant

As bioprocessing evolves, companies must adopt next-generation technologies and intensification strategies to stay competitive. This talk will explore how process intensification, digital tools, and PAT can accelerate time to market, reduce costs, and support sustainability. Outlining a strategic roadmap for integrating these and demonstrating how companies can optimise their processes and scale effectively. Giving actionable insights into building an approach to process improvement—balancing speed, cost-efficiency, and environmental responsibility.

16:50 Advancing Bioprocessing with Continuous Microfluidic Technologies

Raquel Aires-Barros, PhD, Professor, Bioengineering, Instituto Superior Tecnico

Integrated continuous bioprocessing boosts biomolecule production efficiency, reducing material use, equipment size, and carbon footprint. However, scaling is costly, necessitating innovative screening methods. Microfluidic devices accelerate biomanufacturing by testing many variables with minimal reagents and time. Most studies optimise individual operations rather than entire processes. An integrated microfluidic platform simulating bioprocessing has been developed, incorporating modules for production, chemical lysis, and ATPE to optimise both individual and combined operations.

17:20 NEW Planova™ FG1 Virus Removal Filter - Promise of Unrivaled Performance

AsahiKASEI BIOPROCESS

Haiko Fischer, Product Manager, Bioprocess, Asahi Kasei Bioprocess Europe

The future of Virus Removal Filters has arrived: Planova™ FG1's rapid filtration performance allows users to process a large amount of solution in a limited amount of time, all while ensuring reliable performance and robust virus removal capability.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

ADVANCES IN RECOVERY AND PURIFICATION

8:25 Chairperson's Remarks

Cecilia Roque, PhD, Associate Professor in Bioengineering, NOVA University of Lisbon

8:30 Development of Downstream Processing for Novel Scaffold Therapeutics

David O'Connell, PhD, Associate Professor, School of Biomolecular & Biomedical Science, University College Dublin

Small scaffold proteins engineered for improved half-life and protease resistance require bespoke purification schemes. The SXkmer scaffold presents single constrained hypervariable peptide sequences for target binding, and rather than include affinity tags for downstream purification, we aim to utilise charge characteristics of the protein to achieve high-level purity from bacterial expression systems without compromising protein function or requiring post-purification tag cleavage. Examples from a GPCR targeting programme will be presented.

9:00 Process Development of Magnetic Separation Using Mechanistic Models

Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich

Are you familiar with protein or DNA separation with magnetic particles on a small scale and are wondering whether this can also be applied on an industrial scale for the rapidly growing field of biopharmaceuticals? Using a pilot-scale magnetic separator and the integration of Pharma 4.0 principles, we show how the process control works and how the purification process of antibodies from CHO supernatants is optimised.

9:30 Matching Affinity and Mixed-Modes Ligands with Purification Matrices

Cecilia Roque, PhD, Associate Professor in Bioengineering, NOVA University of Lisbon

How relevant are the matrix and ligands when developing adsorbents with improved functionality? In this talk, we will show how robust peptidomimetics can be easily adapted to several targets and to chromatographic and non-chromatographic matrices and purification processes.

10:00 Presentation to be Announced

ECOLAB LIFE SCIENCES

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Presentation to be Announced

BIO-RAD

12:45 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

14:00 Close of Advances in Recovery and Purification - Part 1 Conference

Cambridge Healthtech Institute's 8th Annual

19–20 MARCH 2025 ALL TIMES CET

Advances in Recovery and Purification - Part 2

Novel Modalities and Digitalisation

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

DIGITALISATION AND PROCESS CONTROL

14:15 Chairperson's Remarks
Geoff Smith, PhD, Professor, Pharmaceutical Process Analytical Technology, De Montfort University

14:20 KEYNOTE PRESENTATION: Host Cell Proteins Profiling and Characterisation for Model-Based DSP Design
Marcel Ottens, PhD, Professor, Biotechnology, Delft University of Technology
This presentation explores the integration of host cell proteins (HCP) profiling into model-based downstream process (DSP) design. By examining the characterisation techniques and quantification of HCPs, we demonstrate how these data inform the optimisation of purification strategies, enhancing product purity and process efficiency. Case studies illustrate the impact of advanced HCP analytics on biopharmaceutical production, emphasising practical applications and theoretical implications for DSP workflows.

14:50 Digitalisation Strategies to Enhance Efficiency and Product Quality
Oliver Hesse, Lead, CMC Digital Transformation and Data Science
This presentation will highlight our manufacturing platform strategy for cell therapies—emphasising data science, modelling, and PAT—to enhance manufacturing efficiency and product quality. By integrating automation and machine learning, we want to accelerate the development of robust processes. Join us in exploring how smart manufacturing practices can redefine the future of cell therapy production.

15:20 Pharmaceutical Freeze-Drying: Applications for Multi-PAT Sensors
Geoff Smith, PhD, Professor, Pharmaceutical Process Analytical Technology, De Montfort University
A novel program of work (Digital_Lyo) will be presented that is being undertaken by a consortium or academic, industrial, and regulatory authority partners, including AstraZeneca, Siemens, the Medicines and Healthcare Regulatory Agency (UK), and smaller industrial enterprises with specialist capability in sensor development. The talk will present highlights of the Digital_Lyo programme, including the applications for a novel process analytical technology called through-vial impedance spectroscopy (TVIS).

15:50 Presentation to be Announced

16:05 Sponsored Presentation *(Opportunity Available)* HAMILTON

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

DIGITAL TWINS AND PROCESS MODELLING

17:00 Automated Generation of Digital Twins and Their Use in Real-Time Monitoring of Process Chromatography
Daniel Espinoza, PhD Student, Advanced Process Engineering, Lund University
For biomanufacturing to reach the standards of Industry 4.0, digital twins are crucial. To accelerate digitalisation efforts in downstream processing, we have developed a framework for automatic generation of mechanistic chromatography models. These models are then used to create a digital shadow of the process by means of Kalman filtering. The result gives improved monitoring of the chromatographic elution, combining both real-time data and mechanistic modelling.

17:20 Monitoring Protein Aggregation in Downstream Processing Using Automated Raman Spectroscopy
Jakob Heyer-Mueller, PhD Student, Institute of Engineering in Life Sciences, KIT
The presented case study investigates the application of automated Raman spectroscopy as an in-line tool for the monitoring of protein aggregation during downstream processing. Spectral effects associated with multiple aggregation phenomena were analysed to provide insights into structural changes of different proteins. Leveraging this knowledge, the potential of Raman spectroscopy for real-time monitoring of critical quality attributes in chromatographic processes was demonstrated.

17:40 Improving the Sustainability of Biopharmaceutical Downstream Processing through Buffer Recycling
Madelène Isaksson, Doctoral Student, Department of Process and Life Science Engineering, Lund University
The production of biopharmaceuticals is both chemical- and water-intensive. The downstream process, which typically involves multiple chromatography steps, requires large volumes of buffers. With the global commitment to sustainable development goals and the anticipated growth of the biopharmaceutical market, buffer consumption is expected to become increasingly problematic. To mitigate this issue, we propose introducing buffer recycling in chromatography to reduce the consumption of water and chemicals.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete

Cambridge Healthtech Institute's 8th Annual

19–20 MARCH 2025 ALL TIMES CET

Advances in Recovery and Purification - Part 2

Novel Modalities and Digitalisation

listing of topics and descriptions.

18:30 Close of Day

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

DOWNSTREAM PROCESSING FOR COMPLEX THERAPIES AND FEEDSTOCKS

8:25 Chairperson's Remarks

Cristina C. Peixoto, PhD, Head Downstream Process, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica

8:30 Purification of Recombinant Proteins from Complex Feedstocks

Johannes Felix Buyel, PhD, Head, Institute for Biochemical Engineering, University of Natural Resources and Life Sciences (BOKU)

Secreted recombinant proteins often account for a large fraction of the total protein in cultivation supernatants facilitating purification. If, however, cell or tissue disruption is required for product recovery, purification becomes substantially more challenging due to abundant host cell proteins, DNA, and other impurities. Here, we discuss which options exist to build scalable and cost-efficient purification when handling such complex feedstocks.

9:00 FEATURED PRESENTATION: Streamlining the Purification of a Clinical-Grade Oncolytic Virus for Therapeutic Applications

Cristina C. Peixoto, PhD, Head Downstream Process, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica

Oncolytic virotherapy manufacturing continues to face significant challenges, primarily due to absence of suitable analytical methodologies for monitoring downstream processing and characterising the final drug product. This presentation will focus on both the challenges and achievements faced during the development of an end-to-end process for a novel chimeric oncolytic virus (OV). Key topics will include the scale-up process and the advanced analytical methods implemented to ensure product quality and consistency.

9:30 Model-Assisted Development and Dynamic Control of Multicolumn Countercurrent Solvent Gradient Purification of Oligonucleotides

Mattia Sponchioni, PhD, Assistant Professor, Department of Chemistry, Materials and Chemical Engineering, Politecnico di Milano

A model-based strategy is presented for the optimisation of yield and productivity, at a fixed purity specification, in the reversed-phase chromatographic purification of an oligonucleotide. Through this approach, the roles of collection window, column loading, and gradient slope on process performance were elucidated. In addition, it allowed the rapid design of an efficient MCSGP, which, when coupled to a dynamic process controller based on UV signal, ensured a robust operation.

10:00 Presentation to be Announced

10:15 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

DOWNSTREAM PROCESSING FOR VIRAL VECTORS, PLASMIDS, VLPs, AND EVs

11:10 Lord of the Rings: Optimisation of a Plasmid Purification Process Combining HTS and Mechanistic Modelling

Sabrina Simpson-Koch, PhD, Scientist, Gene Therapy Technical Development, Roche Diagnostics GmbH

Plasmids are the key starting material for viral vector manufacturing. Due to the rapid growth of the CGT field and increased demand for high-quality pDNA, plasmid supply became a significant bottleneck. Here we present process optimisation using a combination of HTS and mechanistic modelling. The suggested process marks one of the key elements for Roche's fast growing gene therapy activities, while facilitating the cost decrease of gene therapy products.

11:40 What about Chromatin? The Importance of Selecting the Right Endonuclease in Bionanoparticle Purification

Patricia P. Aguilar, PhD, Research Group Leader, ACIB GmbH

Separating bionanoparticles (BNP) from chromatin is particularly challenging due to the wide range of chromatin fragment sizes and charges. While endonuclease treatment reduces host cell DNA, tightly packed DNA within chromatin is resistant to conventional enzymes. Salt-active nucleases effectively remove DNA in chromatin form. This presentation will highlight their use in downstream processing of enveloped bionanoparticles such as HIV-1 gag VLPs and the measles virus.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

13:25 Chairperson's Remarks

Patricia P. Aguilar, PhD, Research Group Leader, ACIB GmbH

13:30 Dual-Stage Cross-Flow Filtration—Integrating VLP Recovery, Isolation, and Concentration Following Selective VLP Precipitation

Annabelle Dietrich, PhD Student, Biomolecular Separation Engineering, Karlsruhe Institute of Technology

Toward standardised platform processing—an innovative dual-stage cross-flow filtration setup is introduced for integrated VLP capture and purification. Selective VLP precipitation and washing of the precipitate in the first membrane stage are combined with simultaneous recovery, isolation, and concentration of the re-dissolved VLPs in the second membrane stage. This study spotlights the potential to broaden the setup's applicability to diverse (viral) vectors, distinct process conditions, and continuous processing.

14:00 Phase-Separated Zwitterionic Polymeric Coacervates for the Isolation of Extracellular Vesicles

Jonathan Garlipp, PhD, Student, ETH Zurich

Despite growing interest in extracellular vesicles (EVs), their manufacturing is still limited by low yields and scalability issues. Current separation methods are challenged by co-isolation of impurities, scale-up, and potential changes in physicochemical properties of EVs. Here we show an isolation strategy for EVs based on zwitterionic polymeric coacervates, exhibiting stimulus-responsiveness, anti-fouling, and liquid-like properties. We demonstrate how this method leads to a versatile, gentle, and scalable purification strategy.

14:30 Nanofiber-Based Adsorbent to Address Extracellular Vesicle Subpopulation Isolation

Emma Burman, EngD Student, Department of Biochemical Engineering, UCL

Extracellular vesicles (EVs) facilitate intercellular communication by transporting bioactive molecular cargo and can be exploited as therapeutic agents. However, their purification from physiochemically similar impurities poses a manufacturing challenge. We evaluated the effectiveness of bind-elute ion exchange chromatography (IEX) with a nanofiber-based adsorbent for EV purification. IEX preserved EV bioactivity, and achieved high purity and recovery comparable to widely adopted size-based methods, with the advantage of separating distinct EV subpopulations.

15:00 Close of Summit

18-19 MARCH 2025

Gene Therapy CMC and Analytics

VIEW PROGRAM »»

19-20 MARCH 2025

Gene Therapy Manufacturing

VIEW PROGRAM »»

Stream 3 GENE THERAPY

The Gene Therapy stream focuses on the critical challenges facing the analysis, characterisation, quality control, and manufacture of gene therapies, viral and non-viral-based. Topics include upstream and downstream processing of AAV and LVs, scale-up, product and process characterisation, impurities, quality control, comparability, capsid design, formulation, and commercial manufacturing.

Cambridge Healthtech Institute's 6th Annual

18–19 MARCH 2025 ALL TIMES CET

Gene Therapy CMC and Analytics

Improving the Analysis, Control, and Quality of Gene Therapies towards Commercialisation

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

ADVANCING GENE THERAPY DEVELOPMENT

8:25 Chairperson's Remarks

Tony Bou Kheir, PhD, Head, Analytical Development and QC, Purespring Therapeutics

8:30 Common Growing Pains for Early-Stage CGTs

Pamela Whalley, PhD, Associate Director, CMC, Complement Therapeutics Ltd.

With so many viral-vector-based gene therapies approved by the FDA across different types of viral vectors (AAV, lentivirus, herpes simplex virus 1) and many in late-stage development or clinical trials, the number of approved therapies is growing. There are many challenges that investor-led start-up companies navigate through, from the process of viral-vector manufacturing and CMC analytical method development, to quality issues and regulatory hurdles all in a highly competitive landscape.

9:00 Commercialising Gene Therapies: Late-Stage to Launch

Morgan O'Brien, PhD, Associate Director, Gene Therapy R&D, Johnson & Johnson Innovative Medicine

This presentation will share experience on tech transfer and CMC challenges for AAV gene therapy products, with a focus on late-phase and preparation for process validation and launch.

9:30 Sponsored Presentation *(Opportunity Available)*

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

CMC STRATEGIES, RAW MATERIALS, CONTROL STRATEGIES

10:45 FEATURED PRESENTATION: Regulatory Feedback for ATMPs across Multiple Submissions

Kathleen Retterson, Senior Vice President, Regulatory Affairs Practice CMC, ELIQUENT Life Sciences

ATMPs use cutting-edge technology about which regulatory agencies around the world are still learning what is (and is not) important with respect to product safety, identity, strength, purity, and quality. Guidance on CMC and clinical matters is limited and generally very high level. This section will explore feedback received from across multiple products in the form of meeting advice, information requests, and hold/non-hold comments.

11:15 Smells Like Plasmid Spirit—In-House Manufacturing for the Critical Starting Material in Cell and Gene Therapy

Selina Baeder, Senior Associate, Cell and Gene Therapy, Roche

In the CGT-sector, plasmids are considered the critical starting material. Within the latest growth in this CGT-sector, the demand for plasmids increased tremendously. Here we present our in-house cutting-edge pDNA production process for off-the-shelf CGT products. We will address our efforts of establishing a robust and scalable process capable of plasmid production for different modalities. By overcoming widespread challenges, we demonstrate production of high-quality plasmids in gram quantity.

11:45 Analytical Techniques for rAAV Genome Integrity and Identity Assessment

Christoph Gstöttner, PhD, Scientist, Roche

Recently, the development of therapies based on recombinant adeno-associated viruses (rAAV) has gained huge interest in the pharmaceutical industry. To ensure a safe and effective gene therapy product, a smart control strategy for the assessment of the rAAVv genome is of utmost importance. In this presentation, different analytical techniques for rAAV genome integrity and identity assessment will be discussed, highlighting their benefits and drawbacks.

12:15 Presentation to be Announced

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

BIOPHYSICAL ANALYSIS AND STABILITY

13:45 Chairperson's Remarks

Morgan O'Brien, PhD, Associate Director, Gene Therapy R&D, Johnson & Johnson Innovative Medicine

13:50 Essential Biophysical Assessments of AAV Vectors for in-Process Sample and Drug Product at Early Clinical Stages

Susumu Uchiyama, PhD, Professor, Biotechnology, Osaka University

Demand of small-scale manufacturing and quality assessment of AAV vectors for early clinical trials has increased recently, especially from academia and start-up companies. I'll introduce developed methods for essential biophysical assessments of AAV vectors for in-process sample and drug product at early clinical stages. The methods include absolute quantitation of FP/EP/PP/OP, VP, and DNA characterisations, and impurity assessments.

14:20 Impact of Genome DNA Size on AAV Biophysical Properties and Stability

Marilia Barros, PhD, Principal Scientist, Regeneron Pharmaceuticals

The development of stable adeno-associated virus (AAV)-based formulations poses many challenges often due to AAV's intrinsic physico-chemical and structural complexity. Several key vector properties that may impact critical quality attributes of the final product need to be efficiently and reliably characterized and monitored to guide optimal AAV formulation development. Recently, these differences were also noted for AAV drug product of the same serotype but with genome of differing lengths.

LESSONS LEARNED FROM VIRAL VACCINES

14:50 Applying Viral Vector Vaccine Learnings to Gene Therapy: To Expect the Unexpected

Martinus A. H. Capelle, PhD, Distinguished Scientist, Drug Product Development & Delivery, Johnson & Johnson Innovative Medicine

This presentation highlights how over a decade of viral vector vaccine development informs gene therapy advancements. Key insights include formulation development, surface interactions, fit-for-purpose analytical methods, modelling, and innovative approaches to create stable, robust gene therapy products.

15:20 Sponsored Presentation *(Opportunity Available)*

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

16:20 Transfer and Application of Analytical Methods to Support AAV Product Release

Tony Bou Kheir, PhD, Head, Analytical Development and QC, Purespring Therapeutics

Purespring Therapeutics utilises a hybrid platform for AAV development in the treatment of kidney diseases, integrating analytical method development at its research facilities with the efficient transfer of technology to manufacturing sites. This strategy ensures rigorous support for product release and stability evaluation. This presentation will highlight case studies of successful method transfers and their application in generating stability data, underscoring advancements in gene therapy for renal disorders.

Cambridge Healthtech Institute's 6th Annual

18–19 MARCH 2025 ALL TIMES CET

Gene Therapy CMC and Analytics

Improving the Analysis, Control, and Quality of Gene Therapies towards Commercialisation

CONTROLLING AND REMOVING IMPURITIES

16:50 Challenges in Downstream Processing for AAV: Addressing Product and Process Related Impurities

Katerina Farukshina, Associate Lead Scientist, Technology & Process Innovation, Cell & Gene Therapy Catapult

Downstream processing (DSP) faces challenges due to increased impurities from intensified upstream processing. This presentation will focus on removing host-cell impurities and optimising residual DNA analysis for regulatory compliance. Data on DNA removal for secreted and intracellular AAV serotypes using high-throughput workflows will be presented. DSP strategies for intensified harvest streams, emphasising innovative impurity control and characterisation, will also be discussed.

17:20 Downstream Processing for Viral Vectors

Aline Hughson, PhD, Principal Scientist, AAVantgarde Bio

One of the most significant challenges in adeno-associated virus (AAV) manufacturing is the effective removal of "empty" capsids that lack the gene of interest. Anion exchange chromatography has proven to be the most effective solution for scalable enrichment of full capsids. However, the removal of empty capsids is just one hurdle in this complex process. This work will highlight the critical importance of peak characterisation and its impurity profile.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

CMC FOR mRNA AND RNA-BASED THERAPIES

8:25 Chairperson's Remarks

Niels Delamotte, Director Analytical Development, Etherna

8:30 Analytical Lifecycle Management in Support of Product and Process Development

Niels Delamotte, Director Analytical Development, Etherna

In the evolving mRNA vaccine and therapeutic landscape, robust quality control and advanced analytical capabilities are essential. This presentation addresses strategies to overcome QC challenges and enhance capabilities for mRNA drug substance and lipid nanoparticle product development. It covers traditional QC analytics and emerging trends for deeper product characterisation, ensuring safety, efficacy, and quality, with the goal of fostering dialogue to collectively advance the field and improve global public health.

9:00 KEYNOTE PRESENTATION: Navigating the Complexities in Formulating mRNA-Containing Lipid Nanoparticles

Advait V. Badkar, PhD, Executive Director & Head, Nanoparticle Development, Pfizer Inc.

The formulation of mRNA-containing lipid nanoparticles (LNPs) represents a frontier in the realm of drug delivery and vaccine development. This talk will cover the status of the field and highlight some of the challenges and opportunities for scientists who are involved in designing and optimising LNPs to encapsulate and deliver mRNA molecules effectively.

9:30 Establishing Analytical Methods for the Development of RNA-Based Therapeutics

Sara Trabulo, PhD, Associate Principal Scientist, AstraZeneca

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

14:00 Close of Gene Therapy CMC and Analytics Conference

Cambridge Healthtech Institute's 6th Annual

19–20 MARCH 2025 ALL TIMES CET

Gene Therapy Manufacturing

Improving Production, Expression, and Yield to Reduce Costs

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

SCALING UP AND PREPARING FOR COMMERICALISATION

14:15 Chairperson's Remarks
Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics

14:20 Scaling AAV Vector Production: Challenges and Future Directions
Mark Bell, Principal Bioprocessing Scientist, Purespring Therapeutics
Purespring Therapeutics is pioneering advancements in gene therapy for kidney diseases by integrating cutting-edge technologies in AAV manufacturing. With a focus on precision therapies, Purespring is shaping future trends in gene therapy manufacturing through innovative solutions and scalable platforms. This presentation explores the company's approach to overcoming challenges in vector manufacturing and highlights the future direction of gene therapy, setting new standards for manufacturing and therapeutic outcomes.

14:50 FEATURED PRESENTATION: Manufacturing Process Improvements and Scale Up
Kyle A. Zingaro, PhD, Head, Gene Therapy Process Sciences, UCB Pharma SA
Recombinant adeno-associated viral vectors (rAAV) are the leading modality for *in vivo* gene therapies. These advanced therapeutics are complex products that are challenged by the nascent state of process understanding at the interface of product quality, process yield, and cost of goods. Here we present on the advances in rAAV manufacturing process at UCB and how we are managing that development in the context of future pipeline growth.

15:20 Process Improvements for Scalable rAAV Manufacturing
Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics
Recombinant adeno-associated virus (rAAV) vectors have been demonstrated as gene delivery vehicles for addressing debilitating chronic diseases and conditions. However, a major challenge lies in developing a cost-efficient, optimised, and scalable manufacturing process to meet the growing global demand for these therapies. Forge Biologics has developed a scalable platform process and performed process improvements through enhanced starting materials and optimised process for high vector yield and product quality.

15:50 Sponsored Presentation *(Opportunity Available)*

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Optimising rAAV Production: The Role of Adenoviral Helper Components and AAV Promoter Activity
Sofia Fernandes, PhD, Senior Scientist, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica
Recombinant AAVs are crucial for gene therapy due to their safety and lasting transgene expression. This study explores the interplay between AAV promoter activity and helper virus components. We evaluated AAV promoter activity in different mammalian cells and identified the minimal components of the adenovirus E2A and E4 that significantly impacted the overall rAAV productivity and quality of produced virus. These findings aim to improve scalability, advancing gene therapy applications.

17:30 Towards Continuous Upstream Manufacturing: The Future of AAV Production
Molly B. Tregidgo, EngD, Senior Scientist, Bioprocess, Cell & Gene Therapy Catapult
Intensified high cell density processes and continuous harvest are innovative strategies that tackle challenges associated with high AAV dose requirements. Here we present the development of a perfusion platform for the generation of cell densities exceeding 20E6 at high viability and transient transfection methods optimised for high cell density, with 10x improved transfection efficiency compared to batch-optimised methodologies, and perfusion culture methods facilitating continuous AAV harvest for improved yield.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

18:30 Close of Day

Cambridge Healthtech Institute's 6th Annual

19–20 MARCH 2025 ALL TIMES CET

Gene Therapy Manufacturing

Improving Production, Expression, and Yield to Reduce Costs

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

OPTIMISING CELL LINE AND PROCESS DEVELOPMENT

8:25 Chairperson's Remarks

Ana Sofia Coroadinha, PhD, Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

8:30 Optimising Cell Line Development for Viral Vectors

Fabian Lindel, PhD, Principal Scientist II, Novartis Pharma AG

Lentiviral vectors are powerful tools for gene delivery mainly due to their ability to transduce non-dividing cells, large cargo capacity, and stable transgene integration. The standard production process is transient transfection. While suitable for small-scale screening, this method is cumbersome for large-scale production in terms of consistency, stability, reliability, and cost-efficiency. To address these issues, we have developed stable, lentiviral packaging clones for reliable production in oncology and gene therapy.

9:00 Stable AAV Cell Line Development

Helena CM Meyer-Berg, PhD, Scientist, Gene Therapy, Roche

9:30 KEYNOTE PRESENTATION: Extending AAV Genome Cargo for the Delivery of Large Therapeutic Genes: Treating Duchenne Muscular Dystrophies

Ana Sofia Coroadinha, PhD, Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

Adeno-associated virus (AAV) vectors are the platform of choice for *in vivo* gene therapy. However, AAV vectors have a small packaging capacity impairing delivery of therapeutic genes larger than 3.5 kb in size. We are developing dual AAV systems to overcome this limitation. Duchenne Muscular Dystrophy is one of innumerous genetic diseases affecting larger genes. We will show how mini-dystrophin proteins (220 KDa) can be re-constituted with Dual-AAV vector co-delivery.

10:00 Presentation to be Announced

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PROCESS DEVELOPMENT FOR VIRAL VECTORS

11:10 AAVs for Gene Therapies

Antonio Roldao, PhD, Head of Cell-Based Vaccines Development Laboratory, Animal Cell Technology Unit, Instituto de Biologia Experimental e Tecnológica (iBET)

A CRISPR-Cas9 pipeline for genetic engineering of insect Sf9 cells yielding higher editing efficiencies than other existing methods (67% vs. 12%, respectively) was implemented. It was then applied to knock-out caspase initiator Sf-Dronc, as proof-of-concept gene, aimed at alleviating cell apoptosis during a baculovirus expression vector system (BEVS) process. The resulting engineered cell lines were characterised as per their phenotype and production of recombinant adeno-associated viruses (rAAVs).

11:40 Insect Cell Production Platform for Scalable Production of AAV for Gene Therapy

Pranav Puri, PhD, Head, Process Development, VectorY Therapeutics

VectorY develops Vectorised Antibodies (VecTabs) which utilise an AAV vector to deliver the transgene to the target CNS cells where the therapeutic antibody is subsequently produced, and clears the toxic variants of target proteins to improve neuronal health and halt disease progression. The presentation will present AAV production platform "ManuVec" which produces VecTabs from an optimised Baculovirus/insect cell platform in high yields, quality, and potency in a robust manner.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

DIGITALISATION AND AUTOMATION IN ADVANCED THERAPIES

13:25 Chairperson's Remarks

David Estape, PhD, Technology Manager and Senior Fellow, Process Engineering, CRB Group GmbH, Member, BioPhorum, ISPE

13:30 Development of a Digital Twin for AAV Production

Frank Baganz, PhD, Associate Professor, Fermentation and Cell Culture, Biochemical Engineering, University College London (UCL)

rAAV processes with complex dynamic behaviour requires high experimental effort, and is time consuming and expensive. Digital Twins (DT) that are based on mathematical models can be used for process development and optimisation. A mechanistic model of an rAAV9 production process has been developed and parameterised using in-house experimental data. The validation of the DT models and its application to increase the functional rAAV9 titre will be demonstrated.

14:00 Lentiviral Vector Manufacturing Process Development and Modelling for Cell & Gene Therapies

Laurence Guianvarch, Director, Viral Vector Technical Development, Orchard Therapeutics

Orchard's approach to gene therapy is designed to deliver a functional version of the mutated gene, or transgene, to a patient's own blood stem cells—called hematopoietic stem cells or HSCs—to produce the desired therapeutic protein. This talk will discuss lentiviral process development and scale-up.

14:30 Navigating Regulatory Challenges for Closed Processing in ATMPs

David Estape, PhD, Technology Manager and Senior Fellow, Process Engineering, CRB Group GmbH, Member, BioPhorum, ISPE

Focusing on regulatory challenges, this presentation explores the role of closed processing in Advanced Therapy Medicinal Products (ATMPs). Closed systems, together with standard process platforms and automation-digitalisation, are key for the future of ATMP manufacturing. Through the analysis of the current guidelines, this presentation draws how regulatory frameworks may either support or hinder closed systems adoption. The final goal is to align closed processing with current and future regulations.

15:00 Close of Summit

18-19 MARCH 2025

Cell Therapy CMC and Manufacturing

VIEW PROGRAM »»

19-20 MARCH 2025

Gene Therapy Manufacturing

VIEW PROGRAM »»

Stream 4 CELL THERAPY

The Cell Therapy stream examines recent advances in analytical characterisation, gene editing, CMC, and regulatory strategies. In-depth case studies will address the practical challenges faced during the scale-up and manufacture of cell therapies and viral vectors, addressing both autologous and allogeneic production platforms.

Cambridge Healthtech Institute's 7th Annual

18–19 MARCH 2025 ALL TIMES CET

Cell Therapy CMC and Manufacturing

Optimise CMC, Analytical, and Manufacturing Strategies to Achieve Commercial Success

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

CMC & EMERGING ANALYTICAL METHODS

8:25 Chairperson's Opening Remarks

Stephan Croft, Head of Quality and Senior Principal Consultant, Dark Horse Consulting Group

8:30 CMC Challenges and Opportunities for Cell & Gene Therapies

Katie Miller, PhD, Vice President, Global Head of Biologics Development Analytics and Quality, Bayer

Cell and Gene Therapy (CGT) product development comes with a high number of CMC challenges that often result in significant regulatory delays. FDA guidance documents have recognised these obstacles, offering new insights into addressing the most prevalent CMC challenges. This presentation will discuss some of the most common CMC challenges in CGT in the context of applicable guidance, while underscoring the vital importance of proactive planning strategies for CGT sponsors.

9:00 Potency Assays and Functional Characterisation—Going Hand-in-Hand during Product Development up to Commercial Licensing

Therese Choquette, PhD, Head of Analytical and Translational Sciences, Tigen

The potency assay is a highly critical assay for cell and gene therapy products and is one of the assays on the release specification. The potency assay needs to reflect the main mechanism of action/s of the product and the CQA. Using cellular function characterisation assays during development provides critical insights which help to establish the most relevant and appropriate potency assay for the product.

9:30 Presentation to be Announced

9:45 Presentation to be Announced

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

10:45 Developing a Potency Assurance Strategy for a Complex Multimodal Cell Therapy

Damian Marshall, PhD, Vice President, Analytical Development, Resolution Therapeutics

Developing potency assays and demonstrating that they measure appropriate biological activities has long been a significant challenge, particularly with the evolving regulatory landscape. But what if you are developing a pioneering new therapy with a multimodal mechanism-of-action? This presentation will showcase the challenges of developing a potency assay matrix for an engineered macrophage therapy and will consider how these assays support future commercial manufacturing strategies.

11:15 The Case for Process Characterisation to Drive Quality in Cell Therapy Process Development

Jahid Hasan, PhD, Lead, Technical, Cell and Gene Therapy Catapult

Cell therapy process development is costly and time-consuming. Implementation of quality-by-design principles can provide a structured approach; however, this can be hampered by a lack of relevant analytics. Characterisation of starting material, processes, and products is often limited to existing methods and can overlook critical measurements. Here we present a case study for allogeneic cell therapy that demonstrates the power of in-depth characterisation to drive decision-making.

11:45 KEYNOTE PRESENTATION: Leveraging Cell and Gene Therapy Products' Quality Through a Bioanalytics Avenue

Paula Alves, PhD, CEO, iBET

The use in clinics of advanced therapy medicinal products (ATMPs) is growing at a fast pace, requiring efficient and orthogonal bioanalytics tools for comprehensive molecular characterisation. At iBET we have been developing analytics for ATMPs with increased resolution, sensitivity, and throughput. A thorough characterisation of these products' quality attributes will streamline bioprocess understanding and product design. In this talk we will present recent contributions to this important R&D area.

12:15 Sponsored Presentation *(Opportunity Available)*

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

REGULATORY STRATEGIES

13:45 Chairperson's Remarks

Christiane Niederlaender, PhD, Vice President, Technical CMC, Parexel

13:50 New Developments in Regulatory Requirements for Cell Therapies

Florence Salmon, PhD, Vice President Regulatory Affairs, Hookipa Pharma

Cell therapies are reaching late clinical phase and commercial-stage in high numbers, and the regulatory vacuum is being filled rapidly by agencies and pharmacopoeias with new guidelines and expectations. This presentation gives an overview of new global regulatory trends in the manufacturing and control space for cell therapies, and provides a high-level blueprint for developing such therapies, avoiding common pitfalls and enhancing compliance.

14:20 Regulatory Considerations for the Manufacturing of iPSC-Based Cell Therapies

Christiane Niederlaender, PhD, Vice President, Technical CMC, Parexel

Development of iPSC-based therapies has been hampered by the challenge of navigating the complex regulatory pathway for these products. The presentation discusses how a robust manufacturing process with appropriate quality controls can be implemented to meet regulatory expectations at different stages. Regulatory requirements for donor tissue sourcing, quality control, and sequential banking approaches, as well as key aspects of product and process characterisation are addressed.

14:50 Regulatory Strategies and Quality Control

Sharon Longhurst, PhD, Director, Advanced Biologics Consulting

This presentation will cover the following topics: Characterisation vs. release assays (qualification vs. validation), for information vs. release assays; when to use FIO and why, specification evolution during clinical development through to MAA and lastly, the need for adaptably of the quality parameters tested for release, as a function of the type of product under development and regulatory consideration.

15:20 Sponsored Presentation *(Opportunity Available)*

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

Cambridge Healthtech Institute's 7th Annual

18–19 MARCH 2025 ALL TIMES CET

Cell Therapy CMC and Manufacturing

Optimise CMC, Analytical, and Manufacturing Strategies to Achieve Commercial Success

ADVANCED MANUFACTURING PROCESSES

16:20 FEATURED PRESENTATION: Manufacturing Processes: Scaling-Up and Commercialisation
Vered Caplan, CEO, Octomera and Orgenesis

16:50 Manufacturing Innovations of TCR T Cells Translate to Durable Responses in Solid Tumors
Ali Mohamed, PhD, Senior Vice President, CMC, Immatics

TCR T based product candidates targeting PRAME are being evaluated. Manufacturing innovations led to improved product characteristics, manufacturing success rates, and reaching higher doses. These favorable TCR-T product characteristics and high TCR-T levels in patients led to durable clinical responses in solid tumour indications in heavily pretreated patients. Immatics has aligned with FDA on patient population, trial design, CMC targeting registration-enabling Phase 3 trial in melanoma.

17:20 Your Way to Success: Navigating Comparability in Drug Development
Sara Mills, Principal, Dark Horse Consulting Group

Industry must juggle business and scientific risks to thread the needle of successful C&GT drug product development. Key to this success is knowing why, when, and how to perform formal drug product comparability studies—and why, when, and how not to. This talk will provide road-tested and actionable feedback to guide sponsors when asking key questions related to navigating drug product comparability throughout the development lifecycle.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

ADVANCED MANUFACTURING PROCESSES

8:25 Chairperson's Opening Remarks
Sarah Snykers, PhD, Director of Operations, Legend Biotech

8:30 Manufacturing Case Study from Legend Biotech
Sarah Snykers, PhD, Director of Operations, Legend Biotech

Legend BioTech will present their real-life experience, expanding their CAR T production footprint worldwide in partnership with Johnson & Johnson. Topics to be presented include: construction of brown and green field GMP production facility; preclinical stage/start-up mentality, including GMP accreditation license; clinical phase with staggered ramp-up; and commercial phase with ramp-up to steady state.

9:00 Optimised Manufacturing of Autologous HSC Gene Therapies
Vassilis Paraskevas, Senior Scientist, Cell Process Development, Technical Operations & Global Technical Development, Orchard Therapeutics

Haematopoietic Stem Cell Gene Therapies are being developed to address a range of severe genetic diseases. However, manufacturing challenges have the potential to limit the applications of these therapies to a broader number of diseases. Here we present development on closing and automating the manufacturing process using state-of-the art equipment. Encouraging results were obtained, significantly reducing hands-on and overall processing time, and with comparable or improved product attributes.

9:30 Cryopreservation of Starting and Final Product Cell Therapies
Marty Giedlin, PhD, Senior Team Lead, Cell & Gene Therapy Consultant, MG Consulting

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

14:00 Close of Cell Therapy CMC and Manufacturing Conference

Cambridge Healthtech Institute's 6th Annual

19–20 MARCH 2025 ALL TIMES CET

Gene Therapy Manufacturing

Improving Production, Expression, and Yield to Reduce Costs

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

SCALING UP AND PREPARING FOR COMMERICALISATION

14:15 Chairperson's Remarks
Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics

14:20 Scaling AAV Vector Production: Challenges and Future Directions
Mark Bell, Principal Bioprocessing Scientist, Purespring Therapeutics
Purespring Therapeutics is pioneering advancements in gene therapy for kidney diseases by integrating cutting-edge technologies in AAV manufacturing. With a focus on precision therapies, Purespring is shaping future trends in gene therapy manufacturing through innovative solutions and scalable platforms. This presentation explores the company's approach to overcoming challenges in vector manufacturing and highlights the future direction of gene therapy, setting new standards for manufacturing and therapeutic outcomes.

14:50 FEATURED PRESENTATION: Manufacturing Process Improvements and Scale Up
Kyle A. Zingaro, PhD, Head, Gene Therapy Process Sciences, UCB Pharma SA
Recombinant adeno-associated viral vectors (rAAV) are the leading modality for *in vivo* gene therapies. These advanced therapeutics are complex products that are challenged by the nascent state of process understanding at the interface of product quality, process yield, and cost of goods. Here we present on the advances in rAAV manufacturing process at UCB and how we are managing that development in the context of future pipeline growth.

15:20 Process Improvements for Scalable rAAV Manufacturing
Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics
Recombinant adeno-associated virus (rAAV) vectors have been demonstrated as gene delivery vehicles for addressing debilitating chronic diseases and conditions. However, a major challenge lies in developing a cost-efficient, optimised, and scalable manufacturing process to meet the growing global demand for these therapies. Forge Biologics has developed a scalable platform process and performed process improvements through enhanced starting materials and optimised process for high vector yield and product quality.

15:50 Sponsored Presentation *(Opportunity Available)*

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Optimising rAAV Production: The Role of Adenoviral Helper Components and AAV Promoter Activity
Sofia Fernandes, PhD, Senior Scientist, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica
Recombinant AAVs are crucial for gene therapy due to their safety and lasting transgene expression. This study explores the interplay between AAV promoter activity and helper virus components. We evaluated AAV promoter activity in different mammalian cells and identified the minimal components of the adenovirus E2A and E4 that significantly impacted the overall rAAV productivity and quality of produced virus. These findings aim to improve scalability, advancing gene therapy applications.

17:30 Towards Continuous Upstream Manufacturing: The Future of AAV Production
Molly B. Tregidgo, EngD, Senior Scientist, Bioprocess, Cell & Gene Therapy Catapult
Intensified high cell density processes and continuous harvest are innovative strategies that tackle challenges associated with high AAV dose requirements. Here we present the development of a perfusion platform for the generation of cell densities exceeding 20E6 at high viability and transient transfection methods optimised for high cell density, with 10x improved transfection efficiency compared to batch-optimised methodologies, and perfusion culture methods facilitating continuous AAV harvest for improved yield.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

18:30 Close of Day

Cambridge Healthtech Institute's 6th Annual

19–20 MARCH 2025 ALL TIMES CET

Gene Therapy Manufacturing

Improving Production, Expression, and Yield to Reduce Costs

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

OPTIMISING CELL LINE AND PROCESS DEVELOPMENT

8:25 Chairperson's Remarks

Ana Sofia Coroadinha, PhD, Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

8:30 Optimising Cell Line Development for Viral Vectors

Fabian Lindel, PhD, Principal Scientist II, Novartis Pharma AG

Lentiviral vectors are powerful tools for gene delivery mainly due to their ability to transduce non-dividing cells, large cargo capacity, and stable transgene integration. The standard production process is transient transfection. While suitable for small-scale screening, this method is cumbersome for large-scale production in terms of consistency, stability, reliability, and cost-efficiency. To address these issues, we have developed stable, lentiviral packaging clones for reliable production in oncology and gene therapy.

9:00 Stable AAV Cell Line Development

Helena CM Meyer-Berg, PhD, Scientist, Gene Therapy, Roche

9:30 KEYNOTE PRESENTATION: Extending AAV Genome Cargo for the Delivery of Large Therapeutic Genes: Treating Duchenne Muscular Dystrophies

Ana Sofia Coroadinha, PhD, Lab Head, Health & Pharma Division, Animal Cell Technology Unit Cell Line Development and Molecular Biotechnology Lab, IBET

Adeno-associated virus (AAV) vectors are the platform of choice for *in vivo* gene therapy. However, AAV vectors have a small packaging capacity impairing delivery of therapeutic genes larger than 3.5 kb in size. We are developing dual AAV systems to overcome this limitation. Duchenne Muscular Dystrophy is one of innumerous genetic diseases affecting larger genes. We will show how mini-dystrophin proteins (220 KDa) can be re-constituted with Dual-AAV vector co-delivery.

10:00 Presentation to be Announced

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PROCESS DEVELOPMENT FOR VIRAL VECTORS

11:10 AAVs for Gene Therapies

Antonio Roldao, PhD, Head of Cell-Based Vaccines Development Laboratory, Animal Cell Technology Unit, Instituto de Biologia Experimental e Tecnológica (iBET)

A CRISPR-Cas9 pipeline for genetic engineering of insect Sf9 cells yielding higher editing efficiencies than other existing methods (67% vs. 12%, respectively) was implemented. It was then applied to knock-out caspase initiator Sf-Dronc, as proof-of-concept gene, aimed at alleviating cell apoptosis during a baculovirus expression vector system (BEVS) process. The resulting engineered cell lines were characterised as per their phenotype and production of recombinant adeno-associated viruses (rAAVs).

11:40 Insect Cell Production Platform for Scalable Production of AAV for Gene Therapy

Pranav Puri, PhD, Head, Process Development, VectorY Therapeutics

VectorY develops Vectorised Antibodies (VecTabs) which utilise an AAV vector to deliver the transgene to the target CNS cells where the therapeutic antibody is subsequently produced, and clears the toxic variants of target proteins to improve neuronal health and halt disease progression. The presentation will present AAV production platform "ManuVec" which produces VecTabs from an optimised Baculovirus/insect cell platform in high yields, quality, and potency in a robust manner.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

DIGITALISATION AND AUTOMATION IN ADVANCED THERAPIES

13:25 Chairperson's Remarks

David Estape, PhD, Technology Manager and Senior Fellow, Process Engineering, CRB Group GmbH, Member, BioPhorum, ISPE

13:30 Development of a Digital Twin for AAV Production

Frank Baganz, PhD, Associate Professor, Fermentation and Cell Culture, Biochemical Engineering, University College London (UCL)

rAAV processes with complex dynamic behaviour requires high experimental effort, and is time consuming and expensive. Digital Twins (DT) that are based on mathematical models can be used for process development and optimisation. A mechanistic model of an rAAV9 production process has been developed and parameterised using in-house experimental data. The validation of the DT models and its application to increase the functional rAAV9 titre will be demonstrated.

14:00 Lentiviral Vector Manufacturing Process Development and Modelling for Cell & Gene Therapies

Laurence Guianvarch, Director, Viral Vector Technical Development, Orchard Therapeutics

Orchard's approach to gene therapy is designed to deliver a functional version of the mutated gene, or transgene, to a patient's own blood stem cells—called hematopoietic stem cells or HSCs—to produce the desired therapeutic protein. This talk will discuss lentiviral process development and scale-up.

14:30 Navigating Regulatory Challenges for Closed Processing in ATMPs

David Estape, PhD, Technology Manager and Senior Fellow, Process Engineering, CRB Group GmbH, Member, BioPhorum, ISPE

Focusing on regulatory challenges, this presentation explores the role of closed processing in Advanced Therapy Medicinal Products (ATMPs). Closed systems, together with standard process platforms and automation-digitalisation, are key for the future of ATMP manufacturing. Through the analysis of the current guidelines, this presentation draws how regulatory frameworks may either support or hinder closed systems adoption. The final goal is to align closed processing with current and future regulations.

15:00 Close of Summit

18-19 MARCH 2025

Cell Culture and Cell Line Engineering - Part 1

VIEW PROGRAM »»

19-20 MARCH 2025

Intensified and Continuous Processing

VIEW PROGRAM »»

Stream 5 INTENSIFIED AND CONTINUOUS PROCESSING

The Intensified and Continuous Processing stream presents the latest efforts to implement semi-, hybrid, and fully continuous processing across perfusion to purification (at GMP and non-GMP). Topics include advanced process modelling and control, digitalisation, robustness and monitoring, digital twins, viral safety, cost analysis and ramping up production from clinical to commercialisation, all in line with international regulations.

Cambridge Healthtech Institute's 8th Annual

18–19 MARCH 2025 ALL TIMES CET

Cell Culture and Cell Line Engineering – Part 1

Advancing Upstream Strategies for Process Efficiency

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

CHEMOMETRICS & MODELLING

8:25 Chairperson's Remarks
Mark Duerkop, CEO, Novasign GmbH

8:30 Deep Learning for Optimisation of Protein Expression
Diego A. Oyarzun, PhD, Reader in Computational Biology, Informatics Forum, University of Edinburgh

Deep learning is a promising approach for building sequence-to-expression models for strain optimisation. But these need large, costly data sets that create steep entry barriers for many laboratories. In this talk, I will discuss data requirements and how they impact predictive accuracy, alongside training strategies for improved prediction of protein expression in new regions of the sequence space. These results provide guidelines for balancing data cost/quality in predictive strain design.

9:00 How to Develop and What to Expect from Predictive Process Models
Michael Sokolov, PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG

This presentation will delve into strategies for developing accurate predictive models from limited and yet complex data, the necessary data inputs, and the potential challenges faced during implementation. Based on many industrial use cases, attendees will gain insights into how these models can forecast performance, reduce variability, and streamline manufacturing, improving both efficiency and product quality in biologic drug development.

9:30 Presentation to be Announced

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

10:45 Automated Knowledge Generation, Valorisation, and Exchange Strategies Reshape Bioprocess Development
Peter Neubauer, PhD, Lab Head, Bioprocess Engineering, TU Berlin

Complex self-driving intelligent experiments for bioprocess development are only possible by integrating all aspects of cell cultivation, analytics, and modelling into a comprehensive framework and steered by an effective Workflow Management System. This is realised in the KIWI-biolab and its opportunities for process optimisation and collaboration are demonstrated by a number of developmental projects. The strict implementation of such fully automated approaches promotes the application of FAIR principles.

11:15 Digital Twin–Enhanced Process Development: Success Stories from mAbs, C&CT, and Continuous Processing
Mark Duerkop, CEO, Novasign GmbH

The application of modelling tools in bioprocess development and manufacturing has garnered considerable interest. But what does it really take to develop digital bioprocess twins? This talk dives into key topics such as the business impact of process modelling, experimental design strategies, tailored modelling approaches, accelerated process development, seamless scale-up, and the real-time use of models for monitoring and control. These principles will be demonstrated through several industrial case studies.

11:45 Physics-Informed Artificial Intelligence: A Groundbreaking Technology in the Biopharmaceutical Industry
Ignasi Bofarull-Manzano, CMC Data Scientist, Mechanical Engineering, RWTH Aachen University

While AI's transformative power is well recognised across industries, its potential in pharmaceutical bioprocessing remains underexploited due to limited data. In 2019, Raissi et al. introduced Physics-Informed Neural Networks (PINNs), creating a new paradigm by integrating deep learning with first-principles laws. This method enables the use of AI even with scarce data, presenting a groundbreaking chance to revolutionise biopharmaceutical processes by cutting costs and accelerating the time-to-market for new therapies.

12:15 Fast-Track Your Way to Process Understanding and Control—A Case Study on How to Simplify PAT Implementation
Milla Neffling, Senior Manager, Bioprocess Applications, Marketing, 908 Devices Inc.

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

PROCESS EFFICIENCY

13:45 Chairperson's Remarks
Philip Probert, PhD, Technology Lead, CPI, United Kingdom

13:50 Increasing Process Efficiency in mAb Production through Perfusion-Based Approaches
Jan Ott, Researcher, Biotechnology and Cell Cultivation Technique, Zurich University of Applied Sciences

Increasing demand and the approval of biosimilars are forcing biopharmaceutical manufacturers to make their processes more efficient. Perfusion processes play an important role in this so-called process intensification. In this presentation, an overview of possible applications of the perfusion mode in the upstream process of antibody productions will be given and case studies from the cell culture lab of the ZHAW will be presented.

14:20 Cell Factory Robustness and Burden-Driven Production
Peter Rugbjerg, PhD, Lecturer, Chalmers University; CSO and Founder, Enduro

Bioproduction at manufacturing scale can be limited by cellular variation. Using synthetic biology, it is possible to addict cells to product formation. Such technology efficiently selects for production in the bioreactor by coupling cell growth to high-level production using essential genes linked to product biosensors. We will present cases and ways of diagnosis in diverse microorganisms, including *E. coli*, *Bacillus*, and yeast.

14:50 KEYNOTE PRESENTATION: Industry 4.0 Implementation in Biomanufacturing: Models and Data Collection
Krist V. Gernaey, PhD, Professor, Chemical & Biochemical Engineering, Technical University of Denmark

Industry 4.0 can potentially transform biomanufacturing, and digital twins play an important role. However, the digital twin is useless without data. The focus is on different modelling approaches for obtaining a digital twin, and on the challenges related to collecting informative data on a biomanufacturing process. Issues of model validation are highlighted, and the need for improved data collection is presented and illustrated with application examples.

15:20 Sponsored Presentation *(Opportunity Available)*

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

Cambridge Healthtech Institute's 8th Annual

18–19 MARCH 2025 ALL TIMES CET

Cell Culture and Cell Line Engineering - Part 1

Advancing Upstream Strategies for Process Efficiency

SUSTAINABILITY IMPROVEMENTS

16:20 Transforming Biologics Medicines Manufacturing: Technical Barriers and Solutions for a Sustainable Future

Philip Probert, PhD, Technology Lead, CPI, United Kingdom

With the UKNHS setting ambitious targets to be net zero by 2045, there is an increasing impetus for manufacturers to prioritise sustainability. This presentation describes the challenges to be addressed and the innovations being adopted, including energy efficiency improvements, waste reduction strategies, and resource optimisation. Solutions discussed will provide pathways to greener processes, demonstrating how sustainability and productivity can coexist in the biologics manufacturing landscape, shaping a more responsible future.

16:50 Potential of the Diversity of Single-Use Bioreactors in Upstream Processing: Cell Physiology and Sustainability Considerations

Stefan Junne, PhD, Associate Professor, Bioscience and Engineering, Aalborg University

Single-use equipment offers various strategies of power input and gas mass transfer. This variety is often not used—as, for a long time, geometrical similarity was one of the most important criteria for applicants. This parameter is, however, not relevant for achieving an optimal cell viability and additionally the maximum sustainability and cost efficiency. This talk aims to present strategies for suitable hybrid bioreactor application under consideration of these parameters.

17:20 "Organised Stress" and Tricks for Robust and Productive Intensified Process

Bassem Ben Yahia, PhD, Senior Scientist, Upstream Process Sciences, UCB Pharmaceuticals, S.A.

This research work is focussed on intensified processes with high seeding density inoculated from seed bioreactor in fed-batch mode using Chinese Hamster Ovary cells. The impact of the feeding strategy and specific power input (P/V) in the seed bioreactor and on the production step with two different cell lines (CL1 and CL2) producing two different monoclonal antibodies was investigated and the "organised stress" concept is introduced.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

UPSTREAM PROCESSING FOR EMERGING MODALITIES

8:25 Chairperson's Remarks

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria

8:30 Process Development for Production of Complex or Difficult-to-Express Proteins

Martin Bertschinger, PhD, Director, Drug Substance Development, Ichnos Sciences

The increased complexity of bi and multispecific formats makes these molecules difficult to express compared to standard mAbs. This session explores a holistic approach to overcoming these challenges, featuring techniques such as signal peptide optimisation, vector design, and cell line selection. Attendees will learn how these strategies have successfully increased expression levels and titres of BEAT and TREAT antibodies by up to 10-fold, reaching titres as high as 11 g/L.

9:00 Cell Engineering and Cell-Line Development Challenges for Emerging Modalities

Zorica Dragic, PhD, Executive Director, Cell Line Screening and Development, Novartis Pharma AG

Emerging therapeutic modalities present unique challenges in cell engineering and cell line development. I will present innovative strategies to address these complexities, focused on genetic optimisation of expression systems and overcoming hurdles specific to novel biologics. Attendees will gain insights into the advanced techniques designed to improve productivity, stability, and quality when working with cutting-edge modalities in biologic drug development.

9:30 Digital Applications to Robustify Bioprocessing despite Starting-Material Variability

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, Vienna University of Technology; CPO, Fermify GmbH; Senior Scientific Advisor, Körber Pharma Austria

Process development focusses on quality-by-design principles and is often focused on CQA to CPP relationships. However, in many bioprocesses, such as bioeconomy or CGT processes, the effect of raw material attributes is the main source for variation. This contribution proposes digital tools to make the process more robust despite raw material variability using PAT, random effect modelling using linear mixed models, and MIMO feedback control tools.

10:00 Presentation to be Announced

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Presentation to be Announced

12:45 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

14:00 Close of Cell Culture and Cell Line Engineering - Part 1 Conference

Cambridge Healthtech Institute's 8th Annual

19–20 MARCH 2025 ALL TIMES CET

Intensified and Continuous Processing

Process Intensification and Digitalisation towards a Sustainable Future

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

PROCESS INTENSIFICATION, KNOWLEDGE MANAGEMENT, AND CONTROL

14:15 Chairperson's Remarks
Antonio Roldao, PhD, Head of Cell-Based Vaccines Development Laboratory, Animal Cell Technology Unit, Instituto de Biologia Experimental e Tecnológica (iBET)

14:20 FEATURED PRESENTATION: Integrated and Continuous Processing
Lara Fernandez-Cerezo, PhD, Associate Principal Scientist, Merck
Merck & Co. Inc., Rahway, NJ, USA, is exploring the use of a Process Knowledge Management (PKM) tool to streamline technology transfers, aiming to address issues of duplication and enhance standardisation in the process. The PKM tool encompasses process calculations, automation, and documentation depository capabilities, and has demonstrated successful performance in a biological continuous manufacturing process case study.

14:50 Process Intensification Strategies at Novartis
Benjamin Sommer, PhD, Associate Director, Upstream Process Development, Novartis

15:20 Advancing Clinical Manufacturing through Novel PAT Tools for Biologics
Michael H. Olma, PhD, Supervisor GMP Advanced Analytics, Biologics Analytical R&D, MSD Werthenstein BioPharma GmbH
At our clinical manufacturing site here in Switzerland, we introduced novel Process Analytical Technologies (PAT) for Biologics. For this, we successfully established a variety of PAT tools in a GMP compliant way for upstream and downstream processing, for example Endress+Hauser Rxn4 and Repligen FlowVPX. This allows us to deploy advanced process control strategies and to support improved manufacturing processes. We would like to present our experiences with these tools.

15:50 Presentation to be Announced

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing SARTORIUS

CONTINUOUS PROCESSING: STATE-OF-THE-ART TECHNOLOGIES AND ECONOMIC VALUE

17:00 KEYNOTE PRESENTATION: State-of-the-Art Technologies in Continuous Processing
Richard D. Braatz, PhD, Edwin R. Gilliland Professor, Massachusetts Institute of Technology
This presentation describes upstream, downstream, and formulation technologies for continuous processing with experimental results presented for monoclonal antibodies, gene therapies, and viral, mRNA, and subunit protein vaccines.

17:30 A Techno-Economic Perspective on Continuous Bioprocessing: Is It Really Worth It?
Tommas De Santis, Institute of Bioprocess Science and Engineering, BOKU
This presentation explores the techno-economic viability of continuous bioprocessing, comparing it with batch processes in terms of cost-efficiency, scalability, and technological readiness. Through examining recent advancements and economic analyses, it evaluates whether the benefits, such as increased yield and reduced downtime, justify the initial high investment. The study aims to provide a clear economic perspective to aid in decision-making for adopting continuous bioprocessing in pharmaceutical manufacturing.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

18:30 Close of Day

Cambridge Healthtech Institute's 8th Annual

19–20 MARCH 2025 ALL TIMES CET

Intensified and Continuous Processing

Process Intensification and Digitalisation towards a Sustainable Future

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

SUSTAINABILITY IN BIOMANUFACTURING

8:25 Chairperson's Remarks

Andrew Sinclair, MSc, CEng, FIChemE, FREng, President & Founder, BioPharm Services Ltd.

8:30 FEATURED PRESENTATION: Minimising the Environment Impact of Biomanufacturing

Clare Thompson, Global Change Facilitator, BioPhophorum

This presentation will focus on the opportunities we have to understand and progressively minimise the environmental impact of biomanufacturing—highlighting hotspots of concern across the value chain including water, plastics, and energy use. We will showcase the BioPhorum maturity model which provides organisations with a guide to improving their sustainability maturity, highlighting specific actions manufacturing operations can take.

9:00 Use of Digital Models to Predict and Optimise Process Economic and Sustainability in Early Process Development

Andrew Sinclair, MSc, CEng, FIChemE, FREng, President & Founder, BioPharm Services Ltd.

Around 80% of costs and environmental impacts are set early in development. New digital process facility models can now predict the Cost of Goods and CO2e emissions at this stage. These models evaluate different technologies and methods, understand trade-offs, and optimize downstream processes to cut costs and reduce environmental impact, thereby maximising benefits. Assessments of different DSP intensification approaches are used to illustrate these models' utility.

9:30 Green Metrics to Guide Process Development towards More Sustainable Production of Biologics

Felix Dieringer, Scientist, Takeda, PhD Student, BOKU University

In this talk we will delve into the topic of green metrics to measure and improve sustainability of biologics. In early development, emphasis is typically placed on mass-based metrics, whereas in commercial production the focus often shifts to carbon footprint. How do we address the challenge of finding suitable metrics that are simple to calculate yet effectively predict commercial emissions? How can software like BioSolve help?

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

CONTINUOUS PROCESSING OF MICROBIAL SYSTEMS

11:10 Continuous Processing of *E. coli*

Gerald Striedner, PhD, Head, Institute of Bioprocess Science and Engineering, Professor, Biotechnology, University of Natural Resources and Life Sciences Vienna (BOKU), Austria

Genome-integrated, as well as growth-decoupled *E. coli* expression systems, enable continuous protein production. Efficient implementation requires suitable process strategies for cultivation, and product recovery and purification. The presentation will show two case studies inclusive of an economic evaluation with standard fed-batch as benchmark. We will also present results from a cutting-edge, highly-funded, innovative R&D project named ECOnti.

11:40 ECOnti—Accelerated, Low Ecological Footprint, Manufacturing Platform for Continuous Production of Biotechnological Products

Juergen Mairhofer, CEO & Co-Founder, enGenes Biotech GmbH

The ECOnti consortium was created to advance continuous manufacturing using *Escherichia coli* (*E. coli*) with a capacity of up to 10 litres per batch. By leveraging advanced model predictive control and conducting detailed economic modelling, our goal is to elucidate the cost-effectiveness of continuous manufacturing frameworks as opposed to conventional batch-based approaches.

12:10 Hybrid Modelling Enables Autonomous, Fully Continuous Bioprocesses

Benedikt Haslinger, Bioprocess Modelling Engineer, Novasign

An innovative approach for integrated, continuous protein production will be presented, focusing on dynamic process modelling and simulation. By utilising physics-informed machine learning, we explore the possibilities of characterisation, optimisation, and predictive control of a bioprocess chain involving a two-stage bioreactor system in combination with membrane filtration and multi-column chromatography (MCC). These findings extend their impact to a multitude of industries, including pharmaceuticals, industrial enzymes, and cultured meat production.

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

CONTINUOUS PROCESSING OF VLPs, mRNA , pDNA

13:25 Chariperson's Remarks

Lukas Gerstweiler, PhD, Lecturer, School of Chemical Engineering, The University of Adelaide

13:30 Continuous Processing of Non-Enveloped Virus-Like Particles

Lukas Gerstweiler, PhD, Lecturer, School of Chemical Engineering, The University of Adelaide

Virus-like particles (VLPs) are highly efficient vaccines and possible drug delivery vehicles. Their purification is challenging with low recoveries, making them relatively expensive. This presentation outlines the main challenges during downstream processing and basic design and process principles for continuous and integrated purification of non-enveloped VLPs that can be used as vaccines.

14:00 Development of an Integrated Continuous Precipitation-Based Process for mRNA Purification

Carme Pons Royo, PhD, Postdoctoral Associate, Massachusetts Institute of Technology

mRNA-based therapeutics have emerged as cutting-edge technologies for treating various diseases. Current downstream processing, which relies on a series of chromatography methods and TFF, remains challenging with low yields and significantly impacted final production costs. We will present our integrated and continuous manufacturing process for mRNA production and purification. We are investigating novel methods for continuous mRNA precipitation-based purification, including various precipitating agents, and following precipitation with continuous flow filtration.

14:30 Development and Characterisation of a Continuous Cell Lysis Device for the Production of High Quality pDNA

Patrick Werder, Research Scientist, Bioprocess Technology Group, University of Applied Sciences Northwestern Switzerland

The increasing demand for plasmid DNA (pDNA) in gene therapy and vaccines requires scalable production methods. This work introduces a continuous lysis device with low-shear pumps and a loop reactor for precise lysis control, reducing shear damage. Paired with Natrix Q membrane chromatography, it enables high flow rates and RNA reduction without chemicals, offering a faster, cost-effective process for producing high-purity, supercoiled pDNA.

15:00 Close of Summit

18-19 MARCH 2025

Accelerating Analytical Development

VIEW PROGRAM »»

19-20 MARCH 2025

Next-Generation Analytical Methods

VIEW PROGRAM »»

Stream 6 ANALYTICAL & QUALITY

The Analytical and Quality stream focuses on accelerating analytical development and next-generation methods for complex therapeutics. It covers best practices, new technologies, and integration of analytical methods, emphasising AI applications, developability analysis, and advances in automation. The stream explores emerging technologies for protein science, modality-specific solutions, core analytical method evolution, and process analytics. It provides a platform for scientists and managers to exchange ideas and explore innovative solutions in this rapidly evolving field.

Cambridge Healthtech Institute's Inaugural

18–19 MARCH 2025 ALL TIMES CET

Accelerating Analytical Development

New Technologies to Optimise the Speed and Efficiency of Biotherapeutic Development

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

AUTOMATION & MINIATURISATION

8:25 Chairperson's Remarks

Shahid Uddin, PhD, Senior Director, Formulation Development and Laboratory Operations, Immunocore

8:30 PAT and Automation for Robust Upstream Stem Cell Processing

Jens Traenkle, PhD, Head, PAT & Automation, Product Supply, Pharmaceuticals, Bayer AG

We will present our recent advances for Bayer's Cell Therapy Platform. Especially, I will focus on how our progress in PAT and automation supports switching from highly manual adherent iPSC cultivation processes to fully automated and closed robotic-controlled cultivation systems with a portfolio of in-line and at-line PAT methods supporting close process monitoring.

9:00 Integration of Microfluidics and Microsensors in Bioprocess Technology

Janina Bahnemann, PhD, Professor, Cell Culture and Microsystems Technology, University of Augsburg

This topic explores the integration of microfluidics and miniaturised sensors in bioprocess technology, emphasising lab-on-a-chip systems for real-time monitoring. The combination of microfluidics and automation enables precise control and manipulation of biological samples, while integrated sensors allow for continuous monitoring of key process parameters. Examples include the use of micromixers for cell handling and biosensor systems for real-time detection of analytes in cell culture processes, enhancing bioprocess efficiency and control.

9:30 Presentation to be Announced

halo labs

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

PLATFORMS & WORKFLOWS

10:45 Adapting Internal Workflows to Accommodate Accelerated Development Timelines

Christina Vessely, PhD, Senior Consultant, CMC Analytics & Formulation Development, Biologics Consulting Group, Inc.

Accelerated development timelines present unique challenges for analytical workflows. This presentation highlights strategies for adapting internal processes to maintain high standards of quality and compliance while meeting rapid development goals. Explore practical solutions for streamlining analytical methods, integrating automation, and improving cross-functional collaboration to ensure efficiency without compromising the robustness of biotherapeutic development.

11:15 Overcoming the Barriers to Further Adoption of MAM

Alexander Buettner, PhD, Senior Scientist, Pharma Technical Development, Roche

The multi-attribute method (MAM) shows promise in biopharmaceutical analysis, potentially replacing traditional methods and closing control-system gaps. This presentation will address challenges such as IT system and instrumentation preparation, method development, suitability assessment, and validation. As Roche/Genentech implements MAM for quality control, practical insights and experiences in overcoming these barriers will be shared.

11:45 KEYNOTE PRESENTATION: MS-Based Approaches for in-Depth and Automated Biotherapeutic Monitoring

Elena Dominguez Vega, PhD, Assistant Professor, Center for Proteomics and Metabolomics, Leiden University Medical Center

Mass spectrometry (MS) has become a fundamental tool in the biopharmaceutical industry. Yet, MS characterisation of biotherapeutics may be tedious and time-consuming, requiring extensive sample preparation and analysis steps. This presentation will highlight novel MS-based approaches that provide high-resolution MS data while automating the analysis process. Using multidimensional liquid chromatography and fluidic approaches, different sample preparation and separation steps are incorporated in one platform, providing a solution for fast characterisation.

12:15 Presentation to be Announced

synTQ by Optimal

12:30 Sponsored Presentation *(Opportunity Available)*

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

METHODS FOR DEVELOPABILITY ANALYSIS

13:45 Chairperson's Remarks

Christina Vessely, PhD, Senior Consultant, CMC Analytics & Formulation Development, Biologics Consulting Group, Inc.

13:50 Developability Evaluations for Complex Biologics

Maniraj Bhagawati, PhD, Senior Scientist and Lab Head, Functional Characterization, Large Molecule Research, Roche pRED

The pharmaceutical industry is focusing on patient convenience and decentralised care, driving the need for high-concentration liquid formulations with stable protein behavior. However, predicting protein behavior at high concentrations—including risks like viscosity or aggregation—remains challenging, especially with complex molecular designs. We present an early screening process using high-throughput assays to assess critical solution parameters and predict developability risks across various molecule formats early in drug discovery.

14:20 Comparing the Outlook of Developability Assessment of Monoclonal Antibodies to AAV Therapeutics for Successful Lead Candidate Selection from Discovery to Development

Yogapriya Murugesan, Scientist I, Gene Therapy & Drug Product Development, Biogen

Molecular properties that impact developability attributes and outcomes comprises of conformational, chemical, colloidal, and other interactions. These attributes are measured using relevant analytical methods to assess the developability/ manufacturability of the molecule in different formulation. Developability assessment of mAbs has been studied and applying this assessment using the right tools to new modalities such AAV will help streamline capsid selection and candidate selection from discovery to development for new modalities

14:50 Developability Assessment and Formulation Development for Novel Biotherapeutics

Shahid Uddin, PhD, Senior Director, Formulation Development and Laboratory Operations, Immunocore

Ensuring the success of novel biotherapeutics requires rigorous developability assessments and formulation strategies. This presentation delves into methods for evaluating the physicochemical properties and stability of new biologic candidates. Learn how early-stage assessments can inform

Accelerating Analytical Development

New Technologies to Optimise the Speed and Efficiency of Biotherapeutic Development

formulation development to improve manufacturability, enhance stability, and address potential challenges before clinical stages, ultimately accelerating the path to market for innovative therapeutics.

15:20 Presentation to be Announced

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

APPLICATIONS OF AI AND BIG DATA IN BIOPROCESS ANALYTICS

16:20 Accelerating Development and Formulation Design of Biologics with Bayesian Optimisation

Isabel Waibel, Graduate Student, Biochemical Engineering, ETH Zurich

The development and formulation of therapeutic antibodies is a highly complex optimisation task requiring significant time and resources. This can be particularly problematic for emerging engineered antibody formats, such as fragments and bispecifics, which can suffer from developability issues. Here we show a Bayesian optimisation method to improve multiple developability properties simultaneously through formulation design.

16:50 Presentation to be Announced

17:20 Implementing AI and ML in Analytical Development

Jake Black, PhD, Senior Consultant, Syner-G BioPharma Group

Though AI, ML, and other modern algorithmic data analysis techniques are poised to provide a range of benefits across the biopharmaceutical industry, these advances will be particularly impactful to analytical development. This talk will highlight key considerations from a CMC perspective when implementing AI/ML in analytical development. Additional focus will be placed on recent regulatory guidance pertaining to the development and validation of analytical methodologies utilising algorithmic data processing techniques.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

PROCESS ANALYTICS

8:25 Presentation to be Announced

8:30 Online Liquid Chromatography for Real-Time Monitoring in Downstream Processing of Biopharmaceuticals

Lea Bonnington, Scientist, Development Analytics, Roche Diagnostics GmbH

Data obtained and processed near real-time can provide information to confer consistent product quality, less product and resource wastage, and increased productivity, irrespective of variations in process, materials, and operating environment. The practical implementation of Process Analytical Technologies (PAT) requires, however, analytical methods offering sufficient speed, selectivity, and sensitivity. An online Liquid Chromatography (LC) setup enabling real-time monitoring of product quality will be presented.

9:00 Biomanufacturing Process Analytical Utility of Raman Microscopy, Focusing on Cells for Therapy

James M. Piret, PhD, Professor, Chemical & Biological Engineering, Michael Smith Labs, University of British Columbia

Clinical therapies based on cells have the potential to cure many diseases. However, populations of cells cannot be purified or analysed as stringently as drugs. By analysing changes in macromolecular cell composition, Raman microscopy offers a label-free approach to validate both biomanufacturing processes and final cell products. Using Raman microscopy, we have detected early apoptosis, distinguished stem cells from their differentiated progeny, as well as T cell subtypes and activation states.

9:30 Monitoring the *in vitro* Transcription for mRNA Production Using Raman Spectroscopy

Laurens Vergauwen, Process Development Scientist, Technical and Scientific Solutions, Merck

Precise monitoring of nucleoside triphosphate (NTP) bases and RNA molecules during IVT is essential for optimising reaction conditions and ensuring high-fidelity RNA synthesis. This presentation discusses the innovative use of Raman spectroscopy as a non-destructive analytical tool that overcomes the limitations of conventional techniques. Based on data, it will be shown that this technology can monitor the consumption of each individual NTP and formation of mRNA product during the reaction.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

14:00 Close of Accelerating Analytical Development Conference

Cambridge Healthtech Institute's Inaugural

19–20 MARCH 2025 ALL TIMES CET

Next-Generation Analytical Methods

New Technologies for Characterisation and Formulation of Complex Biotherapeutics

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

NEW MS APPLICATIONS AND TECHNOLOGIES

14:15 Chairperson's Remarks
Hristo Svilenov, PhD, Associate Professor, TUM

14:20 Process Analytics Using an Integrated Autonomous System
Jonathan Bones, PhD, Principal Investigator, Characterisation and Comparability Laboratory, National Institute for Bioprocessing Research and Training (NIBRT)
Development and application of an integrated autonomous system for process analytical monitoring of upstream processes producing monoclonal antibodies will be described. Our platform uses automated aseptic sampling and distribution to analytical destinations, including integrated LC-MS for near real-time product quality assessment. Supporting at-line analytics using various MS analyses were also performed for deeper process characterisation. Application for optimisation of mAb galactosylation using a design of experiments approach will be discussed.

14:50 Expanding the LCMS Toolbox for HCP Analytics: Use of Activity-Based Protein Profiling for Identification of Active Polysorbate/Protein Degrading Enzymes
Veronika Reisinger, PhD, Lab Head, Physico Chemical Characterization, Novartis AG
Residual host cell proteins (HCPs) can impact patient safety and product quality. ELISA and LCMS methods nowadays present standard methods for HCP analytics, but they cannot selectively identify enzymatically active HCPs, such as polysorbate or protein-degrading enzymes. We present a combination of activity-based protein profiling and LCMS analysis, which can close this gap and enables the development of targeted MS-based methods to support process development as next-step.

15:20 KEYNOTE PRESENTATION: Merging Automatic Peak Fractions with MS Characterisation Workflows for Understanding Product Variants
Dan Bach Kristensen, PhD, Scientific Director, Symphogen
During biopharmaceutical development, product quality is monitored by a range of impurity methods, including LC methods such as SEC, RPC, and IEX. Mass spectrometry is an essential analytical tool for characterisation of biopharmaceuticals. Here, we present the merger of automated peak fractionation from any type of LC method with any type of MS characterisation. Case studies will include MS characterisation of biopharmaceutical product variants separated by SEC, CIEX, and RPC.

15:50 Sponsored Presentation *(Opportunity Available)*

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 PANEL DISCUSSION: AI and Big Data Tools in the Analytical Function and Beyond
Moderator: Michael Sokolov, PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG
- Success and failure stories of AI/ML for specific methods and instruments
- Utilised software tools and maintenance of created AI solution
- Benchmark vs. traditional approaches
- Opportunities and challenges
- Experimental method validation in GMP environments
- Holistic digitalisation perspective beyond analytical

Panelists:
Jens Traenkle, PhD, Head, PAT & Automation, Product Supply, Pharmaceuticals, Bayer AG
Shahid Uddin, PhD, Senior Director, Formulation Development and Laboratory Operations, Immunocore
Laurens Vergauwen, Process Development Scientist, Technical and Scientific Solutions, Merck
Sisi Zhang, Principal Scientist, Regeneron Pharmaceuticals, Inc.

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

18:30 Close of Day

Cambridge Healthtech Institute's Inaugural

19–20 MARCH 2025 ALL TIMES CET

Next-Generation Analytical Methods

New Technologies for Characterisation and Formulation of Complex Biotherapeutics

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

ANALYTICAL METHODS FOR FORMULATION DEVELOPMENT

8:25 Chairperson's Remarks

Dan Bach Kristensen, PhD, Scientific Director, Symphogen

8:30 FEATURED PRESENTATION: Developability Assessment of Antibodies with a Focus on Interfacial Stability

Hristo Svilenov, PhD, Associate Professor, TUM

Adsorption and aggregation of antibodies at interfaces presents a risk for developing antibody drug candidates. However, it is difficult to predict this molecule behaviour from the physicochemical properties of the antibodies. In this presentation, I will show our latest work on the developability assessment of antibody drug candidates with a focus on predicting protein adsorption and aggregation induced by interfaces.

9:00 Quantitatively Characterise Polysorbate 80 Oxidation to Establish Placebo Product Shelf-Life Consideration

Sisi Zhang, Principal Scientist, Regeneron Pharmaceuticals, Inc.

A PS80-oxidised product had been discovered and validated to reveal early signs of PS80 oxidation and quantitively describe the status of PS80 oxidation regardless of the stress condition and incubation time. The accuracy and precision of this PS80 oxidation marker measurement agreed with industry guidelines and therefore can be used to indicate the status of PS80 oxidation and applied to establish the shelf-life to the potential for PS stability.

9:30 Considerations for Viral Vector Stability in Manufacturing

Angeles Mecate-Zambrano, Senior Scientist, Merck KGaA

Viral gene therapy holds great promise for treating complex diseases, but its success depends on producing high-quality viral vectors. Manufacturing these vectors presents challenges, particularly in optimising yield and stability. Here, we delve into physiochemical process conditions that affect AAV particle stability and aggregation, and we provide insights into how additives can improve particle stability and resistance to critical manufacturing process conditions.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:10 Nature's Blueprint for Better Drugs: Bioinspired Drug Design and Formulation Strategies

Iris L. Batalha, PhD, La Caixa Junior Leader, Molecular Bionics, Institute for Bioengineering of Catalonia (IBEC)

Many drugs, particularly novel modalities, face significant formulation and delivery challenges, such as stability, unwanted immunogenicity, and poor biodistribution. By leveraging the principles and structures found in nature, bioinspired drug design and formulation strategies offer a promising approach to address these issues.

EMERGING METHODS TO SUPPORT COMPLEX MODALITIES

11:40 Developability Analysis and Considerations for Bispecific Antibodies

Sean Keng Rui Chia, PhD, Associate Staff Scientist, Analytical Science & Technologies, A STAR

Despite their therapeutic potential, bispecific antibodies present additional developability challenges compared to traditional monoclonal antibodies, due to their complex structures. Through case studies, we demonstrate how format changes can exacerbate developability issues for bispecific antibodies, such as their aggregation propensity and polyreactivity. Our findings provide new analytical approaches and perspectives to assess next-generation biologics, in the overall aim of driving their rational development.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

13:25 Chairperson's Remarks

Jimmy Gaudreault, Researcher, Chemical Engineering, Polytechnique Montréal

13:30 New Mass Spectrometry Methodology to Analyse Emerging Biotherapeutics

Thierry Besson, Principal Scientist, BRC, Novartis Pharma AG

Biologics have now evolved from classical mAbs to proteins that are more difficult to analyse, such as therapeutic proteins, multispecifics, novel conjugates, siRNA—and even in the cell and gene therapy space with adeno-associated viruses, for example. With all these new modalities, state-of-the-art analytics must be developed to characterise them in detail, and MS is a major player in this area coupled with diverse liquid chromatography.

14:00 Towards Integration of SPR Measurements for at-Line Characterisation of mAb Glycosylation

Jimmy Gaudreault, Researcher, Chemical Engineering, Polytechnique Montréal

N-glycosylation is a critical quality attribute of monoclonal antibodies (MAbs) as it affects binding to Fcγ receptors (FcγR), which impacts the efficacy and safety of MAbs. Surface plasmon resonance (SPR) represents a promising avenue for glycosylation monitoring online of a bioreactor, as SPR biosensors can record MAb-FcγR interactions in real-time and without labelling. Using FcγRIIA/B and a low experimental temperature, we suggest a rapid quantification method for galactosylation and fucosylation.

14:30 Enabling Broader Adoption of MAM: Comparison of MAM vs. Conventional Methods

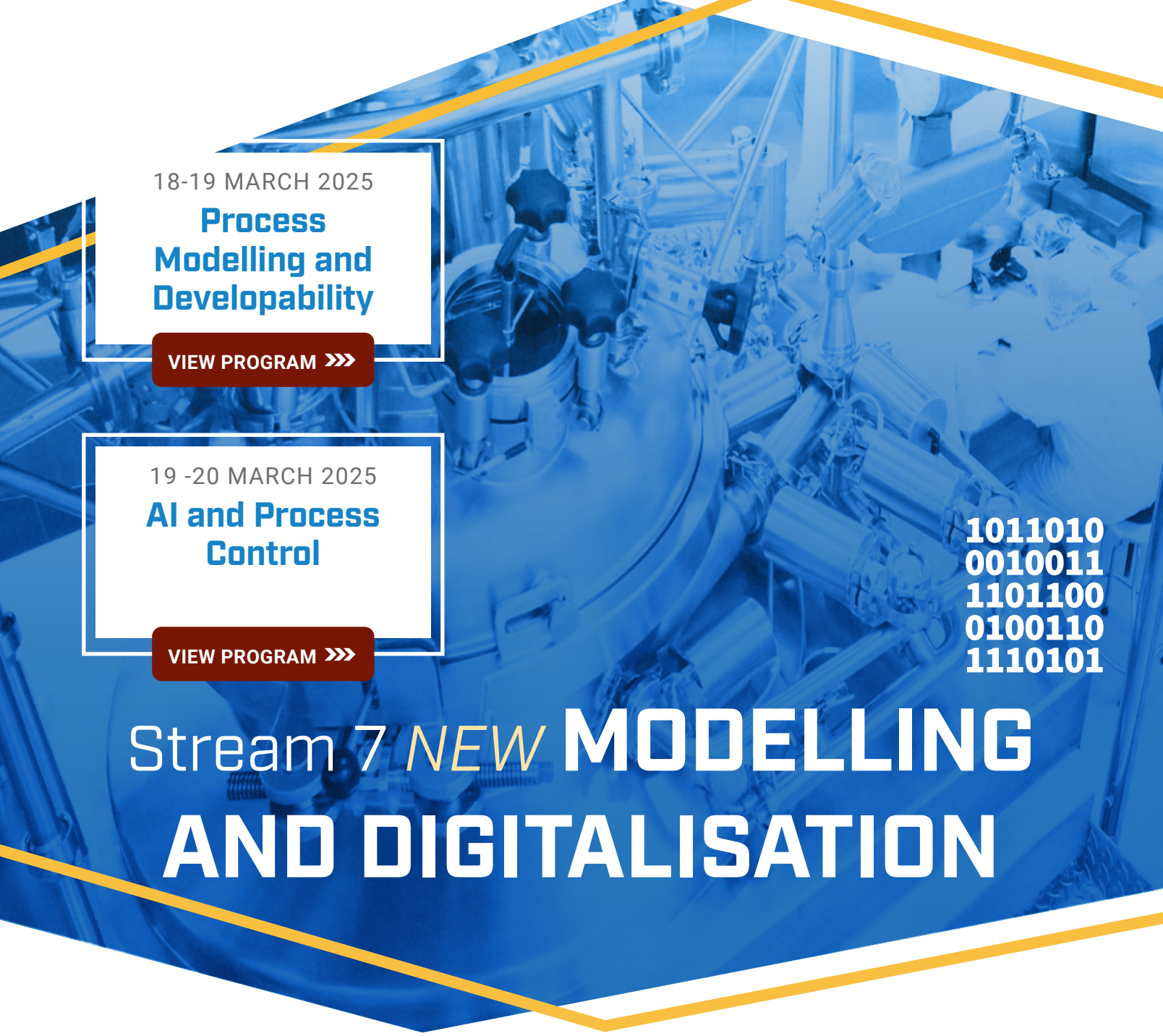
Diane McCarthy, PhD, Senior Scientific Director, Global Biologics, US Pharmacopeia

While the multi-attribute method (MAM) has potential to improve the efficiency and specificity of analytical testing, comparison to conventional methods is critical for implementation in QC. Through a cooperative agreement with US FDA, we have evaluated the performance of MAM versus conventional methods in detecting differences between thermally degraded therapeutic proteins from multiple sources. This presentation will share results and an implementation roadmap to facilitate broader adoption of MAM.

15:00 Close of Summit

"Nice opportunity to keep my knowledge up to date. Learned a lot!"

Florence Salmon, PhD, Ridgeline Discovery



18-19 MARCH 2025

Process Modelling and Developability

VIEW PROGRAM »»

19 -20 MARCH 2025

AI and Process Control

VIEW PROGRAM »»

Stream 7 *NEW* MODELLING AND DIGITALISATION

New for 2025, the Modelling and Digitalisation stream explores the integration of process modelling and control, developability and digitalisation across various aspects of bioprocessing, driven by advances in analytical development, artificial intelligence and machine learning. The stream highlights cutting-edge applications in process monitoring, smart manufacturing, and real-time analytics in compliance with GMP environments, across cell line engineering, cell culture, downstream processing, cell and gene therapy development, and more.

Cambridge Healthtech Institute's Inaugural

18–19 MARCH 2025 ALL TIMES CET

Process Modelling and Developability

Transforming Biotherapeutic Production with Cutting-Edge Computational Tools

TUESDAY 18 MARCH

7:00 Registration and Morning Coffee

CHEMOMETRICS & MODELLING

8:25 Chairperson's Remarks

Mark Duerkop, CEO, Novasign GmbH

8:30 Deep Learning for Optimisation of Protein Expression

Diego A. Oyarzun, PhD, Reader in Computational Biology, Informatics Forum, University of Edinburgh

Deep learning is a promising approach for building sequence-to-expression models for strain optimisation. But these need large, costly data sets that create steep entry barriers for many laboratories. In this talk, I will discuss data requirements and how they impact predictive accuracy, alongside training strategies for improved prediction of protein expression in new regions of the sequence space. These results provide guidelines for balancing data cost/quality in predictive strain design.

9:00 How to Develop and What to Expect from Predictive Process Models

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

This presentation will delve into strategies for developing accurate predictive models from limited and yet complex data, the necessary data inputs, and the potential challenges faced during implementation. Based on many industrial use cases, attendees will gain insights into how these models can forecast performance, reduce variability, and streamline manufacturing, improving both efficiency and product quality in biologic drug development.

9:30 Presentation to be Announced

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

10:45 Automated Knowledge Generation, Valorisation, and Exchange Strategies Reshape Bioprocess Development

Peter Neubauer, PhD, Lab Head, Bioprocess Engineering, TU Berlin

Complex self-driving intelligent experiments for bioprocess development are only possible by integrating all aspects of cell cultivation, analytics, and modelling into a comprehensive framework and steered by an effective Workflow Management System. This is realised in the KIWI-biolab and its opportunities for process optimisation and collaboration are demonstrated by a number of developmental projects. The strict implementation of such fully automated approaches promotes the application of FAIR principles.

11:15 Digital Twin–Enhanced Process Development: Success Stories from mAbs, C&CT, and Continuous Processing

Mark Duerkop, CEO, Novasign GmbH

The application of modelling tools in bioprocess development and manufacturing has garnered considerable interest. But what does it really take to develop digital bioprocess twins? This talk dives into key topics such as the business impact of process modelling, experimental design strategies, tailored modelling approaches, accelerated process development, seamless scale-up, and the real-time use of models for monitoring and control. These principles will be demonstrated through several industrial case studies.

11:45 Physics-Informed Artificial Intelligence: A Groundbreaking Technology in the Biopharmaceutical Industry

Ignasi Bofarull-Manzano, CMC Data Scientist, Mechanical Engineering, RWTH Aachen University

While AI's transformative power is well recognised across industries, its potential in pharmaceutical bioprocessing remains underexploited due to limited data. In 2019, Raissi et al. introduced Physics-Informed Neural Networks (PINNs), creating a new paradigm by integrating deep learning with first-principles laws. This method enables the use of AI even with scarce data, presenting a groundbreaking chance to revolutionise biopharmaceutical processes by cutting costs and accelerating the time-to-market for new therapies.

12:15 Fast-Track Your Way to Process Understanding and Control—A Case Study on How to Simplify PAT Implementation

Milla Neffling, Senior Manager, Bioprocess Applications, Marketing, 908 Devices Inc.

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing

(Sponsorship Opportunity Available)

METHODS FOR DEVELOPABILITY ANALYSIS

13:45 Chairperson's Remarks

Christina Vessely, PhD, Senior Consultant, CMC Analytics & Formulation Development, Biologics Consulting Group, Inc.

13:50 Developability Evaluations for Complex Biologics

Maniraj Bhagawati, PhD, Senior Scientist and Lab Head, Functional Characterization, Large Molecule Research, Roche pRED

The pharmaceutical industry is focusing on patient convenience and decentralised care, driving the need for high-concentration liquid formulations with stable protein behavior. However, predicting protein behavior at high concentrations—including risks like viscosity or aggregation—remains challenging, especially with complex molecular designs. We present an early screening process using high-throughput assays to assess critical solution parameters and predict developability risks across various molecule formats early in drug discovery.

14:20 Comparing the Outlook of Developability Assessment of Monoclonal Antibodies to AAV Therapeutics for Successful Lead Candidate Selection from Discovery to Development

Yogapriya Murugesan, Scientist I, Gene Therapy & Drug Product Development, Biogen

Molecular properties that impact developability attributes and outcomes comprises of conformational, chemical, colloidal, and other interactions. These attributes are measured using relevant analytical methods to assess the developability/ manufacturability of the molecule in different formulation. Developability assessment of mAbs has been studied and applying this assessment using the right tools to new modalities such AAV will help streamline capsid selection and candidate selection from discovery to development for new modalities

14:50 Developability Assessment and Formulation Development for Novel Biotherapeutics

Shahid Uddin, PhD, Senior Director, Formulation Development and Laboratory Operations, Immunocore

Ensuring the success of novel biotherapeutics requires rigorous developability assessments and formulation strategies. This presentation delves into methods for evaluating the physicochemical properties and stability of new biologic candidates. Learn how early-stage assessments can inform formulation development to improve manufacturability, enhance stability, and address potential challenges before clinical stages, ultimately accelerating the path to market for innovative therapeutics.

15:20 Presentation to be Announced

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

Cambridge Healthtech Institute's Inaugural

18–19 MARCH 2025 ALL TIMES CET

Process Modelling and Developability

Transforming Biotherapeutic Production with Cutting-Edge Computational Tools

APPLICATIONS OF AI AND BIG DATA IN BIOPROCESS ANALYTICS

16:20 Accelerating Development and Formulation Design of Biologics with Bayesian Optimisation

Isabel Waibel, Graduate Student, Biochemical Engineering, ETH Zurich

The development and formulation of therapeutic antibodies is a highly complex optimisation task requiring significant time and resources. This can be particularly problematic for emerging engineered antibody formats, such as fragments and bispecifics, which can suffer from developability issues. Here we show a Bayesian optimisation method to improve multiple developability properties simultaneously through formulation design.

16:50 Presentation to be Announced

17:20 Implementing AI and ML in Analytical Development

Jake Black, PhD, Senior Consultant, Syner-G BioPharma Group

Though AI, ML, and other modern algorithmic data analysis techniques are poised to provide a range of benefits across the biopharmaceutical industry, these advances will be particularly impactful to analytical development. This talk will highlight key considerations from a CMC perspective when implementing AI/ML in analytical development. Additional focus will be placed on recent regulatory guidance pertaining to the development and validation of analytical methodologies utilising algorithmic data processing techniques.

17:50 Welcome Reception in the Exhibit Hall with Poster Viewing

18:50 Close of Day

WEDNESDAY 19 MARCH

8:00 Registration and Morning Coffee

PROCESS ANALYTICS

8:25 Presentation to be Announced

8:30 Online Liquid Chromatography for Real-Time Monitoring in Downstream Processing of Biopharmaceuticals

Lea Bonnington, Scientist, Development Analytics, Roche Diagnostics GmbH

Data obtained and processed near real-time can provide information to confer consistent product quality, less product and resource wastage, and increased productivity, irrespective of variations in process, materials, and operating environment. The practical implementation of Process Analytical Technologies (PAT) requires, however, analytical methods offering sufficient speed, selectivity, and sensitivity. An online Liquid Chromatography (LC) setup enabling real-time monitoring of product quality will be presented.

9:00 Biomanufacturing Process Analytical Utility of Raman Microscopy, Focusing on Cells for Therapy

James M. Piret, PhD, Professor, Chemical & Biological Engineering, Michael Smith Labs, University of British Columbia

Clinical therapies based on cells have the potential to cure many diseases. However, populations of cells cannot be purified or analysed as stringently as drugs. By analysing changes in macromolecular cell composition, Raman microscopy offers a label-free approach to validate both biomanufacturing processes and final cell products. Using Raman microscopy, we have detected early apoptosis, distinguished stem cells from their differentiated progeny, as well as T cell subtypes and activation states.

9:30 Monitoring the *in vitro* Transcription for mRNA Production Using Raman Spectroscopy

Laurens Vergauwen, Process Development Scientist, Technical and Scientific Solutions, Merck

Precise monitoring of nucleoside triphosphate (NTP) bases and RNA molecules during IVT is essential for optimising reaction conditions and ensuring high-fidelity RNA synthesis. This presentation discusses the innovative use of Raman spectroscopy as a non-destructive analytical tool that overcomes the limitations of conventional techniques. Based on data, it will be shown that this technology can monitor the consumption of each individual NTP and formation of mRNA product during the reaction.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities

Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech

Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies

Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.

Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

14:00 Close of Process Modelling and Developability Conference

Cambridge Healthtech Institute's Inaugural

19–20 MARCH 2025 ALL TIMES CET

AI and Process Control

Revolutionising Bioprocessing through Intelligent Control

WEDNESDAY 19 MARCH

10:30 Registration Open

PLENARY KEYNOTE: ADAPTING TO GLOBAL DEMANDS AND EVOLVING PIPELINES

11:15 Chairperson's Remarks
Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: CMC Strategies for Diverse Pipelines and Complex Modalities
Christian Hunzinger, PhD, Senior Director and Head, CMC Development Proteins, ADCs and Chemical Entities, BioNTech
Biopharmaceutical treatment paradigms are shifting from monotherapy towards multi-target approaches with complex multimodal entities. This complexity also translates into increasingly complex CMC development and manufacturing strategies. The talk will provide a general overview on recent developments, challenges, and opportunities, along with examples from various stages of the CMC development lifecycle.

11:50 PLENARY PRESENTATION: Enhancing Process Development: Balancing Yields with Downstream Efficiency and Emerging Technologies
Oliver Kaltenbrunner, PhD, Scientific Director, Process Development, Amgen Inc.
Explore the evolving landscape of process development, emphasising the critical balance between maximising yields and optimising downstream processing. This presentation will delve into the impact of upstream processes on primary recovery, integrating cutting-edge technologies like Process Analytical Technology (PAT), advanced modelling, and artificial intelligence. Supported by real-world examples, we'll examine how these innovations are reshaping process efficiency and performance in the industry.

12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

DIGITALISATION AND PROCESS CONTROL

14:15 Chairperson's Remarks
Geoff Smith, PhD, Professor, Pharmaceutical Process Analytical Technology, De Montfort University

14:20 KEYNOTE PRESENTATION: Host Cell Proteins Profiling and Characterisation for Model-Based DSP Design
Marcel Ottens, PhD, Professor, Biotechnology, Delft University of Technology
This presentation explores the integration of host cell proteins (HCP) profiling into model-based downstream process (DSP) design. By examining the characterisation techniques and quantification of HCPs, we demonstrate how these data inform the optimisation of purification strategies, enhancing product purity and process efficiency. Case studies illustrate the impact of advanced HCP analytics on biopharmaceutical production, emphasising practical applications and theoretical implications for DSP workflows.

14:50 Digitalisation Strategies to Enhance Efficiency and Product Quality
Oliver Hesse, Lead, CMC Digital Transformation and Data Science
This presentation will highlight our manufacturing platform strategy for cell therapies—emphasising data science, modelling, and PAT—to enhance manufacturing efficiency and product quality. By integrating automation and machine learning, we want to accelerate the development of robust processes. Join us in exploring how smart manufacturing practices can redefine the future of cell therapy production.

15:20 Pharmaceutical Freeze-Drying: Applications for Multi-PAT Sensors
Geoff Smith, PhD, Professor, Pharmaceutical Process Analytical Technology, De Montfort University
A novel program of work (Digital_Lyo) will be presented that is being undertaken by a consortium or academic, industrial, and regulatory authority partners, including AstraZeneca, Siemens, the Medicines and Healthcare Regulatory Agency (UK), and smaller industrial enterprises with specialist capability in sensor development. The talk will present highlights of the Digital_Lyo programme, including the applications for a novel process analytical technology called through-vial impedance spectroscopy (TVIS).

15:50 Presentation to be Announced

16:05 Sponsored Presentation *(Opportunity Available)*

HAMILTON

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 PANEL DISCUSSION: AI and Big Data Tools in the Analytical Function and Beyond
Moderator: Michael Sokolov, PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG
- Success and failure stories of AI/ML for specific methods and instruments
- Utilised software tools and maintenance of created AI solution
- Benchmark vs. traditional approaches
- Opportunities and challenges
- Experimental method validation in GMP environments
- Holistic digitalisation perspective beyond analytical

Panelists:
Jens Traenkle, PhD, Head, PAT & Automation, Product Supply, Pharmaceuticals, Bayer AG
Shahid Uddin, PhD, Senior Director, Formulation Development and Laboratory Operations, Immunocore
Laurens Vergauwen, Process Development Scientist, Technical and Scientific Solutions, Merck
Sisi Zhang, Principal Scientist, Regeneron Pharmaceuticals, Inc.

18:00 Interactive Breakout Discussions
Interactive Breakout Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Breakout Discussions page on the conference website for a complete listing of topics and descriptions.

18:30 Close of Day

Cambridge Healthtech Institute's Inaugural

19– 20 MARCH 2025 ALL TIMES CET

AI and Process Control

Revolutionising Bioprocessing through Intelligent Control

THURSDAY 20 MARCH

8:00 Registration and Morning Coffee

PROCESS MONITORING AND CONTROL

8:25 Chairperson's Remarks

Zach Pang, PhD, Group Leader, Bioprocess Data Integration, A*STAR

8:30 To Model or Not to Model: When Are Models Really Useful?

Bettina Knapp, PhD, Lab Head, Upstream Development, Boehringer Ingelheim

Cell culture development in biopharmaceuticals uses models to optimise processes and understand complex systems. Defining a model's purpose is crucial, as is starting with good data. Embracing model thinking across all disciplines enhances understanding and effective use of models. Despite challenges, effective modelling can lead to faster, better, and more sustainable processes.

9:00 Non-Invasive Methods for Monitoring Bioprocesses

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

Bio-capacitance has become a standard online method to measure growth in cell-based biomanufacturing. The method offers rapid, continuous monitoring without manual sampling. However, there are noted deviations at the inflection point beyond exponential growth compared to standard staining methods such as trypan blue. This can be explained by different measurement criteria that can be exploited to gain a good understanding of the metabolic changes that arise during the bioprocess.

9:30 KEYNOTE PRESENTATION: Using the Oxygen Transfer Rate as a Basis for Scale-Up of Cell Culture

Jorgen B. Magnus, PhD, Professor & Chair, Biochemical Engineering, RWTH Aachen University

Using the Respiration Activity Monitoring System developed at the RWTH University of Aachen, the oxygen transfer rate can be measured very accurately in deep well plates, shake flasks, and stirred tank bioreactors. Thus, the state of the cell culture can be understood at different scales without the need to take samples. This information, in combination with calculations of volumetric power input and maximum energy dissipation, is used for scale-up.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

DIGITAL APPLICATIONS IN CELL CULTURE AND CLD

11:10 Accelerating Design of New Upstream Bioprocesses with Digital Twins: A Case Study on AAV Production

Inês A. Isidro, PhD, Head of Biosystems and Data Science, iBET

Digital twins can significantly transform bioprocess design. We present a case study on AAV production in insect cells, where digital simulation was used to design a new fed-batch operation. This demonstrates how digital twins can be leveraged for new gene and cell therapy products, which often have limited accumulated data and serotype/donor-specific variability, to unlock faster and more efficient bioprocess development.

11:40 Computational Approach to Accelerate Culture Media Optimisation for New Modalities

Zach Pang, PhD, Group Leader, Bioprocess Data Integration, A*STAR

The current workflow involves experimental DOE to determine the optimal culture media formulation. A paradigm shift is underway in the optimisation of culture media, wherein a modelling approach can be employed to accelerate culture media optimisation. I will introduce a computational approach involving genome-scale metabolic modelling and model-guided DoE approach, and how this workflow can help the industry, particularly for new modalities, to accelerate culture media design and optimisation.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Poster Viewing *(Sponsorship Opportunity Available)*

DIGITALISATION AND AUTOMATION IN ADVANCED THERAPIES

13:25 Chairperson's Remarks

David Estape, PhD, Technology Manager and Senior Fellow, Process Engineering, CRB Group GmbH, Member, BioPhorum, ISPE

13:30 Development of a Digital Twin for AAV Production

Frank Baganz, PhD, Associate Professor, Fermentation and Cell Culture, Biochemical Engineering, University College London (UCL)

rAAV processes with complex dynamic behaviour requires high experimental effort, and is time consuming and expensive. Digital Twins (DT) that are based on mathematical models can be used for process development and optimisation. A mechanistic model of an rAAV9 production process has been developed and parameterised using in-house experimental data. The validation of the DT models and its application to increase the functional rAAV9 titre will be demonstrated.

14:00 Lentiviral Vector Manufacturing Process Development and Modelling for Cell & Gene Therapies

Laurence Guianvarch, Director, Viral Vector Technical Development, Orchard Therapeutics

Orchard's approach to gene therapy is designed to deliver a functional version of the mutated gene, or transgene, to a patient's own blood stem cells—called hematopoietic stem cells or HSCs—to produce the desired therapeutic protein. This talk will discuss lentiviral process development and scale-up.

14:30 Navigating Regulatory Challenges for Closed Processing in ATMPs

David Estape, PhD, Technology Manager and Senior Fellow, Process Engineering, CRB Group GmbH, Member, BioPhorum, ISPE

Focusing on regulatory challenges, this presentation explores the role of closed processing in Advanced Therapy Medicinal Products (ATMPs). Closed systems, together with standard process platforms and automation-digitalisation, are key for the future of ATMP manufacturing. Through the analysis of the current guidelines, this presentation draws how regulatory frameworks may either support or hinder closed systems adoption. The final goal is to align closed processing with current and future regulations.

15:00 Close of Summit

"High relevance and quality of talks, good mix of academia, industry, service providers."

Zorica Dragic, Novartis

SPONSORSHIP OPPORTUNITIES

Podium Presentations—Available within Main Agenda!
Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CHI. Presentations do sell out early.

One-on-One Meetings
Work with us to identify your target prospects and we will schedule meetings for you. Think of us as your inside sales team with all your hottest leads in close reach. Opportunities sold on a very limited basis.

Invitation-Only Dinner/Hospitality Suite
Sponsors will select their top prospects from the conference preregistration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations, conduct follow-up, and confirm attendees. The evening will be customised to meet with your specific objectives.

Exhibit Hall Networking Reception Sponsorship
Your company will be recognised as the exclusive sponsor of either the Welcome Reception on day 1 or the Networking Reception on day 3 to be held in the Exhibit Hall. Use this lively social occasion to launch a new product or solution and drive delegates to your exhibit booth.

Additional sponsorship & branding opportunities include:
- Wall of Fame (Meter Boards)
- Meter Boards
- Lanyards
- Foot Trails—NEW
- Keynote Chair Drop
- Tote Bag Exclusive Sponsorship
- Water Bottles
- Conference Track Notebooks
- Tote Bag Insert
- Chair Drop in Session Room

For more information regarding sponsorship and exhibit opportunities, please contact:

COMPANIES A-K

Phillip Zakim-Yacouby
Senior Business Development Manager
+1 781-247-1815
philzy@cambridgeinnovationinstitute.com

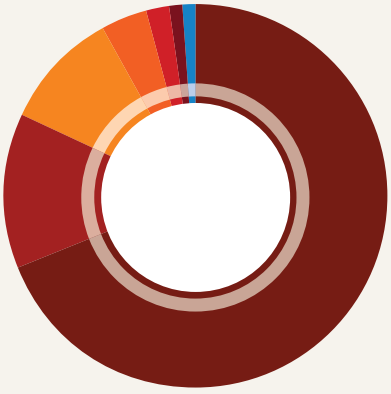
COMPANIES L-Z

Aimee Croke
Business Development Manager
+1 781-292-0777
acroke@cambridgeinnovationinstitute.com

“One of the best events in Bioprocessing!”

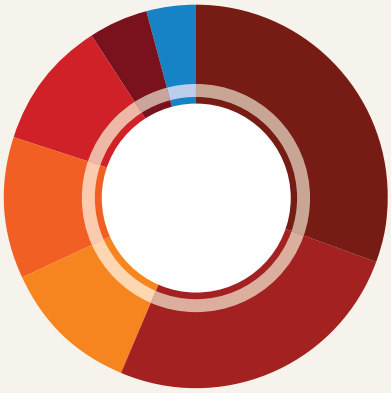
Sebastian Thuermann, Tosoh Bioscience Deutschland GmbH

2024 ATTENDEE DEMOGRAPHICS



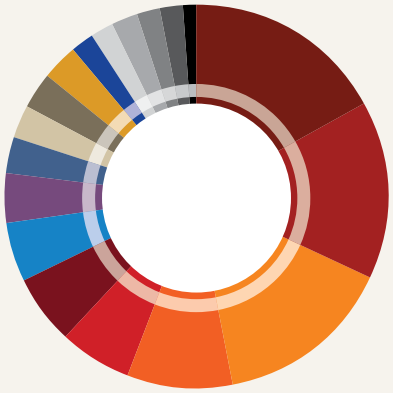
COMPANY TYPE

Biotech	69%
Academic	13%
Pharma	10%
Services	4%
Healthcare	2%
Financial	1%
Other	1%



DELEGATE TITLE

Scientist/Technologist	31%
Sales & Marketing	26%
Director	12%
Manager	12%
Executive	11%
Professor	5%
Assistant	4%



GEOGRAPHIC LOCATION

United Kingdom	17%	Asia	3%
Germany	15%	Sweden	3%
USA	15%	Rest of Europe	3%
France	9%	Portugal	2%
Switzerland	6%	Rest of World	2%
Spain	6%	Italy	2%
Austria	5%	Ireland	2%
The Netherlands	4%	Denmark	2%
Belgium	3%	Poland	1%

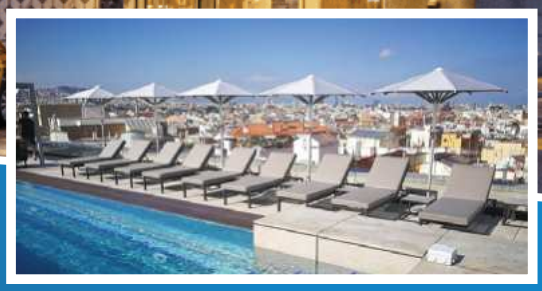
Join Us In Barcelona!

HOTEL & TRAVEL

Conference Venue and Hotel:
InterContinental Barcelona
Avenida de Rius I Taulet, 1-3
Barcelona, 08004, Spain

VISIT THE TRAVEL PAGE
to make your hotel reservations and for additional information

Discounted Room Rate:
€309 Single/€309 Double
Complimentary Wi-Fi
Discounted Room Rate Cut-off Date: 7 February 2025



Can't Make it to Barcelona?

Connect from anywhere. Join via our robust virtual platform and access these dynamic features

- INTUITIVE INTERFACE
- LIVE CHAT
- RECORDED SESSIONS
- POSTER SESSIONS
- COMPANY BRANDING
- LIVE SESSIONS
- DOWNLOADS




Present a Poster and Save €50!

Share Your Data and Discover the Latest Advances in Bioprocess Research

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure an onsite poster board and/or ensure your poster is included in the conference materials, your full submission must be received, and your registration paid in full by **7 February 2025.**