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Cambridge Healthtech Institute's 7th ANNUAL

BIOPROCESSING SUMMIT EUROPE

Practical Solutions for Today's Bioprocess Challenges

19 - 21 MARCH 2024
Intercontinental Barcelona
Spain & Online (CET)

CONFERENCE PROGRAMS TO OPTIMISE YOUR BIOPROCESSES

Stream 1 UPSTREAM
- Cell Culture & Bioproduction
- Cell Line Development

Stream 2 DOWNSTREAM
- Part 1: Recovery & Purification
- Part 2: Recovery & Purification

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

NEW! Stream 4 SMART, SUSTAINABLE MANUFACTURING
- Cell Culture and Bioproduction
- Intensified & Cont. Processing

Stream 5 CELL THERAPY
- Cell Therapy CMC & Manf.
- TS: Potency Assays

Stream 6 ANALYTICS & FORMULATION
- Analytics & Characterisation
- Formulation and Stability

NEW! Stream 7 ALTERNATIVE PROTEIN PRODUCTION
- Cultivated Meat
- Precision Fermentation

Training SEMINARS
- Potency Assays

2024 PLENARY KEYNOTES

What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD
Senior Vice President, Development, Alchemab Therapeutics

Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD
Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneratin Center Salzburg (SCI-TReCS), Paracelsus Medical University

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About Bioprocessing Summit Europe

Bioprocessing Summit Europe brings together 750+ upstream, downstream, bioproduction, analytical, and formulation professionals to advance the manufacture, quality and control of biological, genetic therapies, and new for 2024, alternative proteins such as cultured meat.

This 3-day, 12-track meeting has quickly become a premier meeting in the European bioprocessing calendar and is regarded by many as "the fastest growing bioprocessing meeting in Europe" following record growth in 2023—500 to 700+ attendees—including a sold-out Exhibit Hall of 65 Service Providers.

We look forward to seeing you in Barcelona on 19-21 March 2024, with expanded content on downstream processing, smart and sustainable bioproduction, cell and gene therapy, alternative proteins, and a vastly bigger Exhibit Hall.

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Training SEMINARS

By Cambridge Healthtech Institute

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

Training Seminars Will Be Offered In-Person Only

WEDNESDAY, 20 MARCH: 14:00–18:30
THURSDAY, 21 MARCH: 8:30–15:20

TS5B: Comparability and Potency Assays for Cell, Gene and Biotech Products

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

Comparability studies following process change is an inevitable part of drug development, but with wide ramifications for CMC and process development departments alike. Robust potency assays are fundamental also for comparability studies, process validation and for stability testing. CHI's 1.5 day Training Seminar, Comparability and Potency Assays for Cell, Gene Therapy and Biotech products provides an in-depth look at the application of regulatory science and biological standardization to biological products; what is potency, and how potency assays differ between biotech and cell and gene therapy products; plus principles of comparability and how their application differs between biotech, cell and gene therapy products.

Christopher Bravery founded Consulting on Advanced Biologicals Ltd at the end of 2009 in order to focus his activities within the Regenerative Medicine sector. Advbiols Ltd provides EU regulatory services to the regenerative medicine industry in addition to business and regulatory research and analysis to identify and focus on the real barriers to commercialisation of regenerative medicine. Christopher has a PhD in xenotranplantation immunology and spent 8 years in biotech (Imutran Ltd, A Novartis Pharma AG Co. and Intercytex) before joining the MHRA as a quality (CMC) assessor (biologicals and biotechnology unit). During this time Christopher was involved with National implementation of the new Advanced Therapies Regulation and also involved through his participation in the CHMP's cell products working party (CPWP) in implementation at the EMA level including drafting guidelines.

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

Nic Preyat, PhD, UCB Pharma

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PLENARY KEYNOTES

BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) from mesenchymal stromal cells (MSC) exert anti-inflammatory, anti-fibrotic and regenerative effects. MSC-EV-Tx could optimise healing after acute traumatic injury. Challenges in reproducible EV-Tx manufacturing prevent comprehensive evaluation of their efficacy. In early research, the paradigm of "the-process-is-the-product" is valid for complex biologicals. A "one-size-fits-all" approach to solve technical and regulatory issues is not available for EV-Tx. The claimed disease-related mechanisms of action (MoA) of candidate EV-Tx will determine regulatory requirements to be met. This presentation will introduce concepts to accelerate EV-Tx testing in various target diseases.

Biographies

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Dr. Varley is an expert in biopharmaceutical development with more than 30 years' experience developing antibodies, proteins, and other macromolecules into drugs from research into the clinic and through to commercialization. Paul is currently Senior Vice President, Development, at Alchemab Therapeutics. Previously Paul held similar roles in Cambridge Antibody Technology, Astra Zeneca, MedImmune, and Kymab. Previously Paul had also worked at British Biotech, the UK National Institute of Biological Standards and Control (NIBSC), and the U.S. National Institutes of Health. Dr. Varley holds a degree in Biomolecular Sciences (First Class) from Portsmouth Polytechnic and a PhD in Biochemistry from the University of Newcastle upon Tyne. Paul was until recently a member of the British Pharmacopeia (BP) Commission and Chair of BP Expert Advisory Group on Biological and Biotechnological Products (2013 – 2022). He also currently chairs a MHRA/BP working party on new standards for Biological Medicines (DPS) and is also a member of the European Pharmacopeia (EP) Expert Committee on Monoclonal Antibodies.

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Eva Rohde, MD, is Head of the Clinical Department of Transfusion Medicine at the University Hospital Salzburg, Austria, and Director of the first academic pharmaceutical manufacturing unit for stem cell- and extracellular vesicle-based therapeutics in Europe. Her research at the Paracelsus Medical University (PMU) in Salzburg focuses on the clinical application of stem cell-based therapies with a special emphasis on their extracellular vesicles (EVs). The overarching goal is to develop novel cell-free therapies in conjunction with scientifically solid application-oriented analytical technologies. Eva Rohde actively participates in a global network of academic and industrial partners with the goal of the clinical development of EV-based therapies in diseases with a high unmet need. Eva Rohde chairs the global "Task Force on Regulatory Affairs and Clinical Use of EV-based Therapeutics" of the International Society for Extracellular Vesicles (ISEV) and is a member of the ISCT Exosome Committee.

TRACK KEYNOTE AND FEATURED SPEAKERS

STREAM 1: UPSTREAM

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

David C. James, PhD, *Professor, Bioprocess Engineering, University of Sheffield*

Martina Micheletti, PhD, *Professor, Bioprocess Fluid Dynamics, University College London*

STREAM 2: DOWNSTREAM

Cecile Brocard, PhD, *Director Downstream Development, Bioprocess Science, Boehringer Ingelheim RCV GmbH & Co. KG*

Andreas H. Laustsen, PhD, *Center Director & Professor, Center for Antibody Technologies, DTU Bioengineering, Technical University of Denmark*

Birgit Wiltschi, PhD, *Head of Synthetic Biology Group, ACIB GmbH & University of Natural Resources and Life Sciences, Vienna*

STREAM 3: GENE THERAPY

Markus Haindl, PhD, *Global Head, Gene Therapy Technical Development, Roche Diagnostics GmbH*

Jonathan Bones, PhD, *Principal Investigator, Characterisation and Comparability Laboratory, National Institute for Bioprocessing Research and Training (NIBRT), Ireland*

Parameswari Govindarajan, PhD, *Senior Scientist, Process Development, CSL Behring GmbH*

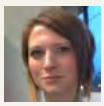
STREAM 4: SMART, SUSTAINABLE MANUFACTURING

Sandra Krause, *Lab Engineer, Biodevelopment Microbial Platform, Sanofi*

Antonio G. Cardillo, PhD, *Scientific Lead Associate Director, TRD-DS Global Innovation Centre, GSK Vaccines*

STREAM 5: CELL THERAPY

Ali Mohamed, PhD, *Vice President, CMC, Immatics US, Inc.*



Sarah Snykers, PhD, *Director of Operations, Legend Biotech*

STREAM 6: ANALYTICS AND FORMULATION

Thomas Waerner, PhD, *Senior Principal Scientist & Laboratory Director, Analytical Development & Quality Control, Boehringer Ingelheim Pharma GmbH & Co. KG*

Ricardo Gomes, PhD, *Senior Researcher, Mass Spectrometry Unit, iBET—Instituto de Biologia Experimental e Tecnológica*

Stefan Braun, *Head of Laboratory, Liquid Formulation R&D, Merck*

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

STREAM 7: ALTERNATIVE PROTEIN PRODUCTION

Petra Hanga, PhD, *Lecturer, Biochemical Engineering and Cellular Agriculture, University College London*

Joachim Schulze, PhD, *CTO, Planetary Group*

Seren Kell, *Senior Science and Technology Manager, The Good Food Institute Europe*

John Morrissey, PhD, *Professor, Microbiology, University College Cork*

CONFERENCE-AT-A-GLANCE

	TUES, 19 MARCH & WED AM, 20 MARCH	WED PM, 20 MARCH & THURS, 21 MARCH
Stream 1 **UPSTREAM**	Cell Culture & Bioproduction	Cell Line Development
Stream 2 **DOWNSTREAM**	Part 1: Recovery & Purification	Part 2: Recovery & Purification
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NEW! Stream 4 **SMART, SUSTAINABLE MANUFACTURING**	Cell Culture and Bioproduction	Intensified & Continuous Processing
Stream 5 **CELL THERAPY**	Cell Therapy CMC & Manufacturing	TS: Potency Assays
Stream 6 **ANALYTICS & FORMULATION**	Analytics & Characterisation	Formulation and Stability
NEW! Stream 7 **ALTERNATIVE PROTEIN PRODUCTION**	Cultivated Meat	Precision Fermentation
Training SEMINARS		Potency Assays

"One of the best events in Bioprocessing!"

Sebastian Thuermann, Tosoh Bioscience Deutschland GmbH

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

Zorica Dragic, Novartis

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

Florence Salmon, PhD, Ridgeline Discovery

19-20 MARCH

Cell Culture and Bioproduction

VIEW PROGRAM

20-21 MARCH

Cell Line Development

VIEW PROGRAM

Stream 1

UPSTREAM

The popular Upstream Processing pipeline at Bioprocessing Summit Europe offers a forum for those working in the disciplines of cell line development, cell engineering, and cell culture to learn the latest scientific updates and hear best practices from leading industry and academic scientists. For 2024, presentations will explore emerging technologies, solutions, upstream processing for new biotherapeutic modalities, and the increasingly important roles of computational modelling, AI, and machine learning.

Cambridge Healthtech Institute's 7th Annual

19 - 20 MARCH 2024 ALL TIMES CET

Cell Culture and Bioproduction

Emerging Technologies, Improved Process Control, and New Opportunities

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

EMERGING AND SUSTAINABLE BIOREACTOR TECHNOLOGIES

8:25 Chairperson's Remarks

Stephan Noack, PhD, Group Leader, Quantitative Microbial Phenotyping, Forschungszentrum Jülich

8:30 FEATURED PRESENTATION: Novel Scale-Down Tools for Perfusion Optimisation in Biopharmaceutical Production

Martina Micheletti, PhD, Professor, Bioprocess Fluid Dynamics, University College London

The complexity of perfusion processes requires the optimisation of multiple parameters as well as the selection of suitable production cell clones. Two scale-down methods have been developed and will be presented in this work: a first microwell-based method operates in semi-perfusion mode with exploration of different medium exchange regimes with and without cell bleed, while a 250mL bioreactor system is able to perform perfusion runs of selected clones.

9:00 Industrialisation of IPSC-Derived Allogenic Cell Therapies Using a Scalable Automated Process for Expansion and Differentiation

Juline Guenat, Associate Lead Scientist, Technology & Process Innovation, Cell & Gene Therapy Catapult

Pluripotent stem cell therapies need high cell doses exceeding traditional 2D capabilities. We present a closed, scalable, semi-automated process to expand pluripotent stem cells as high-density aggregates in stirred tank reactors. It achieves a 22-fold expansion over four days while retaining pluripotency markers. Acoustic perfusion enables automated medium exchange with improved control over aggregate quality. Harvested aggregates were differentiated to natural killer cells in 3D.

9:30 Leap-In Transposase Mediated Stable Cell Line Development: More, Better, Faster

Claes Gustafsson, PhD, Chief Commercial Officer & Co-Founder, ATUM

Monoclonal antibodies in their many divergent formats have revolutionized medicine and today represents >$100B/year in pharmaceutical sales. ATUM has built an integrated pipeline from generation of antigens via affinity maturation, developability, engineering and humanization all the way through scale up and stable cell line generation. The presentation will include case studies highlighting technological breakthroughs in synthetic biology, machine learning, LIMS data integration, robotics and engineered transposases to ensure maximum efficiency.

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

TECHNOFLEX

10:45 Advances in Small-Scale Automation and Robotisation

Stephan Noack, PhD, Group Leader, Quantitative Microbial Phenotyping, Forschungszentrum Jülich

Laboratory automation in biotechnology has made significant progress in recent years, revolutionising the way experiments and research are conducted. The automation of entire workflows from strain engineering to bioprocess optimisation is currently the focus of attention in industry and academia, and various biofoundries are emerging around the world. I will introduce the Jülich Biofoundry and discuss challenges and solutions in the field of automated microbial bioprocess development.

11:15 Upstream Modelling Toolbox for Monoclonal Antibody (mAb) Process Development

Sabine Arnold, PhD, Senior Scientist, Upstream Process Development, Boehringer Ingelheim Pharma GmbH

Mammalian cell-based mAb production is a complex process involving many factors that determine process performance and product quality. To leverage model-based decisions in development, we have established a versatile modelling toolbox with fit-for-purpose models addressing different aspects of the overall process. We will show selected applications of mechanistic, hybrid and machine learning models, and how these digital approaches can help improving the efficiency and timelines in robust process development.

11:45 KEYNOTE PRESENTATION: Revolutionising Bioprocess Innovation: Unleashing the Power of KIWI-Biolab's Robotic Ecosystem by Orchestration of Model-Based DoEs, Fast in-Depth Analytics for Recombinant Protein Processes

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

The KIWI-biolab enables efficient recombinant bioprocess development and optimisation on a robotic platform with fully automatic orchestration of parallel bioreactor systems of different scales, analytical instruments, and a mobile laboratory robot. Based on FAIR data principles it allows self-controlled parallel fed-batch cultivations, integrated sample analysis, and mathematical model-based parameter calibration and CQA optimisation. The power of the platform is demonstrated by industrially relevant recombinant processes including Fabs, elastins, and hydrogenase.

12:15 In-Line Monitoring of Bioprocess Parameters for the 21st Century

908devices

Christopher D. Brown, PhD., Chief Product Officer and Co-founder, 908 Devices

In this presentation, we will review the current state of spectroscopy-based approaches and their associated strengths and limitations. We'll discuss a few use cases showing the use of an innovative platform designed to greatly simplify implementation and interpretation of in-line process parameter data during typical bioprocess runs.

12:45 Networking Lunch *(Sponsorship Opportunity Available)*

COMPUTATIONAL MODELLING AND ML/AI IN UPSTREAM PROCESSING

13:45 Chairperson's Remarks

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

13:50 PAT-Based VCD Soft Sensor Facilitates Model-Based Process Monitoring, Automation, and Control

Benjamin Bayer, PhD, Scientist CMC, Biotherapeutics Technology Development & Implementation, Takeda

The integration of a PAT-based viable cell density (VCD) soft sensor facilitates model-based process monitoring, automation, and control within the biopharmaceutical industry. This technology harnesses real-time data to estimate VCD, enabling biopharmaceutical manufacturers to make informed decisions, e.g., proceeding to the next process step or controlling the feed flow. It enhances product consistency and reduces costs, underscoring the vital role of data-driven strategies in advancing production of pharmaceuticals and biologics.

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Cell Culture and Bioproduction

Emerging Technologies, Improved Process Control, and New Opportunities

14:20 Understanding CHO Cell Biology at Single-Cell Resolution

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

Overcoming the inherent heterogeneity of cells grown *in vitro* is essential to deliver effective, uniform, and safe biological medicines. This talk will focus on the application of single-cell omics to understand the CHO cell biological system, and how the technology can be used to understand the emergence of phenotypic instability. We will provide examples of studies of DNA, RNA, as well as at the protein level.

14:50 Accelerated Process Development and Automated Process Control: Resolving Both by an Appropriate Modelling Approach

Mark Duerkop, CEO, Novasign GmbH

The use of modelling tools for bioprocess development and manufacturing has gained significant attention. But what does it take to create digital bioprocess-twins? Is it only about advanced algorithms, or do we need more to accurately represent and transfer knowledge from development to manufacturing? Key discussion points include the purpose of process modelling, experimental design, tailored modelling approaches, accelerated development, seamless scale-up, and real-time model use for monitoring and control.

15:20 Designing a Next-Generation Bioreactor Platform for Enhanced Biopharmaceutical Development

Andreas Castan, PhD, Strategic Technology Leader, Upstream R&D, R&D, Cytiva

The biopharmaceutical industry grapples with cost pressures and the emergence of new product classes, necessitating innovation in process and equipment design. This presentation unveils the development of a novel bioreactor platform integrating cutting-edge CFD models, enabling process intensification as well as accommodating diverse modalities. It is emphasizing performance, scalability and modularity and a seamless transition from batch to intensified processes, ensuring accelerated timelines

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

UPSTREAM PROCESS CHARACTERISATION AND CONTROL

16:20 End-to-End Digital Twins to Allow Efficient Experimental Design and Real-Time Release

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

Acceleration of commercialisation of biologics, including the filing of a robust control strategy, is of utmost importance for biosimilars up to new modalities. Digital twins capture CMC knowledge and allow multiple deployments. We will show how end-to-end digital twins can help save 50% of experimental effort by incorporating drug substance specification when designing unit operations and how real-time application allows for prediction and control of process performance for real-time release.

16:50 Next-Generation Process Analytics for Upstream Processing

Jeremy Peyrol, USP Innovation Expert, Innovation for Biologics, Merck Biodevelopment SAS

Raman spectroscopy plays an important role in bioprocessing by providing *in situ* measurements and enabling real-time process control. In this study, we demonstrate the use of Raman spectroscopy as a key solution for inline and real-time monitoring of CPPs and CQAs along the upstream space from cell culture media preparation to cell culture expansion.

17:20 Real-Time Model Predictive Control of Industrial Bioprocesses: Challenges and Solutions

Nadav Bar, PhD, Professor, Chemical Engineering, Norwegian University of Science and Technology

In industrial bioprocess control, conventional PI controllers are limited in handling complex interactions among variables. Model Predictive Control (MPC) offers a versatile multi-input, multi-output framework, addressing multiple factors and constraints simultaneously. Challenges include model development, computational demands, human skills and expertise, and real-time implementation. We'll showcase MPC's practical efficacy in case studies across batch, fed-batch, and continuous processes, highlighting its advantages.

INTERACTIVE BREAKOUT DISCUSSIONS

17:50 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: Digital Bioprocessing and Industry 4.0: How Far Along Are We?

Mark Duerkop, CEO, Novasign GmbH

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

PROBLEMS AND SOLUTIONS

8:25 Chairperson's Remarks

Mark Duerkop, CEO, Novasign GmbH

8:30 Towards Continuous Bioproduction—Integration of Microfluidic Systems into Small-Scale Bioreactors

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

Monoclonal antibodies are increasingly dominating the market for therapeutic agents. For this reason, continuous methods—such as perfusion processes—are constantly being explored to increase product yields. We demonstrate a 3D-printed microfluidic spiral separator for cell retention integrated in a small-scale bioreactor. This device achieves a separation efficiency of up to 100% and can readily be adapted according to process conditions due to its flexible fabrication process.

9:00 Environmental Assessment of Single-Use Technology in Pharmaceutical Production

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

Single-use technologies are well established in biopharma production. In this context, the question arises to what extent sustainability aspects play a role in the choice between reusable and disposable equipment. How can model processes and procedures be established in order to be able to carry

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Cell Culture and Bioproduction

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out meaningful comparative studies and provide standardisable decision-making tools in an open access format? What exists and what still needs to be achieved?

9:30 Optimise Upstream Intensification to Achieve More Sustainable Processes

Anne Steinkämper, PhD, Scientist, Development Biologicals, Boehringer Ingelheim Pharma GmbH & Co. KG

Bioprocessing has made significant progress in the last decades, with advancements in cell-line engineering, media platforms, and process control. Delivering product with an increased space-time-yield, intensified processes seem to replace classical cell culture fed-batch processes step-by-step. Still, it is worth to discuss at which point even the combined use of process intensification and good producer cell lines has its limitations.

10:00 Future-Proofing Bioprocessing: Building Resilience with AI-Powered Digital Process Twins

Belma Alispahic, Head of Business Development, AnalysisMode

Imagine a bioprocessing future where development is faster, quality is assured, and robust reigns supreme. This future is closer than you think, thanks to the transformative power of AI-powered digital process twins that optimizes production processes, unlocking a new era of:

• Effective R&D: Virtual experiments translate to lightning-fast development and reduced costs, and

• Unwavering Quality: Consistent, superior biologics pave the way for safer, more effective treatments.

10:15 Presentation to be Announced

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

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

11:20 PLENARY PRESENTATION: What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

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Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Novel Approaches in an Efficient Affinity Chromatography Strategy for Your Antibody Variants & Recombinant Proteins

Helen Cheek, Global Product Manager, Marketing, Cytiva

Antibodies are the largest class of biotherapeutics today and are likely to remain so in the future. As this class grows, so does its diversity - projects in preclinical stages through to commercial manufacturing increasingly involve variants such as bispecifics, conjugates, or fragments.

Platform approaches have eased the development of purification protocols but selecting purification schemes can be challenging for antibody variants given the wide range in the pipeline

13:05 Networking Lunch *(Sponsorship Opportunity Available)*

14:05 Close of Cell Culture and Bioproduction Conference

Cambridge Healthtech Institute's 6th Annual

20 - 21 MARCH 2024 ALL TIMES CET

Cell Line Development

New Technologies, Big Data Solutions, and Best Practices for Engineering Robust Cell Lines

WEDNESDAY 20 MARCH

10:30 Registration Open

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

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11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

CELL ENGINEERING

14:15 Chairperson's Remarks

Emanuel Kreidl, PhD, Senior Expert, Science & Technology, Technical Research & Development, Novartis Pharmaceutical Manufacturing GmbH

14:20 FEATURED PRESENTATION: CHO Synthetic Promoters Improve Expression and Product Quality of Biotherapeutic Proteins

Susie Sou, PhD, Associate Principal Scientist, Cell Line Development and Engineering, AstraZeneca

Strong viral promoters commonly used for recombinant biotherapeutics production in mammalian cells enable maximal expression but provide limited scope to alter their transcription dynamics. In contrast, synthetic promoters designed to provide tunable transcriptional activity can aid more precise regulation for product quality, yield, or reduction of product related-contaminants. Here, we highlight the advantages of employing synthetic promoters with different transcriptional activities for improved production of more complex recombinant proteins.

14:50 Mid-Stage Re-Engineering of Cell Line to Eliminate Problematic HCP

Emanuel Kreidl, PhD, Senior Expert, Science & Technology, Technical Research & Development, Novartis Pharmaceutical Manufacturing GmbH

Despite the definition of critical quality attributes early in the development process having long been the standard in the industry, the sudden identification of novel risk factors can lead to a need for major redevelopment at mid- or even late-stage process development. We show how the redevelopment of a production cell line to remove an HCP can result in suddenly having to focus on completely different attributes.

15:20 RNA Modifications to Improve Biologics Production

Niall Barron, PhD, Principal Investigator, National Institute for Bioprocessing Research & Training (NIBRT)

Epigenetic modifications to the nucleotides in RNA species have been generating considerable interest in recent years. The role of methylation in particular, including characterising the proteins that add (writers), remove (erasers), and interpret (readers) this epigenetic mark, will be discussed. This talk will consider the potential of targeted methylation as an enhancer of mRNA translation and how this mechanism might be applied to improving biologics production.

15:50 Talk Title to be Announced

CYTENA A BICO COMPANY

Jolanda Scheenhart, Sales Manager Europe, CYTENA GmbH

16:05 Presentation to be Announced

IDBS

16:35 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Cell Line Engineering for the Characterisation of Macromolecular Complexes Expressed in Physiological Conditions

Arnaud Poterszman, PhD, Research Director, Integrated Structural Biology, IGBMC

Macromolecular complexes are cornerstones of most, if not all, biological processes in cells. We will illustrate how the CRISPR/Cas9 editing technology can be used for gene tagging in order to introduce affinity tags and facilitate the purification of proteins/macromolecular assemblies expressed in physiological conditions. We will also discuss tagging proteins with fluorescent reporters in view of imaging and functional proteomics applications.

Cambridge Healthtech Institute's 6th Annual

20 - 21 MARCH 2024 ALL TIMES CET

Cell Line Development

New Technologies, Big Data Solutions, and Best Practices for Engineering Robust Cell Lines

17:30 KEYNOTE PRESENTATION: Synthetic Biology for Tailored Genetic Vectors

David C. James, PhD, Professor, Bioprocess Engineering, University of Sheffield

Synthetic biology offers a new paradigm for genetic vector design, enabling product-specific cell engineering based on combinatorial tuning of primary cellular synthetic processes such as transcription, translation, and translocation. Our engineering design system utilises a unique platform of genome-scale mining and informatic tools to generate libraries of synthetic parts with user-defined functionality and that can boost biologic manufacturability, replacing "one-size-fits-all" vectorology with design of context-specific genetic systems.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: The Role and Future of Cell Line Engineering for Product Quality Optimization

Emanuel Kreidl, PhD, Senior Expert, Science & Technology, Technical Research & Development, Novartis Pharmaceutical Manufacturing GmbH

18:30 Close of Day

THURSDAY 21 MARCH

8:00 Registration and Morning Coffee

EMERGING TECHNOLOGIES

8:25 Chairperson's Remarks

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

8:30 Next-Generation Cell Line Selection Methodology Leveraging Data Lakes, Natural Language Generation, and Advanced Data Analytics

Stephen Goldrick, PhD, Lecturer, Digital Bioprocess Engineering, University College London

We present *CLD4*, a four-step method for autonomous lead clone selection for biopharmaceutical processes. Step 1 digitises and stores data in a structured data lake. Step 2 calculates the cell line manufacturability index (*MICL*). Step 3 deploys machine learning for process understanding. Step 4 uses NLG to generate automated reports. *CLD4* revealed hidden issues in a CHO cell line, showcasing the power of industry 4.0 principles for informed decision-making.

9:00 Baculovirus-Free Production of Proteins and Virus-Like Particles in Insect Cells

Nina Lehmler, Researcher, Biotechnology, TU Braunschweig

Insect cells are a high-yield and low-cost expression system with mammalian-like post-translational modifications. In contrast to the commonly used baculovirus expression vector system (BEVS), the plasmid-based system enables faster production in high yield and quality, especially of secreted proteins and Virus-Like Particles (VLP). We here present the production of different proteins as well as of Hanta, influenza, entero-, and noro-VLPs, and their applications for antibody development.

9:30 High-Throughput Screening for Product Quality Attributes Early during Mammalian Process Development

Chi-Ting Ho, PhD, Process Expert, Development Operation, Boehringer Ingelheim Pharma GmbH & Co. KG

Cell-line development typically starts with pool generation, and is followed by single-cell cloning, starting with thousands or hundreds of clones and several rounds of ranking and selection, until the final clone can be nominated. Selection and ranking is usually based on cell growth, productivity, monoclonality, stability, and product quality attributes. The latter is gaining more and more importance—highlighting the need to look at product quality attributes as early as possible.

10:00 Talk Title to be Announced

Maja Lieven, Dr, Head of Protein Solutions, Protein Solutions, LenioBio

LenioBio

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

11:00 Protein Engineering and Production Platform Based on Cell-Free Technologies

Takanori Kigawa, PhD, Senior Scientist, RIKEN Center for Biosystems Dynamics Research

Protein production using recombinant DNA technology is time-consuming and labor-intensive. We have established a protein production platform based on the cell-free technologies that can produce milligram quantities of proteins totally without the use of recombinant DNA technology. By using this platform, time-consuming and labor-intensive protein expression/purification processes are dramatically accelerated, especially when combined with automated equipment. This platform is therefore very useful for upstream processing.

11:30 Industrial Use of *Drosophila* S2 Cells for Production of Highly Immunogenic Antigens

Max Søgaard, PhD, Senior Vice President, R&D and Technology, ExpreS2ion Biotechnologies

Viral vaccine antigens produced in mammalian cells often hide from the immune system using glycan shields. S2 cell-produced antigens can reduce glycan shielding due to paucimannosidic glycosylation. Conversely, glyco-engineering S2 cells enhances vaccine effectiveness. Suitable for large-scale production, S2-produced antigens have reached Phase III clinical trials. Utilizing image-based confirmation of monoclonality and micro-scale cultivation accelerates monoclonal S2 cell-line generation, improving efficiency and throughput in cell-line development.

Cambridge Healthtech Institute's 6th Annual

20 - 21 MARCH 2024 ALL TIMES CET

Cell Line Development

New Technologies, Big Data Solutions, and Best Practices for Engineering Robust Cell Lines

12:00 Exploring Gene Regulatory Networks of IgG Glycosylation Using CRISPR/dCas9 Technology

Anika Mijakovac, PhD, Researcher, University of Zagreb

Immunoglobulin G (IgG) glycans regulate inflammation and as such participate in both disease and aging. To unravel the unknown mechanisms responsible for changes in IgG glycome composition, we utilize a dual approach: large-scale genome-wide association studies (GWAS) to identify genes that associate with IgG glycosylation, and CRISPR/dCas9-based *in vitro* systems for gene validation. We have discovered that the regulatory networks of IgG glycosylation extend far beyond the known glycosylation-related genes.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch *(Sponsorship Opportunity Available)*

CLD FOR CELL AND GENE THERAPIES

13:45 Chairperson's Remarks

Chrysanthi Sitmalidou, Scientist II, Cell & Gene Therapy Technologies, Technical Operations & Global Technical Development, Orchard Therapeutics

13:50 Advancing Complex Modalities from Genes to Therapies—Impact of Optimized Cell Line Development

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

14:20 Establishing a Cell-Line Development Platform for Improved GMP LVV Manufacturing in Cell and Gene Therapies

Chrysanthi Sitmalidou, Scientist II, Cell & Gene Therapy Technologies, Technical Operations & Global Technical Development, Orchard Therapeutics

Stable cell lines are widely considered to be the stepping stone to simplify manufacturing processes and further increase yields. In this presentation you will be given an overview of the importance of lentiviral vectors for cell and gene therapy and presentation of Orchard's stable cell-line development platform. Details on steps to an optimised CLD workflow and an overview of GMP requirements when manufacturing LVV with stable cell lines.

14:50 Towards a Scalable Bioprocess for rAAV Production Using a HeLa Stable Cell Line

Jose Escandell, PhD, Senior Scientist, Animal Cell Technology Unit, iBET

In this presentation we will discuss key aspects related to rAAV production systems' scalability plus current challenges and potential directions for product characterisation. Our presentation focus lies in improving the scalable HeLaS3-based production system. Efforts involve optimising the cell line generation process and improving the cell host; relevant genes for rAAV production, identified through CRISPR-Cas9 genetic screens, will be engineered to create a cell host with enhanced production capabilities.

15:20 Close of Summit

19-20 MARCH

Advances in Recovery and Purification — Part 1

VIEW PROGRAM »»

20-21 MARCH

Advances in Recovery and Purification — Part 2

VIEW PROGRAM »»

Stream 2

DOWNSTREAM

The Downstream Processing Stream brings together industry and academia to discuss the latest developments in the capture, recovery, and purification of biotherapeutics—mAb and non-mAb—with data-driven case studies on next-generation technologies and strategies in affinity chromatography, clarification, depth filtration, automation, HTPD, new membranes, and flocculation. Part 1 will focus on the use of DSP in more traditional modalities such as antibodies, fragments, bispecifics, and ADCs. Part 2 will focus more on viral vectors, mRNA, and VLPs—plus digitalisation, process modelling, continuous downstream processing, and sustainability.

Cambridge Healthtech Institute's 7th Annual

19 - 20 MARCH 2024 ALL TIMES CET

Advances in Recovery and Purification — Part 1 Optimizing DSP, Reducing Costs

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

ADVANCES IN CAPTURE AND RECOVERY

8:25 Chairperson's Opening Remarks

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

8:30 Design and Discovery of Affinity and Mixed-Mode Adsorbents

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

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

9:00 Engineering Calcium-Dependent Affinity Proteins for Protein Purification: From Design to Continuous Processing

Sophia Hober, PhD, Professor, School of Biotechnology, KTH Royal Institute of Technology

Strategies to address the harsh conditions often required for efficient affinity chromatography purification will be presented. Novel domains with calcium-dependent affinity, developed through a semi-rational design combined with directed evolution, will be described. Further, insight on the molecular mechanism underlying the calcium switch, investigated by analysing protein structure and dynamics with NMR spectroscopy will be shared.

9:30 Continuous Manufacturing Lifecycle Management An Agile Risk and Data-Driven Framework VALGENESIS

Rui Almeida, Director, Product Lifecycle Management Services, ValGenesis

This talk presents a digital loop leveraging ICH Q9(R1) and ICH Q13 regulatory packages, integrating process data acquisition (via CPV plan) and QRM systems, applied in the context of Continuous Manufacturing. This retrofitting digital loop enables companies to refine process control strategies supported by process insights and data, then incorporate them into a pre-defined formal structure, helping to build organizations with an agile data/knowledge-centric approach to risk management.

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

ADVANCES IN DOWNSTREAM PROCESSING. PROCESS OPTIMIZATION

10:45 FEATURED PRESENTATION: Manufacturing Strategy for Recombinant Proteins Expressed in Microbials

Cecile Brocard, PhD, Director Downstream Development, Bioprocess Science, Boehringer Ingelheim RCV GmbH & Co. KG

This talk will focus on the development of downstream processes for recombinant proteins expressed in microbial systems such as *E. coli*. We will cover automation, parallelization, and integrated process modelling for non-mAb biopharmaceuticals, emphasising their role in efficiency and optimisation. The presentation will underscore Boehringer Ingelheim RCV's commitment to advanced technologies and AI-assisted strategies in delivering innovative bioprocess solutions targeted at streamlining the biopharmaceutical industry.

11:15 pH-Independent Potential-Controlled Antibody Purification

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

This study introduces a novel proof-of-concept for antibody purification through potential- controlled chromatography, addressing cost and efficiency in large-scale production. A 2.5 V cell potential was able to disrupt Protein A-antibody interactions and achieved ~90% elution rates. Membrane chromatography itself offers faster cycle times and eliminates mass transfer limitations. Additionally, it reduces reliance on buffer exchange, potentially enhancing sustainability.

11:45 How an Old-Fashioned Test Can Help to Improve a Whole Process

Karl Behler, PhD, Senior Scientist, MSAT, Novartis Pharma GmbH

This study focusses on the identification of byproducts in plasmid DNA (pDNA). Despite being vintage, agarose gel electrophoresis confirmed pDNA identity whilst uncovering additional bands. Through examination using size-specific next-generation sequencing, these bands were identified as deletion variants, with low significance for subsequent processing. By lowering the incubation temperature during upstream processing, the occurrence of deletion variants was significantly minimised, eliminating the need for rigorous cleaning and enhancing process efficiency.

12:15 Presentation to be Announced

12:45 Networking Lunch *(Sponsorship Opportunity Available)* Pfanstiehl

DOWNSTREAM PROCESSING FOR COMPLEX MODALITIES

13:45 Chairperson's Remarks

Sophia Hober, PhD, Professor, School of Biotechnology, KTH Royal Institute of Technology

13:50 Downstream Processing of DuoBody Bispecific Antibodies

Marija Mucibabic, PhD, Senior Scientist, Downstream Processing, Genmab

The DuoBody platform is a versatile and dependable technology for generating bispecific antibodies. Unlike other bispecific antibody platforms, the process is based on controlled Fab-arm exchange, which is performed post-production using purified monospecific antibodies. The process yields bispecific antibodies that retain the molecular structure and quality attributes of therapeutic IgGs. Case studies are presented detailing downstream processing approaches in the development of a range of bispecific antibody therapeutics.

14:20 Modular High-Throughput Platform for the Purification of scFvs and Multispecific Antibody-Based Therapeutics

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

Automated ÄKTA-based purification protocols have been developed, consisting of autosampler systems (Teledyne, ALIAS) to facilitate injections during overnight and idling times, two- and three-column schemes to automate purifications, and novel affinity chromatography membrane technology to reduce cyclisation time. Those protocols enable the cost-effective screening and purification of hundreds of single-chain variable fragments (scFvs) and multispecific antibody-based therapeutics per week, with high monomeric purity.

Cambridge Healthtech Institute's 7th Annual

19 - 20 MARCH 2024 ALL TIMES CET

Advances in Recovery and Purification — Part 1 Optimizing DSP, Reducing Costs

14:50 Development of Downstream Processing for Novel Scaffold Therapeutics: Monomers, Multimers, and FC Fusions

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

Development of novel protein scaffolds through protein engineering strategies requires the complementary development of downstream processing methods for the non-natural proteins. Further steps taken in one expression host may need to be altered or optimised in another. We describe here the development of novel 10kDa scaffolds, SXkmers, and the development of techniques to purify and polish for *in vitro* and *in vivo* studies with monomers, dimers, and Fc fusion variants.

15:20 Unlocking Potential: Practical Applications of Multi-Column Chromatography in Manufacturing

TOSOH

Sebastian Thuermann, Product Manager MCC EMEA, Tosoh Bioscience GmbH

15:35 Presentation to be Announced

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

Selvita

VIRAL VACCINES, ANTIBODIES FOR SNAKE VENOMS

16:20 Revisiting Membrane Chromatography and Absorbers Viral Vaccine Purification

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

A lot of choices of membrane absorbers and fiber materials for virus purification, compared to the past. What is the selection criterion for a membrane adsorber and fiber material? The ideal separation process for a viral vaccine.

16:50 KEYNOTE PRESENTATION The Technical Challenges of Developing Monoclonal Antibodies against Snake Venoms

Andreas H. Laustsen, PhD, Center Director & Professor, Center for Antibody Technologies, DTU Bioengineering, Technical University of Denmark

Snakebite envenoming is a serious medical challenge that each year claims the lives of >100,000 people and leaves many more maimed for life. The only existing specific therapy against envenoming is antivenom based on polyclonal animal-derived antibodies. In this talk, I will present my group's ongoing work on developing recombinant antivenoms based on human monoclonal antibodies and nanobodies, and provide perspectives on the challenges of bringing these to patients worldwide.

17:20 Intelligent Sensors for Critical Process Parameters in Downstream Unit Operations

HAMILTON

Giovanni Campolongo, Senior Market Segment Manager Process Analytics, Process Analytics, Hamilton Bonaduz AG

Downstream Processing comprises a series of operational units, including the separation, purification, and viral inactivation of therapeutic proteins and Active Pharmaceutical Ingredients. This presentation centers on the Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs), particularly pH and conductivity, within these units, or more precisely, within these skids. We will also highlight the importance of real-time CPP monitoring through advanced intelligent sensors.

17:35 Presentation to be Announced

INTERACTIVE BREAKOUT DISCUSSIONS

17:50 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: BREAKOUT DISCUSSION: ICH Q5 A (R1) Revision: Viral safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

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

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

NOVEL APPROACHES TO CHROMATOGRAPHY

8:25 Chairperson's Remarks

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

8:30 Adaptive Model Predictive Control for Mitigating Column Aging Effects in Process Chromatography

Touraj Eslami, PhD, Automation Engineer, Downstream Processing, Institute of Bioprocess Science and Engineering, University of Natural Resources & Life Sciences

This presentation unveils an adaptive Model Predictive Control (MPC) framework designed to mitigate the challenges of column aging in process chromatography. Through a nonlinear MPC, extended Kalman filter, and a soft sensor mechanism, the framework dynamically adapts to resin capacity reduction, optimising bioprocesses. Experiments demonstrate a 50% reduction in processing time, improved resin and buffer utilisation, marking a stride towards sustainable production aligned with BioPharma 4.0.

9:00 Preparative Chromatography—A Different Perspective on Biomolecule Adsorption Mechanism Provided by Flow Microcalorimetry

Cristina M. Dias-Cabral, PhD, Professor, Chemistry, University of Beira Interior

Comprehending biomolecules-chromatography resin interactions is essential. While conventional methods have shed light on biomolecule adsorption complexities, they fall in resolving thermodynamic differences related to protein loading and temperature. Flow microcalorimetry emerges, enabling precise heat signal measurement during chromatography processes. Profound insights are gained into biomolecule-resin interactions, encompassing various support types, surface heterogeneous adsorption, and adsorbed biomolecules dynamic rearrangement. These findings drive chromatographic techniques' refinement and advance biomolecule adsorption mechanisms' understanding.

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Advances in Recovery and Purification — Part 1 Optimizing DSP, Reducing Costs

9:30 Process Improvements Using Continuous Mode with Ceramic Hydroxyapatite Resin

Vincent Dechavanne, Master 2 of Science, Senior Scientist II, DSP Process Development, Fresenius-Kabi Biopharma

Biosimilar manufacturing unlocks patients access to affordable therapies. To decrease the cost of production of biosimilars, comparison studies between batch and continuous processes were performed for two downstream processes. This case study consisted of the use of CHT™ Ceramic Hydroxyapatite media in a continuous mode, allowing an improvement of productivity and resin usage while maintaining purity and yield performance.

10:00 High Productivity Protein A Membrane Devices Complement Disposable Upstream Technology for a Fully Single-Use Process

William Barrett, PhD, Product Specialist, PharmBIO, W. L. Gore & Associates, Inc.

An intensified and fully single use downstream operation was demonstrated to process a monoclonal antibody cell culture harvest at a manufacturing scale. The results of the study were extrapolated to show the potential for high productivity affinity capture sufficient up to 10 g/L titers at the 2000 L scale.

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

FORMULATRIX

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING— ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

11:20 PLENARY PRESENTATION: What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Novel Approaches in an Efficient Affinity Chromatography Strategy for Your Antibody Variants & Recombinant Proteins

cytiva

Helen Cheek, Global Product Manager, Marketing, Cytiva

Antibodies are the largest class of biotherapeutics today and are likely to remain so in the future. As this class grows, so does its diversity - projects in preclinical stages through to commercial manufacturing increasingly involve variants such as bispecifics, conjugates, or fragments.
Platform approaches have eased the development of purification protocols but selecting purification schemes can be challenging for antibody variants given the wide range in the pipeline

13:05 Networking Lunch (Sponsored Opportunity Available)

14:05 Close of Advances in Recovery and Purification – Part 1

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Advances in Recovery and Purification — Part 2

Optimizing DSP for Complex Modalities

WEDNESDAY 20 MARCH

10:30 Registration Open

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

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12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

THE DIGITALISATION OF BIOPROCESSING

14:15 Chairperson's Opening Remarks

Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

14:20 The Role of Digitalisation in Continuous Processing of Therapeutic Proteins

Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

To sustain the rapid expansion of biopharmaceuticals whilst preserving their quality, the Quality-by-Design (QbD) initiative was introduced, which has process intensification as a main pillar. Process integration and continuous operations are valuable strategies towards consistent product quality and high throughput. However, digitalisation is the keystone to express their full potential as it allows a model-based process control, a reduction in time-to-market and costs, and fulfillment of the QbD guidelines.

14:50 KEYNOTE PRESENTATION Improving DSP Processes Based on Big Data and Visualisation Tools—What Happens When the (Data) Lake Is Overflowing

Sandra Krause, Lab Engineer, Biodevelopment Microbial Platform, Sanofi

Digital transformation is the keyword in the beginning of the 21st century. Companies, including biotech and pharma, push forward to keep pace with customer needs and competitors. Here, we describe how to handle big data, with visualisation tools for a quick insight into our DSP processes, enabling data-driven decision-making in experiment design and execution. With executing digitalisation in our labs we play an important role in Sanofi's global digital transformation.

15:20 Process Analytical Technologies (PAT) Integrated into Digital Twin Deployment for Downstream Processes

Antonio G. Cardillo, PhD, Scientific Lead Associate Director, TRD-DS Global Innovation Centre, GSK Vaccines

Biopharmaceutical industry traditionally relies on pharmaceutical manufacturing practices to monitor processes and release products. The use of Process Analytical Technologies (PAT) can improve the process monitoring and control, and increase the process understanding. PAT also enable real-time control when integrated into a digital twin. This talk is concerned with the implementation of PAT and development of digital twins in GSK for purification processes.

15:50 Talk Title to be Announced

Alain Medina, Field Application Scientist, Bioprocessing, Purolite, An Ecolab Company

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

DOWNSTREAM PROCESSING OF NOVEL THERAPIES

17:00 FEATURED PRESENTATION Production and Purification of Non-Canonical Amino Acids

Birgit Wiltschi, PhD, Head of Synthetic Biology Group, ACIB GmbH & University of Natural Resources and Life Sciences, Vienna

Non-canonical amino acids (ncAA) are valuable assets to expand the genetic code. Their diverse side-chain moieties install structural, chemical, or functional modifications in proteins. ncAAs can be incorporated into proteins by ribosomal translation under tightly controlled conditions. However, the scale-up is hampered by the high costs for the ncAAs. Our focus is to develop biosynthesis pathways for ncAAs with reactive side chains, bioprocesses for their production, and appropriate purification procedures.

17:30 Mild Solubilisation of Inclusion Bodies—Quo Vadis?

Oliver Spadiut, PhD, Associate Professor, Integrated Bioprocess Development, TU Wien, Vienna

More than 25% of all biopharmaceuticals are produced in *E. coli*. However, a common consequence of recombinant protein production in *E. coli* is the formation of insoluble product aggregates, Inclusion Bodies (IBs). To obtain correctly folded protein, IBs are solubilised with strong chaotropic denaturants. I will present strategies for mild solubilisation, preserving secondary protein structures, thus alleviating IB processes.

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Advances in Recovery and Purification — Part 2

Optimizing DSP for Complex Modalities

18:00 Demonstrating Effective Scaling of Rapid Cycling Chromatography (RCC) With The Sartobind® Rapid A Platform

SARTORIUS

Mario Grünberg, PhD, Senior Scientist DSP, Modalities & Analytics, Sartorius Stedim Biotech

Membrane-based Protein A chromatography represents an opportunity to replace packed-bed operations with a ready- for-to-use, intensified solution. It eliminates the pain points of capital expenditure on columns, operational challenges (column packing, testing, cleaning, storage, etc.), and resin batch management. Our recent case study showcases the main benefits of Sartobind® Rapid A, and new data showing how the concept can be scaled-up seamlessly from PD to production scale.

18:30 Close of Day

THURSDAY 21 MARCH

8:00 Registration and Morning Coffee

CONTINUOUS DOWNSTREAM PROCESSING

8:25 Chairperson's Remarks

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

8:30 Improving the Robustness of Multicolumn Countercurrent Solvent Gradient Purification (MCSGP) of Oligonucleotides through Dynamic Process Control

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

Multicolumn Countercurrent Solvent Gradient Purification (MCSGP) was demonstrated as a valuable process to improve the efficiency associated with the chromatographic purification of oligonucleotides through the automated internal recycling of impure side-fractions. A dynamic process controller AutoPeak, adjusting in real time the characteristic times for internal recycling and product collection based on the recorded UV signal, is presented as a key technology to improve process robustness, rejecting disturbances during manufacturing.

9:00 Inert Tracers for Continuous Biomanufacturing

Narges Lali, PhD Candidate, Researcher, Austrian Centre of Industrial Biotechnology (ACIB)

It is recommended by ICH guidelines to use residence time distribution (RTD) for characterising material flow. RTD can be measured experimentally by injecting an inert tracer into the inlet and tracing it in the outlet. For antibody production in continuous mode, periodic counter-current chromatography (PCC) is widely used. Fluorescent-labeled antibody was used as an inert tracer. It was injected into the inlet, then traced during the loading and elution phase.

9:30 The Development of Continuous Biologics Manufacture at CPI

Daniel Myatt, PhD, Senior Analytical Scientist, Biologics, Center for Process Innovation Ltd.

The Centre for Process Innovation (CPI) is part of the UK High Value Manufacturing Catapult (HVMC). CPI has been, and is currently, involved in several continuous biologics manufacturing and process analytical technology (PAT) projects. In this talk, I will discuss previous and current projects involving continuous manufacturing and the use of novel process analytical technologies (PATs).

10:00 Sponsored Presentation *(Opportunity Available)*

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

SEPARATION AND PURIFICATION OF VIRAL VECTORS

11:00 Improving Virus-Based Biopharmaceuticals Purification Using New Adsorbents

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

New modalities are a challenging task for downstream processing. Alternative purification strategies that can improve the purification yield—such as affinity chromatography or the use of new adsorbent materials—are regarded nowadays as enabling technologies to overcome the capacity bottleneck in biomanufacturing. The current talk will focus on the development of new engineering ligands and new matrices aimed at the purification of viral vectors; some case studies will be discussed.

11:30 Integration of Upstream and Downstream Processes in AAV Production

Ricardo J.S. Silva, PhD, Senior Scientist, Downstream Process Development, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica

Process intensification and integration are often viewed as tools to improve bioprocess efficiency. This talk will explore the use of perfusion bioreaction and continuous chromatography to seamlessly integrate and connect upstream and downstream stages. AAV expression, harvesting, and clarification processes are integrated using tangential flow depth filtration. The cases of continuous AAV affinity capture and polishing will be presented, with an emphasis on the challenges and opportunities for future developments.

12:00 Non-Woven Material for Bionanoparticle Separation and Purification

Alexander Zollner, University of Natural Resources and Life Sciences, Vienna

Bionanoparticles, like virus-like particles, are promising candidates for future vaccines and gene therapies. For the production of safe pharmaceuticals, a major focus lies on the downstream processing. Within our research, we are investigating the fundamental principles of bionanoparticle purification with the goal of moving from resin-based chromatography to more environmentally friendly, biodegradable, membrane-based methods. This shift enhances process efficiency and aligns with our commitment to sustainable production.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch *(Sponsorship Opportunity Available)*

DIGITALISATION OF GENE THERAPIES

13:45 Chairperson's Remarks

Ricardo J.S. Silva, PhD, Senior Scientist, Downstream Process Development, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica

13:50 Mastering the Digitalization Challenge for Biopharma Processes – From mAbs to Emerging Modalities

Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

In this presentation, we show how advanced machine learning and hybrid modeling approaches can be exploited to significantly improve process understanding, performance, and automated operation as digital twins. All presentations will be centered on industrial implementation examples for mAb, cell & gene therapy, and mRNA processes with numerous big pharma and CDMO partners allowing to quantify efficiency gains in and improved understanding in process development.

Cambridge Healthtech Institute's 7th Annual **20 - 21 MARCH 2024 ALL TIMES CET**

Advances in Recovery and Purification — Part 2 Optimizing DSP for Complex Modalities

PROCESS DEVELOPMENT FOR VIRUS-LIKE PARTICLES

14:20 Continuous Production of Influenza VLPs Using IC-BEVS: A Multi-Stage Bioreactor Approach

Ricardo Correia, PhD, Postdoctorate Researcher, Cell-Based Vaccines Development Lab, iBET Instituto de Biologia Experimental Tecnologica

14:50 Enhancing VLP Purification Strategies: Metal-ion Affinity Precipitation as a Paradigm Shift for His-Tagged Virus-Like Particles

Khai Wooi Jason Lee, PhD, Senior Lecturer, School of Biosciences, Taylors University

We present a novel purification method for recombinant multimeric virus-like particles (VLPs) using metal-ion affinity precipitation. The study focused on VLPs made of turnip yellow mosaic virus coat protein, produced in *Escherichia coli*. Remarkably, a mere 15 µM (or lower) of transition-metal salt, such as nickel chloride, proved sufficient to induce precipitation, leading to an impressive recovery rate of up to 70% with a purity exceeding 0.90.

15:20 Close of Summit

19-20 MARCH

Gene Therapy CMC & Analytics

VIEW PROGRAM >>>

20-21 MARCH

Gene Therapy Manufacturing

VIEW PROGRAM >>>

Stream 3

GENE THERAPY

The Gene Therapy stream focuses on the critical challenges facing the analysis, characterization, quality control and manufacture of gene therapies, viral and non-viral-based. Topics include process development, product and process characterization, potency assays, comparability, emerging analytical technologies, impurities, quality control, comparability, process development, purification, formulation, scale-up and commercial manufacturing.

Cambridge Healthtech Institute's 5th Annual

19 - 20 MARCH 2024 ALL TIMES CET

Gene Therapy CMC and Analytics

Improving the Analysis, Control, and Quality of Gene Therapies

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

ADVANCING TECHNICAL DEVELOPMENT OF GENE THERAPIES

8:25 Manufacturing Challenges and Control Strategies for Dual AAV Vectors

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

Sensorion is a biotech company dedicated to the development of therapies for genetic forms of hearing loss. Two novel gene therapy programs include deafness due to otoferlin deficiency as well as GJB2 mutation. Since the Otoferlin gene is large and exceeds the AAV packaging capacity, two AAV vectors have been developed. The product manufacturing and a deep characterisation of the dual vectors will be presented.

8:30 FEATURED PRESENTATION Host Cell Protein Monitoring in AAV-Based Gene Therapy Products Using LC-MS/MS

Jonathan Bones, PhD, Principal Investigator, Characterisation and Comparability Laboratory, National Institute for Bioprocessing Research and Training (NIBRT), Ireland

AAV-based gene therapies present a considerable analytical challenge due to their molecular size and complexity. Strategies for the characterisation of various quality attributes of AAV using liquid phase separations and mass spectrometry will be presented. Examples include the characterisation of intact viral proteins using LC-MS and CE-MS, determination of the capsid full state using LC-MS, and charge-detection mass spectrometry for mass-based analysis of capsid fill state and heterogeneity.

9:00 KEYNOTE PRESENTATION: Challenges and Opportunities in Gene Therapy Technical Development

Markus Haindl, PhD, Global Head, Gene Therapy Technical Development, Roche Diagnostics GmbH

Gene therapies are currently where monoclonal antibodies were 25 years ago; we need a shift of our development paradigms and transformative innovation for reliable supply, more sustainable cost of manufacturing, as well as enhanced molecular understanding of these next-generation therapeutics.

9:30 Work Smarter Not Harder: Digital Innovation in Bioprocess Development

Genedata

Wen Clifford PhD, Scientific Account Manager, Genedata

During bioprocess development, organizations typically utilize highly fragmented digital ecosystems —such as combinations of electronic lab notebooks (ELN), laboratory information management systems (LIMS), and data lakes—to capture and analyze information. This makes decision-making and PAT implementation very challenging. We will discuss technical innovations that enable structured CMC data capture, efficient analysis, and transfer to regulatory agencies, with special focus on commonly used technologies such as mass spectrometry (MS), chromatography, and next generation sequencing (NGS). We will also discuss special requirements of new biologic modalities such as antibodies, bi- and multispecifics, cell and gene therapies, and RNA.

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

TECHNOFLEX

STANDARDS, COMPARABILITY, ANALYTICS

10:45 USP Standards to Support Gene Therapy Product Development

Fouad Atouf, PhD, Senior Vice President, Global Biologics, USP

Establishing standards to enable gene therapy development is essential to maintaining safe and effective therapeutics, and to overcoming the complexity and diversity of gene therapy products. In this presentation, we will provide updates on the development of documentary standards and reference materials to support the analytical development for gene therapies, process residuals, and raw materials. Case studies related to quality of plasmid DNA and AAV-based gene therapies will be discussed.

11:15 Key Takeaways from the FDA's Draft Comparability Guidance

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

The ICH guideline for comparability was released in Nov 2004. Since then, ICH Q5E has been the only comprehensive guideline for comparability, but was written for biotech recombinant proteins. Nineteen years on, the FDA has released a draft comparability guideline specifically for cell and gene therapy products. How does this differ from ICH Q5E? Does it address the unique issues faced by these products?

11:45 Analytical Developments of rAAVs for Process Development and Product Quality Control

Susumu Uchiyama, PhD, Professor, Biotechnology, Osaka University

Factors contributing to change in transgene expression (potency) level in rAAV are presented. For example, VP ratio is highly influential to potency and varies lot-to-lot. A reliable approach to accurately determine the ratio will be introduced. Size distribution analysis, including full and empty determination using several orthogonal methods within the limitation of each method, will be introduced.

12:15 Presentation to be Announced

CATUG

12:30 In-line and on-line monitoring of CQAs for biologics, vaccines and gene vectors

Waters | WYATT

Dan Some, Principal Scientist, Wyatt Technology

Real-Time Multi-Angle Light Scattering is a key Process Analytical Technology in drug development, especially for complex drugs like gene vectors. It provides instant feedback on quality attributes such as molar mass and particle size, essential for monitoring product identity and purity. RT-MALS is particularly effective for gene vectors like AAV, tracking empty-full ratios and titers. This talk discusses RT-MALS' principles, capabilities, limitations and case studies in bioprocessing.

12:45 Networking Lunch *(Sponsorship Opportunity Available)*

SUPPORTING PRODUCT QUALITY

13:45 Chairperson's Opening Remarks

Fouad Atouf, PhD, Senior Vice President, Global Biologics, USP

13:50 Overcoming in-Process Sample Suitability Challenges for AAV Characterisation during Process Development

Nathan Sweeney, PhD, Lead Scientist, Technology & Process Innovations, Cell & Gene Therapy Catapult

Early analytical assays for AAV are typically established using purified high-titre reference material, yet most in-process samples have relatively low titre and are in challenging matrices such as cell lysates. This presentation will detail the challenges we have identified and improvements we have implemented to enable product characterisation throughout process development. This will include assays to determine genomic and capsid titre, potency, residual DNA concentration, and full/empty ratios.

Cambridge Healthtech Institute's 5th Annual

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Gene Therapy CMC and Analytics

Improving the Analysis, Control, and Quality of Gene Therapies

14:20 Supporting AAV Manufacturing Developments by Improving Analytical Characterisation

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

AAV quality assessment requires monitoring several attributes from the protein capsid and genome. While several analytical technologies have been established, still there are limitations in regard to their accuracy, sensitivity, sample consumption, and user-friendliness. We have developed new chromatographic approaches for the assessment of protein capsid and genome integrity as well as empty/full ratio.

14:50 Manufacturing Challenges and Control Strategies for Dual AAV Vectors

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

Sensorion is a biotech company dedicated to the development of therapies for genetic forms of hearing loss. Two novel gene therapy programs include deafness due to otoferlin deficiency as well as GJB2 mutation. Since the Otoferlin gene is large and exceeds the AAV packaging capacity, two AAV vectors have been developed. The product manufacturing and a deep characterisation of the dual vectors will be presented.

15:20 Optimization of AAV Downstream Process Development from Harvest to Final Product SARTORIUS

Rok Žigon, Head of Product-Application Area (AAV and Adeno), Process development for viruses and vaccines, Sartorius BIA Separations

This presentation will cover considerations and examples of case studies for various AAV serotypes for all DSP steps. We will present data from initial lysate clarification and pre-capture options to reduce contaminants, comparison of affinity and ion-exchange capture step and finally optimization of polishing (full enrichment) step on various monolithic columns, all supported with orthogonal analytics.

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

ANALYTICAL AND FORMULATION STRATEGIES

16:20 Evaluating Analytical Strategies to Quantify Capsid Titre: Towards a Platform-Method Approach to Accelerate AAV Drug Product Development

Marilia Barros, PhD, Principal Scientist, Regeneron Pharmaceuticals

Traditional capsid titre methods rely on ELISA which commonly suffers from long turnaround times, low throughput, and large volume sample requirements. This limits the application of ELISA-based methods to routine analysis, thus requiring development of alternative high-throughput (HTP) capsid titre methods. We have performed a comprehensive assessment on currently available orthogonal capsid titre methods using multiple serotypes at concentration range relevant in IND-enabling preclinical and first-in-human (FIH) clinical studies.

16:50 In-Depth Characterisation of Adeno-Associated Viruses (AAVs) Using Microchip CE-MS

Sara Carillo, PhD, Team Lead, Application Development, National Institute for Bioprocessing Research & Training (NIBRT)

The use of adeno-associated viruses (AAVs) viral vectors as delivery systems for gene therapy is expanding rapidly. As a consequence, establishing analytical techniques able to fully characterize capsid viral proteins (VPs) and their modifications is critical to ensure product quality. Microchip-based capillary electrophoresis with mass spectrometry detection resulted in a powerful tool to decipher VPs' features and heterogeneity, even with limited sample availability, allowing extensive characterization across serotypes.

17:20 Analytical Methods for AAV Characterisation

Charlotte Graham, PhD, Team Leader, Analytical, Ctr for Process Innovation Ltd

For the characterisation of AAV, the monitoring of empty vs. full capsids is a critical quality attribute (CQA) as empty capsids are considered impurities, therefore it is imperative to establish reliable analytical techniques. The current gold standard techniques for determining empty vs. full capsids is a combination of ddPCR and ELISA. Here we discuss and compare existing analytical tools as well as the challenges that come with AAV analysis.

INTERACTIVE BREAKOUT DISCUSSIONS

17:50 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: BREAKOUT DISCUSSION: Analyze This: AAV-based Gene Therapies

Rajiv Gangurde, PhD, Vice President, Technical Operations, Parexel

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

OPTIMISING GENE THERAPY AND mRNA DEVELOPMENT

8:25 Chairperson's Opening Remarks

Rajiv Gangurde, PhD, Vice President, Technical Operations, Parexel

8:30 Challenges with Gene Therapy CMC

Andrea Martorana, PhD, Lead Scientist, Analytical Development, AviadoBio

AviadoBio has developed a next-generation AAV gene therapy platform focused on controlling gene expression and is complemented by a suite of unique delivery solutions to deliver gene therapies directly to the brain and spinal cord. We are also building additional platforms and capabilities as well as proprietary RNA silencing and subpial delivery technologies. This talk will discuss some common CMC challenges.

9:00 Analytical Development Strategy: Biotech versus CDMO

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

Gene therapies dominate the current ATMP clinical trial landscape. In recent years we experienced a significant investment in CDMO/CRO acquiring specialised capabilities, offering a competitive market for both gene therapy manufacture and characterisation. In my talk, I will discuss the challenges in the field and address how Purespring Therapeutics strategically built a robust analytical platform while maintaining the balance between innovation and need.

9:30 Technology Transfer/New Product Introduction for Gene Therapy

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

This presentation will discuss: What is Tech Transfer & Why is it important? Tech Transfer Roadmap – key phases; Fitting Your Process To Your Plant; Specific Challenges/Considerations for Gene Therapy products

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Gene Therapy CMC and Analytics

Improving the Analysis, Control, and Quality of Gene Therapies

10:00 Accelerating AAV process development and release testing with a walk-away immunoassay platform

GYROS PROTEIN Technologies

Joris Venet, MSc, Field Application Scientist, Sales, Gyros Protein Technologies

While scaled-down models and high-throughput testing in bioprocess development generate large numbers of samples for analysis, analytical impurity testing remains largely manual in many companies. Here we present a case study of a biopharmaceutical customer seeking the next generation technology to replace their manual ELISA for accelerated analytical impurity testing in their AAV process development and product release testing.

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

FORMULATRIX

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

11:20 PLENARY PRESENTATION: What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

14:05 Close of Gene Therapy CMC and Analytics Conference

Cambridge Healthtech Institute's 5th Annual

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Gene Therapy Manufacturing

Scale-Up and Purification of Viral Vectors

WEDNESDAY 20 MARCH

10:30 Registration Open

PLENARY KEYNOTE SESSION
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12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

OPTIMISING VIRAL VECTOR PROCESS DEVELOPMENT

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

14:20 Exploring AAV Scale-Up: Experiences, Challenges, and Learnings
Amna Anwar, PhD, Associate Senior Scientist, Downstream Processing, Cell & Gene Therapy Catapult
In the presentation we will explore the journey of up-scaling an Adeno-Associated Virus (AAV) production process. We will share an overview of the experiences and insights gained during the scale-up work, highlighting the complexities faced during the most challenging steps of the upstream and downstream processes. Furthermore, we will discuss the valuable lessons learned and the innovative solutions we are implementing to address the remaining challenges effectively.

14:50 Improving Efficiency and Scalability of rAAV Upstream Processing
Priyanka Amba Gupta, Senior Scientist, Gene Therapy, Upstream, UCB
rAAVs are at the forefront of gene therapy, but the manufacturing processes for these remain a significant challenge. Specifically, the focus of product developers is on scalability and achieving high productivity consistently to ensure economic viability. While this field is still emerging, innovative approaches in upstream processing have shown potential. Here, we explore the evolving landscape of upstream rAAV production, highlighting the promising strategies to enhance efficiency and scalability.

15:20 FEATURED PRESENTATION: Using Stable Producer Cell Lines for Manufacturing of Lentiviral Vectors in Perfusion Mode
Parameswari Govindarajan, PhD, Senior Scientist, Process Development, CSL Behring GmbH
The large-scale production of clinical-grade lentiviral vectors (LVs) for gene therapy applications is a remaining challenge. We present a novel state-of-the-art platform for LV production using HEK293T-based stable packaging cell lines. We describe the generation of stable producer cell lines and monoclonal cell line generation, identifying top producer clones. Based on the producer cell lines we have developed a perfusion process resulting in high Lentivirus (LV) titer.

15:50 In 2024, What Tools are Available to Improve AAV Productivity and Quality?
Paul Giroud, Scientific Support Specialist, Polyplus
Enhancing AAV productivity and quality is key to enable more Gene Therapy products to reach commercialization. There are several approaches to improve productivity, of which a cost-effective approach whereby early on during process development, multiple parameters can be optimized thanks to DOE at both Upstream and Downstream levels. Combining using latest generation reagents and plasmid engineering tools with DOE can have a significant and positive impact on process efficiency.

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

FUTURE DIRECTIONS IN GENE THERAPY MANUFACTURING

17:00 KEYNOTE PRESENTATION Leveraging a Flexible Gene Therapy Process Development Platform to Create Efficiencies for AAV Manufacturing
Patrick M. Hossler, PhD, Senior Director, Pharmaceutical Development, Ultragenyx
Major challenges abound in gene therapy commercialization including inconsistencies in manufacturing performance, low yields, long timelines, and high costs. Process development has a pivotal role towards unlocking efficiency and helping facilitate global patient access to GT products. Through an extended pipeline of rAAV therapies, we developed a PD platform that integrates seamlessly with our manufacturing network. Studies of leveraging a flexible platform to create efficiencies in manufacturing will be presented.

17:30 Optimization of AAV Production for High-Yielding and Scalable GMP Processes
Mark Bell, Principal Bioprocessing Scientist, Purespring Therapeutics
Gene therapy is an emerging treatment modality for a wide range of monogenetic disease indications, including those in the kidney. Meeting the demand for these clinical indications requires innovative manufacturing strategies to boost rAAV productivity. Our success in triple plasmid

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Gene Therapy Manufacturing

Scale-Up and Purification of Viral Vectors

transfection has elevated AAV productivity in small-scale platforms, and we outline our scaling and implementation approach at our CDMO to address these emerging therapeutic needs.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: Future Directions in Gene Therapy Manufacturing

Eduard Ayuso, DVM, PhD, CEO, DINAMIQS; Chairman of Manufacturing, European Society of Gene and Cell Therapy

BREAKOUT DISCUSSION: Process Development

Tarik Senussi, PhD, Senior Director Process & Formulation Development, MSAT, Gyroscope Therapeutics, a Novartis Company

18:30 Close of Day

THURSDAY 21 MARCH

8:00 Registration and Morning Coffee

PROCESS DEVELOPMENT FOR VIRAL VECTORS

8:25 Chairperson's Remarks

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

8:30 Successful Development and Scaling-Up of a Suspension HEK293 Platform for AAV Manufacturing

Laurence Guianvarch, Head, Viral Vector Process Development, TaRGeT UMR1089

Recombinant AAV vector is the most widely used viral vector for *in vivo* gene therapy. This work is aimed to develop a powerful rAAV production platform based on transient transfection of HEK293 cells in suspension delivering large rAAV amounts. After only a few months of development through a holistic approach, an end-to-end process was defined showing high productivity up to $5x10^{11}$ vg/mL in bulk harvest, up to 50L-scale.

9:00 A Novel Three-Plasmid Packaging System for High-Yield and rcAAV-Free rAAV Production

Su Xiao, PhD, PhD, Co-Founder & Chief Tech Operations Officer, Neurophth Biotechnology

We developed a novel three-plasmid packaging system, Higher-Expression Recombinant AAV (HERA) system, which increased the rAAV yield by 5 to 10-fold (to 1E15vg/L across different serotypes) and reduced rcAAV to undetectable level. Herein, we present process and quality attributes summaries of historical batches to demonstrate the HERA system not only significantly reduced manufacturing scale, but also achieved improved quality profile

9:30 Challenges in AAV Vectors-Based Gene Therapies

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

Adeno-associated virus (AAV) vectors are widely used as a gene therapy vector. One of the current limitations on the use of AAV vectors is their small packaging capacity impairing delivery of therapeutic genes over 3.5kb in size. Herein, dual AAV co-delivery strategies are discussed and presented, namely the use of protein trans-splicing systems, to deliver larger genes. AAV vector doses are also analysed.

10:00 Synthetic, enzymatically produced DNA for gene therapy and vaccine applications

Amy Walker, Dr., VP of Research and Business Development, Research & Development, 4basebio Discovery Limited

Plasmid DNA is a major bottleneck in the production of C&G therapies and vaccines. Synthetic DNA offers a paradigm shift in GMP DNA production, conferring benefits including an enhanced safety profile, improved performance, and significantly accelerated turnaround times. Here, we show how 4basebio's enzymatically produced DNA can outperform plasmid in the production of mRNA, AAV and in gene editing applications.

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

SEPARATION AND PURIFICATION OF VIRAL VECTORS

11:00 Improving Virus-Based Biopharmaceuticals Purification Using New Adsorbents

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

New modalities are a challenging task for downstream processing. Alternative purification strategies that can improve the purification yield—such as affinity chromatography or the use of new adsorbent materials—are regarded nowadays as enabling technologies to overcome the capacity bottleneck in biomanufacturing. The current talk will focus on the development of new engineering ligands and new matrices aimed at the purification of viral vectors; some case studies will be discussed.

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12:00 Non-Woven Material for Bionanoparticle Separation and Purification

Alexander Zollner, University of Natural Resources and Life Sciences, Vienna

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DIGITALISATION OF GENE THERAPIES

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Gene Therapy Manufacturing

Scale-Up and Purification of Viral Vectors

13:50 Mastering the Digitalization Challenge for Biopharma Processes – From mAbs to Emerging Modalities

Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

In this presentation, we show how advanced machine learning and hybrid modeling approaches can be exploited to significantly improve process understanding, performance, and automated operation as digital twins. All presentations will be centered on industrial implementation examples for mAb, cell & gene therapy, and mRNA processes with numerous big pharma and CDMO partners allowing to quantify efficiency gains in and improved understanding in process development.

PROCESS DEVELOPMENT FOR VIRUS-LIKE PARTICLES

14:20 Continuous Production of Influenza VLPs Using IC-BEVS: A Multi-Stage Bioreactor Approach

Ricardo Correia, PhD, Postdoctorate Researcher, Cell-Based Vaccines Development Lab, iBET Instituto de Biologia Experimental Tecnologica

14:50 Enhancing VLP Purification Strategies: Metal-ion Affinity Precipitation as a Paradigm Shift for His-Tagged Virus-Like Particles

Khai Wooi Jason Lee, PhD, Senior Lecturer, School of Biosciences, Taylors University

We present a novel purification method for recombinant multimeric virus-like particles (VLPs) using metal-ion affinity precipitation. The study focused on VLPs made of turnip yellow mosaic virus coat protein, produced in *Escherichia coli*. Remarkably, a mere 15 µM (or lower) of transition-metal salt, such as nickel chloride, proved sufficient to induce precipitation, leading to an impressive recovery rate of up to 70% with a purity exceeding 0.90.

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15:20 Close of Summit

19-20 MARCH

Cell Culture and Bioproduction

VIEW PROGRAM »»

20-21 MARCH

Intensified & Continuous Processing

VIEW PROGRAM »»

NEW! Stream 4

SMART, SUSTAINABLE MANUFACTURING

Digital transformation and sustainability in bioprocessing has arrived. The Smart, Sustainable Biomanufacturing stream presents the latest digitalisation strategies and sustainability initiatives to enable next-generation biopharm production. Topics include process modelling and control, AI/ML intensified processes, digital twins, and the latest efforts by vendors and sponsors to improve the sustainability of biomanufacturing locally and globally.

Cambridge Healthtech Institute's 7th Annual

19 - 20 MARCH 2024 ALL TIMES CET

Cell Culture and Bioproduction

Emerging Technologies, Improved Process Control, and New Opportunities

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

EMERGING AND SUSTAINABLE BIOREACTOR TECHNOLOGIES

8:25 Chairperson's Remarks

Stephan Noack, PhD, Group Leader, Quantitative Microbial Phenotyping, Forschungszentrum Jülich

8:30 FEATURED PRESENTATION: Novel Scale-Down Tools for Perfusion Optimisation in Biopharmaceutical Production

Martina Micheletti, PhD, Professor, Bioprocess Fluid Dynamics, University College London

The complexity of perfusion processes requires the optimisation of multiple parameters as well as the selection of suitable production cell clones. Two scale-down methods have been developed and will be presented in this work: a first microwell-based method operates in semi-perfusion mode with exploration of different medium exchange regimes with and without cell bleed, while a 250mL bioreactor system is able to perform perfusion runs of selected clones.

9:00 Industrialisation of IPSC-Derived Allogenic Cell Therapies Using a Scalable Automated Process for Expansion and Differentiation

Juline Guenat, Associate Lead Scientist, Technology & Process Innovation, Cell & Gene Therapy Catapult

Pluripotent stem cell therapies need high cell doses exceeding traditional 2D capabilities. We present a closed, scalable, semi-automated process to expand pluripotent stem cells as high-density aggregates in stirred tank reactors. It achieves a 22-fold expansion over four days while retaining pluripotency markers. Acoustic perfusion enables automated medium exchange with improved control over aggregate quality. Harvested aggregates were differentiated to natural killer cells in 3D.

9:30 Leap-In Transposase Mediated Stable Cell Line Development: More, Better, Faster

Claes Gustafsson, PhD, Chief Commercial Officer & Co-Founder, ATUM

Monoclonal antibodies in their many divergent formats have revolutionized medicine and today represents >$100B/year in pharmaceutical sales. ATUM has built an integrated pipeline from generation of antigens via affinity maturation, developability, engineering and humanization all the way through scale up and stable cell line generation. The presentation will include case studies highlighting technological breakthroughs in synthetic biology, machine learning, LIMS data integration, robotics and engineered transposases to ensure maximum efficiency.

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

10:45 Advances in Small-Scale Automation and Robotisation

Stephan Noack, PhD, Group Leader, Quantitative Microbial Phenotyping, Forschungszentrum Jülich

Laboratory automation in biotechnology has made significant progress in recent years, revolutionising the way experiments and research are conducted. The automation of entire workflows from strain engineering to bioprocess optimisation is currently the focus of attention in industry and academia, and various biofoundries are emerging around the world. I will introduce the Jülich Biofoundry and discuss challenges and solutions in the field of automated microbial bioprocess development.

11:15 Upstream Modelling Toolbox for Monoclonal Antibody (mAb) Process Development

Sabine Arnold, PhD, Senior Scientist, Upstream Process Development, Boehringer Ingelheim Pharma GmbH

Mammalian cell-based mAb production is a complex process involving many factors that determine process performance and product quality. To leverage model-based decisions in development, we have established a versatile modelling toolbox with fit-for-purpose models addressing different aspects of the overall process. We will show selected applications of mechanistic, hybrid and machine learning models, and how these digital approaches can help improving the efficiency and timelines in robust process development.

11:45 KEYNOTE PRESENTATION: Revolutionising Bioprocess Innovation: Unleashing the Power of KIWI-Biolab's Robotic Ecosystem by Orchestration of Model-Based DoEs, Fast in-Depth Analytics for Recombinant Protein Processes

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

The KIWI-biolab enables efficient recombinant bioprocess development and optimisation on a robotic platform with fully automatic orchestration of parallel bioreactor systems of different scales, analytical instruments, and a mobile laboratory robot. Based on FAIR data principles it allows self-controlled parallel fed-batch cultivations, integrated sample analysis, and mathematical model-based parameter calibration and CQA optimisation. The power of the platform is demonstrated by industrially relevant recombinant processes including Fabs, elastins, and hydrogenase.

12:15 In-Line Monitoring of Bioprocess Parameters for the 21st Century

Christopher D. Brown, PhD., Chief Product Officer and Co-founder, 908 Devices

In this presentation, we will review the current state of spectroscopy-based approaches and their associated strengths and limitations. We'll discuss a few use cases showing the use of an innovative platform designed to greatly simplify implementation and interpretation of in-line process parameter data during typical bioprocess runs.

12:45 Networking Lunch *(Sponsorship Opportunity Available)*

COMPUTATIONAL MODELLING AND ML/AI IN UPSTREAM PROCESSING

13:45 Chairperson's Remarks

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

13:50 PAT-Based VCD Soft Sensor Facilitates Model-Based Process Monitoring, Automation, and Control

Benjamin Bayer, PhD, Scientist CMC, Biotherapeutics Technology Development & Implementation, Takeda

The integration of a PAT-based viable cell density (VCD) soft sensor facilitates model-based process monitoring, automation, and control within the biopharmaceutical industry. This technology harnesses real-time data to estimate VCD, enabling biopharmaceutical manufacturers to make informed decisions, e.g., proceeding to the next process step or controlling the feed flow. It enhances product consistency and reduces costs, underscoring the vital role of data-driven strategies in advancing production of pharmaceuticals and biologics.

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Cell Culture and Bioproduction

Emerging Technologies, Improved Process Control, and New Opportunities

14:20 Understanding CHO Cell Biology at Single-Cell Resolution

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

Overcoming the inherent heterogeneity of cells grown *in vitro* is essential to deliver effective, uniform, and safe biological medicines. This talk will focus on the application of single-cell omics to understand the CHO cell biological system, and how the technology can be used to understand the emergence of phenotypic instability. We will provide examples of studies of DNA, RNA, as well as at the protein level.

14:50 Accelerated Process Development and Automated Process Control: Resolving Both by an Appropriate Modelling Approach

Mark Duerkop, CEO, Novasign GmbH

The use of modelling tools for bioprocess development and manufacturing has gained significant attention. But what does it take to create digital bioprocess-twins? Is it only about advanced algorithms, or do we need more to accurately represent and transfer knowledge from development to manufacturing? Key discussion points include the purpose of process modelling, experimental design, tailored modelling approaches, accelerated development, seamless scale-up, and real-time model use for monitoring and control.

15:20 Designing a Next-Generation Bioreactor Platform for Enhanced Biopharmaceutical Development

Andreas Castan, PhD, Strategic Technology Leader, Upstream R&D, R&D, Cytiva

The biopharmaceutical industry grapples with cost pressures and the emergence of new product classes, necessitating innovation in process and equipment design. This presentation unveils the development of a novel bioreactor platform integrating cutting-edge CFD models, enabling process intensification as well as accommodating diverse modalities. It is emphasizing performance, scalability and modularity and a seamless transition from batch to intensified processes, ensuring accelerated timelines

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

UPSTREAM PROCESS CHARACTERISATION AND CONTROL

16:20 End-to-End Digital Twins to Allow Efficient Experimental Design and Real-Time Release

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

Acceleration of commercialisation of biologics, including the filing of a robust control strategy, is of utmost importance for biosimilars up to new modalities. Digital twins capture CMC knowledge and allow multiple deployments. We will show how end-to-end digital twins can help save 50% of experimental effort by incorporating drug substance specification when designing unit operations and how real-time application allows for prediction and control of process performance for real-time release.

16:50 Next-Generation Process Analytics for Upstream Processing

Jeremy Peyrol, USP Innovation Expert, Innovation for Biologics, Merck Biodevelopment SAS

Raman spectroscopy plays an important role in bioprocessing by providing *in situ* measurements and enabling real-time process control. In this study, we demonstrate the use of Raman spectroscopy as a key solution for inline and real-time monitoring of CPPs and CQAs along the upstream space from cell culture media preparation to cell culture expansion.

17:20 Real-Time Model Predictive Control of Industrial Bioprocesses: Challenges and Solutions

Nadav Bar, PhD, Professor, Chemical Engineering, Norwegian University of Science and Technology

In industrial bioprocess control, conventional PI controllers are limited in handling complex interactions among variables. Model Predictive Control (MPC) offers a versatile multi-input, multi-output framework, addressing multiple factors and constraints simultaneously. Challenges include model development, computational demands, human skills and expertise, and real-time implementation. We'll showcase MPC's practical efficacy in case studies across batch, fed-batch, and continuous processes, highlighting its advantages.

INTERACTIVE BREAKOUT DISCUSSIONS

17:50 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: Digital Bioprocessing and Industry 4.0: How Far Along Are We?

Mark Duerkop, CEO, Novasign GmbH

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

PROBLEMS AND SOLUTIONS

8:25 Chairperson's Remarks

Mark Duerkop, CEO, Novasign GmbH

8:30 Towards Continuous Bioproduction—Integration of Microfluidic Systems into Small-Scale Bioreactors

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

Monoclonal antibodies are increasingly dominating the market for therapeutic agents. For this reason, continuous methods—such as perfusion processes—are constantly being explored to increase product yields. We demonstrate a 3D-printed microfluidic spiral separator for cell retention integrated in a small-scale bioreactor. This device achieves a separation efficiency of up to 100% and can readily be adapted according to process conditions due to its flexible fabrication process.

9:00 Environmental Assessment of Single-Use Technology in Pharmaceutical Production

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

Single-use technologies are well established in biopharma production. In this context, the question arises to what extent sustainability aspects play a role in the choice between reusable and disposable equipment. How can model processes and procedures be established in order to be able to carry out meaningful comparative studies and provide standardisable decision-making tools in an open access format? What exists and what still needs to be achieved?

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Cell Culture and Bioproduction

Emerging Technologies, Improved Process Control, and New Opportunities

9:30 Optimise Upstream Intensification to Achieve More Sustainable Processes

Anne Steinkämper, PhD, Scientist, Development Biologicals, Boehringer Ingelheim Pharma GmbH & Co. KG

Bioprocessing has made significant progress in the last decades, with advancements in cell-line engineering, media platforms, and process control. Delivering product with an increased space-time-yield, intensified processes seem to replace classical cell culture fed-batch processes step-by-step. Still, it is worth to discuss at which point even the combined use of process intensification and good producer cell lines has its limitations.

10:00 Future-Proofing Bioprocessing: Building Resilience with AI-Powered Digital Process Twins

Belma Alispahic, Head of Business Development, AnalysisMode

Imagine a bioprocessing future where development is faster, quality is assured, and robust reigns supreme. This future is closer than you think, thanks to the transformative power of AI-powered digital process twins that optimizes production processes, unlocking a new era of:

• Effective R&D: Virtual experiments translate to lightning-fast development and reduced costs, and

• Unwavering Quality: Consistent, superior biologics pave the way for safer, more effective treatments.

10:15 Presentation to be Announced

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

#FORMULATRIX

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

11:20 PLENARY PRESENTATION: What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Novel Approaches in an Efficient Affinity Chromatography Strategy for Your Antibody Variants & Recombinant Proteins

cytiva

Helen Cheek, Global Product Manager, Marketing, Cytiva

Antibodies are the largest class of biotherapeutics today and are likely to remain so in the future. As this class grows, so does its diversity - projects in preclinical stages through to commercial manufacturing increasingly involve variants such as bispecifics, conjugates, or fragments.

Platform approaches have eased the development of purification protocols but selecting purification schemes can be challenging for antibody variants given the wide range in the pipeline

13:05 Networking Lunch *(Sponsorship Opportunity Available)*

14:05 Close of Cell Culture and Bioproduction Conference

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Intensified and Continuous Processing

Digitalisation, Control, and Sustainability

WEDNESDAY 20 MARCH

10:30 Registration Open

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12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

THE DIGITALISATION OF BIOPROCESSING

14:15 Chairperson's Opening Remarks

Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

14:20 The Role of Digitalisation in Continuous Processing of Therapeutic Proteins

Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

To sustain the rapid expansion of biopharmaceuticals whilst preserving their quality, the Quality-by-Design (QbD) initiative was introduced, which has process intensification as a main pillar. Process integration and continuous operations are valuable strategies towards consistent product quality and high throughput. However, digitalisation is the keystone to express their full potential as it allows a model-based process control, a reduction in time-to-market and costs, and fulfillment of the QbD guidelines.

14:50 KEYNOTE PRESENTATION Improving DSP Processes Based on Big Data and Visualisation Tools—What Happens When the (Data) Lake Is Overflowing

Sandra Krause, Lab Engineer, Biodevelopment Microbial Platform, Sanofi

Digital transformation is the keyword in the beginning of the 21st century. Companies, including biotech and pharma, push forward to keep pace with customer needs and competitors. Here, we describe how to handle big data, with visualisation tools for a quick insight into our DSP processes, enabling data-driven decision-making in experiment design and execution. With executing digitalisation in our labs we play an important role in Sanofi's global digital transformation.

15:20 Process Analytical Technologies (PAT) Integrated into Digital Twin Deployment for Downstream Processes

Antonio G. Cardillo, PhD, Scientific Lead Associate Director, TRD-DS Global Innovation Centre, GSK Vaccines

Biopharmaceutical industry traditionally relies on pharmaceutical manufacturing practices to monitor processes and release products. The use of Process Analytical Technologies (PAT) can improve the process monitoring and control, and increase the process understanding. PAT also enable real-time control when integrated into a digital twin. This talk is concerned with the implementation of PAT and development of digital twins in GSK for purification processes.

15:50 Talk Title to be Announced

Alain Medina, Field Application Scientist, Bioprocessing, Purolite, An Ecolab Company

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

INTEGRATED CONTINUOUS PROCESSING

17:00 Bringing Integrated Processes to Steady-State: Startup and Shutdown

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

In ICB, the startup and shutdown depends mainly on the residence time distribution (RTD). A wide RTD also renders a fast process in a slow startup and shutdown phase. The removal of surge tanks between unit operations, by the adoption of tubular reactors, maintains a continuous harvest and mass flow of product with the advantage of a narrow RTD.

17:30 Implementing Advanced Process Control Strategies to Advance Continuous Manufacturing

Lara Fernandez-Cerezo, PhD, Associate Principal Scientist, Merck

Switching from standard fed-batch processes to intensified continuous manufacturing (CM) can significantly improve the cost-effectiveness of biologics production. Different CM technological advances will be covered in this talk from novel process knowledge management tools for a holistic control to mass flow tracking and new walk-up development stations at the unit operation level. Developing and eventually implementing these initiatives will help in advancing the field.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions

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BREAKOUT DISCUSSION: BREAKOUT DISCUSSION: Digitalization of

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Intensified and Continuous Processing

Digitalisation, Control, and Sustainability

Biomanufacturing
Michael Sokolov, PhD, Lecturer, ETH Zurich, COO, DataHow AG

18:30 **Close of Day**

THURSDAY 21 MARCH

8:00 **Registration and Morning Coffee**

PROCESS INTENSIFICATION

8:25 **Chairperson's Remarks**
Margit Holzer, PhD, Owner, Ulysse Consult

8:30 **Addressing Perfusion Cell Culture Limitation to Promote Longer Operating Times and Reduced Losses in the Bleed**
Loic Chappuis, PhD, Scientist, Upstream Processing, Merck
This presentation will explore some of the challenges associated with developing long perfusion processes with stable product quantity and quality output over time. The focus will be on the simultaneous reduction of the bulk fraction (bleed) removal needed to maintain the biomass and on the filtration limitations (flow rate, sieving, clogging). A continuous single-use centrifuge for cell retention was, for example, tested at pilot-scale.

9:00 FEATURED PRESENTATION: **Smart Tools for High Cell-Density Perfusion Culture Process**
Veronique Chotteau, Professor, Director of AdBIOPRO, Centre for Advanced Bioproduction by Continuous Processing, Industrial Biotechnology, KTH Royal Institute of Technology
Sugars are known to influence the antibody (mAb) N-glycosylation. We have studied this effect in high cell-density perfusion of CHO cells and developed a model for the simulation of this effect. We show that N-glycosylation tuning can be obtained by varying the concentration of glucose, mannose and/or galactose, and we propose a model-based approach to control the N-glycosylation in high cell density perfusion culture.

9:30 **Optimisation of Commercial-Scale Intensified Cell Culture**
Sa'ad Ojeili, Bioprocess Consultant, BioPharm Services Ltd
Scaling-up a bioprocess for manufacturing is complex and the impact of cell culture parameters influences manufacturing modalities. BioSolve process incorporating multi-objective Bayesian optimisation is used to analyse the complex design space to help identify optimal solutions. This case study identifies optimal configurations for fed batch, perfusion, or intensified fed batch. The outcomes of the optimisation studies identify those factors that maximise economic, and sustainable benefits.

10:00 **A Novel In-line Sensor System for Real-time Bioprocess Monitoring**
Erik Martinsson, CEO, ArgusEye
Bioprocessing still relies on time-consuming off-line analysis for quality control, with very limited technologies available for in-line or on-line detection. In this presentation, we introduce AugaOne, an innovative in-line sensor system designed for enhanced bioprocessing. Utilizing a nanoplasmonic sensing technology platform, AugaOne offers real-time monitoring of critical quality attributes and process parameters, ensuring optimal process control. Its modular design integrates seamlessly into existing equipment, increasing process efficiency, and intensifying process development.

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

ICH Q13, SUSTAINABILITY IN BIOPROCESSING

11:00 **ICH Q13 Requirements for Continuous Bioprocessing**
Margit Holzer, PhD, Owner, Ulysse Consult
The ICH Q13 guideline provides scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of continuous manufacturing (CM) of drug substances and drug products. This presentation will discuss the application to biomanufacturing.

11:30 **Transferable Raman-Based Soft Sensors as Enablers of Continuous Processing**
Alexandra Umprecht, PhD, Scientist, Digital CMC Sustainability and Technology, Pharmaceutical Sciences, R&D, Takeda Pharmaceuticals
Shift towards continuous bioprocessing relies on availability of robust real-time sensors enabling monitoring and control of such processes. Soft sensors are utilized where direct measurement is not possible or practical. Raman spectroscopy has emerged as a prominent soft-sensing technique, but road blocks to wider deployment remain, such as limited model transferability between processes, scales, or instruments. This talk will explore common causes of lack of transferability, their classification, and potential mitigation strategies.

12:00 **Emerging Technologies for Sustainable Manufacturing in Biopharma**
Dimitrios Lamprou, PhD, Chair of Biofabrication and Advanced Manufacturing, Queen's University Belfast
Emerging technologies are at the forefront of promoting a sustainable message by delivering plausible environmental standards whilst maintaining efficacy and economic viability. Additive manufacturing processes are highly customisable, allowing for their optimisation in terms of sustainability, from reducing printing time to reducing material usage by removing supports. Microfluidics too are supporting sustainability via reduced material wastage and providing a sustainable means for point-of-care analysis.

12:30 **Sponsored Presentation** *(Opportunity Available)*

13:00 **Networking Lunch** *(Sponsorship Opportunity Available)*

INTENSIFIED SOLUTIONS FOR *E.COLI* AND COMPLEX PROTEINS

13:45 **Chairperson's Remarks**
Gerald Striedner, PhD, University Professor, Biotechnology, University of Natural Resources and Life Sciences Vienna (BOKU), Austria

13:50 **Continuous Processing of *E. coli***
Gerald Striedner, PhD, University Professor, Biotechnology, University of Natural Resources and Life Sciences Vienna (BOKU), Austria
Genome-integrated, as well as growth-decoupled *E. coli* expression systems, enable continuous protein production. Efficient implementation requires suitable process strategies for cultivation, and product recovery and purification. The presentation will show two case studies inclusive of an economic evaluation with standard fed-batch as benchmark. We will also present results from a cutting-edge, highly-funded, innovative R&D project named ECOnti.

14:20 **Sustainable, Continuous Enzyme Production with Microbial Hosts**
Julian Kopp, PhD, Postdoc Researcher, Chemical & Environmental & Biological Engineering, Vienna University of Technology
As the human population increases, the demand for biotechnologically produced, value-added products rises. Facing the drastic climate change, processes require severe transformation to produce fewer greenhouse gas emissions at lower water consumption. Continuous bioprocessing allows us to tackle these issues. In my talk, I will demonstrate the potential of continuous bioprocessing for targeted-enzyme production with diverse microbials.

14:50 **Hybrid Modelling Enables Autonomous Fully Continuous Bioprocesses**
Benedikt Haslinger, Bioprocess Modelling Engineer, Novasign
In this talk, a fully continuous microbial production process involving a two-stage bioreactor system in combination with membrane filtration and MCC will be presented. By utilising mechanistic knowledge and machine learning algorithms, the entire process chain is modelled and optimised while the effect of each unit operation on the full control strategy is considered. This approach has the potential to impact the production of pharmaceuticals, industrial enzymes, and novel food.

15:20 **Close of Summit**

19-20 MARCH

Cell Therapy CMC & Manufacturing

VIEW PROGRAM »»

Stream 5

CELL THERAPY

The Cell Therapy CMC and Manufacturing stream brings together leading industry, academic, and technology experts who have agreed to highlight their experiences, share their advice, and present case studies on how your company can best address core CMC and manufacturing challenges, including: selecting appropriate technologies to enable process efficiency, autologous and allogeneic manufacturing strategies (including CAR Ts, NK cells, TCRs, TILs, MSCs, IPSCs, and gamma delta T cells), impact of automation and AI, managing data, analytical trends, current regulatory guidelines and compliance, managing supply chain and logistics, and facility design considerations.

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Cell Therapy CMC and Manufacturing

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

CMC AND ANALYTICS

8:25 Chairman's Remarks

Anthony Ting, Chief Scientific Officer, Kiji Therapeutics, Chief Commercialization Officer and Board Member, ISCT

8:30 Standards Can Facilitate Cell Therapies' Product Development

Fouad Atouf, PhD, Senior Vice President, Global Biologics, USP

Standardisation enables the adoption of new technologies used in the manufacturing and testing of emerging therapies. In this presentation, we will share information on standards-setting activities at the United States Pharmacopeia (USP) and the type of tools and solutions to support implementing quality principles from early stages of cell therapy development, to manufacturing, and release of these products to patients. Cases studies on recently released standards, will be discussed.

9:00 Adventitious Agent Controls for Biological Raw Materials

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

Compared to other medicinal products, cell therapy products (including gene-modified) tend to use a lot of biological raw materials. These can be human, animal, microbial, or even plant-derived. Without understanding how these materials are made, it is not possible to ensure their adventitious agent risks are addressed. Using real examples, this talk will discuss the principles and how to assess and mitigate the identified risks.

9:30 Optimizing CD4+ T Cells Long-term Expansion Process in Stirred-tank Bioreactors: Impact of the Dissolved Oxygen

Françoise de Longueville, Dr., Managing Director / Head of Core Test Lab, Eppendorf Application Technologies S.A.

This study explores the use of Single-Use Bioreactors for the long-term expansion of CD4+ T cells, central to adaptive immunity and cell therapies. It focuses on producing large quantities of high-quality T cells using stirred-tank bioreactors, providing a controlled cultivation environment. Additionally, the impact of different oxygen tensions on T cell proliferation is examined, highlighting the bioreactor's effectiveness in homogeneous T cell cultivation.

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

CMC and ANALYTICS (CONT.)

10:45 Digital Solutions for CMC Optimization

Stuart M Curbishley, PhD, Chief Manufacturing and Development Officer, adthera bio

Cell therapies are transforming the way diseases are treated. This presentation will discuss current challenges in cell therapy CMC optimization and how digital technologies are playing a key role.

11:15 A Strategy and Practical Case for Process Characterisation

Jean-Charles Epinat, PhD, Director, Process Development, Cellectis

Process characterization is a critical phase of process development supported by regulatory guidance for biologics development. Its experimental work plan aims at defining the design space for the process, secure a robust execution and ensure constant product quality. This presentation highlights how this is critical for cell therapies as they transition into off-the-shelf pharmaceutical products.

11:45 KEYNOTE PRESENTATION: Process Development to Improve the Quality and Yield of TCR T Cells for Solid Tumors

Ali Mohamed, PhD, Vice President, CMC, Immatics US, Inc.

IMA203 & IMA203CD8 are Immatics' TCR T product candidate(s) using a PRAME-specific TCR with or without a CD8 co-receptor. The manufacturing process for GMP-compliant production of TCR T cells products for various clinical trials has been developed in our process development laboratory and transferred to the GMP facility. Manufacturing improvements enhanced key features of the cell product. Continuous enhancements are in progress in preparation of later-stage clinical trials.

12:15 Establishing a Viral Vector Manufacturing Processing Using a Quality by Design Approach

Johann Christoph Dettmann, PhD, Senior MSAT Clinical Products, Lentiviral Vector Manufacturing, Miltenyi Biotec B.V. & Co. KG

This talk explores our innovative approach for robust lentiviral vector manufacturing, emphasizing a QbD strategy. Adhering to stringent regulatory requirements for Process Performance Qualification to facilitate commercialization, we employed DoE during Stage 1 Process Design to enable comprehensive process characterization for identifying CPPs and establishing PARs. This talk contributes to the scientific discourse on advancing manufacturing practices for lentiviral vectors, emphasizing a rational and effective approach to process development.

12:45 Networking Lunch *(Sponsorship Opportunity Available)*

MANUFACTURING

13:45 Chairperson's Remarks

Angela Osborne, PhD, CEO & Founder, eXmoor Pharma Concepts Ltd.

As cell therapy products reach the market the conversation is changing from "can you manufacture it" to can you manufacture it suitable for millions of patients compared to hundreds. The role of local academic/hospital GMP centres which got the industry started, continues to be important but alternative solutions are needed for therapies to reach all patients who need them once they are approved.

13:50 Opportunities and Challenges of a Decentralized Manufacturing Network – A Small Biotech's Perspective

Christopher Baldwin, Vice President, Manufacturing and Supply, Resolution Therapeutics

Resolution Therapeutics is developing a macrophage cell therapy to treat inflammatory organ disease. This presentation will discuss the challenges and opportunities of implementing a decentralized manufacturing strategy in a phase appropriate manner and the associated benefits and risks in providing patients with access to quality advanced therapeutics

14:10 Overcoming Conventional CGT Processing Challenges with Point-of-Care (POCare) Solutions

Vered Caplan, CEO, Octomera and Orgenesis

This presentation highlights how POCare solutions leveraging the latest technology and data advances can overcome conventional CGT processing challenges and enable standardisation. By working to develop closed, automated, and reproducible processes, it is possible to bring treatments closer to patients of local hospitals and treatment facilities. The mission is to decentralise and standardise production to make therapies more affordable and accessible to all patients across the globe.

Cambridge Healthtech Institute's 7th Annual

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Cell Therapy CMC and Manufacturing

14:30 Innovative Strategies for a More Robust (yet Adaptable, Accessible, and Cost-Effective) Global Advanced Therapies Supply Chain

Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America

Cell therapies require unique and complex starting material, production, and affordability supply chain challenges. This presentation will discuss innovative strategies being tested and employed to optimise the production and delivery of these therapies to patients in community settings—outside of large urban research centers—across the globe.

14:50 PANEL DISCUSSION: The Role of Decentralised vs. Centralised Manufacturing

Moderator: Angela Osborne, PhD, CEO & Founder, eXmoor Pharma Concepts Ltd.

The role of local academic/hospital GMP centres which got the industry started continues to be important but alternative solutions are needed for therapies to reach all patients who need them once they are approved.

Panelists:

Lee Buckler, Senior Vice President, Advanced Therapies, Blood Centers of America

Vered Caplan, CEO, Octomera and Orgenesis

Christopher Baldwin, Vice President, Manufacturing and Supply, Resolution Therapeutics

Kathryn Golden, SVP Technical Operations & Cell Manufacturing, Tech Operations & Cell Mfg, bit bio

Stephen Judd, Process Subject Matter Expert, Biologics, Cell and Gene Therapy, DPS Group Global

15:20 Sponsored Presentation *(Opportunity Available)*

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

Selvita

MANUFACTURING (CONT.)

16:20 FEATURED PRESENTATION: Identifying and Overcoming Challenges to Ramp Up Global CAR T Production Capacity

Sarah Snykers, PhD, Director of Operations, Legend Biotech

This presentation will provide insight on Legend BioTech's tech transfer strategy to support its manufacturing process, how the company created and currently manages a global CAR T manufacturing footprint, and its approach to identifying and overcoming challenges to ramp up production capacity.

16:50 Considerations of the Selection Criteria of Starting Materials and Bioprocess Design in the Scale-Up Production of MSC-Based Therapies

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

Optimisation of scale-up manufacturing strategies for the production of cell-based therapies requires the establishment of robust criteria for eligibility of human origin starting materials and reliable bioprocess designs. In this presentation, we will present the strategy followed in our laboratory for the production of mesenchymal stromal cells derived from the Wharton's jelly of the umbilical cord. Our approach involves the use of microcarriers and single-use bioreactors.

17:10 TechOps and Manufacturing Excellence in Cell Therapy

Christopher Crowell, Vice President Operations, Site Head EU Manufacturing and Managing Director, Kite Pharma, a Gilead Company

Chris Crowell, Kite's vice president of operations, site head EU manufacturing and managing director provides his insights and perspectives into unique processes and challenges in the manufacturing of cell therapies; Kite's manufacturing network and delivery of cell therapies to eligible patients across Europe and the world; and the importance of site qualification and teamwork throughout the full cell journey.

17:25 Exclusive Fireside Chat with Chris Crowell

Christopher Crowell, Vice President Operations, Site Head EU Manufacturing and Managing Director, Kite Pharma, a Gilead Company

Chris sits down 1:1 with moderator Lee Buckler to share his personal experiences and advice focusing on: (1) Building on existing capabilities to meet increasing patient demand; (2) Delivering innovative therapies in Europe - barriers to access CAR T-cell therapy; (3) The next chapter in commercializing cell therapies.

17:40 ISCT PANEL DISCUSSION: Allogeneic Productivity and Technologies: Unique Challenges - Common Threads

Moderator: Anthony Ting, Chief Scientific Officer, Kiji Therapeutics, Chief Commercialization Officer and Board Member, ISCT

This panel representing biopharma and technology providers will deep-dive and discuss challenges and solutions to overcome allogeneic development and manufacturing challenges, including: (1) batch logistic strategies; (2) improving operator skill levels; (3) design facility footprint; (4) addressing operational constraints; (5) process optimisation; (6) increasing batch potency; (7) technology gaps; and (8) implementing AI, ML, and automation.

Panelists:

Cenk Sumen, PhD, Advisor, MaxCyte Inc.; PDM Committee Member, ISCT

Kathryn Golden, SVP Technical Operations & Cell Manufacturing, Tech Operations & Cell Mfg, bit bio

Julie G. Allickson, PhD, Michael S. and Mary Sue Shannon Family Director, Mayo Clinic Center for Regenerative Medicine, Member, ISCT

18:05 ISCT Panel Discussion: Autologous Productivity and Technologies: Unique Challenges-Common Threads

Moderator: Anthony Ting, Chief Scientific Officer, Kiji Therapeutics, Chief Commercialization Officer and Board Member, ISCT

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Panelists:

Ali Mohamed, PhD, Vice President, CMC, Immatics US, Inc.

Dominic Clarke, Vice President of Technical Operations, IntegriCell; PDM Committee Chair, ISCT

Stephen Judd, Process Subject Matter Expert, Biologics, Cell and Gene Therapy, DPS Group Global

Steven Binninger, Head of Collaborative Technology Development & Commercialisation, Sartorius; PDM Committee Member, ISCT

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

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

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Cell Therapy CMC and Manufacturing

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

PROCESS EFFICIENCY

8:25 Chairperson's Remarks

Klaus Graumann, PhD, CEO, Phoenestra GmbH

Cell & gene therapies have brought a new level of complexity into biologics manufacturing. Consequently, complex manufacturing processes, significant batch failure rates, and high cost of goods are quite common. In this session we will frame current issues and discuss several approaches to further improve translation of products into clinical development (and commercialisation) or during technical lifecycle management.

8:30 Shorten Time-to-Clinic with Stable HEK 293 Lentiviral Vector Producer Cells

Rolf Werner, PhD, Professor, Industrial Biotechnology, University of Tuebingen

Gene and cell therapy are gaining more importance in efficient personalised precision medicine. From a manufacturing aspect, transient production of lentiviral vectors for gene and cell therapeutics is fairly demanding Shortcuts to lentiviral vector transfection of T cells are stable HEK 293 packaging cell lines for explorative research of transforming plasmids, stable HEK 293 producer cell lines for Phase III, and commercial manufacturing of autologous or allogenic T cells.

9:00 Standardising Cryopreservation

Julia Neubauer, Head of Department, Cryo & Stem Cell Technology, Fraunhofer Institute, IBMT

Cryopreservation of iPS cells in large numbers or of functional, differentiated cells is also crucial for later success in therapy or other applications. Therefore, to meet the increasing demand in downstream applications, we have established robust, scalable cryopreservation protocols for iPS cells and several derivatives. This includes the use of large volume cryobags, ready-to-use formats and cryopreservation of tissue engineered products

9:30 Harnessing the Power of Cell Therapy—A Large Pharma's Approach to ATMP Development

Rakesh Koppram, Senior Scientist, Astra Zeneca

Cell therapy is a promising, rapidly advancing field with the potential to transform medicine across disease areas where significant need exists. This presentation will highlight the array of cutting-edge technologies Astra Zeneca is implementing to drive important advances in cell therapy, including gene editing to create 'universal cells' that can be given to any patient, and antibodies to target our cell therapies where they are needed most.

10:00 Sponsored Presentation *(Opportunity Available)*

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

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

11:20 PLENARY PRESENTATION: What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

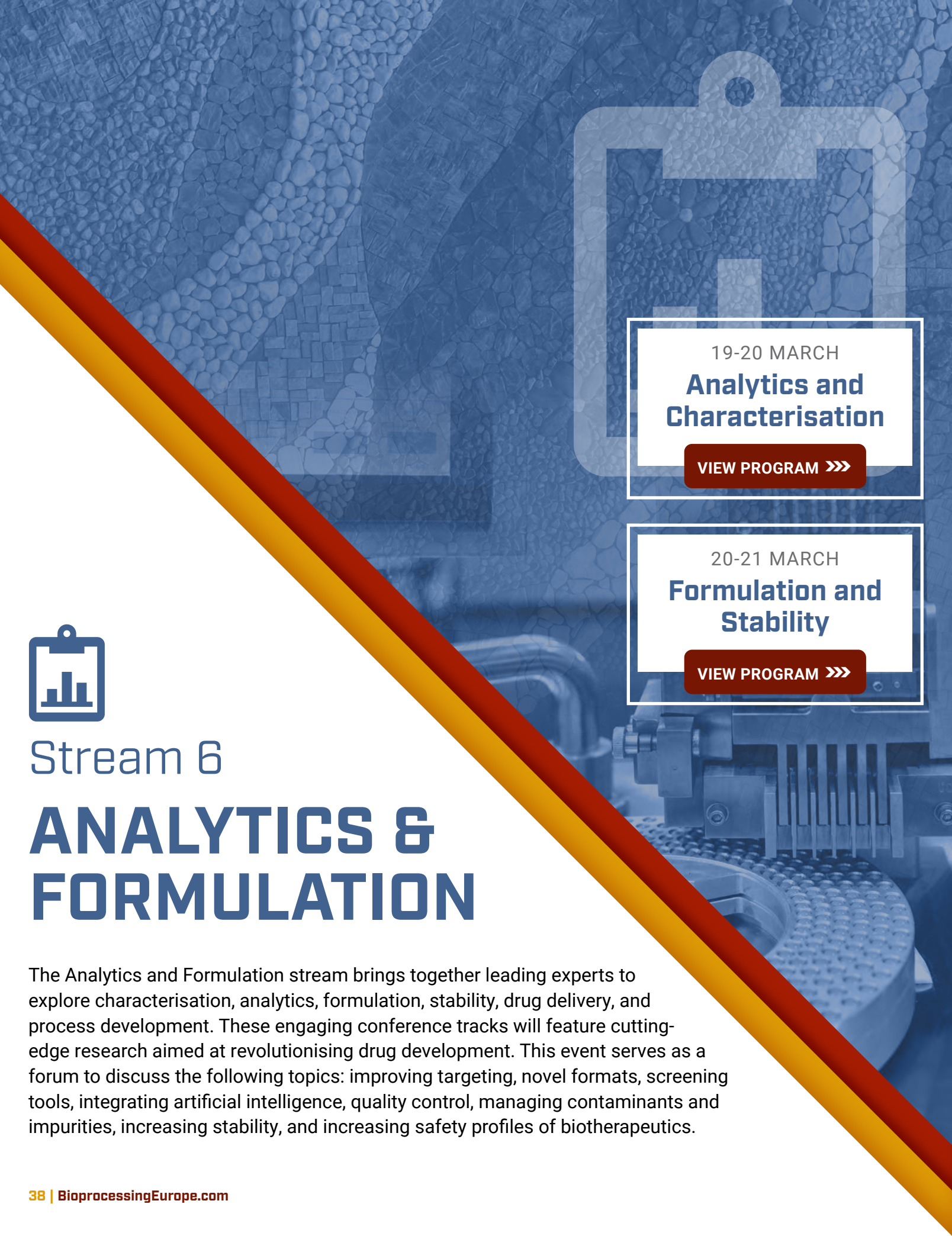
Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

14:05 Close of Cell Therapy CMC and Manufacturing Conference



19-20 MARCH

Analytics and Characterisation

VIEW PROGRAM »»

20-21 MARCH

Formulation and Stability

VIEW PROGRAM »»

Stream 6

ANALYTICS & FORMULATION

The Analytics and Formulation stream brings together leading experts to explore characterisation, analytics, formulation, stability, drug delivery, and process development. These engaging conference tracks will feature cutting-edge research aimed at revolutionising drug development. This event serves as a forum to discuss the following topics: improving targeting, novel formats, screening tools, integrating artificial intelligence, quality control, managing contaminants and impurities, increasing stability, and increasing safety profiles of biotherapeutics.

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Analytics and Characterisation

Unlocking Biotherapeutic Potential with Advanced Technologies and Process Optimisation

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

ADVANCES IN ANALYTICAL TECHNOLOGIES AND TECHNIQUES

8:25 Chairperson's Opening Remarks

Miroslav Nikolov, PhD, Senior Scientist & Laboratory Head, Roche

8:30 FEATURED PRESENTATION: Multi-Attribute Method (MAM) Using Electron-Activated Dissociation (EAD)-Mass Spectrometry: Superior Characterisation and Monitoring of Biotherapeutic Quality Attributes

Ricardo Gomes, PhD, Senior Researcher, Mass Spectrometry Unit, iBET–Instituto de Biologia Experimental e Tecnológica

The increasing complexity of biotherapeutics requires the development of advanced bioanalytical methods. Mass spectrometry-based methods such as the multi-attribute method (MAM) allow for the simultaneous identification, quantification, and monitoring of critical quality attributes. In this work, we will discuss the use of the newly developed electron-activated dissociation (EAD)-QTOF mass spectrometer as an improved analytical tool for the accurate identification and characterisation of challenging product quality attributes.

9:00 New Developments in the Field of Developability Assessment for Therapeutic Proteins

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

Developability assessment is a well-established concept at pharmaceutical industry to mitigate early on possible risks for drug candidates, which in absence of identification might endanger whole programs. But are these concepts addressing all the critical parameters? And how can the higher candidate assessment demand be optimised to not overburden the resources of the organisation? Examples of new modules in the developability assessment concept for biologics will be shown.

9:30 From Cell Line To Final Formulation: Characterizing MAb Stability Throughout The Development Pathway

halo labs

Paul Dyer, PhD, Field Application Scientist, Halo Labs

Antibody-producing cell lines have been used to produce antibodies, often without any consideration for aggregation. Aura+ is used to characterize antibody stability during cell line development (CLD). Aura+ enables low volume, high throughput subvisible particle imaging, counting, sizing, and identification. It easily handles and analyses biologically complex cellular and protein samples present in CLD to characterize protein stability at the point of production.

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

TECHNOFLEX

10:45 Automating Analytical Characterisation of Next-Generation Protein Therapeutics

Miroslav Nikolov, PhD, Senior Scientist & Laboratory Head, Roche

I will present the latest advances in end-to-end automation, digitalisation, and data management of the protein analytics workflows in the pharma research and early development (pRED) unit of Roche, focusing on mass spectrometry analysis of complex antibody-based drug candidates. It is routinely applied to a variety of sample types and throughput, from early binder screening to clone selection, and bioprocess development.

11:15 Development of CE-SDS-Based New Approach towards Characterisation of Spike Protein

Rahul Mishra, PhD, Senior Analytical Scientist, AstraZeneca

SARS-CoV-2 spike protein has emerged as a prime target for vaccine development and serological assays. The heavily glycosylated structure with host-derived glycans two O-glycans sites not only aids the virus in evading the host immune response but further makes it challenging to characterise its physicochemical attributes such as its stability and fragmentation. This was overcome by performing buffer exchange and deglycosylation, thereby optimising inherent migration behaviour in capillary electrophoresis.

11:45 Analytical Challenges and Opportunities for Development of mRNA/LNP-Based Therapeutics

Gunilla Nilsson, MSc, Associate Director, Advanced Drug Delivery, Pharmaceutical Sciences, AstraZeneca

Due to the chemical properties of mRNA, including its size, charge, polydispersity, and susceptibility to degradation, the quality control of mRNA therapeutics is complex. Approaches for control strategies and the quality attributes for release and stability testing of mRNA lipid nanoparticle drug products will be outlined. The main impurities and degradation pathways to consider will be described. In addition, key methods for mRNA LNP analysis will be showcased.

12:15 Advances in Process Analytical Technology (PAT) Knowledge Management Software

synTQ by Optimal

Michael Sachpekidis, BEng MSc MIET, Business Development Manager - Europe, Optimal Industrial Technologies Limited

Comprehensive PAT solutions enable manufacturers to measure CQAs and provide closed-loop control in real time. PAT supports automated, multi-instrument, holistic quality assurance; provides timely critical quality predictions; and captures all necessary, regulatory-compliant data and metadata. Beyond this, advancements in PAT software provide for more targeted improvements, as required by the increasing complexity of the monitored processes. This leads to more advanced control strategies, continuous manufacturing and Real-Time Release Testing.

12:45 Networking Lunch *(Sponsorship Opportunity Available)*

CHARACTERISATION OPTIMISATION

13:45 Chairperson's Remarks

Dan Bach Kristensen, PhD, Principal Scientist, Symphogen

13:50 Enabling Efficient and Automated Sample Preparation in Bottom-up Characterisation of mAbs Using Multidimensional Chromatography

Christoph Gstoettner, PhD, Postdoctoral Researcher, Center for Proteomics and Metabolomics, Leiden University Medical Center

Characterisation of antibody biopharmaceuticals largely relies on mass-spectrometric approaches which involves various sample preparation steps including protein digestion. These steps are time-consuming and can increase the risk of inducing artificial modifications. Using multidimensional LC-MS we have developed a platform that enables automated sample preparation (including digestion with different enzymes) and MS analysis. The results were comparable to offline approaches, while drastically reducing analysis and hands-on time.

14:20 An Optimised Platform Method for the Characterisation of Disulfide Linkages and Free Thiols in Challenging Antibodies, Fusion Proteins, and Replacement Enzymes

Yan Jiang, PhD, Principal Scientist, Biologics Development Bioanalytics, Sanofi

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Analytics and Characterisation

Unlocking Biotherapeutic Potential with Advanced Technologies and Process Optimisation

Disulfide bond formation plays an important role in protein folding, stability, and biological functions, and therefore should be well-characterised during biotherapeutics development, to ensure correct cysteine pairing and protein-structural integrity. A mass spectrometry-based disulfide mapping method was developed to provide accurate relative quantitation of free thiols, and high recovery of disulfide-linked peptides. This platform has been successfully applied to a diverse variety of therapeutic proteins.

14:50 Characterisation of RNA in Lipid Nanoparticles for Base Editing

Siddharth Bhoraskar, PhD, Scientist II, Beam Therapeutics

15:20 Host Cell Protein ELISAs: The Scientific and Business Decisions to Ensure Successful Outcomes

Eric Bishop, Vice President of Research and Development, R&D, Cygnus Technologies

Host cell protein analytics have come a long way over the last 25 years. We have gone from a "black-box" type approach to ELISA that produced numbers that were semiquantitative at best to ground-breaking Mass Spectrometry techniques that can identify every host cell protein in a drug substance sample. This presentation will focus on the scientific, regulatory, and business decisions that should be considered when deciding to use a commercial HCP ELISA or a custom HCP ELISA when moving a product into Phase 3 clinical trials.

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

16:20 Automatic Peak Fractionation of Any LC Separation Combined with Any MS Workflow for Flexible, Robust, Ultra-Sensitive, and in-Depth Biopharmaceutical Characterisation

Dan Bach Kristensen, PhD, Principal Scientist, Symphogen

Recent progress in MS characterisation platform will be presented. Topics include automated fraction collection from any type of LC separation (including non-MS compatible LC methods) combined with a broad range of MS characterisation workflows (including intact LC-MS, peptide mapping by LC-MS/MS, and direct-infusion MS) of the individual LC fractions. The characterisation platform provides highly flexible, robust, ultra-sensitive, and in-depth characterisation of proteoforms. Case studies and perspective will be presented.

IMPROVED SAFETY, WORKFLOW, AND REGULATORY NAVIGATION

16:50 Navigating the Gaps between Phase-Appropriate and Marketing Applications—And Cleaning Up the Messes Made along the Way

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

17:20 From Liquid to Solid Transition: The Role of Phase Separation in Protein Stability and Aggregation

Vito Foderà, PhD, Associate Professor, Biophysics, University of Copenhagen

The ability of proteins to aggregate is a challenge in the development of therapeutic products. By fluorescence microscopy, X-ray scattering, spectroscopy, and molecular dynamics, we identify the interactions responsible for protein phase separation, conformational changes, and colloidal instability, and how those aspects are linked to the variability in the morphologies. Our findings provide a scenario in which heterogeneous structures can be generated as a result of interconnected aggregation pathways.

INTERACTIVE BREAKOUT DISCUSSIONS

17:50 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: Challenges and Opportunities Towards Analytical Development for Next Generation Manufacturing (NGM) Process Optimization

Rahul Mishra, PhD, Senior Analytical Scientist, AstraZeneca

- How we can proceed with the High throughput analytical methods (size, charge, fragments, and glycan) to support the NGM process?
- Is there opportunity for characterization methods to be scaled up for High throughput analysis?
- What are the risk and challenges?

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

IMPROVED SAFETY, WORKFLOW, AND REGULATORY NAVIGATION

8:25 Presentation to be Announced

8:30 Process Control Strategy Development for Cell and Gene Therapy Products

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

Analytical characterisation of cell and gene therapy manufacturing processes is essential for process understanding and driving quality-by-design development. Incorporation of higher-content analytical techniques that result in meaningful outputs which can be used to drive higher-quality process development and integrate into a manufacturing setting is a challenge and one that the Cell and Gene Therapy Catapult is looking to address for allogeneic cell therapy manufacturing processes.

9:00 Defining Patient-Centric Specification in a Risk-Based Control System

Gerald Gellermann, PhD, Scientific Officer, Analytical Development, Novartis

Defining limits for analytical method outputs is a central element of a control strategy. Traditional approaches usually focus on ensuring process consistency, while, in more advanced approaches, the understanding of structural-function relationships is utilised. This enables definition of limits that may extend outside those determined by clinical experience.

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Analytics and Characterisation

Unlocking Biotherapeutic Potential with Advanced Technologies and Process Optimisation

9:30 KEYNOTE PRESENTATION Detecting Low-Abundance HCPs in Biopharmaceuticals: Advances & Applications

Thomas Waerner, PhD, Senior Principal Scientist & Laboratory Director, Analytical Development & Quality Control, Boehringer Ingelheim Pharma GmbH & Co. KG

Host Cell Proteins (HCPs) represent undesirable contaminants in biopharmaceutical products. The presence of even low-abundance HCPs can significantly affect product quality. In this study, we present our latest research on utilising tandem mass spectrometry (MS/MS), coupled with HCP enrichment techniques for detecting low-abundance HCPs. We also provide case studies demonstrating the application of these findings to enhance biopharmaceutical product quality, with a particular emphasis on CHO production.

10:00 Mass Photometry - a fast and accurate analytical tool for biomolecular characterisation

Racha Majed, Dr., Refeyn

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

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

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Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

14:05 Close of Analytics and Characterisation Conference

Cambridge Healthtech Institute's 5th Annual

20 - 21 MARCH 2024 ALL TIMES CET

Formulation and Stability

Innovative Solutions for Improved Safety, Design, and Delivery of Biotherapeutics

WEDNESDAY 20 MARCH

10:30 Registration Open

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

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13:05 Networking Lunch (Sponsored Opportunity Available)

NOVEL TECHNOLOGIES AND APPROACHES

14:15 Chairperson's Opening Remarks

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

14:20 KEYNOTE PRESENTATION: The Viscosity Reduction Platform—Accelerating SC-Suitable High-Concentration Protein Formulations Using Machine Learning

Stefan Braun, Head of Laboratory, Liquid Formulation R&D, Merck

Viscosity is one major challenge in formulating highly concentrated protein therapeutics. Already during filtration steps in downstream processing, attractive interactions might lead to an increase in viscosity before reaching the final concentration. The Viscosity Reduction Platform provides a tailored approach to address these issues in manufacturing and final formulation. We developed a machine learning-based digital application to minimise the number of experiments needed to obtain tailor-made solutions for high-viscosity formulations.

14:50 Lab-on-a-Chip and Microfluidic Technologies in Nanomedicine

Dimitrios Lamprou, PhD, Chair of Biofabrication and Advanced Manufacturing, Queen's University Belfast

Progress in drug design has led to the development of new molecules. However, the limited ability to selectively deliver these molecules at well-defined dosing regimens and screening them remains a significant challenge. The talk will cover the manufacturing of polymer-based and lipid-based nanomedicines using microfluidics and comparison with traditional formulation methods. Moreover, the manufacturing of lab-on-a-chip by 3D printing for drug screening will also be discussed.

15:20 FEATURED PRESENTATION: Next-Gen Nanomedicine—The Supramolecular Drug

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

Nanoparticles have traditionally been seen as mere carriers for small molecules and biotherapeutics, but this might soon become a paradigm of the past. At Molecular Bionics, we are working on the design of multifunctional nanomedicines that are intrinsically and structurally therapeutic. With an initial focus on inflammation and infection, we combine the phenotypic targeting of specific cell populations with naturally metabolisable polymers that activate disease-specific biological pathways.

15:50 Uncover the secrets of your ADC with Unchained Labs

Andre Mueller, PhD, Marketing Manager, Biologics Solutions, Marketing, Unchained Labs

Antibody conjugates are powerful drugs – but also notorious: they aggregate and there's never enough sample to do everything you want. Unchained Labs provides the right tools for this job: low volume, high throughput, integrated solutions making it easy to scope out any biologic – even ADCs. Join my talk and see how our solutions quantitate ADC and DAR, check quality, aggregation, conformational and colloidal stability, helping you optimize formulation conditions.

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

17:00 Novel 505b2 Formulation Approaches

Devendra Ridhurkar, PhD, Director, R&D, Adalvo

In this presentation, we delve into groundbreaking strategies for developing 505(b)(2) formulations. Our focus is on advanced approaches, and we aim to highlight how optimising drug delivery and bioavailability can lead to improved outcomes for patients undergoing treatment. Join us as we explore the intricacies of these innovative methods and their tangible impact on enhancing patient care.

Cambridge Healthtech Institute's 5th Annual

20 - 21 MARCH 2024 ALL TIMES CET

Formulation and Stability

Innovative Solutions for Improved Safety, Design, and Delivery of Biotherapeutics

INCREASING STABILITY AND SAFETY PROFILES

17:30 Innovative Vaccine Formulations for Equitable Access

Renske Hesselink, PhD, CMC Technology Lead, Mfg & Supply Chain, CEPI Coalition for Epidemic Preparedness Innovations

The COVID-19 pandemic has shown how critical formulation and stability are for equitable access to vaccines. Stable presentations that are easy to distribute and administer are essential to make these vaccines available to all people who need them, both in outbreak situations and for routine immunization. CEPI is investing in novel presentations, such as microarray patches and solid dosage forms, to improve equitable access to vaccines.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions

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

BREAKOUT DISCUSSION: Technical Transfer of Drug Product Manufacturing Process for Early Stage Programs (Phase I)

Japneet Kaur, PhD, Senior Scientist, CMC, Takeda Pharmaceuticals

- Limited process information
- Limited drug substance availability for scale up
- Tight timelines for tech transfer and CTM batch manufacturing
- Internal vs external manufacturing
- CMO/CDMO selection process

18:30 Close of Day

THURSDAY 21 MARCH

8:00 Registration and Morning Coffee

INCREASING STABILITY AND SAFETY PROFILES

8:25 Chairperson's Opening Remarks

Michelle P. Zoeller, PhD, Senior Scientist, Liquid Formulation R&D, Merck Life Science KGaA

8:30 Formulation Development of an Early-Stage Hydrophobic Bispecific Antibody

Japneet Kaur, PhD, Senior Scientist, CMC, Takeda Pharmaceuticals

Speed of formulation development of early-stage biologics is critical for regulatory filing and first in-human dose. Platform formulations are often implemented to meet the accelerated timelines for Phase I formulation development of standard monoclonal antibodies. However, for other modalities like bispecific antibodies, additional buffer/excipient screening might be needed to get a stable formulation. Here, we will discuss a case study for formulation development of a hydrophobic bispecific antibody.

9:00 The Protein Stabilising Capability of Surfactants against Agitation- and Surface-Induced Stresses

Michelle P. Zoeller, PhD, Senior Scientist, Liquid Formulation R&D, Merck Life Science KGaA

The application of surfactants, mainly polysorbates, is a common practice to prevent surface- or agitation-induced protein aggregation in liquid formulation. However, polysorbates, despite their common application, bring along disadvantages, including chemical and enzymatic instability. This presentation will provide an overview of the protein-stabilising capability of surfactants against agitation- and interface-induced stresses, and corresponding assays for its evaluation. Furthermore, a focus is set to alternative surfactants suitable to replace polysorbates.

9:30 Calibration Verification of Sub-Visible Particle Analysis Systems: Polystyrene Standards Formulation Optimisation and Stability in Deep Well Plates

Tobias Werk, PhD, CEO, Bionter AG

This study rigorously evaluates the suitability of deep well plates for formulation screening and analyses particle load variability across four DWP variants. Utilizing EVE for sub-visible particle load assessment, we examine inter- and intra-batch variability. Additionally, accelerated stability studies of polystyrene particle suspensions provide crucial insights into calibration-standard shelf-life. The results are anticipated to guide optimal DWP selection for formulation screening and ensure accuracy in analytical assessments.

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:00 Predicting and Increasing the Long-Term Stability of Lyophilised mAb Solutions Based on Water Activity

Christoph Brandenbusch, PhD, Assistant Professor, Bioprocess Separations & Biologics Formulation Development, TU Dortmund University

Excipients and excipient mixtures within liquid and lyophilised biopharmaceutical formulations are mainly identified based on screening or heuristic approaches. Physically sound modelling approaches, especially predictive modelling approaches, are desirable to identify excipients and excipient mixtures based intermolecular interactions in solution. We will present a novel approach, considering water activity as criterion to determine the optimal excipient mixture for a given liquid/lyophilised formulation in an early development stage.

11:30 A Universal Tool for Stability Predictions of Biotherapeutics, Vaccines, and *in vitro* Diagnostic Products

Hermine Achard, MS, Biotechnology Engineer, R&D, Sanofi

Biopharmaceutical companies utilise Advanced Kinetic Modeling (AKM) to ensure the stability and efficacy of delicate biomolecules during storage and transport. Following quality-by-design principles, AKM predicts long-term shelf-life based on accelerated stability studies. Evaluated across various biotherapeutics and vaccines, AKM demonstrates accurate stability forecasts up to 3 years, confirming its universal reliability for diverse products, even those with temperature excursions.

12:00 Prediction of Long-Term Polysorbate Degradation According to Short-Term Degradation Kinetics

Hui Xiao, PhD, Senior Principal Scientist, Regeneron Pharmaceuticals, Inc.

We've developed a rapid platform for predicting the long-term degradation of polysorbates in protein therapeutic formulations, crucial for preventing denaturation and aggregation. Using a temperature-dependent equation derived from existing PS20 degradation data, we accurately forecasted PS20 and PS80 hydrolysis for up to 2 years within just 2 weeks of short-term kinetics studies. This platform significantly expedites the assessment of PS degradation, aiding in refining purification processes and optimising antibody formulations.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch *(Sponsorship Opportunity Available)*

Cambridge Healthtech Institute's 5th Annual

20 - 21 MARCH 2024 ALL TIMES CET

Formulation and Stability

Innovative Solutions for Improved Safety, Design, and Delivery of Biotherapeutics

SOLUTIONS FOR DELIVERY AND PROCESS DEVELOPMENT

13:45 Presentation to be Announced

13:50 Biopharmaceutical Formulation—Platform Approaches or Innovation?

Jan Jezek, CSO, R&D, Arecor

Formulation is an integral part of drug product development. Platform formulation approaches are often used for specific types of therapeutic modalities to ensure efficient "fast-to-clinic" development. At the same time there are increasing demands for convenient patient-centric products that may require innovative formulation approaches. The talk, which will include several case studies, will demonstrate benefits of innovative formulation and address the balance between routine vs. innovative formulation.

14:20 Methods for Addressing Host Cell Protein Impurities in Biopharmaceutical Product Development

Nicholas J Darton, PhD, Associate Director, AstraZeneca

A key challenge to the cost and stability of monoclonal antibodies (mAb) is in the control of host cell protein (HCP) impurities. HCPs often co-purify with the desired mAb product and can impact the stability of the final mAb protein product. Here, we explore established and new techniques for HCP mitigation that could be implemented in the future to improve the quality and stability of the final mAb drug product.

14:50 Platform Polymer Technologies for Targeting Solid-Tumor Cancers; Druggable Targets for Advanced Therapeutics

Kadie Edwards, PhD, Post Doc, Swansea University

In this presentation, we will discuss cutting-edge Platform Polymer Technologies tailored for the targeted treatment of solid-tumor cancers. Delving into druggable targets, our exploration advances the frontier of therapeutic possibilities. Join us for insights into groundbreaking strategies that promise enhanced precision and efficacy, heralding a new era in advanced cancer therapeutics.

15:20 Close of Summit

19-20 MARCH

Cultivated Meat

VIEW PROGRAM »»

20-21 MARCH

Precision Fermentation

VIEW PROGRAM »»

NEW! Stream 7

ALTERNATIVE PROTEIN PRODUCTION

The new Alternative Protein Production stream was added to Bioprocessing Summit Europe to recognise the synergies between the manufacturing technologies used for these nascent food products and biologic drugs. This meeting provides an opportunity for those working in cultivated meat and precision fermentation to share best practices and explore prospects for collaborations and technological innovations.

Cambridge Healthtech Institute's Inaugural

19 - 20 MARCH 2024 ALL TIMES CET

Process Optimisation for Cultivated Meat

New Technologies and Strategies to Optimise Manufacturing Steps and Reduce Production Costs

TUESDAY 19 MARCH

7:00 Registration and Morning Coffee

CELL LINE DEVELOPMENT

8:25 Chairperson's Remarks

Michael Sulu, PhD, Lecturer, Biochemical Engineering; Senior Fellow, Higher Education Academy (SFHEA), University College London

8:30 Cultivated Pork on Microalgae Base

Vladislav Strmiska, PhD, Senior Scientist, Mewery

Cultivated pork meat in multi-organism combination is a challenging hybrid technological process which pays off. Microalgae, as the key substrate in a process of porcine cells cultivation, are used for three separate platforms: for FBS replacement, as microcarrier, and for growth factors production.

9:00 Developing a Scalable Process for Cultivated Meat Production Begins with High-Quality Cells

Jef Pinxteren, Vice President, Development, Roslin Technologies Limited

Roslin Technologies is a pioneer in pluripotent stem cell development for cultivated meat applications. Our multi-species, indefinitely self-renewing, karyotypically-normal stem cells are developed from elite animal breeding stocks and supplied with full traceability and data-supporting cultivated meat regulatory dossiers. We share our latest bioprocess metrics supporting the development of robust, scalable cultivated meat production solutions.

9:30 Sponsored Presentation *(Opportunity Available)*

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

TECHNOFLEX

UPSTREAM PROCESSING

10:45 Challenges and Opportunities in Upstream Processing

Michael Sulu, PhD, Lecturer, Biochemical Engineering; Senior Fellow, Higher Education Academy (SFHEA), University College London

This talk will set out the challenges and opportunities in upstream processing for alternative protein production. It will seek to identify knowledge- and skills-gaps in the domain, as well as what can be learnt from the various sectors of biotechnology, and conclude by circling back to the gaps to identify the areas that could provide the greatest opportunities in the research and industrial environment.

11:15 Media Optimisation Strategies: Peeling Off the Levels of Uncertainty

Aleksandra Fuchs, PhD, Senior Scientist, Austrian Centre of Industrial Biotechnology

Media optimisation strategies have evolved significantly in recent decades, benefiting from recent advances in various interdisciplinary fields. These encompass a broader comprehension of cellular processes, AI-driven protein design, simulation of protein-protein interactions, experimental design, and omics-based modelling of cellular processes within digital twins. When sequentially applied, these approaches not only deepen our understanding of the processes, but also improve the predictability of the system, ultimately resulting in superior performance.

11:45 Computer-Aided Design and Computational Fluid Dynamics Software for Bioreactor Design

Akin Odeleye, PhD, Head, Bioprocessing, Ivy Farm Technologies

Computer-aided design (CAD) and computational fluid dynamics (CFD) are playing key roles in the digital transformation of bioprocesses. CAD and CFD can be used to enable scale-up, predicting performance of lab and production scale reactors. Such models play a key role in large-scale bioreactor design, whilst computational methods of predicting cell growth are being combined with CFD to enable digital twins of bioreactors.

12:15 Cost Efficient Cultivated Meat Production Through Deeper Process Insights

HAMILTON

Yavuz Çelik, Product Manager, Process Analytics, Hamilton Bonaduz AG

Explore efficiency and cost-saving strategies in cultivated meat processes using process analytics. This presentation highlights how Hamilton sensors address cultivated meat production challenges, ensuring improved process control and optimization through inline, real-time measurements. Gain insights into critical process parameters and KPIs essential for optimal product growth and yield. Understand how controlling these parameters can significantly reduce process costs and downtime.

12:30 Presentation to be Announced

12:45 Networking Lunch *(Sponsorship Opportunity Available)*

SCALE-UP AND PROCESS SYSTEMS ENGINEERING

13:45 Chairperson's Remarks

Petra Hanga, PhD, Lecturer, Biochemical Engineering and Cellular Agriculture, University College London

13:50 From Cell to Tissue Processing—Enabling Cultivated Meat Production at-Scale

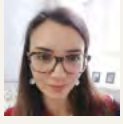
Barak Zohar, PhD, CTO, Ever After Foods

Traditional cell processing systems, such as stirred tank bioreactor, fail to provide the conditions for growing tissues at-scale. We developed a proprietary scalable packed-bed bioreactor technology consisting of plant based edible scaffolds for growing tissues in extremely high productivity. Our technology can increase the production yield of cultivated meat 13-fold and reduce the cost of production in more than 90%.

14:20 Scaling-Up Strategies for Cell-Cultured Seafood

Keerthi Srinivas, PhD, Director, Bioprocess Development, Bluenalu

Scaling-up cell culture requires understanding and improving cell kinetics, bioreactor hydrodynamics, and substrate/nutrient feeding strategies, using process analytics, empirical kinetic & mechanistic modelling, and effective bioreactor designs. This presentation will focus on implementing effective scaling techniques in suspension cell culture for accelerating delivery of high-quality, delicious seafood to market, and advancing sustainability in our food system.



14:50 FEATURED PRESENTATION: Bioprocess Intensification Strategy for Cultivated Meat Production

Petra Hanga, PhD, Lecturer, Biochemical Engineering and Cellular Agriculture, University College London

We have developed a scalable, microcarrier based, intensified bioprocess for the expansion of bovine adipose-derived stem cells as precursors of fat, a component of cultivated meat, first in spinner flasks of different sizes and then translated to fully controlled litre scale benchtop bioreactors. Bioprocess intensification utilised the bead-to-bead transfer phenomenon and the combined addition of microcarrier and medium to double the existing surface area and working volume in the bioreactor.

15:20 Sponsored Presentation *(Opportunity Available)*

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

Selvita

16:20 Scale-Up of the Cocoon Protein Expression Platform

Romy Moreno Dalton, PhD, COO, Cocoon Bioscience

Cocoon Bioscience has developed an automated, baculovirus-based platform that utilises living insects in their chrysalis state as natural bioreactors for producing complex recombinant proteins with high activity that are difficult or impossible to produce in traditional expression systems. Initially developed for production of vaccines at a gram-scale, Cocoon is currently scaling the technology—on upstream, downstream, and starting material input—to the gram-scale at an industrial facility.

Cambridge Healthtech Institute's Inaugural

19 - 20 MARCH 2024 ALL TIMES CET

Process Optimisation for Cultivated Meat

New Technologies and Strategies to Optimise Manufacturing Steps and Reduce Production Costs

16:50 Prediction and Optimisation of Cultivated Meat Bioreactor Yield

Simon Hubbard, PhD, Consultant Engineer & Owner, Upstream Applied Science

A variety of challenges exist in predicting cultivated meat bioreactor yield. This presentation describes the development and application of new workflows, utilising computational fluid dynamics modelling and Bayesian optimisation, that couple cell metabolism with bioreactor dynamics to predict and optimise yield in production-scale stirred tank and airlift bioreactors. These workflows allow for the effects of production scale spatial inhomogeneity on cell growth to be captured for the first time.

17:20 Prospects for Producing Cultured Meat at a Farm: Scale-Up Strategy and Realisation Aspects

Nico Oosterhuis, Senior Bioprocess Consultant, RESPECTfarms

Ira van Eelen, PhD, Co-Founder, RESPECTfarms

Respect Farms aims at offering farmers a reasonable alternative or additional business model to conventional meat production by applying cellular agriculture. Our process design will be based on a scale-out approach, applying single-use bioreactors instead of large steel bioreactors. This makes processes more flexible, easier to operate, and in terms of sterility, more reliable. A process based on single-use components requires fewer investments and less infrastructure.

INTERACTIVE BREAKOUT DISCUSSIONS

17:50 Interactive Breakout Discussions

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BREAKOUT DISCUSSION: Technological Hurdles Cultivated Meat Still Needs to Master

Aleksandra Fuchs, PhD, Senior Scientist, Austrian Centre of Industrial Biotechnology

18:30 Welcome Reception in the Exhibit Hall with Poster Viewing

19:30 Close of Day

WEDNESDAY 20 MARCH

8:00 Registration and Morning Coffee

TRENDS, CHALLENGES, AND OPPORTUNITIES

8:25 Chairperson's Remarks

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

8:30 FEATURED PRESENTATION: Cultivated Meat in Europe: Major Trends and Opportunities

Seren Kell, Senior Science and Technology Manager, The Good Food Institute Europe

This talk will cover the growing need for transforming our global food system in order to sustainably feed the world by 2050, introducing the role that cultivated meat can play in this transition. It will also overview the present commercial, investment, and socio-political landscape in Europe, as well as the scientific and industrial challenges presently preventing cultivated meat from achieving large-scale market uptake.

9:00 Navigating Regulatory and Quality Challenges in Europe and Beyond

Hannah Lester, PhD, CEO & Principal Consultant, Atova Consulting

This presentation will explore the complex landscape of cultivated meat regulation and quality standards in Europe and global markets. We will delve into the legal frameworks, addressing hurdles and opportunities for cultivated meat industry players. This session will discuss the main pain points from a regulatory and quality perspective, and provide insights to navigate the evolving landscape to ensure safe, sustainable, and delicious cultured meat and seafood products for consumers.

9:30 Sustainability and Innovation in Production Economics

Stefano Lattanzi, PhD, CEO, BrunoCell

Cultivated meat is a disruptive technology and an anthropological revolution. News in the media suggests the field is at an advanced technology readiness level (TRL), ready to hit the market at scale. But, with current manufacturing processes, cultured meat is still extremely expensive and faces a challenging route to scaling up. With the perspective of an insider in this field since 2009, we describe promises and challenges of this field.

10:00 Sponsored Presentation *(Opportunity Available)*

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

PLENARY KEYNOTE SESSION
BACK TO THE FUTURE OF BIOPROCESSING—ANTIBODIES TO EXTRACELLULAR VESICLES

11:15 Chairperson's Opening Remarks

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

11:20 PLENARY PRESENTATION: What Have Monoclonal Antibodies Ever Done for Us? Past, Present, and Future Perspectives on Antibodies and How They Have Driven Bioprocessing Progress

Paul Varley, PhD, Senior Vice President, Development, Alchemab Therapeutics

Advances in bioprocessing have been pivotal to the emergence of monoclonal antibodies as one of the most successful classes of drugs in modern medicine. In this talk, we will consider this journey and ask what's next for antibodies. We will also explore how advances in antibody bioprocessing continue to enable the next generation of biological medicines through the emergence of new product modalities.

11:50 PLENARY PRESENTATION: Extracellular Vesicles as Promising Drug Modalities in Spinal Cord Injury and Other (Neuro-)Degenerative Diseases

Eva Rohde, MD, Chair, Transfusion Medicine, Director GMP Unit, Spinal Cord Injury and Tissue Regeneration Center Salzburg (SCI-TReCS), Paracelsus Medical University Salzburg

Extracellular vesicles (EVs) have emerged as promising new biologic drug modalities. EV therapeutics (EV-Tx) derived from mesenchymal stromal cells (MSC) contain factors known to exert anti-inflammatory, anti-fibrotic, and regenerative effects. MSC-EV-Tx could therefore optimise healing after acute traumatic injury. Challenges in reproducible manufacturing prevent comprehensive evaluation of therapeutic efficacy. Concepts to accelerate clinical testing of EV-Tx and examples of clinical translation for various clinical target diseases are presented.

12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

14:05 Close of Process Optimisation for Cultivated Meat Conference

Cambridge Healthtech Institute's Inaugural

20 - 21 MARCH 2024 ALL TIMES CET

Process Optimisation for Precision Fermentation

Upstream and Downstream Production Strategies for Scale-Up and Cost Reduction

WEDNESDAY 20 MARCH

10:30 Registration Open

PLENARY KEYNOTE SESSION
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12:20 Session Break

12:35 Sponsored Presentation *(Opportunity Available)*

13:05 Networking Lunch (Sponsored Opportunity Available)

UPSTREAM PRODUCTION

14:15 Chairperson's Remarks

Seren Kell, Senior Science and Technology Manager, The Good Food Institute Europe

14:20 KEYNOTE PRESENTATION: Rational Strain Engineering for Precision Fermentation

John Morrissey, PhD, Professor, Microbiology, University College Cork

Precision fermentation deploys engineered microbes to produce desired biochemicals and proteins. Although the use of microbes in industrial fermentations is not novel, the advent of new molecular techniques to precisely repurpose microbial pathways and processes has shifted paradigms. Using methods such as CRISPR, genome engineering, and Golden Gate *in vitro* DNA assembly, it is now possible to rapidly construct tailored microbial strains to use in novel fermentative bioprocesses.

14:50 Beyond Temperature Control: How to Enable Advanced Control of Precision Fermentation to Achieve Your High Titres

Nadav Bar, PhD, Professor, Chemical Engineering, Norwegian University of Science and Technology

Precision fermentation goes beyond genetics, aiming for high compound yields. We explore real-time bioprocessing control techniques, from basic temperature control to more advanced multivariate cascade control, model predictive control, and reinforcement learning. Challenges include model development, imprecise measurements, process noise, and model uncertainty. We introduce bioprocess estimators and combine them with machine learning for improved control and data analysis. Real-world case studies highlight precise control in aerobic precision fermentation.

15:20 Lessons Learned from Pharmaceutical Bioprocessing Combined with Essential Ingredients to Achieve Cost Parity with Vegan Cheese

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

Biopharmaceutical recombinant proteins need to be competitive in the Euro/g range; for novel food we need to target Euro/kg. This contribution shows the main ingredients for a disruptive step towards achieving cost parity for recombinantly produced casein for vegan cheese. The main enablers are robust continuous microbial biomanufacturing controlled by feedback digital twins for individual unit operations and along the complete process chain.

15:50 Navigating the challenges of alternative protein production : Explore the role of culture media optimization

Benoît DrogueBenoît Drogue, Ph.D., Global Innovation Manager, Global Innovation, Procelys by Lesaffre

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

17:00 FEATURED PRESENTATION: Scaling-Up New Technologies: The Engineer's Perspective

Joachim Schulze, PhD, CTO, Planetary Group

New bioprocesses are started in the laboratory—under laboratory conditions. Downstream is often undervalued—the upstream is the focus. Okay for the start, but we need to understand the complete process to calculate CAPEX and OPEX evaluating the feasibility of the technology. A TEA (techno-economical analysis) in early-stage, including sensitivity analysis, shows potential weaknesses and will control the R&D. Guidelines of a practitioner.

17:30 Unleashing the Power of CO2-Fixation for Proteinogenic Amino Acid Production

Barbara Reischl, Process Developer, Arkeon Bio

Greenhouse gas emissions to the atmosphere, including anthropogenic released CO_2, are major contributors to the accelerating climate crisis. A promising technology for carbon capture and utilisation (CCU) of CO_2 is gas fermentation. Methanogenic archaea possess metabolic characteristics, such as high CO_2 uptake rates, which makes them advantageous in different biotechnological applications. *Methanothermobacter* sp. strain Arkeon is able to convert CO_2 into proteinogenic amino acids and excrete them to the supernatant.

INTERACTIVE BREAKOUT DISCUSSIONS

18:00 Interactive Breakout Discussions

Cambridge Healthtech Institute's Inaugural

20 - 21 MARCH 2024 ALL TIMES CET

Process Optimisation for Precision Fermentation

Upstream and Downstream Production Strategies for Scale-Up and Cost Reduction

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BREAKOUT DISCUSSION: Essential Ingredients for Economic Precision Fermentation Solutions

Christoph Herwig, PhD, former Professor, Bioprocess Engineering, TU Wien; CPO, Fermify GmbH; Founder, Lisalis

18:30 Close of Day

THURSDAY 21 MARCH

8:00 Registration and Morning Coffee

SCALE-UP STRATEGIES

8:25 Chairperson's Remarks

Giovanni Campolongo, Senior Market Segment Manager, Process Analytics, Hamilton Bonaduz AG

HAMILTON

8:30 Optimisation Strategies for Downstream Processing

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

Optimisation typically refers to a cost reduction, which can be achieved, for example, through an increase in volumetric productivity. In addition, there are also "soft" optimisation goals, such as improved product safety and, especially in light of climate change, a reduced ecologic/environmental footprint. Here, we will discuss implications of these optimisation goals in the context of precision fermentation focusing on technology fit, scalability, and adaptability of unit operations.

9:00 Challenges in Upscaling New Technologies

Gero Grieve, Head, Project Development, ERIDIA GmbH

To be successful in biotechnological development, several challenges must be overcome and practical solutions implemented. Starting from the definition of the end product of the process and the existing equipment, an optimised upstream and downstream process must be defined in the early phase of process development and integrated into the laboratory activities.

9:30 Strategies to Scale-Up Capacity for Long-Term Category Growth

Dominic Silvester, Senior Consultant, Integration Consulting

Alternative protein companies encounter numerous manufacturing-related challenges when seeking to utilise precision fermentation—from initial strain development to executing large-scale commercial production. Ensuring long-term category growth rests upon mapping, understanding, and developing strategies to effectively address these challenges in economically viable ways. This talk introduces key hurdles encountered at different product development stages, provides an overview of existing production capacity, and highlights strategies being employed to overcome capacity constraints.

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:00 Computational Fluid Dynamics (CFD) for Designing Bioprocess Scale-Up

Cees Haringa, PhD, Assistant Professor, TU Delft

Local environmental conditions may have considerable impact on cellular—and consequently—bioprocess performance. Using computational fluid dynamics (CFD) combined with biokinetic models allows study of this impact. We utilise agent-based modelling to study bioprocesses from the cellular perspective, how cells observe variations in their environment, and how this can be translated to representative downscaling experiments to unravel the impact on process performance.

11:30 Precision Fermentation—From Strain Development to Production at-Scale

Reza Ranjbar, PhD, Head of Technology Strategy—Biotechnology, CPI

Precision fermentation offers a compelling alternative to animal-derived proteins and fats and alternatives to sugar, synthetic colourants, and preservatives—aligning with sustainability and ethics. Over 200 companies are active in the field, yet commercial viability remains a challenge, necessitating process improvement and cost reduction. This talk addresses pivotal decisions: selecting efficient hosts, optimising fermentation process from small-scale to industrial-scale, and employing scale-down approaches for a seamless scale-up process.

12:00 Engineering Enzymes for the Food Industry

Claes Gustafsson, PhD, Chief Commercial Officer & Co-Founder, ATUM

The last decade has seen an explosion in new engineered biocatalysts designed to improve food manufacturing. This presentation will illustrate how ATUM's ProteinGPS platform has provided novel enzymes for the food industry. As technology advances, the use of these enzymes in food production is poised to grow, offering a promising future for the industry.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch *(Sponsorship Opportunity Available)*

PROCESS SYSTEM ENGINEERING

13:45 Chairperson's Remarks

Gero Grieve, Head, Project Development, ERIDIA GmbH

13:50 Fermentation Process Monitoring and Optimisation Using Soft Sensors

Ram Uritski, PhD, Vice President, Bioprocess, Remilk

Soft sensors are an emerging technology that helps optimise bioprocesses by providing real-time data on key process variables, predictive analytics, and fault detection. Remilk uses soft sensors to monitor and optimise its fermentation processes, resulting in significant improvements in R&D throughput, product quality, and cost-effectiveness. This presentation will discuss the use of soft sensors for predictive bioprocess optimisation and will provide the latest advances in soft sensor technology.

14:20 Navigating the Interface between Bio and Food Technology

Aditya Shah, MSc, Co-Founder, Nayamylk Products

Alternative proteins are used in food-related applications. Therefore, there are three fundamental differences between alternative proteins and proteins manufactured for the traditional pharma or enzyme industry: (1) taste reigns supreme; (2) costs need to be significantly lower; and (3) food safety regulations need to be followed. Considering this, the presentation will focus on how best to approach process systems engineering by optimising strategies available from the food and bioprocess industries.

14:50 Close of Precision Fermentation Track

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

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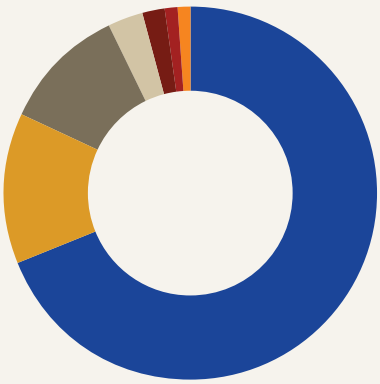
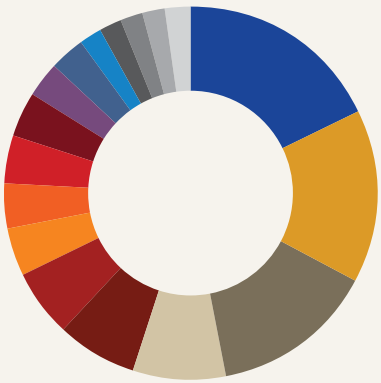


COMPANY TYPE

Biotech	69%
Pharma	13%
Academic	11%
Services	3%
Healthcare	2%
Government	1%
Other	1%



GEOGRAPHIC LOCATION

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USA	15%
Germany	14%
Switzerland	8%
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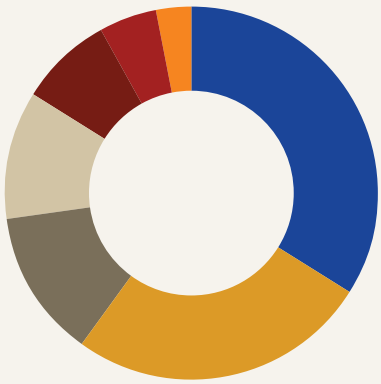
Spain	6%
Austria	4%
The Netherlands	4%
Rest of Europe	4%
Asia	4%
Belgium	3%
Denmark	3%
Portugal	2%
Sweden	2%
Ireland	2%
Rest of World	2%
Italy	2%



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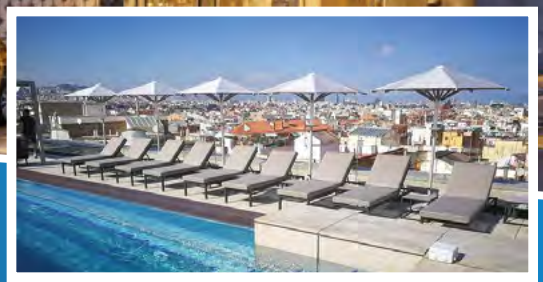

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