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Cambridge Healthtech Institute's 9th ANNUAL

BIOPROCESSING SUMMIT EUROPE

TRANSFORMING BIOPROCESSING THROUGH DATA, DIGITALISATION, AND EMERGING TECHNOLOGIES

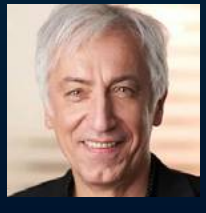
10-12 MARCH 2026 InterContinental Barcelona, Spain + Virtual (CET)

Europe's Leading Forum for Bioprocessing Innovation and Collaboration

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 **CELL AND GENE THERAPY**	Cell Therapy Manufacturing	Gene Therapy Manufacturing
Stream 4 *NEW* **PEPTIDES AND OLIGOS**	*NEW for 2026* Peptide and Oligo Manufacturing	Advances in Recovery and Purification - Part 2
Stream 5 **INTENSIFIED AND CONTINUOUS PROCESSING**	Cell Culture and Cell Line Engineering - Part 1	Intensified and Continuous Processing
Stream 6 **ANALYTICAL AND DEVELOPABILITY**	Accelerating Analytical Development	*NEW for 2026* Biophysical Analysis and Developability
Stream 7 **AI AND DIGITALISATION**	Process Modelling and Digitalisation	AI and Process Control

PLENARY KEYNOTE PRESENTERS

Shaping the Future of Bioprocessing through Biology, Data, and AI



Current Trends and Opportunities in Bioprocessing

Konstantin Konstantinov, PhD
CTO, Ring Therapeutics, Flagship Pioneering

Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and Artificial Intelligence

Jack Prior, PhD
Head, Process Monitoring & Data Science & AI Strategy, Sanofi

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BioprocessingEurope.com

ABOUT

BIOPROCESSING SUMMIT EUROPE

Bioprocessing Summit Europe brings together 650+ professionals from industry and academia, along with 60+ exhibitors, to advance the manufacture, quality, and control of cutting-edge biologics, genetic therapies, peptides, and oligonucleotides.

This 3-day, 14-track event is recognised as Europe's premier scientifically-driven bioprocessing gathering, offering actionable insights and practical solutions to enhance efficiency, speed, and cost-effectiveness in biomanufacturing.

New for 2026, we're introducing a track on peptides and oligonucleotide manufacturing, alongside expanded sessions on bi- and multi-specifics, antibody-drug-conjugates, AI/ML, advanced process control, digitalisation, developability, cell culture, downstream processing, sustainability, and the latest in cell, gene, and RNA therapies.

Come join the conversation, connect with industry leaders, and be part of the next wave of innovation. See you there!

"A **GREAT** conference to attend for the **LATEST** in cell expansion and technology!"

Jessica de Rooij
Marketing Manager, I&L Biosystems

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PLENARY KEYNOTE PRESENTERS

WEDNESDAY 11 MARCH 2026 | 11.15AM – 12.20PM

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

Current Trends and Opportunities in Bioprocessing

Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering

This presentation explores how advances in biology are redefining bioprocessing to enable scalable, efficient, and reproducible manufacturing of emerging therapeutic modalities. By integrating synthetic biology, cell engineering, and data-driven design, the field can move beyond traditional methods toward biologically driven, industrialised platforms. The session highlights how biological innovation underpins the transformation of biomanufacturing for the next generation of complex biologics.

Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and Artificial Intelligence

Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

Digital transformation promises to revolutionise biopharmaceutical manufacturing, yet most organisations leverage a fraction of their process data, with the challenges paradoxically increasing with globalisation and digitisation. This talk presents a practical maturity model for effectively navigating bioprocess monitoring and AI implementation. Drawing on assessments of 25 products, the presentation examines how companies can transform data challenges into competitive advantages by ensuring critical data is made available and delivered effectively.

BIOGRAPHIES

Konstantin B. Konstantinov, PhD

CTO, Ring Therapeutics, Flagship Pioneering

Before joining Ring, Konstantin Konstantinov was responsible for the late-stage bioprocess and technology development at Sanofi's Boston Hub, including all functions, from cell banking to fill/finish/lyophilisation. Prior to Sanofi, Dr. Konstantinov worked for Bayer in Berkeley, California for 14 years, advancing to the position of Head of Process Sciences. He has published 60 peer-reviewed papers and has more than 15 patents and patent applications. During the last 23 years, Dr. Konstantinov has worked on the development and commercialisation of various products, including monoclonal antibodies, blood factors and enzymes expressed in mammalian cells. Most recently, he has pioneered the development of an end-to-end integrated continuous biomanufacturing platform, which is becoming a strategic technological trend for the biomanufacturing industry worldwide. Dr. Konstantinov received his PhD in Biochemical Engineering from Osaka University, Japan, which was followed by a post-doctoral assignment at DuPont and the University of Delaware. He is a member of the board of directors for Repligen.

Jack Prior, PhD

Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

Dr. Jack Prior leads MSAT Process Monitoring & Data Science/AI Strategy at Sanofi, where he spearheads global initiatives in process monitoring and AI-driven yield improvement for biologics manufacturing. Previously as Head of MSAT Digital, he led teams working to develop global process data analytics systems and to digitise laboratory operations for Industrial Affairs Specialty Care drug substance and drug product manufacturing. Jack's career at Sanofi-Genzyme spans nearly 3 decades, where he has led manufacturing science organisations supporting process characterisation, modeling, technology transfer, and manufacturing operations for critical therapies treating rare genetic disorders. Throughout his career, he has focused on integrating process modeling and advanced analytics with manufacturing science to enhance biologics production across US and European operations. Dr. Prior holds a Doctor of Science in Chemical Engineering from MIT and a Bachelor of Science in Chemical Engineering from the University of Connecticut.

TRACK KEYNOTE AND FEATURED SPEAKERS

Stream 1: UPSTREAM

Veronique Chotteau
Professor, Director, AdBIOPRO, Centre for Advanced Bioproduction by Continuous Processing, Industrial Biotechnology, KTH Royal Institute of Technology

Hooman Hefzi, PhD
Associate Professor, Advanced Mammalian Cell Engineering Group, Biotechnology and Biomedicine, Technical University of Denmark

Stream 2: DOWNSTREAM

Stefano Menegatti, PhD
Professor, Chemical and Biomolecular Engineering, North Carolina State University

Matthias Franzreb, PhD
Department Leader, Bioengineering and Biosystems, Institute for Functional Interfaces, KIT

Stream 3: CELL AND GENE THERAPY

Ian Rees
Assessor, MHRA

Thomas K Villiger, PhD
Head, Bioprocess Technology Laboratory, FHNW

Stream 4: PEPTIDES AND OLIGOS

Fernando Albericio, PhD
Research Professor, School of Chemistry, University of Kwazulu-Natal

Birgit Wiltschi, PhD
Head of Synthetic Biology Group, ACIB GmbH & BOKU University, Vienna

Stream 5: INTENSIFIED AND CONTINUOUS PROCESSING

Zanele Eimert-Bujara, PhD
Senior Expert, Science & Technology, Novartis

Marieke E Klijn, PhD
Assistant Professor, Biotechnology, Delft University of Technology

Stream 6: ANALYTICAL AND DEVELOPABILITY

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

Jennifer McManus, PhD
Associate Professor, Physics, University of Bristol, United Kingdom

Stream 7: AI AND DIGITALISATION

Ayca Cetinkaya, PhD
Senior Scientist, AstraZeneca

Christopher J Roberts, PhD
Professor, Chemical & Biomolecular Engineering, University of Delaware

> "An **INTERESTING** conference program with **PLENTY** of opportunities to network."
>
> **Fernando Bozoglian**
> *Sales Rep, Thermo Fisher Scientific*

CONFERENCE-AT-A-GLANCE

	TUESDAY 10 MARCH - WEDNESDAY 11 MARCH	WEDNESDAY 11 MARCH - THURSDAY 12 MARCH
Stream 1 **UPSTREAM**	Cell Culture and Cell Line Engineering - Part 1	Cell Culture and Cell Line Engineering - Part 2
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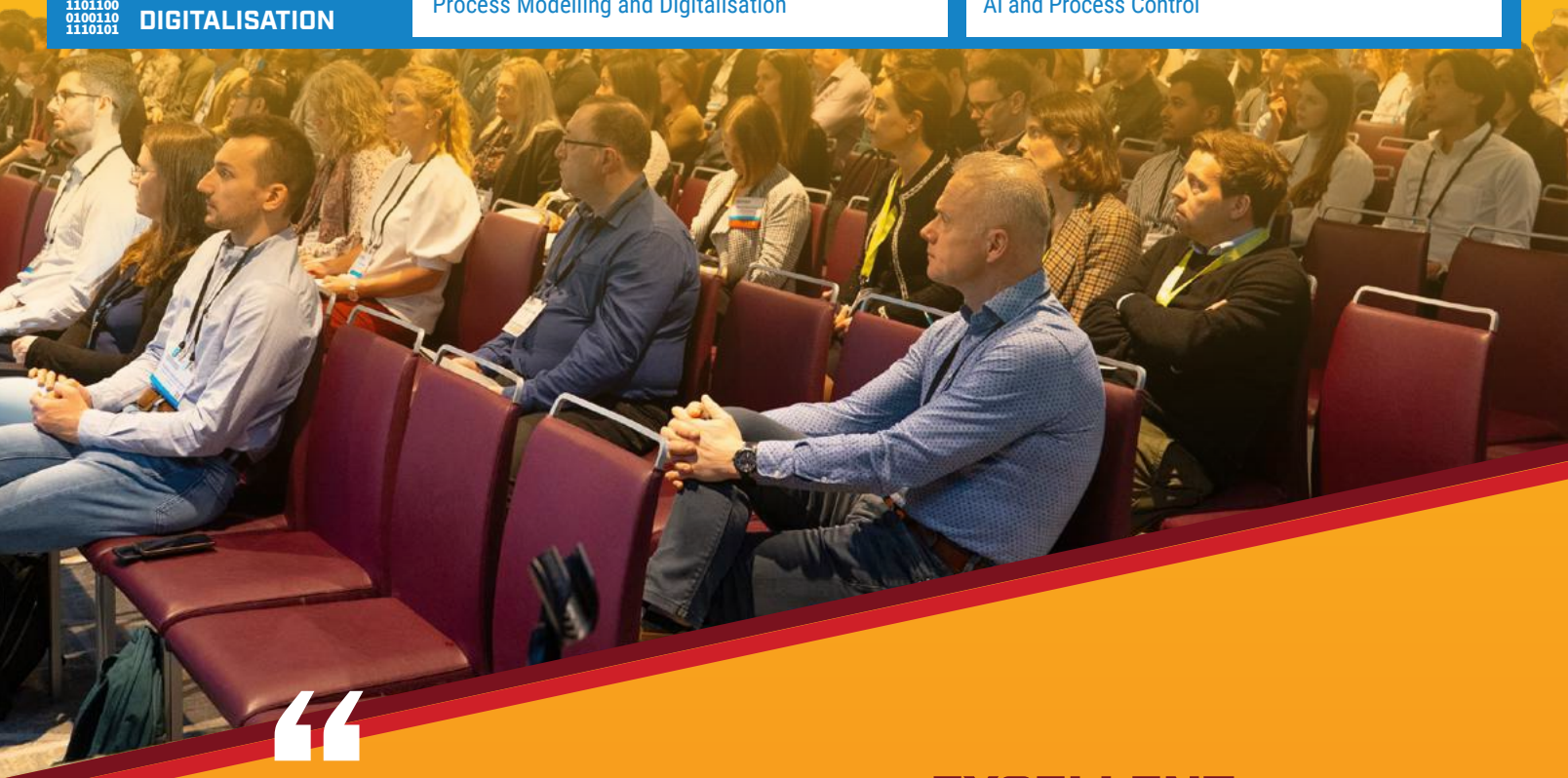

> Bioprocessing Summit Europe is an **EXCELLENT** conference to learn about **CUTTING EDGE** technologies, meet experts and **SHARE IDEAS.**

Nuria Morales Camps,
Global Business Dev. Manager, Croda

Stream 1 UPSTREAM

The Cell Culture and Cell Line Engineering 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.

10-11 MARCH 2026

Cell Culture and Cell Line Engineering - Part 1

VIEW PROGRAM »»

11-12 MARCH 2026

Cell Culture and Cell Line Engineering - Part 2

VIEW PROGRAM »»

Cambridge Healthtech Institute's 9th Annual

10 - 11 MARCH 2026 ALL TIMES CET

Cell Culture and Cell Line Engineering - Part 1

Upstream Technologies and Strategies to Optimise Process Efficiency

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

DIGITAL PROCESS MODELLING

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

8:30 FEATURED PRESENTATION: USP Development and *in silico* Modelling
Ayca Cetinkaya, PhD, Senior Scientist, AstraZeneca
Biopharmaceutical manufacturing faces increased modality complexity and rising operational costs, requiring innovative bioprocess development strategies. Metabolic modelling provides in-depth system analysis, reducing experimental trial-and-error and saving time, materials, and resources. This talk presents real-world case studies where flux balance analysis optimises feed strategies, demonstrating how modelling informs supplement selection to improve productivity while supporting efficient decision-making in the development of advanced biologics.

9:00 Speed2Clinic: Continuously-Learning AI Model for Efficient and Accelerated Cell-Line Development for Monoclonal-Antibody Production
Stella Papadaki, Researcher, Cell Technologies, Roche
The identification of suitable cell lines for monoclonal antibody (mAb) manufacturing is a complex and resource-intensive process. We have developed an AI-driven approach using machine learning to accelerate clone selection. The model uses early-stage multi-omics data to predict late-stage cell line productivity, enabling early detection of high-producer cell lines. This shift to a model-centric process significantly reduces project timelines, accelerates mAb delivery, and fosters a data-driven culture in bioprocessing.

9:30 Presentation to be Announced

BECKMAN COULTER

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

10:45 End-to-End Bioprocessing with Digital Twins: Industrial Showcases from Batch to Fully-Continuous Modalities
Mark Duerkop, CEO, Novasign GmbH
Digital twins are transforming bioprocessing by accelerating development and enabling robust, automated control. This talk will present industrial case studies spanning monoclonal antibodies, viral vectors, and advanced therapies. Showcases will cover the transition from batch to continuous manufacturing. Emphasis will be placed on tailored modelling, experimental design, and real-time applications, demonstrating how digital twins enable end-to-end integration, seamless scale-up, and industrial implementation across multiple modalities.

11:15 KEYNOTE PRESENTATION: Innovations in Modelling Mammalian Cell Culture
Veronique Chotteau, Professor, Director, AdBIOPRO, Centre for Advanced Bioproduction by Continuous Processing, Industrial Biotechnology, KTH Royal Institute of Technology
Mammalian cell culture remains central to biologics production, yet optimising performance at scale requires predictive tools that capture complex cellular behaviors. This presentation explores recent innovations in modelling approaches, from data-driven methods to mechanistic and hybrid models, that enhance understanding of cell metabolism, growth, and productivity in bioprocess. By integrating experimental data with advanced simulations, these strategies accelerate process development, and support more efficient, robust upstream manufacturing of biologics.

11:45 Novel ML-Driven Sampling Strategies for Model-Based DoE in Bioprocesses
Sam Stricker, Researcher, Chemical Engineering, Imperial College London
Efficient experimentation is critical in bioprocess development, where time, cost, and complexity constrain traditional DoE. We introduce a model-based algorithm that leverages Pareto fronts and Bayesian optimisation to balance exploitation of high-performing regions with exploration of uncertain areas. This approach accelerates learning, reduces experimental burden, and scales effectively to high-dimensional design spaces, providing a robust and resource-efficient strategy for modern bioprocess optimisation that effectively explores trade-offs among performance and quality.

12:15 Presentation to be Announced by ATUM

ATUM

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

INNOVATIONS IN UPSTREAM PAT

13:45 Chairperson's Remarks
Mario P. Pereira, PhD, Director, Technology & Business Development, ATUM

13:50 Development and Optimisation of an Intensified Process for a High-Value Commercial Process Using Advanced at-Line Metabolic Data
Emanuel Kreidl, PhD, Senior Expert, Science & Technology, Technical Research & Development, Novartis Pharmaceutical Manufacturing GmbH
This presentation describes the development and optimisation of an intensified upstream process for a high-value commercial biologic. By leveraging advanced at-line metabolic data, our team identified key drivers of cell growth and productivity, enabling rapid process adjustments and improved consistency. We will share the analytical approach, decision-making framework, and performance outcomes that demonstrate how real-time metabolic insights can accelerate scale-up and ensure robust, cost-effective manufacturing.

14:20 Deep Hybrid Modelling in Biomanufacturing: Deep Learning for Next-Generation Hybrid Models
Rui M. Oliveira, PhD, Professor, Chemical Engineering & Biochemistry, Nova School of Science and Technology
Hybrid modelling that combines first-principles with machine learning is emerging as a cornerstone of Biopharma 4.0. In this work, we explore deep hybrid model architectures that seamlessly integrate deep neural networks with mechanistic equations. Our results demonstrate a consistent generalisation advantage of deep hybrid models across multiple CHO platforms. This study highlights the transformative potential of deep hybrid modelling for accelerating process development in modern biomanufacturing.

14:50 Self-Driving Laboratories as Innovative Entities to Revolutionise Bioprocess Development
Peter Neubauer, PhD, Professor, Bioprocess Engineering, TU Berlin
The KIWI-biolab at TU Berlin exemplifies a cognitive self-driving laboratory integrating automated fermentation, analytics, and model-based optimisation within a reproducible workflow. The presentation outlines the essential components required to realise such laboratories—covering automation, modelling, and workflow orchestration—and illustrates their functionality through examples of adaptive process control and model-based optimisation for antibody Fab fragment production in *Escherichia coli*.

15:20 Presentation to be Announced

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

Cambridge Healthtech Institute's 9th Annual

10 - 11 MARCH 2026 ALL TIMES CET

Cell Culture and Cell Line Engineering - Part 1

Upstream Technologies and Strategies to Optimise Process Efficiency

PANEL DISCUSSION: UNLOCKING SMARTER BIOPROCESSING

16:30 PANEL DISCUSSION: Unlocking Smarter Bioprocessing through Better Data Collection, Quality, and Analysis
Moderator: Mark Duerkop, CEO, Novasign GmbH
Data is central to the future of bioprocessing, yet many organisations struggle with incomplete or inconsistent information that limits the training of next-generation AI/ML models. Without addressing these gaps, the promise of digitalisation remains out of reach. This panel will explore why data challenges persist and share strategies to transform raw information into actionable insight—unlocking smarter, faster, and more efficient bioprocessing to accelerate the industry's digital transformation.
Panelists:
Andrea Arsiccio, PhD, Senior Scientist & Team Lead, In Silico, Coriolis Pharma Research GmbH
Ayca Cetinkaya, PhD, Senior Scientist, AstraZeneca
Nicole Mather, DPhil, Life Sciences Lead & HLS Data and AI Lead, IBM Consulting UK & Ireland
Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

17:30 Welcome Reception in the Exhibit Hall with Poster Viewing

18:30 Close of Day

WEDNESDAY 11 MARCH

8:00 Registration Open and Morning Coffee

GLYCOSYLATION CONTROL

8:25 Chairperson's Remarks
Anika Mijakovac, PhD, Researcher, University of Zagreb

8:30 Development of a Novel Automated Workflow for Quantifying Glycogen in Tissue Lysate with Enhanced Sensitivity
Avraham Rosenberg, MS, Senior Scientist, Analytical Chemistry, Regeneron
Accurate quantification of glycogen in biological samples is critical for studying metabolism, disease mechanisms, and therapeutic impact. This presentation describes the development of a novel automated workflow for measuring glycogen in tissue lysates with improved sensitivity and reproducibility. Leveraging optimised sample preparation, advanced detection methods, and automation, the approach minimises variability and enables high-throughput analysis. The enhanced performance supports deeper insights into glycogen biology and reliable evaluation of metabolic interventions.

9:00 New CRISPR Model Cell Lines and Discovery of Novel Pathways for Glycoengineering of Therapeutic Proteins
Anika Mijakovac, PhD, Researcher, University of Zagreb
Glycans attached to antibodies mediate inflammatory pathways in disease and aging but the mechanisms that regulate antibody glycosylation are still largely unknown. To decipher the molecular determinants of antibody glycosylation, specifically immunoglobulin G (IgG), we developed a series of robust CRISPR/dCas9 cell line platforms based on our flexible and extendible EpiToolbox scaffold. We discovered that the control of IgG glycosylation extends far beyond the known glycosylation-related genes.

9:30 Glycoengineered CHO Cells
Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark
Leveraging CHO cells' established role in producing human-like glycosylated therapeutics, we developed a panel of 30 glycoengineered CHO (geCHO) cells. This platform enables tailored glycosylation for protein production. Screening with geCHO we have identified therapeutic candidates exhibiting enhanced activity, optimised immunogenicity, and improved stability, thereby demonstrating the panel's potential to optimise next generation biotherapeutics.
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10:00 Hamilton Unveils the Future of CPP Monitoring
Giovanni Campolongo, Senior Market Segment Manager, Biopharma, Hamilton Company
HAMILTON
Join Hamilton Process Analytics as we reveal our latest breakthrough in real-time monitoring of Critical Process Parameters (CPPs) for cell culture. Building on our legacy of pioneering in-line sensor technologies, we continue to drive smarter, more efficient bioprocessing. You'll have the chance to see our newest innovative process sensors—live. Stay tuned for more.

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

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

11:20 PLENARY KEYNOTE PRESENTATION: Current Trends and Opportunities in Bioprocessing
Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering
This presentation explores how advances in biology are redefining bioprocessing to enable scalable, efficient, and reproducible manufacturing of emerging therapeutic modalities. By integrating synthetic biology, cell engineering, and data-driven design, the field can move beyond traditional methods toward biologically driven, industrialised platforms. The session highlights how biological innovation underpins the transformation of biomanufacturing for the next generation of complex biologics.

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Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group
Digital transformation promises to revolutionise biopharmaceutical manufacturing, yet most organisations leverage a fraction of their process data, with the challenges paradoxically increasing with globalisation and digitisation. This talk presents a practical maturity model for effectively navigating bioprocess monitoring and AI implementation. Drawing on assessments of 25 products, the presentation examines how companies can transform data challenges into competitive advantages by ensuring critical data is made available and delivered effectively.

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 Culture and Cell Line Engineering – Part 1 Conference

Cambridge Healthtech Institute's 9th Annual

11 - 12 MARCH 2026 ALL TIMES CET

Cell Culture and Cell Line Engineering - Part 2

Upstream Technologies and Strategies to Optimise Process Efficiency

WEDNESDAY 11 MARCH

10:30 Registration Open

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

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

CELL LINE ENGINEERING AND SELECTION STRATEGIES

14:15 Chairperson's Remarks
Bjørn Voldborg, MSc, Head, National Biologics Facility, DTU Bioengineering, Technical University of Denmark

14:20 Scaling Gene Therapy: Innovative Strategies for Cost-Effective rAAV Manufacturing
Jose Miguel Escandell Planells, PhD, Principal Scientist, iBET - Instituto de Biologia Experimental e Tecnológica
In this presentation, we will address major challenges in rAAV-based gene therapy manufacturing, highlighting two recent breakthroughs in the HeLaS3 production platform: (1) a novel cell engineering strategy to boost productivity under intensified conditions, achieving up to 10-fold higher yields, and (2) a streamlined selection system that accelerates stable cell line generation to ~2 months while maintaining high titers and vector quality. Together, these approaches tackle key bottlenecks in rAAV production.

14:50 What the HEK Is Going On? Clonal Selection in HEK293 Using an Augmented Reference and Cohort Thresholds
Eva Price, PhD, Researcher, University College London
Whole-genome data from HEK293 and derivative cell lines across multiple laboratories were analysed using a standardised pipeline. A HEK293-specific, viral-augmented reference was generated, which outperformed the standard human reference genome by improving mapping accuracy, stabilising copy number detection, and reducing false variation calls. Cohort-based thresholds translated these gains into practical genomic QC tools. This framework enables consistent genomic characterisation of HEK293 derivatives, strengthening quality control in biopharma development and manufacturing.

15:20 KEYNOTE PRESENTATION: Reimagining Cho Cell Metabolism
Hooman Hefzi, PhD, Associate Professor, Advanced Mammalian Cell Engineering Group, Biotechnology and Biomedicine, Technical University of Denmark
Despite advances in process intensity and efficiency, universal mammalian cell phenotypes such as lactate and ammonia production, as well as the obligate requirement for numerous media components CHO cannot natively synthesise, have led to challenges in process optimisation without a one-size-fits-all solution. Over the last 9 years, we have developed genetic engineering strategies fundamentally reimagining these ubiquitous phenotypes in CHO and will present case studies around each in turn.

15:50 Sponsored Presentation *(Opportunity Available)*

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

17:00 Gene Tagging to Enable the Characterisation and Purification of Proteins and Macromolecular Assemblies Expressed in Physiological Conditions
Arnaud Poterszman, PhD, Research Director, Integrated Structural Biology, IGBMC
Macromolecular complexes are fundamental to nearly all cellular biological processes. This presentation will illustrate how CRISPR/Cas9 genome editing can be applied for gene tagging, enabling the insertion of affinity tags to simplify the purification of proteins and macromolecular assemblies produced under physiological conditions. The use of fluorescent reporter tags for proteins, highlighting their applications in imaging and functional proteomics will also be discussed.

17:30 Leveraging Multiple Orthogonal Transposases as an Alternative Genetic-Engineering Tool in Bioprocessing
Mario P. Pereira, PhD, Director, Technology & Business Development, ATUM
This talk introduces a multiplexable orthogonal transposon system for advanced bioprocessing. We demonstrate its use in CHO cells for both gene knock-in and knockdown, allowing for precise control of cellular physiology. This tool enables the creation of new host cell lines and the modulation of product quality. Our findings are supported by data confirming precise integration and long-term stability, showcasing a significant step forward in engineering next-generation biotherapeutic cell lines.

18:00 Interactive Breakout Discussion Groups
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 9th Annual

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Cell Culture and Cell Line Engineering - Part 2

Upstream Technologies and Strategies to Optimise Process Efficiency

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

OPTIMISING PRODUCTIVITY

8:25 Chairperson's Remarks

Colin Clark, PhD, Principal Investigator, NIBRT; Associate Professor, University College Dublin

8:30 Applications of Single-Cell Transcriptomics in CLD and Upstream Processing

Colin Clark, PhD, Principal Investigator, NIBRT; Associate Professor, University College Dublin

In this presentation, we will explore how single-cell omics technologies are advancing our understanding of biological systems, with a focus on monoclonal antibody–producing CHO cell lines. Our studies integrate measurements of chromatin accessibility, gene expression, and protein abundance at single-cell resolution to uncover cellular heterogeneity and regulatory mechanisms. We will also highlight the platforms used for single-cell profiling and the computational strategies employed to analyse and interpret these data.

9:00 Digital Twin Controlled Integrated Continuous Microbial Processing at Pilot Scale

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

Production of recombinant proteins with microbials is mainly performed in fed-batch, because strong metabolic variations occur. However, continuous processing leads to much higher time space yields. Here, we demonstrate how metabolic behaviour is controlled using cascaded continuous processing. The trajectory of specific productivity is described as a function of cell age, basis for smooth control via multiple feeds. The process was scaled to pilot scale using automation and digital twins.

9:30 Addressing Scale-Up Challenges of Implementing APEX: an AAV Perfusion Process for Enhanced Expression

Jan Panteli, PhD, Associate Director, Upstream Process Development, Ultragenyx Pharmaceutical

The demand for recombinant adeno-associated virus (rAAV) vectors is driving the need for scalable, efficient manufacturing solutions. Herein we describe a novel AAV perfusion-enhanced expression (APEX) process, resulting in a 3–6 fold increase in volumetric productivity while maintaining robust and consistent product quality in Pinnacle PCL™ cell lines. This presentation will highlight the scale-up challenges of implementing the APEX process from bench to 250L pilot scale.

10:00 Presentation to be Announced

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

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DIGITISATION IN CELL CULTURE AND CELL LINE DEVELOPMENT

11:10 Data-Driven Dynamic Control for Fed-Batch Upstream Bioprocess Operations

Duygu Dikicioglu, PhD, Associate Professor, Biochemical Engineering, University College London

Bioprocess control is complex due to evolving, non-linear cell population dynamics. This work proposes a novel data-driven control scheme for fed-batch upstream processes using graph theory to identify dynamic control parameters. Machine learning and optimisation algorithms use historical data to adaptively recalibrate control actions in real-time. This closed-loop, multi-attribute strategy addresses deviations and variability, outperforming static methods and ensuring cultures stay on a desired trajectory across diverse conditions.

11:40 Real-Time Prediction and Control of Cellular Behaviour in Microbial Upstream Processes

Julian Kager, PhD, Assistant Professor, Chemical and Biochemical Engineering, DTU

During the course of a bioprocess strain, physiology is likely to change. By natural selection, the performance of the cultivation can be positively affected—or more often—during the production of recombinant proteins the culture is degenerated and loses its metabolic capabilities. Under usage of models these changes can be foreseen and preventative control actions can occur to stabilise the cultivation.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

PROBLEMS AND SOLUTIONS

13:25 Chairperson's Remarks

Duygu Dikicioglu, PhD, Associate Professor, Biochemical Engineering, University College London

13:30 Towards Continuous Bioproduction—Application of Microfluidic Systems for Cell Separation, Perfusion, and Chromatography at Scale

Michaela Dehne, Researcher, Technical Biology, University of Augsburg

Continuous bioprocesses on a small scale are becoming increasingly important due to rising yields, improved product quality, and the shift toward personalised medicine. This presentation introduces 3D-printed microfluidic systems for efficient cell retention in perfusion processes. It also features a miniaturised periodic counter-current chromatography system for continuous monoclonal antibody purification, providing a compact, integrated solution for streamlined upstream and downstream bioprocessing.

14:00 Upstream and Downstream Data and Process Integration for Cell and Gene Therapies

Joaquim Vives, PhD, Research Team Leader, Banc de Sang i Teixits

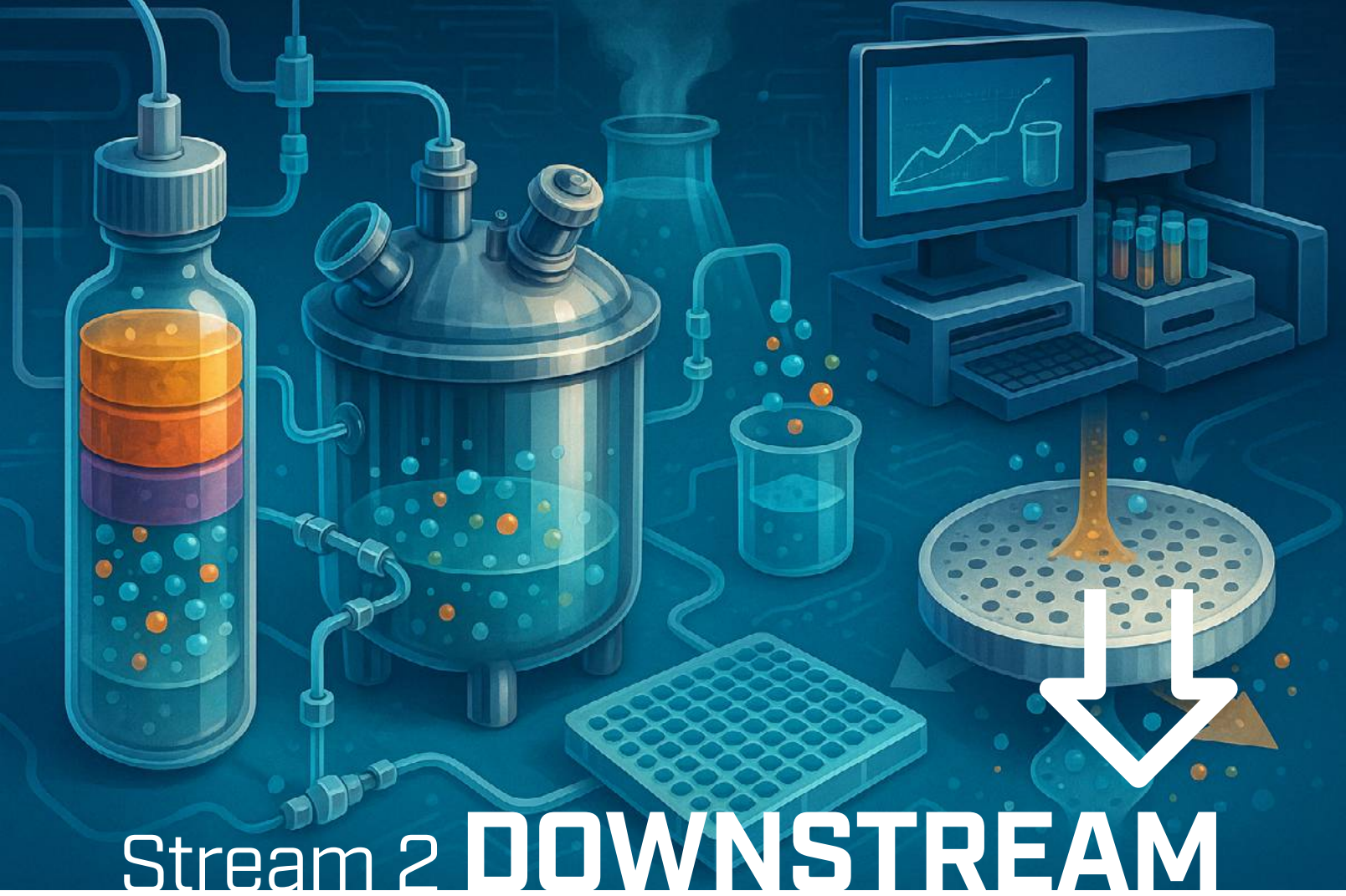
Cell and gene therapy manufacturing requires seamless integration across upstream and downstream processes to ensure efficiency, consistency, and regulatory compliance. This presentation will explore strategies for unifying process data, enabling end-to-end visibility and control. Case studies will demonstrate how integrated data platforms and advanced analytics improve decision-making, support technology transfer, and enhance scalability—helping organisations accelerate development and deliver high-quality therapies more reliably to patients.

14:30 CHO Engineering to Avoid Toxic Byproduct Production

Bhanu Chandra Mulukutla, PhD, Senior Principal Scientist, Group Leader, Process Development, Pfizer Inc.

Chinese hamster ovary (CHO) cells remain the dominant host for biologics production, yet metabolic imbalances can generate toxic byproducts that limit cell growth and product quality. This presentation will discuss engineering strategies to reprogram CHO metabolism and reduce accumulation of inhibitory compounds. Examples will highlight genetic modifications, pathway optimisation, and analytical approaches that enable healthier cultures, improved productivity, and more consistent performance in large-scale biomanufacturing.

15:00 Close of Summit



Stream 2 DOWNSTREAM

Rapid advances in chromatography, digitalisation, and emerging modalities are reshaping downstream processing. CHI's 9th Annual Recovery and Purification 3-day conference stream highlights innovations spanning DSP strategies for bispecifics, ADCs, and complex biologics, as well as new approaches for viral vectors, mRNA, EVs, and nanoparticle-based therapeutics. Speakers will share new strategies for novel DSP methods, continuous purification, and AI-driven monitoring and control. Additional sessions will explore sustainable DSP solutions, next-generation resins, and digital twins for process development, bringing together purification scientists, process engineers, and digital leaders to explore how these tools are advancing efficiency and product quality.

10-11 MARCH 2026

Advances in Recovery and Purification - Part 1

VIEW PROGRAM »»

11-12 MARCH 2026

Advances in Recovery and Purification - Part 2

VIEW PROGRAM »»

Cambridge Healthtech Institute's 9th Annual

10 - 11 MARCH 2026 ALL TIMES CET

Advances in Recovery and Purification - Part 1

Optimising Downstream Efficacy and Yield

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

DOWNSTREAM PROCESSING OF COMPLEX MODALITIES

8:25 Chairperson's Remarks

Harald Bradl, PhD, Director & Head, Downstream Development, Boehringer Ingelheim Pharma GmbH & Co KG

8:30 Unique Considerations in Bispecific Antibody Purification

Wei Zhang, PhD, Principal Scientist & DSP Group Head, Downstream Processing, Bioprocessing Technology Institute

Bispecific antibodies (BsAbs) are promising therapeutics due to their dual-targeting capability. However, BsAbs present greater purification challenges than traditional monoclonal antibodies, owing to their high format diversity and structural complexity. This presentation will outline distinct considerations in BsAb purification, each of which represent common bottlenecks in BsAb CMC. Case studies will be provided to illustrate strategies used to address these challenges.

8:50 Downstream Processing of Complex Biologics

Tingting Cui, PhD, Associate Director, Downstream Processing, AstraZeneca

9:10 Downstream Processing: Current Challenges, Recent Advances and Future Perspectives

Fabian Vogt, PhD, Lab Head, Downstream Development, Boehringer Ingelheim Pharma GmbH & Co KG

9:30 Streamlining Biotherapeutic Manufacturing: Integrated Chromatography Strategies for Enhanced Purity and Efficiency BIO-RAD

Artur Stanczak, Field Application Specialist EMEA, Process Chromatography, Bio Rad Laboratories

Explore advanced downstream strategies for biotherapeutic purification. Case studies will highlight the integration of mixed-mode chromatography technologies to address selectivity, scalability, and process robustness, enabling efficient capture and polishing workflows for complex modalities.

9:45 Sponsored Presentation *(Opportunity Available)*

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

10:45 KEYNOTE PRESENTATION: Transforming the Portfolio of Purification and Sensing Technologies for Viral-Vector and Monoclonal-Antibody Therapeutics

Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University

Revolutionary peptide-protein biorecognition mechanisms and affinity purification innovations are reshaping therapeutic manufacturing. This presentation will introduce our latest contribution in developing next-generation chromatographic platforms, integrating machine learning–guided purification of AAVs, LVVs, mRNA, novel affinity ligands for antibody therapeutics, and real-time sensing technologies. These breakthroughs enable unprecedented selectivity, productivity, and cost-effectiveness in viral vector and monoclonal antibody production, accelerating gene therapy and immunotherapy translation from bench to bedside.

CONTINUOUS DOWNSTREAM PROCESSING

11:15 Latest Industry Trends and Challenges in Downstream Processing

Pierre Djillali, Engineer, Downstream Processing, Sanofi

Accelerated Seamless Antibody Purification (ASAP) was developed at Sanofi as a simplified, continuous purification strategy to enhance process efficiency and deliver a direct productivity impact. Initial demonstrations showed that ASAP can reduce mAb purification time by up to threefold. The next step is to transition this approach from laboratory proof-of-concept to GMP implementation. Ongoing efforts across Sanofi's mammalian platform aim to make this innovation a reality for all Phase 1 programs.

11:45 Optimising Bioprocessing through Advances in DSP and Continuous Processing

Lara Fernandez-Cerezo, PhD, Associate Principal Scientist, Merck Sharp Dohme (MSD)

This presentation explores how innovations in downstream processing (DSP) and continuous bioprocessing are driving efficiency, scalability, and quality in biomanufacturing. It highlights emerging technologies, process intensification strategies, and integration approaches that streamline workflows and reduce costs. By examining case studies and industry trends, the session provides insights into optimizing productivity and ensuring consistent product performance across biologics development and manufacturing pipelines.

12:15 Galactose and Mannose Supplementation in Cell Culture: Glycoform Modulation and Other Considerations Pfanstiehl

Thomas Nsenda, Director Business Development , Pfanstiehl

Galactose and mannose are key carbohydrates used in cell-culture media for recombinant protein production. They support glycoform modulation, energy production, and synthesis of glycoproteins. High purity and low metal content are critical, as contaminants can affect cell growth. Case studies highlight their importance, and Pfanstiehl offers high-purity, low-endotoxin versions for reliable cell-culture applications.

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

SUSTAINABLE APPROACHES TO DSP

13:45 Chairperson's Remarks

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

13:50 FEATURED PRESENTATION: Sustainable Integrated Continuous Antibody Downstream Processing Using Buffer Intensification

Bernt Nilsson, PhD, Professor, Chemical Engineering, Lund University

The production of biopharmaceuticals is a chemical- and water-intensive process. The consumption of water and chemicals is partly due to the need for many different buffers in large volumes during the downstream process to perform different wash and cleaning procedures. We will present three different techniques for buffer intensification (i.e. enhancement of the use of buffer) by: 1. local recycle, 2. counter-current usage and 3. process-wide reuse.

14:20 New DSP Materials and Technologies

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

Bioseparation is a critical step in biopharmaceutical manufacturing. It employs sustainable polymeric adsorbents decorated with affinity ligands to increase the selective capture of target biological products. The EU-funded PURE project aims to develop precisely functionalised adsorbents. The project has brought together an interdisciplinary team of leading scientists from academia and industry with expertise in biology, chemistry, computational modelling, materials science, bioprocess engineering and applied social sciences.

14:50 Model-Based Evaluation of Product and Solvent Recycling Technologies in Downstream Processing

Oskar Bergmann, Industrial PhD Student, Novo Nordisk

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Advances in Recovery and Purification - Part 1

Optimising Downstream Efficacy and Yield

Downstream API production steps frequently suffer from high solvent and resin consumption, as well as yield losses. Internal recycling of product and solvent streams can provide a way to improve these metrics. Understanding which recycling technology is preferred is challenging due to the high-dimensional space of objectives, constraints, and system properties. We propose a model-based methodology to systematically explore this space to enable faster and better decision-making.

15:20 Presentation to be Announced

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

MAXIMISING DSP RECOVERY AND PRODUCTIVITY

16:30 Hybrid Processing

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

The current challenge is to produce antibodies at a COGs > 10 $/g. One approach to achieving this goal is through economies of scale. Another is to implement hybrid processes that integrate alternative capture methods or continuous biomanufacturing with rapid cycling or a combination. The downstream processing design for these three scenarios will be compared, with an evaluation of pros and cons.

17:00 Maximising Productivity of Protein A Capture

Isabelle Savoy, Senior Manager, Science and Technology, Novartis Pharma

We present an approach to maximise volumetric productivity in chromatography. Optimisation was achieved by balancing flow rates with dynamic binding capacity, and by reducing bed height and process volumes. In the second part, we compare Protein A resin attributes across different manufacturing scenarios, calculating their impact on productivity, cycle count, and resin costs. Finally, we propose an outlook on future strategies to further enhance productivity beyond current benchmarks.

17:30 Welcome Reception in the Exhibit Hall with Poster Viewing

18:30 Close of Day

WEDNESDAY 11 MARCH

8:00 Registration Open and Morning Coffee

ADDRESSING DOWNSTREAM BOTTLENECKS IN HIGH-TITRE BIOPROCESSING

8:25 Chairperson's Remarks

Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University

8:30 Addressing Downstream Bottlenecks in High-Titre Bioprocessing: Innovative Solutions for Enhanced Throughput

Andreja Pirnat, PhD, Scientific Expert, Science, Novartis

Upstream advances now enable titres above 10 g/L, boosting productivity but creating downstream bottlenecks. Larger intermediates exceed tank capacity, and chromatography, filtration, and concentration steps take longer. To address this, we are testing high-capacity resins, flow-through chromatography, and single-pass TFF to reduce volumes and streamline processing. New virus filters with higher membrane loading also enhance throughput, helping downstream operations keep pace with upstream gains for efficient, high-titre biotherapeutic production.

9:00 Viral Clearance and Removal of Host-Cell Proteins

Bas Kokke, PhD, Principal Scientist, Downstream Processing, Byondis B V

The position of virus filters in the DSP process was evaluated. The currently employed Planova 15N filter was compared to the new Planova filters—i.e., BioEx, S20N and FG-1. Several (modified) mAbs were selected, and a comparison using process performance and viral clearance studies, was made of the virus filter step between the usual location halfway through the purification process and after polishing.

9:30 3D Imaging for Enhancing Design of 3D-Printed Chromatography Columns

Thomas F. Johnson, PhD, Lecturer, Biochemical Engineering, University College London

3D printed chromatography columns provide advantages over conventional packed bed resins, in particular, control over the multiscale structure that can be tailored to the needs of the separation. However, possible disparities between design and fabricated columns lessens this benefit. We apply 3D imaging to evaluate and compare printed structures to original CAD files to refine the design process, creating more effective separation capabilities for emergent biological products.

10:00 Presentation to be Announced

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

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

11:20 PLENARY KEYNOTE PRESENTATION: Current Trends and Opportunities in Bioprocessing

Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering

This presentation explores how advances in biology are redefining bioprocessing to enable scalable, efficient, and reproducible manufacturing of emerging therapeutic modalities. By integrating synthetic biology, cell engineering, and data-driven design, the field can move beyond traditional methods toward biologically driven, industrialised platforms. The session highlights how biological innovation underpins the transformation of biomanufacturing for the next generation of complex biologics.

11:50 PLENARY KEYNOTE PRESENTATION: Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and Artificial Intelligence in Biologics Manufacturing

Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

Digital transformation promises to revolutionise biopharmaceutical manufacturing, yet most organisations leverage a fraction of their process data, with the challenges paradoxically increasing with globalisation and digitisation. This talk presents a practical maturity model for effectively navigating bioprocess monitoring and AI implementation. Drawing on assessments of 25 products, the presentation examines how companies can transform data challenges into competitive advantages by ensuring critical data is made available and delivered effectively.

12:20 Session Break

12:30 Presentation to be Announced

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

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Advances in Recovery and Purification - Part 2

Optimising Downstream Efficacy and Yield

WEDNESDAY 11 MARCH

10:30 Registration Open

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

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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, PROCESS MODELLING, AND ML/AI APPROACHES TO DSP

14:15 Chairperson's Remarks
Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich

14:20 Advancing Bioprocess Understanding through Real-Time Monitoring, Data-Driven Modelling, and Experimental Design
Theresa Scharl, PhD, Senior Scientist, BOKU University
Implementing model-based real-time monitoring in biopharmaceutical production represents a key advancement toward Quality by Design and provides the foundation for model-predictive control. Data-driven models are capable of making predictions for monoclonal antibody (mAb), double-stranded DNA, host cell protein, and high molecular weight impurity concentrations during elution from a Protein A chromatography capture step. Ensuring explainability of machine learning models and applying efficient experimental design are key to enhancing modern process control.

14:50 KEYNOTE PRESENTATION: The Autonomous Future of DSP: Self-Driving Labs, ML Integration, and Digital Twins
Matthias Franzreb, PhD, Department Leader, Bioengineering and Biosystems, Institute for Functional Interfaces, KIT
This talk presents a fully automated workflow for bioprocess development, starting with experiment planning in an ELN and ending with report generation. Key elements include ML-supported optimisation of bioprocess steps, integration of simulation tools such as mechanistic models and molecular dynamics, and strategies for linking digital tools into a unified, autonomous system that accelerates development cycles and enhances decision-making in DSP.

15:20 Electric Double-Layer–Informed Binding for IEX: Minimal Calibration, Robust Prediction
Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich
We present a physics-grounded binding isotherm for ion-exchange chromatography derived from electrical double layer (EDL) theory. Incorporating nonlinear screening, ion valency, and crowding, the model achieves predictive elution from minimal calibration. Its parameters map directly to physical properties, enhancing interpretability over existing models. Calibrated on a single dataset, we validate predictions across gradients, step elutions, salt types, and load densities with model proteins, and highlight the effect of divalent ions.

15:50 Presentation to be Announced

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

PROCESS MODELLING TO OPTIMISE CHROMATOGRAPHY

17:00 Using the Laplace-Beltrami-Operator to Generate Molecular Descriptors of Protein Shape for QSAR Chromatography Models
Johannes Felix Buyel, PhD, Head, Institute for Biochemical Engineering, University of Natural Resources and Life Sciences (BOKU)
The development of effective shape descriptors is essential for representing the unique geometric features of protein surfaces. In this work, we introduce a novel approach based on spectral geometry: the Laplace-Beltrami spectrum. By encoding protein structures as fixed-length feature vectors derived purely from geometric properties, shape descriptors aim to facilitate the a priori prediction of protein separation, reducing modeling efforts, and accelerating chromatographic process design.

17:30 Optimising a Flowthrough Multimodal Chromatography
Wendi Zhang, PhD, Senior Scientist, Downstream Processing, AbbVie Inc.
This work focuses on improving flowthrough multimodal chromatography for broader applications in biomolecule purification. By refining operational parameters and understanding key interactions, we aim to enhance process efficiency, product recovery, and impurity removal. The findings support more robust and scalable workflows, making this technique a valuable tool in both research and industrial settings. This approach highlights practical considerations for optimising chromatography without compromising performance or throughput.

18:00 Interactive Breakout Discussion Groups
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,

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Optimising Downstream Efficacy and Yield

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

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

DOWNSTREAM PROCESSING FOR VIRAL VECTORS AND BIONANOPARTICLES

8:25 Chairperson's Remarks

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

8:30 Lentiviral Vector Determinants of Anion Exchange Chromatography Elution Heterogeneity

George Pamenter, PhD Researcher, UCL

The demand for Lentiviral Vector (LV) drug substance is increasing. However, primary capture using convective anion-exchange chromatography remains a significant manufacturing challenge. This presentation explores the factors influencing elution heterogeneity of lentiviral vectors during anion exchange chromatography.

9:00 Translating Novel Purification Strategies into Practice: Insights from Lentivirus and EV Case Studies

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

This presentation will delve into how alternative purification strategies are being explored to meet the demand for higher yields, improved vector quality, and shorter processing times. We will discuss the implementation of novel adsorbent materials and non-conventional operational modes, with a focus on lentiviral vectors and extracellular vesicles.

9:30 Nonwoven Fibers for the Purification of Bionanoparticles (Viruses, VLPs, and EVs)

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

Purification of bionanoparticles (BNPs), such as viruses and extracellular vesicles, is challenging due to their complexity, large size, and the presence of similar nanoparticle impurities. Conventional chromatography resins often exhibit low productivity due to slow mass transfer and limited binding capacity. Non-woven fiber-based convective media offers a promising alternative, enabling efficient purification of BNPs in both flowthrough and bind-elute modes. This approach addresses key limitations, improving productivity and BNP purity.

10:00 Presentation to be Announced

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

11:10 Viral Capsomere-Nucleic Acid Interaction: Impact on Purification and *in vitro* Loading

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

Viral capsomere–nucleic acid interactions present unique challenges for downstream processing and *in vitro* assembly of virus-like particles, as well as *in vitro* loading of viral vectors. We explore how these interactions influence purification efficiency and product quality. By examining key drivers of nucleic acid association, we outline strategies to optimise recovery and enable *in vitro* loading of viral vectors.

11:40 Peptides and Peptide–Nucleic Acid Ligands for the Affinity Purification of Next-Generation Gene Therapies: Viral Vectors and mRNAs

Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University

Novel peptide-based affinity ligands enable serotype-agnostic purification of AAV vectors and monoclonal antibodies, delivering yields up to 99% with 230-400-fold host cell protein reduction. Machine learning-guided Bayesian optimisation accelerates chromatography parameter development while preserving transduction activity. Advanced process analytical technologies, including quantum dot-enabled biosensors and electrochemical platforms, provide real-time monitoring of critical quality attributes. These innovations transform viral vector and mAb biomanufacturing through improved efficiency, scalability, and product quality.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

RECOVERY AND PURIFICATION OF COMPLEX BIOLOGICS

13:25 Chairperson's Remarks

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

13:30 Advancing rAAV Manufacturing: Continuous DSP Integrated with Digital Process Development

Bilal Ozdoganoglu, Associate Senior Scientist, Cell and Gene Therapy Catapult

As demand for rAAV gene therapies grows, continuous downstream processing (DSP) is key to achieving scalable, cost-effective, and safe manufacturing. This work integrates mechanistic modelling, digital twins, and Process Analytical Technology (PAT) to enable real-time monitoring, simulation, and optimisation. The approach improves process efficiency and consistency, supporting faster production and robust quality control—essential for meeting clinical and commercial needs in a rapidly evolving gene therapy landscape.

14:00 Purification and Analytical Strategies to Overcome Production Challenges for Hexameric IgGs

Rujin Cheng, PhD, Principal Scientist, Biotherapeutics, ImmunEdge

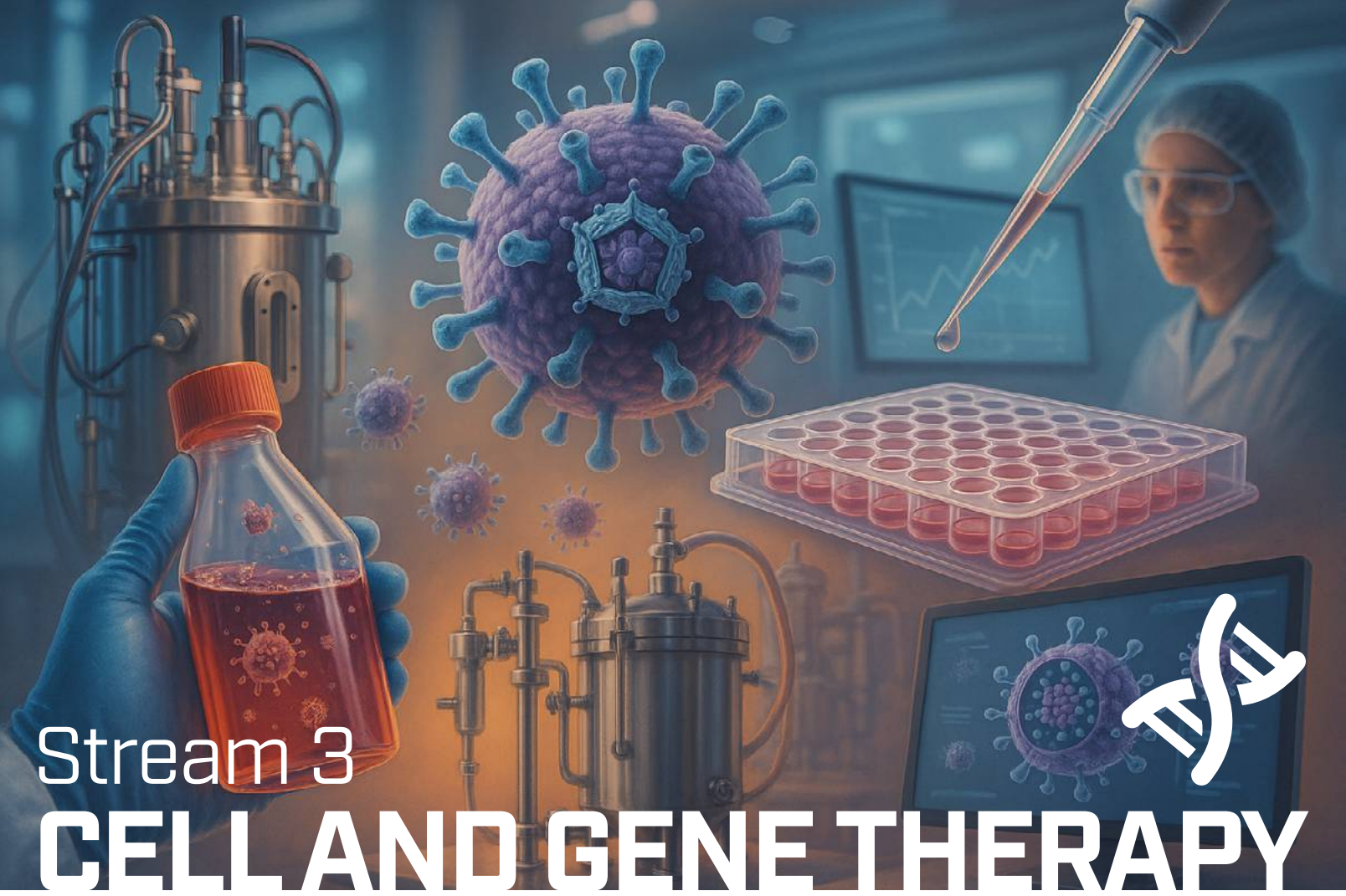
Hexameric IgGs are a class of complex biologics that offers unique pharmacokinetics and pharmacodynamic properties due to their high valency, molecular weight, or hydrodynamic radius. Despite their attractive profile for certain therapeutic indications, technical challenges in purification and analytics hinder their broader application. This talk aims to demystify some of the challenges by providing comprehensive molecule analysis/illustration and a couple of successful examples where key problems are identified and resolved.

14:30 Selective Affinity Capture of Secretory IgA Using Engineered Bacterial Ligands on Macroporous Resins

David Scheich, PhD Student, BOKU

Secretory immunoglobulin A (sIgA) is emerging as a powerful tool for passive immunisation. Current affinity resins suffer from co-purification of product-related impurities and severe mass transfer limitations. A novel resin was developed by immobilising a *Streptococcus pneumoniae* surface protein as affinity ligand, targeting the secretory component of sIgA, on a macroporous resin with appropriate pore size. Data will be presented on how ligand design and resin architecture influence chromatographic performance.

15:00 Close of Summit



Stream 3
CELL AND GENE THERAPY

The Cell and Gene Therapy stream highlights cutting-edge solutions for scaling, controlling, and expanding access to advanced therapies. The Cell Therapy track explores strategies to cut costs, enhance quality, and streamline manufacturing. Topics include lessons from approved products, centralised and point-of-care models, automation, digital twins, and AI/ML integration. The program also examines *in vivo* CAR T as a disruptive manufacturing paradigm with distinct CMC and regulatory considerations. The Gene Therapy track focuses on advancing viral and non-viral vector manufacturing, process intensification, and control strategies for safer, more scalable therapies. Sessions cover novel capsids, scaling next-generation vectors, mRNA-LNP platforms, and gene editing, showcasing how innovation in manufacturing and CMC is driving next-generation therapies toward broader patient access.

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Cell Therapy Manufacturing and CMC

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Gene Therapy Manufacturing and CMC

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Cell Therapy Manufacturing and CMC

Reducing the Cost and Complexity of Cell Therapy Production

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

SCALING AND COMMERCIALISING CELL THERAPIES

8:25 Chairperson's Remarks

Florence Salmon, PhD, Global Head, Cell and Gene Therapy, Regulatory, F. Hoffmann-La Roche Ltd.

8:30 FEATURED PRESENTATION: Building an Autologous CAR T Manufacturing Facility from a Greenfield to Operation

Frederik Buysse, Vice President, General Manager EU, Legend Biotech

Establishing CAR T operations and building new facilities requires overcoming significant challenges in infrastructure, workforce, and scalability. Recruiting and training specialised staff remains one of the most pressing hurdles, with limited pools of qualified candidates. This presentation will highlight considerations for facility design, staffing strategies, and operational readiness. We discuss how technological innovation, regulatory evolution, and workforce development will shape the future of CAR T manufacturing.

9:00 FEATURED PRESENTATION: Operational Challenges of Manufacturing Allogeneic Cell Therapies

Astou Gaye, Vice President, General Manager, Hillsboro Innovative Therapies, Genentech

Allogeneic cell therapy manufacturing faces significant hurdles. Challenges include inherent process variability from biological starting materials, supply chain limitations (raw material scarcity/variability), and labor-intensive manual processes that increase contamination risk. Critical logistics constraints in cryopreservation and distribution are also key challenges. Overcoming these issues requires an urgent transition to robust, closed, and automated platform technologies to ensure cost-efficiency and regulatory compliance.

9:30 Presentation to be Announced

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

DECENTRALISED MANUFACTURING IN PRACTICE

10:45 KEYNOTE PRESENTATION: UK Update on Implementation of the Decentralised Manufacturing Framework

Ian Rees, Assessor, MHRA

This presentation will outline the origin, scope, and structure of the Decentralised Manufacturing (DM) framework, key regulatory-guidance documents, and measures supporting successful implementation. International workstreams and cross-agency collaboration among assessors, inspectors, and scientists at MHRA will also be highlighted, illustrating how this integrated approach supports regulation, licensing, and oversight of DM products in practice.

11:15 Decentralised Autologous Cell Therapy: Balancing Opportunities with Key Challenges

Lantz Mackey, PhD, Director, CAR T Process Development, Galapagos BV

11:45 Centralised vs. Decentralised Manufacturing: Update from Orgenesis

Vered Caplan, CEO, Octomera; CEO, Orgenesis

This presentation will show how Point-of-Care (POCare) solutions, powered by advanced technology and data, can overcome conventional CGT processing challenges. By enabling closed, automated, and reproducible workflows, therapies can be manufactured near hospitals and treatment centers within hours. The mission is to decentralise and standardise production, making innovative therapies more affordable, scalable, and accessible to patients worldwide—not only those in major or wealthier markets.

12:15 Sponsored Presentation *(Opportunity Available)*

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

AI AND DIGITALISATION IN ADVANCED THERAPIES

13:45 Chairperson's Remarks

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

13:50 Digital Transformation of Advanced Therapies

Nicole Mather, DPhil, Life Sciences Lead & HLS Data and AI Lead, IBM Consulting UK & Ireland

Broadening access by driving down the cost of manufacture using predictive and adaptive digital systems including the use of AI and AI agentic management systems.

14:20 Digitalised Platforms for Driving Quality and Accelerating Cell-Therapy Development

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

Cell therapies are at a critical juncture with patient demand outstripping current manufacturing capacity. To address this challenge, the Cell and Gene Therapy Catapult has developed cell therapy manufacturing platforms that offer step-changes in throughput for autologous and allogeneic products by integrating end-to-end automation and digitising data flow and decision-making.

14:50 Digital Shadows of CAR T Cell Expansion in Perfusion Bioreactors: Using Online Data to Predict Cell Concentration in Real Time

Joseph R. Egan, PhD, Research Associate, Teesside University; Honorary Senior Research Fellow, UCL

This presentation will show how digital shadows can be used to predict CAR T cell concentration based on online nutrient and metabolite data, including dissolved oxygen, glucose, and lactate concentrations. Such predictive modelling is designed to utilise the hard sensors that are already embedded in the bioreactor for process monitoring and control. As no additional process analytical technology is required, digital shadows provide a cost-effective soft sensor of cell concentration.

15:20 Sponsored Presentation *(Opportunity Available)*

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

PERSONALISED CELL THERAPIES

16:30 Personalised Muscle-Tissue Engineering for Common Highly Debilitating Diseases: Lessons Learned

Deana Mohr-Haralampieva, PhD, CEO & Co-Founder, MUVON Therapeutics AG

MUVON Therapeutics is a clinical-stage life-science spin-off from the University of Zurich, developing a novel therapy platform for the regeneration of skeletal muscle tissue based on autologous cells. We aim to provide safe, effective, and

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affordable treatments to millions of patients suffering from seriously debilitating diseases by increasing the regenerative potential of weakened muscles. Our initial area of focus is the treatment of stress urinary incontinence in women.

GLOBAL REGULATORY UPDATES

17:00 Current Changes to the Global Framework for ATMPs

Florence Salmon, PhD, Global Head, Cell and Gene Therapy, Regulatory, F. Hoffmann-La Roche Ltd.

This presentation reviews recent and upcoming updates to the global regulatory framework governing advanced therapy medicinal products (ATMPs). It highlights evolving guidance on clinical development, manufacturing, and quality requirements, as well as new initiatives aimed at accelerating innovation and patient access. Emphasis is placed on understanding how these changes impact compliance and commercialisation strategies.

17:30 Welcome Reception in the Exhibit Hall with Poster Viewing

18:30 Close of Day

WEDNESDAY 11 MARCH

8:00 Registration Open and Morning Coffee

CMC AND ANALYTICS FOR EX VIVO AND IN VIVO CAR T

8:25 Chairperson's Remarks

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

8:30 CMC and Release Testing for *in vivo* CAR T Therapies

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

In vivo CAR T therapies redefine cell-therapy manufacturing by shifting engineering into the patient, but they introduce unique CMC and release testing challenges. Ensuring quality, consistency, and safety requires novel analytical frameworks for vector characterisation, potency assays, and biodistribution studies. This session will discuss evolving regulatory expectations, assay development strategies, and lessons learned in establishing robust CMC processes for first-generation *in vivo* CAR T products.

9:00 Optimising an Immunoprecipitation Mass-Spectrometry Workflow for Enrichment of Surface Proteins: Applications to Surrogate CAR T Cells.

Nicolle Serrano SantoDomingo, Senior Scientist, Novartis

The IP-MS workflow is a powerful technique designed to enrich and analyse cell surface proteins, an area of growing importance in cancer immunotherapy given how these other proteins can affect T cell biology. By applying this workflow to surrogate CAR T cells, we not only confirmed the surface localisation of the CAR protein but also uncovered its associated proteome, offering valuable insights into molecular interactions that may influence therapeutic efficacy.

9:30 Leaky Bags, Lost Therapies? Risk-Informed Insights for Cell-Therapy Manufacturing

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

To avoid costly batch discards, it's essential to consider manufacturing challenges—such as bag integrity—already during the research phase. Leaks in single-use systems pose a serious contamination risk in ATMP and cell therapy production, threatening product quality and patient safety. This presentation offers a risk-informed approach to evaluating leaks, helping manufacturers reduce unnecessary product loss. Developed within BioPhorum, the insights reflect collaboration between industry experts, suppliers, and manufacturers.

10:00 Sponsored Presentation *(Opportunity Available)*

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

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

11:20 PLENARY KEYNOTE PRESENTATION: Current Trends and Opportunities in Bioprocessing

Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering

This presentation explores how advances in biology are redefining bioprocessing to enable scalable, efficient, and reproducible manufacturing of emerging therapeutic modalities. By integrating synthetic biology, cell engineering, and data-driven design, the field can move beyond traditional methods toward biologically driven, industrialised platforms. The session highlights how biological innovation underpins the transformation of biomanufacturing for the next generation of complex biologics.

11:50 PLENARY KEYNOTE PRESENTATION: Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and Artificial Intelligence in Biologics Manufacturing

Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

Digital transformation promises to revolutionise biopharmaceutical manufacturing, yet most organisations leverage a fraction of their process data, with the challenges paradoxically increasing with globalisation and digitisation. This talk presents a practical maturity model for effectively navigating bioprocess monitoring and AI implementation. Drawing on assessments of 25 products, the presentation examines how companies can transform data challenges into competitive advantages by ensuring critical data is made available and delivered effectively.

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 Manufacturing and CMC Conference

Cambridge Healthtech Institute's 7th Annual

11 - 12 MARCH 2026 ALL TIMES CET

Gene Therapy Manufacturing and CMC

Manufacturing the Next Generation of Gene Therapies and Processes

WEDNESDAY 11 MARCH

10:30 Registration Open

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

MANUFACTURING NEXT-GENERATION VIRAL VECTORS

14:15 Chairperson's Remarks
Eduard Ayuso, DVM, PhD, CTO, Siegfried DINAMIQS; Former Chairman of Manufacturing, European Society of Gene and Cell Therapy

14:20 CMC Strategies for Advancing to IND—Case Study from AAVantgarde
Mardon McFarlane, Senior Director, External Manufacturing, AAVANTGARDE

14:50 CMC Challenges in Bringing a Gene Therapy to Clinic
Pamela Whalley, Associate Director, CMC, Complement Therapeutics Ltd.
Bringing a gene therapy to clinic presents unique CMC challenges requiring strategic foresight and coordination. This presentation shares real-world lessons in preparing CMC packages for clinical trials, focusing on early-phase development, regulatory readiness, and product comparability and justification of specifications. It highlights strategies for robust documentation, managing process changes, and logistics affecting manufacturing timelines. Strategic planning and foresight are essential to overcoming CMC hurdles and enabling smooth clinical progression.

15:20 Bringing Gene Therapy Productivity to the Next Level
Nic Preyat, PhD, Associate Director, Gene Therapy CMC Development, UCB Pharma
Recombinant adeno-associated virus (rAAV) vectors are pivotal for gene therapy, but their manufacturing remains expensive, impacting the overall product development costs and ultimately limiting accessibility for patients. This presentation explores the hurdles and technical avenues for enhancing rAAV process productivity with the aim of reducing the cost per viral genome through cutting-edge bioprocessing technologies.

15:35 Generation of a High Yielding, High Purity AAV Process
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.

15:50 Presentation to be Announced cytiva

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

CONTINUOUS AND INTENSIFIED PROCESSING OF AAVs

17:00 KEYNOTE PRESENTATION: Integrated Continuous Biomanufacturing of AAV
Thomas Villiger, PhD, Head, Bioprocess Technology Laboratory, FHNW
Adeno-associated viruses (AAVs) are the predominant gene-therapy vectors, yet manufacturing remains costly and inefficient. We present an integrated continuous biomanufacturing approach that combines perfusion-based upstream processing with continuous chromatography (CaptureSMB). Furthermore, multi-column solvent gradient chromatography (MCSGP) was employed to enrich full capsids with high yield. This presentation demonstrates how continuous manufacturing provides a cost-effective route to produce high-quality AAVs, while highlighting the challenges that remain to be solved.

17:30 Next-Gen rAAV Manufacturing: Continuous, Intensified, and Smart by Design
Maria Barreira Gonzalez, PhD, Programme Head of Gene Modification, Cell & Gene Therapy Catapult
The Cell and Gene Therapy Catapult (CGTC) is advancing cost-effective, next-generation rAAV manufacturing by developing continuous and intensified upstream processes that enhance productivity, scalability, and consistency. Complementing this, process and mechanistic modelling, integrated with Process Analytical Technology (PAT) and automation, provides real-time monitoring, predictive insights, and adaptive control. Together, these innovations create smart-by-design platforms that accelerate development, reduce costs, and enable robust rAAV manufacturing at commercial scale.

18:00 Interactive Breakout Discussion Groups
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,

Cambridge Healthtech Institute's 7th Annual

11 - 12 MARCH 2026 ALL TIMES CET

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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

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

NOVEL VECTORS AND CAPSID ENGINEERING TO IMPROVE PRODUCTION

8:25 Chairperson's Remarks

Frank K. Agbogbo, PhD, Vice President, Process Development, Forge Biologics

8:30 Engineering the Biology of AAV for Improved Gene-Therapy Manufacturing

Darren N. Nesbeth, PhD, Associate Professor, Biochemical Engineering, UCL

This presentation details engineering biology approaches applied to adeno-associated virus (AAV) biomanufacturing. Our research group systematically improved transient transfection protocols, engineered capsid variants, and modified the MAAP (membrane-associated accessory protein) to enhance AAV secretion efficiency and optimise the empty-to-full capsid ratio. These integrated engineering strategies demonstrate how rational design principles can address key manufacturing challenges in AAV vector production, potentially improving scalability and the therapeutic efficacy of gene therapy applications.

9:00 Manufacturing Challenges and Control Strategies for Dual AAV Vectors

Christine Le Bec, PhD, Head, CMC Gene Therapy, Sensorion

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

9:30 Capsid Engineering and Dual AAV

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 represent one of the most versatile clinical platforms for gene delivery. However, AAV vectors transduce cells poorly, resulting in the administration of exceedingly high doses in the clinic, which increases the risk of adverse events. To improve vector cargo delivery capacity and transduction efficiency, we are rationally designing novel capsids. We assessed and identified different sites for capsid engineering that do not impact vector yields while enhancing transduction.

10:00 Sponsored Presentation *(Opportunity Available)*

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

DRUG SUBSTANCE AND NOVEL DELIVERY METHODS

11:10 Can Viruses Flee from Ice Crystals? Understanding Freeze/Thaw Effects in Virus-Drug Substance (Large-Scale) Handling

Matthias Schad, Senior Scientist, Advanced Therapy Medicinal Products, Boehringer Ingelheim Pharma GmbH & Co. KG

For scale-up of virus formulation processing, we have developed a scale-down freezing system that mimics large-scale freezing and thawing. This system serves dual purposes: it acts as a stress model for formulation development, aiding the selection of excipients. Furthermore, it provides insights into the microscopic and macroscopic effects expected in large scale operations, such as ice front formation, cryoconcentration, and phase separation after thaw.

11:40 Target, Deliver, Edit: Engineering VLPs for Precision Genome Editing

Lúcia Santos, PhD, Scientist, Cell Line Development & Molecular Virology Lab Animal Cell Technology Unit, iBET

CRISPR technologies enable precise correction of disease-causing mutations but require transient expression to minimise off-target effects. Delivering ribonucleoproteins (RNPs) via virus-like particles (VLPs) to target cells, provides a safer alternative. In proof-of-concept experiments, VLPs pseudotyped with various viral glycoproteins targeted lung cells carrying a mutated GFP gene. Our results demonstrated the successful delivery of editing components, precise correction of the mutation, and restoration of fluorescence, thereby emphasising VLPs' therapeutic potential.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

GENE-THERAPY CMC AND ANALYTICS

13:25 Chairperson's Remarks

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

13:30 AAV Analytics to Monitor Efficacy and Quality

Christoph Gstöttner, PhD, Scientist, Roche

This presentation highlights analytical approaches used to evaluate the efficacy and quality of AAV-based gene therapies. It discusses general strategies for characterising vector components, assessing potency, and ensuring product consistency. Emphasis is placed on the importance of reliable analytical tools to support development, manufacturing, and regulatory expectations across the gene therapy lifecycle.

14:00 A Case Study on Analytical Challenges with Engineered AAVs: Why Evaluation Methods Matter

Chelsey Mattison, Senior Scientist, Novartis

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

14:30 CMC Challenges of *in situ* Tumour Delivery of IL-15 Superagonist via RedTail Gene Therapy

Lina Schulte, Scientist, Process & Analytical Development, StemVAC GmbH/Calidi Biotherapeutics

RedTail is a gene therapy platform using enveloped vaccinia virus for systemic, tumor-targeted delivery. It resists immune clearance and enables direct payload delivery to metastatic sites. CLD-401 expresses an IL-15 superagonist and evades complement lysis and antibodies. Manufacturing of the enveloped RedTail products requires specialised processes to maintain membrane integrity and ensure consistent potency.

15:00 Close of Summit

Stream 4 *NEW*
PEPTIDES AND OLIGOS

Explosive demand for GLP-1 agonists and the broadening applications of therapeutic oligonucleotides is fueling urgent innovation in manufacturing approaches that balance both scale and sustainability. Cambridge Healthtech Institute's Inaugural Peptide and Oligo Manufacturing conference convenes experts from the worlds of bioprocessing and process chemistry to explore the latest developments in synthetic, hybrid, and recombinant production platforms to improve the production of therapeutic peptides, antimicrobials, ASOs, siRNAs, and more. Sessions will address advances in solid and liquid-phase synthesis, upstream and downstream processing, expression systems, continuous purification, green chemistry, drug product and formulation, and overcoming challenges with conjugated and non-canonical molecules. Examples come from therapeutic peptides, antimicrobials, ASOs, siRNAs, and more.

10-11 MARCH 2026

Peptide and Oligo Manufacturing

VIEW PROGRAM »»

11-12 MARCH 2026

Advances in Recovery and Purification - Part 2

VIEW PROGRAM »»

Cambridge Healthtech Institute's Inaugural

10 - 11 MARCH 2026 ALL TIMES CET

Peptide and Oligo Manufacturing

Advancing Scalable, Sustainable Manufacturing

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

PEPTIDE MANUFACTURING IN A NEW AGE OF GLP-1 AND LONGEVITY MEDICINES

8:25 Chairperson's Remarks

Thomas Mueller-Spaeth, PhD, CEO, ChromaCon AG

8:30 Biopharmaceuticals Manufacturing for Peptides, Lifestyle, and Longevity Medicines

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

This presentation explores longevity and lifestyle medicines as a growing market, focusing on challenges in large-scale biopharmaceutical manufacturing and cost-reduction strategies. It highlights advances in peptide bioprocessing and beyond, examining whether these innovations can meet rising market demands for longevity biopharmaceuticals. Emphasis is placed on optimising production efficiency and scalability to align with consumer expectations for effective, accessible, lifestyle and longevity therapies.

9:00 KEYNOTE PRESENTATION: Ensuring Sustainability in the Golden Era of GLP-1 Peptide Agonists

Fernando Albericio, PhD, Research Professor, School of Chemistry, University of Kwazulu-Natal

In this presentation, we will discuss our laboratory's contributions to the state of the art in SPPS and LPPS, paying special attention to resins, linkers, protecting groups, and coupling agents—all within a framework of sustainability and "greening," which adds yet another layer of complexity. Special attention will be paid to the synthetic aspects of GLP-1 peptide agonists.

9:30 Sponsored Presentation *(Opportunity Available)*

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

NEW APPROACHES TO PEPTIDE SYNTHESIS AND MANUFACTURING

10:45 Aqueous Environmental Peptide Synthesis

Sara Ten Have, PhD, CEO, Origin Peptides; Senior Research Associate, Center for Gene Regulation & Expression, University Of Dundee

The environmental challenges with solid- and liquid-phase peptide synthesis are many, particularly with EU legislation moving to ban crucial solvents such as DMF and forever chemicals like TFA. Origin Peptides has discovered and developed a novel method of peptide synthesis which is completely aqueous, solid-phase free, and uses standard amino acids, in a one-pot reaction with high fidelity, reproducibility, and a broad range of applicability.

11:15 FEATURED PRESENTATION: Selective Functionalisation of Proteins and Peptides Using an Expanded Genetic Code

Birgit Wiltschi, PhD, Head of Synthetic Biology Group, ACIB GmbH & BOKU University, Vienna

Expanding the genetic code with non-canonical amino acids enables precise incorporation of unique chemistries into proteins. Using engineered orthogonal aminoacyl-tRNA synthetase/tRNA pairs, these amino acids introduce reactive side chains or bioorthogonal handles for selective labeling and immobilisation. This approach has transformed protein engineering, broadening the chemical diversity achievable *in vivo* and facilitating advanced studies of protein interactions, targeted drug conjugation, and novel therapeutics with enhanced specificity and functionality.

11:45 A Scalable GMP-Ready Platform for End-to-End Manufacture of xRNA-LNP Therapeutics

Harris Makatsoris, PhD, Professor, Sustainable Manufacturing Systems, Kings College London

12:15 Sponsored Presentation *(Opportunity Available)*

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

RECOMBINANT APPROACHES TO PEPTIDE MANUFACTURING

13:45 Chairperson's Remarks

Birgit Wiltschi, PhD, Head of Synthetic Biology Group, ACIB GmbH & BOKU University, Vienna

13:50 Overcoming Disulfide-Bond Challenges in Recombinant Peptide Production

Monika Cserjan, PhD, Senior Scientist, Institute of Bioprocess Science and Engineering, BOKU University

Recombinant peptide production in *E. coli* offers a sustainable alternative to chemical synthesis. Challenges in producing high-yield disulfide-bonded peptides include: degradation by host peptidases, the need for translocation into the periplasm, and the requirement for individualised manufacturing processes. We have developed the CASPON technology, a generic fusion tag-based platform that enables high-titre soluble expression, efficient affinity purification, and tag removal—particularly important for biopharmaceutical applications.

14:20 Unlocking Efficient Peptide Manufacturing through CASPON Technology

Nico Lingg, PhD, Senior Scientist & Area Lead, Health Biotechnology, ACIB

Efficient manufacturing of disulfide-bonded peptides remains challenging due to proteolytic degradation, complex downstream processing, and the need for peptide-specific process development. CASPON technology offers a platform solution, enabling high-titre soluble expression in *E. coli*, affinity purification, and precise tag removal. By combining CASPON with outer membrane engineering, we achieved peptide release into the medium, simplifying DSP. This approach accelerates process development and ensures high-quality peptide production for biopharmaceutical applications.

14:50 Bioproduction Platform to Generate Functionalised Disulfide-Constrained Peptide Analogues

Sunhee Hwang, PhD, Scientist 4, Peptide Therapeutics, Genentech Inc.

A versatile and highly efficient bioproduction platform to generate various forms of disulfide-constrained peptides (DCPs) has been developed as an environmentally sustainable alternative to SPPS. This platform can be used to generate: (1) multivalent DCPs with different geometries, (2) DCPs with functional chemical groups such as biotin, (3) DCPs with unnatural amino acids through amber codon suppression, and (4) isotope-labeled DCPs.

15:20 Sponsored Presentation *(Opportunity Available)*

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

Cambridge Healthtech Institute's Inaugural

10 - 11 MARCH 2026 ALL TIMES CET

Peptide and Oligo Manufacturing

Advancing Scalable, Sustainable Manufacturing

NEXT-GENERATION OLIGONUCLEOTIDE MANUFACTURING

16:30 Next-Generation Oligonucleotide Manufacturing

Barrie Cassey, PhD, Technology Lead, Medicines Manufacturing, CPI

The pipeline of oligonucleotide therapeutics promises to deliver treatments for increasingly large patient populations and oligonucleotide manufacturing needs to respond to this shift in demand. Significant effort has been put into technologies to improve the scalability, sustainability, and cost of oligonucleotide manufacturing, all of which have their advantages and challenges. The potential introduction of these technologies and the interactions between them present a complex yet tantalising opportunity for future supply.

17:00 Continuous Pipeline for Oligonucleotide Manufacturing: Perfusion Cell Cultures and Twin-Column Countercurrent Chromatography

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

Recombinant manufacturing of oligonucleotides has the potential to overcome the severe concerns of poor scalability and yield, as well as the huge waste generation associated with solid-phase synthesis. The development of perfusion cell cultures and multicolumn countercurrent chromatographic purification of oligonucleotides is presented herein as a way of reaching consistent product quality and improved process mass intensity compared to traditional operations.

17:30 Welcome Reception in the Exhibit Hall with Poster Viewing

18:30 Close of Day

WEDNESDAY 11 MARCH

8:00 Registration Open and Morning Coffee

OLIGONUCLEOTIDE MANUFACTURING, QUALITY & CMC

8:25 Chairperson's Remarks

Hagen Cramer, PhD, CTO, QurAlis Corporation

8:30 Strategies and Resources for Assessing Quality Attributes of Starting Materials for Therapeutic Oligonucleotides

Diane McCarthy, PhD, Vice President, Global Biologics, US Pharmacopeia

Therapeutic oligonucleotides represent a rapidly expanding class of drugs, including antisense oligonucleotides, siRNAs, and aptamers. Supporting quality of these products begins with the control of starting materials, particularly phosphoramidites. Key considerations include impurity classification, process-dependent impurity impact, selection of analytical methods for impurity detection and characterisation, and use of reference standards. This presentation will focus on strategies and USP resources to support risk-based quality assessment of phosphoramidite starting materials.

9:00 Control Strategies and Analytical Method Development for Legacy and Emerging Starting Materials in Oligonucleotide Manufacturing

Dennis Rhodes, Assistant Director, Ionis Pharmaceuticals Inc.

Ensuring quality in oligonucleotide therapeutics requires robust controls for both legacy nucleoside phosphoramidites and newer starting materials such as GalNAc ligands and linkers used in conjugates. These inputs present different challenges, ranging from well-established specifications to the added complexity of novel chemistries. This presentation will discuss phase-appropriate control strategies, analytical method development, and how regulatory expectations differ for established versus emerging inputs.

9:30 Latest Challenges in Oligonucleotide Manufacturing and CMC

Hagen Cramer, PhD, CTO, QurAlis Corporation

Oligonucleotide synthesis is performed using a highly automated synthesiser, without in-process controls until the full-length oligonucleotide is cleaved from the solid support. Already a 20-base-long sequence requires 80 reaction steps. To ensure high quality and high yields every reaction step needs to be done almost quantitatively. Today's oligonucleotides are highly modified resulting in unique manufacturing challenges and regulatory hurdles. Latest manufacturing technologies including enzymatic ligation will be discussed.

10:00 Sponsored Presentation *(Opportunity Available)*

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

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks

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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 Peptide and Oligo Manufacturing Conference

Cambridge Healthtech Institute's 9th Annual

11 - 12 MARCH 2026 ALL TIMES CET

Advances in Recovery and Purification - Part 2

Optimising Downstream Efficacy and Yield

WEDNESDAY 11 MARCH

10:30 Registration Open

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

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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, PROCESS MODELLING, AND ML/AI APPROACHES TO DSP

14:15 Chairperson's Remarks
Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich

14:20 Advancing Bioprocess Understanding through Real-Time Monitoring, Data-Driven Modelling, and Experimental Design
Theresa Scharl, PhD, Senior Scientist, BOKU University
Implementing model-based real-time monitoring in biopharmaceutical production represents a key advancement toward Quality by Design and provides the foundation for model-predictive control. Data-driven models are capable of making predictions for monoclonal antibody (mAb), double-stranded DNA, host cell protein, and high molecular weight impurity concentrations during elution from a Protein A chromatography capture step. Ensuring explainability of machine learning models and applying efficient experimental design are key to enhancing modern process control.

14:50 KEYNOTE PRESENTATION: The Autonomous Future of DSP: Self-Driving Labs, ML Integration, and Digital Twins
Matthias Franzreb, PhD, Department Leader, Bioengineering and Biosystems, Institute for Functional Interfaces, KIT
This talk presents a fully automated workflow for bioprocess development, starting with experiment planning in an ELN and ending with report generation. Key elements include ML-supported optimisation of bioprocess steps, integration of simulation tools such as mechanistic models and molecular dynamics, and strategies for linking digital tools into a unified, autonomous system that accelerates development cycles and enhances decision-making in DSP.

15:20 Electric Double-Layer–Informed Binding for IEX: Minimal Calibration, Robust Prediction
Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich
We present a physics-grounded binding isotherm for ion-exchange chromatography derived from electrical double layer (EDL) theory. Incorporating nonlinear screening, ion valency, and crowding, the model achieves predictive elution from minimal calibration. Its parameters map directly to physical properties, enhancing interpretability over existing models. Calibrated on a single dataset, we validate predictions across gradients, step elutions, salt types, and load densities with model proteins, and highlight the effect of divalent ions.

15:50 Presentation to be Announced

TOSOH

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

PROCESS MODELLING TO OPTIMISE CHROMATOGRAPHY

17:00 Using the Laplace-Beltrami-Operator to Generate Molecular Descriptors of Protein Shape for QSAR Chromatography Models
Johannes Felix Buyel, PhD, Head, Institute for Biochemical Engineering, University of Natural Resources and Life Sciences (BOKU)
The development of effective shape descriptors is essential for representing the unique geometric features of protein surfaces. In this work, we introduce a novel approach based on spectral geometry: the Laplace-Beltrami spectrum. By encoding protein structures as fixed-length feature vectors derived purely from geometric properties, shape descriptors aim to facilitate the a priori prediction of protein separation, reducing modeling efforts, and accelerating chromatographic process design.

17:30 Optimising a Flowthrough Multimodal Chromatography
Wendi Zhang, PhD, Senior Scientist, Downstream Processing, AbbVie Inc.
This work focuses on improving flowthrough multimodal chromatography for broader applications in biomolecule purification. By refining operational parameters and understanding key interactions, we aim to enhance process efficiency, product recovery, and impurity removal. The findings support more robust and scalable workflows, making this technique a valuable tool in both research and industrial settings. This approach highlights practical considerations for optimising chromatography without compromising performance or throughput.

18:00 Interactive Breakout Discussion Groups
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

Cambridge Healthtech Institute's 9th Annual

11 - 12 MARCH 2026 ALL TIMES CET

Advances in Recovery and Purification - Part 2

Optimising Downstream Efficacy and Yield

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

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

DOWNSTREAM PROCESSING FOR VIRAL VECTORS AND BIONANOPARTICLES

8:25 Chairperson's Remarks

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

8:30 Lentiviral Vector Determinants of Anion Exchange Chromatography Elution Heterogeneity

George Pamenter, PhD Researcher, UCL

The demand for Lentiviral Vector (LV) drug substance is increasing. However, primary capture using convective anion-exchange chromatography remains a significant manufacturing challenge. This presentation explores the factors influencing elution heterogeneity of lentiviral vectors during anion exchange chromatography.

9:00 Translating Novel Purification Strategies into Practice: Insights from Lentivirus and EV Case Studies

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

This presentation will delve into how alternative purification strategies are being explored to meet the demand for higher yields, improved vector quality, and shorter processing times. We will discuss the implementation of novel adsorbent materials and non-conventional operational modes, with a focus on lentiviral vectors and extracellular vesicles.

9:30 Nonwoven Fibers for the Purification of Bionanoparticles (Viruses, VLPs, and EVs)

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

Purification of bionanoparticles (BNPs), such as viruses and extracellular vesicles, is challenging due to their complexity, large size, and the presence of similar nanoparticle impurities. Conventional chromatography resins often exhibit low productivity due to slow mass transfer and limited binding capacity. Non-woven fiber-based convective media offers a promising alternative, enabling efficient purification of BNPs in both flowthrough and bind-elute modes. This approach addresses key limitations, improving productivity and BNP purity.

10:00 Presentation to be Announced

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

11:10 Viral Capsomere-Nucleic Acid Interaction: Impact on Purification and *in vitro* Loading

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

Viral capsomere–nucleic acid interactions present unique challenges for downstream processing and *in vitro* assembly of virus-like particles, as well as *in vitro* loading of viral vectors. We explore how these interactions influence purification efficiency and product quality. By examining key drivers of nucleic acid association, we outline strategies to optimise recovery and enable *in vitro* loading of viral vectors.

11:40 Peptides and Peptide–Nucleic Acid Ligands for the Affinity Purification of Next-Generation Gene Therapies: Viral Vectors and mRNAs

Stefano Menegatti, PhD, Professor, Chemical and Biomolecular Engineering, North Carolina State University

Novel peptide-based affinity ligands enable serotype-agnostic purification of AAV vectors and monoclonal antibodies, delivering yields up to 99% with 230-400-fold host cell protein reduction. Machine learning-guided Bayesian optimisation accelerates chromatography parameter development while preserving transduction activity. Advanced process analytical technologies, including quantum dot-enabled biosensors and electrochemical platforms, provide real-time monitoring of critical quality attributes. These innovations transform viral vector and mAb biomanufacturing through improved efficiency, scalability, and product quality.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

RECOVERY AND PURIFICATION OF COMPLEX BIOLOGICS

13:25 Chairperson's Remarks

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

13:30 Advancing rAAV Manufacturing: Continuous DSP Integrated with Digital Process Development

Bilal Ozdoganoglu, Associate Senior Scientist, Cell and Gene Therapy Catapult

As demand for rAAV gene therapies grows, continuous downstream processing (DSP) is key to achieving scalable, cost-effective, and safe manufacturing. This work integrates mechanistic modelling, digital twins, and Process Analytical Technology (PAT) to enable real-time monitoring, simulation, and optimisation. The approach improves process efficiency and consistency, supporting faster production and robust quality control—essential for meeting clinical and commercial needs in a rapidly evolving gene therapy landscape.

14:00 Purification and Analytical Strategies to Overcome Production Challenges for Hexameric IgGs

Rujin Cheng, PhD, Principal Scientist, Biotherapeutics, ImmunEdge

Hexameric IgGs are a class of complex biologics that offers unique pharmacokinetics and pharmacodynamic properties due to their high valency, molecular weight, or hydrodynamic radius. Despite their attractive profile for certain therapeutic indications, technical challenges in purification and analytics hinder their broader application. This talk aims to demystify some of the challenges by providing comprehensive molecule analysis/illustration and a couple of successful examples where key problems are identified and resolved.

14:30 Selective Affinity Capture of Secretory IgA Using Engineered Bacterial Ligands on Macroporous Resins

David Scheich, PhD Student, BOKU

Secretory immunoglobulin A (sIgA) is emerging as a powerful tool for passive immunisation. Current affinity resins suffer from co-purification of product-related impurities and severe mass transfer limitations. A novel resin was developed by immobilising a *Streptococcus pneumoniae* surface protein as affinity ligand, targeting the secretory component of sIgA, on a macroporous resin with appropriate pore size. Data will be presented on how ligand design and resin architecture influence chromatographic performance.

15:00 Close of Summit

Stream 5
INTENSIFIED AND CONTINUOUS PROCESSING

The Intensified and Continuous Processing stream showcases strategies for implementing semi-, hybrid, and fully continuous bioprocessing from perfusion through purification. Key topics include process intensification, advanced modelling and control, real-time monitoring, and digital twin applications. The stream highlights efforts to enhance robustness, ensure viral safety, and align with global regulatory expectations. Discussions also address sustainability benefits, cost-efficiency, and digitalisation trends, along with scalable solutions for transitioning from clinical to commercial manufacturing—emphasising how continuous processing is advancing greener, more flexible, and productive biomanufacturing.

10-11 MARCH 2026

Cell Culture and Cell Line Engineering - Part 1

VIEW PROGRAM »»

11-12 MARCH 2026

Intensified and Continuous Processing

VIEW PROGRAM »»

Cambridge Healthtech Institute's 9th Annual

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Cell Culture and Cell Line Engineering - Part 1

Upstream Technologies and Strategies to Optimise Process Efficiency

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

DIGITAL PROCESS MODELLING

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

8:30 FEATURED PRESENTATION: USP Development and *in silico* Modelling
Ayca Cetinkaya, PhD, Senior Scientist, AstraZeneca
Biopharmaceutical manufacturing faces increased modality complexity and rising operational costs, requiring innovative bioprocess development strategies. Metabolic modelling provides in-depth system analysis, reducing experimental trial-and-error and saving time, materials, and resources. This talk presents real-world case studies where flux balance analysis optimises feed strategies, demonstrating how modelling informs supplement selection to improve productivity while supporting efficient decision-making in the development of advanced biologics.

9:00 Speed2Clinic: Continuously-Learning AI Model for Efficient and Accelerated Cell-Line Development for Monoclonal-Antibody Production
Stella Papadaki, Researcher, Cell Technologies, Roche
The identification of suitable cell lines for monoclonal antibody (mAb) manufacturing is a complex and resource-intensive process. We have developed an AI-driven approach using machine learning to accelerate clone selection. The model uses early-stage multi-omics data to predict late-stage cell line productivity, enabling early detection of high-producer cell lines. This shift to a model-centric process significantly reduces project timelines, accelerates mAb delivery, and fosters a data-driven culture in bioprocessing.

9:30 Presentation to be Announced

BECKMAN COULTER

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

10:45 End-to-End Bioprocessing with Digital Twins: Industrial Showcases from Batch to Fully-Continuous Modalities
Mark Duerkop, CEO, Novasign GmbH
Digital twins are transforming bioprocessing by accelerating development and enabling robust, automated control. This talk will present industrial case studies spanning monoclonal antibodies, viral vectors, and advanced therapies. Showcases will cover the transition from batch to continuous manufacturing. Emphasis will be placed on tailored modelling, experimental design, and real-time applications, demonstrating how digital twins enable end-to-end integration, seamless scale-up, and industrial implementation across multiple modalities.

11:15 KEYNOTE PRESENTATION: Innovations in Modelling Mammalian Cell Culture
Veronique Chotteau, Professor, Director, AdBIOPRO, Centre for Advanced Bioproduction by Continuous Processing, Industrial Biotechnology, KTH Royal Institute of Technology
Mammalian cell culture remains central to biologics production, yet optimising performance at scale requires predictive tools that capture complex cellular behaviors. This presentation explores recent innovations in modelling approaches, from data-driven methods to mechanistic and hybrid models, that enhance understanding of cell metabolism, growth, and productivity in bioprocess. By integrating experimental data with advanced simulations, these strategies accelerate process development, and support more efficient, robust upstream manufacturing of biologics.

11:45 Novel ML-Driven Sampling Strategies for Model-Based DoE in Bioprocesses
Sam Stricker, Researcher, Chemical Engineering, Imperial College London
Efficient experimentation is critical in bioprocess development, where time, cost, and complexity constrain traditional DoE. We introduce a model-based algorithm that leverages Pareto fronts and Bayesian optimisation to balance exploitation of high-performing regions with exploration of uncertain areas. This approach accelerates learning, reduces experimental burden, and scales effectively to high-dimensional design spaces, providing a robust and resource-efficient strategy for modern bioprocess optimisation that effectively explores trade-offs among performance and quality.

12:15 Presentation to be Announced by ATUM

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

INNOVATIONS IN UPSTREAM PAT

13:45 Chairperson's Remarks
Mario P. Pereira, PhD, Director, Technology & Business Development, ATUM

13:50 Development and Optimisation of an Intensified Process for a High-Value Commercial Process Using Advanced at-Line Metabolic Data
Emanuel Kreidl, PhD, Senior Expert, Science & Technology, Technical Research & Development, Novartis Pharmaceutical Manufacturing GmbH
This presentation describes the development and optimisation of an intensified upstream process for a high-value commercial biologic. By leveraging advanced at-line metabolic data, our team identified key drivers of cell growth and productivity, enabling rapid process adjustments and improved consistency. We will share the analytical approach, decision-making framework, and performance outcomes that demonstrate how real-time metabolic insights can accelerate scale-up and ensure robust, cost-effective manufacturing.

14:20 Deep Hybrid Modelling in Biomanufacturing: Deep Learning for Next-Generation Hybrid Models
Rui M. Oliveira, PhD, Professor, Chemical Engineering & Biochemistry, Nova School of Science and Technology
Hybrid modelling that combines first-principles with machine learning is emerging as a cornerstone of Biopharma 4.0. In this work, we explore deep hybrid model architectures that seamlessly integrate deep neural networks with mechanistic equations. Our results demonstrate a consistent generalisation advantage of deep hybrid models across multiple CHO platforms. This study highlights the transformative potential of deep hybrid modelling for accelerating process development in modern biomanufacturing.

14:50 Self-Driving Laboratories as Innovative Entities to Revolutionise Bioprocess Development
Peter Neubauer, PhD, Professor, Bioprocess Engineering, TU Berlin
The KIWI-biolab at TU Berlin exemplifies a cognitive self-driving laboratory integrating automated fermentation, analytics, and model-based optimisation within a reproducible workflow. The presentation outlines the essential components required to realise such laboratories—covering automation, modelling, and workflow orchestration—and illustrates their functionality through examples of adaptive process control and model-based optimisation for antibody Fab fragment production in *Escherichia coli*.

15:20 Presentation to be Announced

908devices

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

Cambridge Healthtech Institute's 9th Annual

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Cell Culture and Cell Line Engineering - Part 1

Upstream Technologies and Strategies to Optimise Process Efficiency

PANEL DISCUSSION: UNLOCKING SMARTER BIOPROCESSING

16:30 PANEL DISCUSSION: Unlocking Smarter Bioprocessing through Better Data Collection, Quality, and Analysis

Moderator: Mark Duerkop, CEO, Novasign GmbH

Data is central to the future of bioprocessing, yet many organisations struggle with incomplete or inconsistent information that limits the training of next-generation AI/ML models. Without addressing these gaps, the promise of digitalisation remains out of reach. This panel will explore why data challenges persist and share strategies to transform raw information into actionable insight—unlocking smarter, faster, and more efficient bioprocessing to accelerate the industry's digital transformation.

Panelists:

Andrea Arsiccio, PhD, Senior Scientist & Team Lead, In Silico, Coriolis Pharma Research GmbH

Ayca Cetinkaya, PhD, Senior Scientist, AstraZeneca

Nicole Mather, DPhil, Life Sciences Lead & HLS Data and AI Lead, IBM Consulting UK & Ireland

Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

17:30 Welcome Reception in the Exhibit Hall with Poster Viewing

18:30 Close of Day

WEDNESDAY 11 MARCH

8:00 Registration Open and Morning Coffee

GLYCOSYLATION CONTROL

8:25 Chairperson's Remarks

Anika Mijakovac, PhD, Researcher, University of Zagreb

8:30 Development of a Novel Automated Workflow for Quantifying Glycogen in Tissue Lysate with Enhanced Sensitivity

Avraham Rosenberg, MS, Senior Scientist, Analytical Chemistry, Regeneron

Accurate quantification of glycogen in biological samples is critical for studying metabolism, disease mechanisms, and therapeutic impact. This presentation describes the development of a novel automated workflow for measuring glycogen in tissue lysates with improved sensitivity and reproducibility. Leveraging optimised sample preparation, advanced detection methods, and automation, the approach minimises variability and enables high-throughput analysis. The enhanced performance supports deeper insights into glycogen biology and reliable evaluation of metabolic interventions.

9:00 New CRISPR Model Cell Lines and Discovery of Novel Pathways for Glycoengineering of Therapeutic Proteins

Anika Mijakovac, PhD, Researcher, University of Zagreb

Glycans attached to antibodies mediate inflammatory pathways in disease and aging but the mechanisms that regulate antibody glycosylation are still largely unknown. To decipher the molecular determinants of antibody glycosylation, specifically immunoglobulin G (IgG), we developed a series of robust CRISPR/dCas9 cell line platforms based on our flexible and extendible EpiToolbox scaffold. We discovered that the control of IgG glycosylation extends far beyond the known glycosylation-related genes.

9:30 Glycoengineered CHO Cells

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

Leveraging CHO cells' established role in producing human-like glycosylated therapeutics, we developed a panel of 30 glycoengineered CHO (geCHO) cells. This platform enables tailored glycosylation for protein production. Screening with geCHO we have identified therapeutic candidates exhibiting enhanced activity, optimised immunogenicity, and improved stability, thereby demonstrating the panel's potential to optimise next generation biotherapeutics.

10:00 Hamilton Unveils the Future of CPP Monitoring HAMILTON

Giovanni Campolongo, Senior Market Segment Manager, Biopharma, Hamilton Company

Join Hamilton Process Analytics as we reveal our latest breakthrough in real-time monitoring of Critical Process Parameters (CPPs) for cell culture. Building on our legacy of pioneering in-line sensor technologies, we continue to drive smarter, more efficient bioprocessing. You'll have the chance to see our newest innovative process sensors—live. Stay tuned for more.

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

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks

Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

11:20 PLENARY KEYNOTE PRESENTATION: Current Trends and Opportunities in Bioprocessing

Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering

This presentation explores how advances in biology are redefining bioprocessing to enable scalable, efficient, and reproducible manufacturing of emerging therapeutic modalities. By integrating synthetic biology, cell engineering, and data-driven design, the field can move beyond traditional methods toward biologically driven, industrialised platforms. The session highlights how biological innovation underpins the transformation of biomanufacturing for the next generation of complex biologics.

11:50 PLENARY KEYNOTE PRESENTATION: Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and Artificial Intelligence in Biologics Manufacturing

Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

Digital transformation promises to revolutionise biopharmaceutical manufacturing, yet most organisations leverage a fraction of their process data, with the challenges paradoxically increasing with globalisation and digitisation. This talk presents a practical maturity model for effectively navigating bioprocess monitoring and AI implementation. Drawing on assessments of 25 products, the presentation examines how companies can transform data challenges into competitive advantages by ensuring critical data is made available and delivered effectively.

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 Culture and Cell Line Engineering – Part 1 Conference

Cambridge Healthtech Institute's 9th Annual

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Intensified and Continuous Processing

Optimising Process Intensification, Monitoring, and Control for Efficient Manufacturing

WEDNESDAY 11 MARCH

10:30 Registration Open

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

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12:20 Session Break

12:30 Sponsored Presentation *(Opportunity Available)*

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

CONTINUOUS PROCESSING OF COMPLEX MODALITIES

14:15 Chairperson's Remarks
Lara Fernandez-Cerezo, PhD, Associate Principal Scientist, Merck Sharp Dohme (MSD)

14:20 KEYNOTE PRESENTATION: Novel Technology to Facilitate the Manufacture of Multispecifics in CHO Cells
Zanele Eimert, PhD, Senior Expert, Science & Technology, Novartis

14:50 Plug-and-Play Intensified Fed-Batch with ATF Perfusion: A Model-Based Path to High-Yield Biomanufacturing
Harsha Reddy Borra, Process Lead, Process Development, Accord Healthcare
The therapeutic antibody market demands scalable, cost-efficient manufacturing beyond conventional fed-batch processes. We present a hybrid fed-batch strategy integrating ATF perfusion of the inoculum with model-based process design, enabling high seeding densities and intensified productivity. This plug-and-play approach increased yields 4–6 fold (1.9 g/L to 10–12 g/L) while maintaining quality, reducing costs by ~60%, and proving robust across CHO cell lines—offering a sustainable, adaptable platform for next-generation biomanufacturing.

15:20 Towards Rapid Calibration of Raman Spectroscopy Models
Marieke E. Klijn, PhD, Assistant Professor, Biotechnology, Delft University of Technology
Real-time monitoring and control with Raman spectroscopy is dependent on calibration models that translate spectra to analyte concentrations. This is often performed by chemometric models that require extensive datasets, thereby hindering rapid implementation of PAT. This presentation will go over different methods we applied to support rapid calibration, as well as how different measurement conditions affect the spectra itself.

15:50 Presentation to be Announced SARTORIUS

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

CONTINUOUS AND INTENSIFIED PROCESSING OF AAVs

17:00 KEYNOTE PRESENTATION: Integrated Continuous Biomanufacturing of AAV
Thomas Villiger, PhD, Head, Bioprocess Technology Laboratory, FHNW
Adeno-associated viruses (AAVs) are the predominant gene-therapy vectors, yet manufacturing remains costly and inefficient. We present an integrated continuous biomanufacturing approach that combines perfusion-based upstream processing with continuous chromatography (CaptureSMB). Furthermore, multi-column solvent gradient chromatography (MCSGP) was employed to enrich full capsids with high yield. This presentation demonstrates how continuous manufacturing provides a cost-effective route to produce high-quality AAVs, while highlighting the challenges that remain to be solved.

17:30 Next-Gen rAAV Manufacturing: Continuous, Intensified, and Smart by Design
Maria Barreira Gonzalez, PhD, Programme Head of Gene Modification, Cell & Gene Therapy Catapult
The Cell and Gene Therapy Catapult (CGTC) is advancing cost-effective, next-generation rAAV manufacturing by developing continuous and intensified upstream processes that enhance productivity, scalability, and consistency. Complementing this, process and mechanistic modelling, integrated with Process Analytical Technology (PAT) and automation, provides real-time monitoring, predictive insights, and adaptive control. Together, these innovations create smart-by-design platforms that accelerate development, reduce costs, and enable robust rAAV manufacturing at commercial scale.

18:00 Interactive Breakout Discssion Groups
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

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

Cambridge Healthtech Institute's 9th Annual

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Intensified and Continuous Processing

Optimising Process Intensification, Monitoring, and Control for Efficient Manufacturing

UNLOCKING SUSTAINABILE BIOPROCESSING

8:25 Chairperson's Remarks

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

8:30 Sustainable Antibody Manufacturing: Harnessing PAT and Adaptive Purification to Drive Efficiency

Simon Hawdon, Chief Technologist, CPI

Sustainability in biomanufacturing can be approached through intensification. Achieving higher efficiency production through more responsible use of resources requires process analytical technology and adaptive control to minimise waste and optimise yield. Here we present CPI's work in the intensification of biomanufacturing including the use of adaptive algorithms to drive process development. This approach will lead to more efficient production and therefore greater availability of therapeutics to patients

9:00 Unlocking Sustainable Bioprocessing: Predict, Optimise, and Scale Early

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

Transformative early process development unlocks significant cost and environmental benefits. Limited process data can be used for predictive, rapid, and scalable process optimisation by linking process knowledge, AI-conditioned databases, and innovative process digital-facility modelling—enabling new green metrics and manufacturing optimisation before Phase II. A mAb case study illustrates how process intensification and strategic modelling cut costs, material use, waste streams, and Scope 3 emissions.

9:30 Paving the Path to Green Biomanufacturing: Roche's Life-Cycle Approach to Sustainable Antibody Production

Elina Hutter, MSc, Senior Associate Scientist, PZ Cell Culture Development EU, Roche Diagnostics GmbH

I will provide valuable insights into how life-cycle analysis (LCA) is applied to identify and mitigate environmental hotspots across non-intensified, intensified, and continuous platforms. It further highlights practical pathways for greener production while ensuring that bioprocessing advancements remain both economically viable and environmentally responsible. This talk underscores the pressing need for sustainability in biomanufacturing while demonstrating how it can be effectively integrated into the workflows of large-scale antibody production.

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 for Microbial Processes

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 including an economic evaluation with standard fed batch as benchmark.

11:40 Integrated Continuous and Automated Platform for Plasmid Production

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

Plasmid DNA is vital for gene therapies, viral vectors, and mRNA vaccines, but remains limited by costly, low-yield batch processes. iCAP delivers continuous, automated production using genetically stabilised *E. coli*, enabling long-term plasmid replication in bioreactor cascades. Integrated alkaline lysis, purification, and digital-twin–driven control ensure high throughput and autonomy. Modular and scalable, iCAP reduces costs, boosts sustainability, and supports decentralised DNA vaccine and continuous therapeutic production.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

PROCESS MODELLING AND INTENSIFIED PROCESSING

13:25 Chairperson's Remarks

Maximilian Krippl, PhD, Head of Bioprocess Modeling Consulting, Novasign GmbH

13:30 Workflows and Models for Continuous Microbial Bioprocesses: From Process Development to End-to-End Control

Maximilian Krippl, PhD, Head of Bioprocess Modeling Consulting, Novasign GmbH

This talk presents recent advances in experimental workflows and modeling for continuous microbial bioprocesses. Building on last year's work, we extend the approach to multiple products using a two-stage bioreactor, inline lysis, membrane filtration, and multi-column chromatography. Demonstrating universality across two research projects, we show how modelling workflows accelerates development, reduces timelines, and enables seamless transition from process optimisation to autonomous process control.

14:00 Synthetic Spectral Libraries for Raman-Model Calibration

Vicent Borras, PhD, Bioprocess Technology Laboratory, University of Applied Sciences Northwestern Switzerland (FHNW)

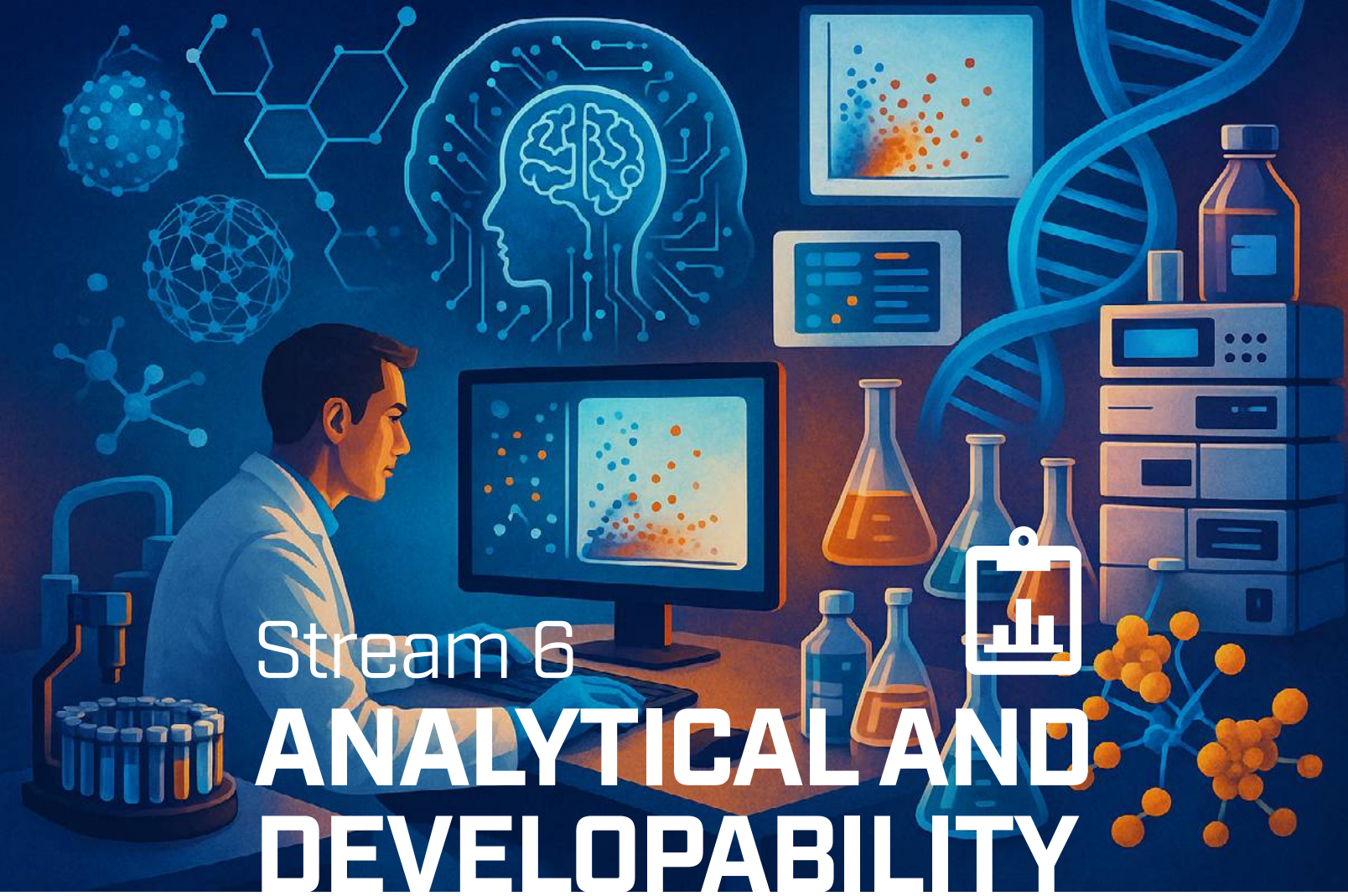
Raman spectroscopy is a powerful tool in process analytical technology (PAT) for bioprocess monitoring. However, developing accurate models is slow and costly. We propose an innovative strategy, where pure spectral fingerprints of target analytes are *in silico* added to calibration datasets. This approach eliminates extensive physical experiments, accelerates workflow, and improves adaptability across diverse bioprocess conditions. The method has potential to significantly streamline PAT model development while maintaining predictive performance.

14:30 Intensifying Oncolytic-Virus Production: Perfusion-Based Manufacturing of VSV-NDV, HSV-1, and NDV

Lennart Jacobtorweihe, Researcher, Genzel Group, Max Planck Institute for Dynamics of Complex Tech Systems

This approach enables integrated clarification within the upstream process, eliminating a downstream unit operation and enhancing both viral titres and productivity. Building on this, we present our results on high-cell-density perfusion cultures (>20 × 10^6 cells/mL) of HEK293 and avian cell lines (EB66 and CCE. X10) for the production of three different oncolytic viruses: We discuss virus-specific challenges encountered during intensification and strategies to maximise productivity and product quality.

15:00 Close of Summit



Stream 6
ANALYTICAL AND DEVELOPABILITY

The Analytical and Developability 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.

10-11 MARCH 2026

Accelerating Analytical Development

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11-12 MARCH 2026

Biophysical Analysis and Developability

VIEW PROGRAM »»

Cambridge Healthtech Institute's 2nd Annual

10 - 11 MARCH 2026 ALL TIMES CET

Accelerating Analytical Development

New Technologies to Optimise the Speed and Efficiency of Biotherapeutic Development

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

AUTOMATION & MINIATURISATION

8:25 Chairperson's Remarks

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

8:30 KEYNOTE PRESENTATION: Automation and Multiplexing for Standard Assays and In-Process Analytics

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

Advances in microfluidic sensor integration, inline process analytics, and continuous bioprocessing enable real-time monitoring and control of upstream and downstream operations. This presentation highlights multiplexed microfluidic platforms for online monitoring and automated assay workflows for scalable in-process analytics. Miniaturised, integrated sensors offer substantial potential for next-generation bioprocess intensification, enabling predictive control, faster process optimisation, and more seamless, efficient integration of continuous manufacturing workflows.

9:00 Assessment of Subvisible Particles in Biopharmaceuticals with Image Feature Extraction and Machine Learning

Jukka Rantanen, PhD, Professor, Pharmacy, University of Copenhagen

An innovative image-based classification tool was developed to address subvisible particle challenges in biopharmaceuticals. By combining feature extraction with machine learning, it delivers over 97% accuracy in distinguishing silicone oil from other particles. The approach provides a cost-effective alternative to complex analytics, strengthening quality control and process reliability. Faster, consistent monitoring supports regulatory compliance, safeguards product integrity, and enhances operational efficiency across biopharmaceutical manufacturing and development.

9:30 Presentation to be Announced

halo labs

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

CHARACTERISING GLYCOSYLATION

10:45 Next-Gen Glycoanalytics: Redefining O-Linked Glycomics and Glycoproteomics

Niclas Karlsson, Professor, Health Science, Oslo Metropolitan University

This presentation highlights emerging methodologies and technologies that expand the resolution, sensitivity, and throughput of O-linked glycomics and glycoproteomics, including the use of mucinases that now are available to improve the glycopeptide generation of the highly O-linked mucin domain frequently found on O-glycoproteins. By redefining analytical capabilities, these next-generation approaches enable deeper biological understanding and support the design, optimisation, and quality control of innovative biologics and complex therapeutic modalities.

11:15 Mass Spectrometric Approaches to Unravel Protein Glycosylation: A Multi-Level Perspective

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

Glycosylation is a common PTM impacting protein function, disease, and therapeutic efficacy. Its characterisation is essential, as glycosylation critically influences stability and pharmacokinetics of biopharmaceuticals. Multi-level mass spectrometry approaches—ranging from released glycans, glycopeptides and intact proteins—provide complementary information on different layers of heterogeneity (e.g., micro and macroheterogeneity). Integration of these data enables comprehensive glycosylation profiling, facilitating a deeper understanding of co-occurring modifications and ensuring reliable assessment of glycosylation.

11:45 Analytics and Predictive Tools for Glycoengineering and Control of Glycosylation Profiles

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

Glycan profiles of therapeutic proteins are key molecular attributes that affect biological function and efficacy. The control of the profile during bioprocessing is difficult because of a multiplicity of factors that affect intracellular glycosylation. An alternative approach is to modify the glycan profile during downstream processing, after purification from the bioreactor. Alternative methods will be explored that include selecting specific glycoforms or enzymatically modifying the glycans on the protein.

synTQ by Optimal

12:15 Presentation to be Announced

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

ACCELERATING FORMULATION DEVELOPMENT

13:45 Chairperson's Remarks

Natalia Markova, PhD, Independent Consultant

13:50 Absolute and Relative LC-MS Quantification of HCPs for Investigation of Polysorbate Degradation

Jared Isaac, PhD, Director, Chromatography and Mass Spectrometry, Cygnus Technologies

Lipases are Host Cell Proteins (HCPs) that co-purify with biological drug substances (DS) and degrade excipients such as Polysorbates. LC-MS can identify and quantify Lipases which can guide process development to revise their purification to remove problematic HCPs. Absolute and Relative LC-MS quantification approaches will be compared with case studies focusing on Lipase quantification in DS samples.

14:20 Method Development for Biophysical Characterisation of Novel Modalities

Natalia Markova, PhD, Independent Consultant

The complexity of lipid nanoparticles (LNPs) for delivery of nucleic acids presents a developability challenge. Fit-for-purpose and complementary analytical tools are required to design successful formulations, and to inform robust production of stable, safe, and efficacious products. This talk will cover some case studies involving novel and repurposed biophysical techniques for mRNA and LNP characterisation with the emphasis on approaches with stability-indicating potential.

14:50 Pulmonary Delivery of Biologics: Challenges and Innovations

Devendra Ridhurkar, PhD, Founder and CEO, R&D, RidNova Pharmaceuticals

Pulmonary drug delivery (PDD) for biologics is an emerging focus in drug delivery research. By exploiting the lungs' large surface area, rich vascularization, and rapid absorption, it offers a promising route for peptides, proteins, and nucleic acids. Advances have deepened understanding of this therapy, yet key challenges persist: maintaining molecular stability during formulation and aerosolization, minimising immunogenicity, and creating effective systems to protect these sensitive molecules while ensuring bioavailability.

15:20 Sponsored Presentation *(Opportunity Available)*

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

Cambridge Healthtech Institute's 2nd Annual

10 - 11 MARCH 2026 ALL TIMES CET

Accelerating Analytical Development

New Technologies to Optimise the Speed and Efficiency of Biotherapeutic Development

PANEL DISCUSSION: UNLOCKING SMARTER BIOPROCESSING

16:30 PANEL DISCUSSION: Unlocking Smarter Bioprocessing through Better Data Collection, Quality, and Analysis
Moderator: Mark Duerkop, CEO, Novasign GmbH
Data is central to the future of bioprocessing, yet many organisations struggle with incomplete or inconsistent information that limits the training of next-generation AI/ML models. Without addressing these gaps, the promise of digitalisation remains out of reach. This panel will explore why data challenges persist and share strategies to transform raw information into actionable insight—unlocking smarter, faster, and more efficient bioprocessing to accelerate the industry's digital transformation.
Panelists:
Andrea Arsiccio, PhD, Senior Scientist & Team Lead, In Silico, Coriolis Pharma Research GmbH
Ayca Cetinkaya, PhD, Senior Scientist, AstraZeneca
Nicole Mather, DPhil, Life Sciences Lead & HLS Data and AI Lead, IBM Consulting UK & Ireland
Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

17:30 Welcome Reception in the Exhibit Hall with Poster Viewing

18:30 Close of Day

WEDNESDAY 11 MARCH

8:00 Registration Open and Morning Coffee

DIGITAL INTEGRATION IN ANALYTICAL DEVELOPMENT

8:25 Chairperson's Remarks
Andrea Arsiccio, PhD, Senior Scientist & Team Lead, In Silico, Coriolis Pharma Research GmbH

8:30 Automated Screening of Post-Translational Modifications Using LC-MSE and Customised Data Processing Tools
Joy Yoon, Scientist, Regeneron Pharmaceuticals
Post-translational modifications (PTMs) are critical for regulating protein function but challenging to analyse due to their complexity. This project aims to create an automated pipeline for high-throughput PTM screening, leveraging LC-MSE (a data-independent acquisition method), alongside customised data processing tools. The workflow automates the integration of spectral analysis, validation, and filtering of PTM fragments based on peptide attributes—ensuring accurate, reproducible results while reducing false-positive errors and minimising manual interpretation.

9:00 Antibody Glycan Quality Predicted from CHO Cell Culture Media Markers and Machine Learning
*Ian Walsh, PhD, Senior Staff Scientist, Bioprocessing Technology Institute (A*STAR), Singapore*
N-glycosylation strongly affects monoclonal antibody (mAb) quality and efficacy. We applied machine learning (ML) to predict N-glycan abundances in CHO cell fed-batch cultures under 12 media conditions. From mass spectrometry data, ML models reduced 167 peaks to 18 predictive features. Integrating simulated annealing enabled media design that improved titer while reducing mannosylation, illustrating how ML-guided monitoring and simulation can accelerate process optimisation in mAb biomanufacturing.

9:30 PAT and Digital Twins Enabled by Merging Advanced Process Analytics and Hybrid Modelling
Michael Sokolov, PhD, Lecturer, ETH Zurich; COO and Chairman, Datahow AG
Hybrid modelling and machine learning techniques are rapidly advancing in process development to optimise performance and accelerate timelines. These techniques primarily focus on offline, iterative modelling, unlike manufacturing applications that require real-time decision support. The presentation will showcase the application of hybrid modelling and transfer learning from the manufacturing perspective and how advanced analytical techniques like Raman and mass spectrometry can enhance knowledge and improve online process monitoring and control.

10:00 Sponsored Presentation *(Opportunity Available)*

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

SHAPING THE FUTURE OF BIOPROCESSING THROUGH BIOLOGY, DATA, AND AI

11:15 Chairperson's Remarks
Alois Jungbauer, PhD, Professor & Head, Biotechnology, Institute of Bioprocess Science and Engineering, BOKU University

11:20 PLENARY KEYNOTE PRESENTATION: Current Trends and Opportunities in Bioprocessing
Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering
This presentation explores how advances in biology are redefining bioprocessing to enable scalable, efficient, and reproducible manufacturing of emerging therapeutic modalities. By integrating synthetic biology, cell engineering, and data-driven design, the field can move beyond traditional methods toward biologically driven, industrialised platforms. The session highlights how biological innovation underpins the transformation of biomanufacturing for the next generation of complex biologics.

11:50 PLENARY KEYNOTE PRESENTATION: Are We There Yet? A Digital Maturity Model for Enabling Process Monitoring and Artificial Intelligence in Biologics Manufacturing
Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group
Digital transformation promises to revolutionise biopharmaceutical manufacturing, yet most organisations leverage a fraction of their process data, with the challenges paradoxically increasing with globalisation and digitisation. This talk presents a practical maturity model for effectively navigating bioprocess monitoring and AI implementation. Drawing on assessments of 25 products, the presentation examines how companies can transform data challenges into competitive advantages by ensuring critical data is made available and delivered effectively.

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

11 - 12 MARCH 2026 ALL TIMES CET

Biophysical Analysis and Developability

New Technologies and Strategies for Predicting and Characterising Biophysical Attributes

WEDNESDAY 11 MARCH

10:30 Registration Open

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12:20 Session Break

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

EMERGING METHODS FOR BIOPHYSICAL CHARACTERISATION

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

14:20 Next-Generation Prediction and Engineering of Protein Aggregation
Salvador Ventura, PhD, Full Professor, Biochemistry and Molecular Biology, Autonomous University of Barcelona
Protein aggregation hinders industrial protein production, downstream processing, and formulation. Aggrescan3D (A3D) became a widely used structure-based predictor to analyse and redesign aggregation-prone globular proteins. Here, we introduce Aggrescan4D (A4D), a major extension of A3D that integrates AI-driven structure prediction, disorder discrimination, pH-dependent aggregation modelling, and an evolutionarily informed automatic mutation protocol, providing a comprehensive platform for engineering protein solubility and enhancing bioprocessing outcomes.

14:50 A Semi-Automated Workflow for Screening Injectable Liquid Fixed-Dose Combination (FDC) Formulations of Large Synthetic Molecules
Dan Lundberg, PhD, Associate Principal Scientist, Pharmaceutical Sciences - Advanced Drug Delivery, AstraZeneca
Fixed-dose combination (FDC) products can offer benefits such as enhanced efficacy and improved patient compliance and convenience. However, optimising co-formulations presents a significant challenge. By introducing a semi-automated workflow for screening injectable FDC formulations of large synthetic molecules, including automated weighing, dispensing, and dilution of solutions, and pH measurement, we have markedly expanded the range of compositions that can be evaluated and substantially increased analytical throughput, accelerating formulation development.

15:20 KEYNOTE PRESENTATION: The Challenge of Protein Design and Consequences for Protein Assembly
Jennifer McManus, PhD, Associate Professor, Physics, University of Bristol, United Kingdom
Designing proteins for functional, therapeutic, or industrial applications presents unique challenges that directly influence their assembly and stability. This presentation will explore how structural considerations, sequence modifications, and biophysical constraints shape protein assembly pathways and stability. I will present recent work with examples of how rational protein design leads to assemblies with tuneable properties, with the ability to integrate functionality.

15:50 Sponsored Presentation *(Opportunity Available)*

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

MODELLING FOR BIOPHYSICAL PROPERTIES

17:00 Structural insights into Antibody-Antibody Interactions in Sandwich ELISA: Implications for Assay Development and Performance
Yue Su, PhD, Scientist, Regeneron
Optimising sandwich ELISA performance necessitates the selection of compatible mAb pairs as capture and detection antibodies. In this study, we investigated the antibody-antibody interactions that contribute to diminished signal and elevated background during therapeutic antibody detection in sandwich ELISA. We identified signal loss due to overlapping binding sites, and elevated background from cross-reactivity between antibodies. Additionally, interactions at distinct epitopes were found to induce varying steric hindrance, affecting oligomerisation.

17:30 *In silico* Models to Speed up and De-Risk Biologics Developability and Formulation Development
Andrea Arsiccio, PhD, Senior Scientist & Team Lead, In Silico, Coriolis Pharma Research GmbH
In silico computations play an increasing role in drug development, but platforms combining multiple models and comprehensively evaluating therapeutic proteins' developability are currently lacking. This presentation covers this gap, showing how different models, spanning structure prediction, bioinformatics, machine learning, and molecular dynamics, can be combined within an automated platform to speed-up and de-risk candidate selection, lead characterisation, and formulation development. Relevant case studies will be presented.

18:00 Interactive Breakout Discssion Groups
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,

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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

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

DEVELOPABILITY PREDICTION MODELS

8:25 Chairperson's Remarks

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

8:30 Ready or Not: Transforming Developability Assessment for What's Next

Paul Wassmann, PhD, Senior Principal Scientist, Biologics Research Center, Novartis

Developability Assessment (DAS) is vital in drug development, enabling early risk identification in lead candidates. With growing biotherapeutic diversity and advanced protein engineering, DAS must adapt case-by-case. Integrating automation, data management, and machine learning reduces this burden and opens new pathways for efficient assessment—key themes to be explored in the upcoming presentation.

9:00 FEATURED PRESENTATION: Combining Computational and Experimental Tools to Predict Self Interactions and Self-Association of Therapeutic Proteins

Christopher J. Roberts, PhD, Professor, Chemical & Biomolecular Engineering, University of Delaware

Aggregation of therapeutic proteins often involves multiple steps, and displays competing pathways for different proteins, particularly for multi-domain proteins. This presentation focuses on combined molecular modelling/experimental approaches to characterise and predict protein-protein self interactions for antibody-fusions and monoclonal antibodies at both low and high concentrations, and identifying key domains or regions of surface-exposed amino acids that are most promising to redevelop to improve net protein-protein interactions and solution behaviour.

9:30 Developability Assessment of Biologics and Formulation of Novel Molecules

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

Highly potent novel biologics require extensive characterisation and formulation approaches to optimise their stability. This presentation will highlight approaches taken in formulation development to optimise the stability of such molecules. Another unique challenge of highly potent molecules is their administration. We will present an approach that demonstrates effective dosing of these highly sensitive molecules.

10:00 Sponsored Presentation *(Opportunity Available)*

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

MASS SPECTROMETRY APPLICATIONS

11:10 Overcoming the Challenges of Biophysical Characterisation of IgG2

Emmanuel Nony, PhD, Director, R&D, Servier

We developed a native cation exchange chromatography-mass spectrometry (CEX-MS) method combined with F(ab')2 middle-up analysis to separate and characterise IgG2 disulfide isoforms A, A/B, and B. This approach, leveraging isotope envelope confidence scores, enables accurate structural elucidation of critical hinge region disulfide linkages in IgG2, as confirmed by optimised non-reduced peptide mapping.

11:40 Ultra-Fast Analysis of Product Quality Attributes by Cyclic Ion Mobility Mass Spectrometry

Camile Jenny, Researcher, Analytical Characterization, Novartis

Monitoring product quality attributes (PQAs) during biopharmaceutical development is essential to ensure safety, stability and efficacy. Liquid chromatography-mass spectrometry (LC-MS) offers unmatched specificity and sensitivity for PQA identification and quantification. However, reducing analysis time is a priority to enable high-throughput and rapid decision making. This talk will explore cyclic ion mobility-mass spectrometry (cIMS) potential as an ultrafast PQA monitoring method in complex mAb digests to inform bioprocess developers.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

PROBLEMS AND SOLUTIONS

13:25 Chairperson's Remarks

Mark O'Hanlon, Graduate Student, Chemical Engineering, University of Manchester

13:30 USP Standards and Resources to Support Cell and Gene Therapy Manufacturing and Analytical Quality Control

Diane McCarthy, PhD, Vice President, Global Biologics, US Pharmacopeia

The complexity of cell and gene therapies necessitates robust quality control throughout the product lifecycle, from raw and starting materials to final drug product. Stakeholders have identified a need for fit-for-purpose standards to support raw material qualification, impurity profiling, and assessment of critical quality attributes. This presentation will provide an overview of USP resources that can facilitate risk-based decision-making and robust characterisation strategies across upstream and downstream bioprocessing.

14:00 Reference Standard Management: Safeguarding the Quality of Biological Products

Yann Galais, PhD, CMC Consultant, Inits Consulting

Reference standards are essential for gene therapy QC, yet their implementation is often challenging due to high material costs, limited batch sizes, time constraints, and evolving product knowledge. A robust strategy is crucial to ensure proper identification, implementation, monitoring, and replacement of reference materials, safeguarding product quality and regulatory compliance.

14:30 A Biophysical Approach for Linking Protein Self-Association to Long-Term Aggregation Propensity

Mark O'Hanlon, Graduate Student, Chemical Engineering, University of Manchester

This study focuses on investigating the reversible self-association (RSA) of a bispecific therapeutic using a range of biophysical techniques, including SAXS, AUC, and dynamic and static light scattering. These methods provide detailed insight into the thermodynamic and hydrodynamic contributions underlying protein–protein interactions. By combining orthogonal scattering data with monomer loss studies, we establish a direct link between reversible self-association and aggregation propensity, demonstrating how RSA impacts long-term stability.

15:00 Close of Summit

Stream 7

AI AND DIGITALISATION

The AI 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.

10-11 MARCH 2026

Process Modelling and Digitalisation

VIEW PROGRAM »»

11-12 MARCH 2026

AI and Process Control

VIEW PROGRAM »»

Cambridge Healthtech Institute's 2nd Annual

10 - 11 MARCH 2026 ALL TIMES CET

Process Modelling and Digitalisation

Transforming Bioprocessing through Digital Innovation

TUESDAY 10 MARCH

7:00 Registration and Morning Coffee

DIGITAL PROCESS MODELLING

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

8:30 FEATURED PRESENTATION: USP Development and *in silico* Modelling
Ayca Cetinkaya, PhD, Senior Scientist, AstraZeneca
Biopharmaceutical manufacturing faces increased modality complexity and rising operational costs, requiring innovative bioprocess development strategies. Metabolic modelling provides in-depth system analysis, reducing experimental trial-and-error and saving time, materials, and resources. This talk presents real-world case studies where flux balance analysis optimises feed strategies, demonstrating how modelling informs supplement selection to improve productivity while supporting efficient decision-making in the development of advanced biologics.

9:00 Speed2Clinic: Continuously-Learning AI Model for Efficient and Accelerated Cell-Line Development for Monoclonal-Antibody Production
Stella Papadaki, Researcher, Cell Technologies, Roche
The identification of suitable cell lines for monoclonal antibody (mAb) manufacturing is a complex and resource-intensive process. We have developed an AI-driven approach using machine learning to accelerate clone selection. The model uses early-stage multi-omics data to predict late-stage cell line productivity, enabling early detection of high-producer cell lines. This shift to a model-centric process significantly reduces project timelines, accelerates mAb delivery, and fosters a data-driven culture in bioprocessing.

9:30 Presentation to be Announced

BECKMAN COULTER

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

10:45 End-to-End Bioprocessing with Digital Twins: Industrial Showcases from Batch to Fully-Continuous Modalities
Mark Duerkop, CEO, Novasign GmbH
Digital twins are transforming bioprocessing by accelerating development and enabling robust, automated control. This talk will present industrial case studies spanning monoclonal antibodies, viral vectors, and advanced therapies. Showcases will cover the transition from batch to continuous manufacturing. Emphasis will be placed on tailored modelling, experimental design, and real-time applications, demonstrating how digital twins enable end-to-end integration, seamless scale-up, and industrial implementation across multiple modalities.

11:15 KEYNOTE PRESENTATION: Innovations in Modelling Mammalian Cell Culture
Veronique Chotteau, Professor, Director, AdBIOPRO, Centre for Advanced Bioproduction by Continuous Processing, Industrial Biotechnology, KTH Royal Institute of Technology
Mammalian cell culture remains central to biologics production, yet optimising performance at scale requires predictive tools that capture complex cellular behaviors. This presentation explores recent innovations in modelling approaches, from data-driven methods to mechanistic and hybrid models, that enhance understanding of cell metabolism, growth, and productivity in bioprocess. By integrating experimental data with advanced simulations, these strategies accelerate process development, and support more efficient, robust upstream manufacturing of biologics.

11:45 Novel ML-Driven Sampling Strategies for Model-Based DoE in Bioprocesses
Sam Stricker, Researcher, Chemical Engineering, Imperial College London
Efficient experimentation is critical in bioprocess development, where time, cost, and complexity constrain traditional DoE. We introduce a model-based algorithm that leverages Pareto fronts and Bayesian optimisation to balance exploitation of high-performing regions with exploration of uncertain areas. This approach accelerates learning, reduces experimental burden, and scales effectively to high-dimensional design spaces, providing a robust and resource-efficient strategy for modern bioprocess optimisation that effectively explores trade-offs among performance and quality.

12:15 Presentation to be Announced by ATUM

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

AI AND DIGITALISATION IN ADVANCED THERAPIES

13:45 Chairperson's Remarks
Damian Marshall, PhD, Vice President, Analytical Development, Resolution Therapeutics

13:50 Digital Transformation of Advanced Therapies
Nicole Mather, DPhil, Life Sciences Lead & HLS Data and AI Lead, IBM Consulting UK & Ireland
Broadening access by driving down the cost of manufacture using predictive and adaptive digital systems including the use of AI and AI agentic management systems.

14:20 Digitalised Platforms for Driving Quality and Accelerating Cell-Therapy Development
Jahid Hasan, PhD, Lead, Technical, Cell and Gene Therapy Catapult
Cell therapies are at a critical juncture with patient demand outstripping current manufacturing capacity. To address this challenge, the Cell and Gene Therapy Catapult has developed cell therapy manufacturing platforms that offer step-changes in throughput for autologous and allogeneic products by integrating end-to-end automation and digitising data flow and decision-making.

14:50 Digital Shadows of CAR T Cell Expansion in Perfusion Bioreactors: Using Online Data to Predict Cell Concentration in Real Time
Joseph R. Egan, PhD, Research Associate, Teesside University; Honorary Senior Research Fellow, UCL
This presentation will show how digital shadows can be used to predict CAR T cell concentration based on online nutrient and metabolite data, including dissolved oxygen, glucose, and lactate concentrations. Such predictive modelling is designed to utilise the hard sensors that are already embedded in the bioreactor for process monitoring and control. As no additional process analytical technology is required, digital shadows provide a cost-effective soft sensor of cell concentration.

15:20 Sponsored Presentation *(Opportunity Available)*

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

Cambridge Healthtech Institute's 2nd Annual

10 - 11 MARCH 2026 ALL TIMES CET

Process Modelling and Digitalisation

Transforming Bioprocessing through Digital Innovation

PANEL DISCUSSION: UNLOCKING SMARTER BIOPROCESSING

16:30 PANEL DISCUSSION: Unlocking Smarter Bioprocessing through Better Data Collection, Quality, and Analysis

Moderator: Mark Duerkop, CEO, Novasign GmbH

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Jack Prior, PhD, Head, Process Monitoring & Data Science & AI Strategy, Sanofi Group

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18:30 Close of Day

WEDNESDAY 11 MARCH

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11:20 PLENARY KEYNOTE PRESENTATION: Current Trends and Opportunities in Bioprocessing

Konstantin B. Konstantinov, PhD, CTO, Ring Therapeutics, Flagship Pioneering

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12:20 Session Break

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

14:00 Close of Process Modelling and Digitalisation Conference

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11 - 12 MARCH 2026 ALL TIMES CET

AI and Process Control

Model-Informed Control for Smarter Bioprocessing

WEDNESDAY 11 MARCH

10:30 Registration Open

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DIGITALISATION, PROCESS MODELLING, AND ML/AI APPROACHES TO DSP

14:15 Chairperson's Remarks
Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich

14:20 Advancing Bioprocess Understanding through Real-Time Monitoring, Data-Driven Modelling, and Experimental Design
Theresa Scharl, PhD, Senior Scientist, BOKU University
Implementing model-based real-time monitoring in biopharmaceutical production represents a key advancement toward Quality by Design and provides the foundation for model-predictive control. Data-driven models are capable of making predictions for monoclonal antibody (mAb), double-stranded DNA, host cell protein, and high molecular weight impurity concentrations during elution from a Protein A chromatography capture step. Ensuring explainability of machine learning models and applying efficient experimental design are key to enhancing modern process control.

14:50 KEYNOTE PRESENTATION: The Autonomous Future of DSP: Self-Driving Labs, ML Integration, and Digital Twins
Matthias Franzreb, PhD, Department Leader, Bioengineering and Biosystems, Institute for Functional Interfaces, KIT
This talk presents a fully automated workflow for bioprocess development, starting with experiment planning in an ELN and ending with report generation. Key elements include ML-supported optimisation of bioprocess steps, integration of simulation tools such as mechanistic models and molecular dynamics, and strategies for linking digital tools into a unified, autonomous system that accelerates development cycles and enhances decision-making in DSP.

15:20 Electric Double-Layer–Informed Binding for IEX: Minimal Calibration, Robust Prediction
Sonja Berensmeier, PhD, Professor, Bioseparation Engineering Group, School of Engineering and Design, Technical University of Munich
We present a physics-grounded binding isotherm for ion-exchange chromatography derived from electrical double layer (EDL) theory. Incorporating nonlinear screening, ion valency, and crowding, the model achieves predictive elution from minimal calibration. Its parameters map directly to physical properties, enhancing interpretability over existing models. Calibrated on a single dataset, we validate predictions across gradients, step elutions, salt types, and load densities with model proteins, and highlight the effect of divalent ions.

15:50 Presentation to be Announced

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

MODELLING FOR BIOPHYSICAL PROPERTIES

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

18:00 Interactive Breakout Discssion Groups
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,

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AI and Process Control

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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

THURSDAY 12 MARCH

8:00 Registration Open and Morning Coffee

DEVELOPABILITY PREDICTION MODELS

8:25 Chairperson's Remarks

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

8:30 Ready or Not: Transforming Developability Assessment for What's Next

Paul Wassmann, PhD, Senior Principal Scientist, Biologics Research Center, Novartis

Developability Assessment (DAS) is vital in drug development, enabling early risk identification in lead candidates. With growing biotherapeutic diversity and advanced protein engineering, DAS must adapt case-by-case. Integrating automation, data management, and machine learning reduces this burden and opens new pathways for efficient assessment—key themes to be explored in the upcoming presentation.

9:00 FEATURED PRESENTATION: Combining Computational and Experimental Tools to Predict Self Interactions and Self-Association of Therapeutic Proteins

Christopher J. Roberts, PhD, Professor, Chemical & Biomolecular Engineering, University of Delaware

Aggregation of therapeutic proteins often involves multiple steps, and displays competing pathways for different proteins, particularly for multi-domain proteins. This presentation focuses on combined molecular modelling/experimental approaches to characterise and predict protein-protein self interactions for antibody-fusions and monoclonal antibodies at both low and high concentrations, and identifying key domains or regions of surface-exposed amino acids that are most promising to redevelop to improve net protein-protein interactions and solution behaviour.

9:30 Developability Assessment of Biologics and Formulation of Novel Molecules

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

Highly potent novel biologics require extensive characterisation and formulation approaches to optimise their stability. This presentation will highlight approaches taken in formulation development to optimise the stability of such molecules. Another unique challenge of highly potent molecules is their administration. We will present an approach that demonstrates effective dosing of these highly sensitive molecules.

10:00 Sponsored Presentation *(Opportunity Available)*

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

DIGITISATION IN CELL CULTURE AND CELL LINE DEVELOPMENT

11:10 Data-Driven Dynamic Control for Fed-Batch Upstream Bioprocess Operations

Duygu Dikicioglu, PhD, Associate Professor, Biochemical Engineering, University College London

Bioprocess control is complex due to evolving, non-linear cell population dynamics. This work proposes a novel data-driven control scheme for fed-batch upstream processes using graph theory to identify dynamic control parameters. Machine learning and optimisation algorithms use historical data to adaptively recalibrate control actions in real-time. This closed-loop, multi-attribute strategy addresses deviations and variability, outperforming static methods and ensuring cultures stay on a desired trajectory across diverse conditions.

11:40 Real-Time Prediction and Control of Cellular Behaviour in Microbial Upstream Processes

Julian Kager, PhD, Assistant Professor, Chemical and Biochemical Engineering, DTU

During the course of a bioprocess strain, physiology is likely to change. By natural selection, the performance of the cultivation can be positively affected—or more often—during the production of recombinant proteins the culture is degenerated and loses its metabolic capabilities. Under usage of models these changes can be foreseen and preventative control actions can occur to stabilise the cultivation.

12:10 Sponsored Presentation *(Opportunity Available)*

12:40 Networking Lunch in the Exhibit Hall with Last Chance for Poster Viewing

PROCESS MODELLING AND INTENSIFIED PROCESSING

13:25 Chairperson's Remarks

Maximilian Krippl, PhD, Head of Bioprocess Modeling Consulting, Novasign GmbH

13:30 Workflows and Models for Continuous Microbial Bioprocesses: From Process Development to End-to-End Control

Maximilian Krippl, PhD, Head of Bioprocess Modeling Consulting, Novasign GmbH

This talk presents recent advances in experimental workflows and modeling for continuous microbial bioprocesses. Building on last year's work, we extend the approach to multiple products using a two-stage bioreactor, inline lysis, membrane filtration, and multi-column chromatography. Demonstrating universality across two research projects, we show how modelling workflows accelerates development, reduces timelines, and enables seamless transition from process optimisation to autonomous process control.

14:00 Synthetic Spectral Libraries for Raman-Model Calibration

Vicent Borras, PhD, Bioprocess Technology Laboratory, University of Applied Sciences Northwestern Switzerland (FHNW)

Raman spectroscopy is a powerful tool in process analytical technology (PAT) for bioprocess monitoring. However, developing accurate models is slow and costly. We propose an innovative strategy, where pure spectral fingerprints of target analytes are *in silico* added to calibration datasets. This approach eliminates extensive physical experiments, accelerates workflow, and improves adaptability across diverse bioprocess conditions. The method has potential to significantly streamline PAT model development while maintaining predictive performance.

14:30 Intensifying Oncolytic-Virus Production: Perfusion-Based Manufacturing of VSV-NDV, HSV-1, and NDV

Lennart Jacobtorweihe, Researcher, Genzel Group, Max Planck Institute for Dynamics of Complex Tech Systems

This approach enables integrated clarification within the upstream process, eliminating a downstream unit operation and enhancing both viral titres and productivity. Building on this, we present our results on high-cell-density perfusion cultures (>20 × 10^6 cells/mL) of HEK293 and avian cell lines (EB66 and CCE. X10) for the production of three different oncolytic viruses: We discuss virus-specific challenges encountered during intensification and strategies to maximise productivity and product quality.

15:00 Close of Summit

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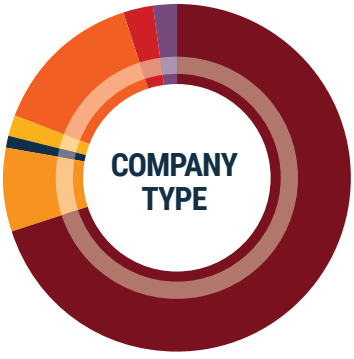

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