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Cambridge Healthtech Institute's 6th ANNUAL

BIOPROCESSING SUMMIT EUROPE

Practical Solutions for Today's Bioprocess Challenges

14 - 16 MARCH 2023 | Intercontinental Barcelona, Spain & Online (CET)

The Fastest Growing Bioprocessing Meeting in Europe

2023 PLENARY KEYNOTE SPEAKERS

Gregory Troiano
Chief Manufacturing Officer, mRNA Center of Excellence, sanofi

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

2023 CONFERENCE PROGRAMS

	TUES, 14 MARCH & WED AM, 15 MARCH	WED PM, 15 MARCH & THURS, 16 MARCH
STREAM #1 UPSTREAM	Cell Culture and Bioproduction	Cell Line Development
STREAM #2 DOWNSTREAM	Advances in Recovery & Purification	Intensified & Continuous Processing
STREAM #3 GENE THERAPY	Gene Therapy CMC and Analytics	Gene Therapy Manufacturing
STREAM #4 CELL THERAPY	Cell Therapy Manufacturing	Cell Therapy CMC and Analytics
STREAM #5 ANALYTICS AND FORMULATION	Analytics and Characterisation	Formulation and Stability
TRAINING SEMINARS	Introduction to Bioprocessing	Design of Experiments (DOE) for Bioprocess Analysis

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BioprocessingEurope.com

BIOPROCESSING SUMMIT EUROPE

About the Bioprocessing Summit Europe

The Bioprocessing Summit Europe brings together 500+ bioproduction, analytical and formulation professionals to advance the manufacture, quality and control of biological and genetic therapies. This 3-day, 10-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 2022 – 350 to 500+ attendees — and a sold-out Exhibit Hall.

We look forward to seeing you in Barcelona, or online, 14-16 March 2023, with expanded content on cell and gene therapy CMC and manufacturing, educational training seminars and a vastly bigger Exhibit Hall.

CONFERENCE-AT-A-GLANCE

	TUES, 14 MARCH & WED AM, 15 MARCH	WED PM, 15 MARCH & THURS, 16 MARCH
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Your Safety Is Our Top Priority

To ensure maximum safety, CHI has instituted mandatory health and safety protocols for all attendees, exhibitors, speakers and staff who attend in person. Attendees who cannot participate because of this policy, or due to travel restrictions, are encouraged to participate using our highly praised virtual event platform. Our virtual events are designed to provide you with an in-person experience at your convenience, anywhere, anytime. We are actively following news and recommendations around COVID-19 and the Omicron variant. These protocols are subject to change as we continue to learn more.

ALL IN-PERSON ATTENDEES *MUST*:

Have a negative COVID-19 test result from an FDA-authorized, a WHO-authorized, or European authorized over-the-counter antigen test within 24 hours prior to arriving at the event. You will be asked your results at registration.

CHI *RECOMMENDS* ALL ATTENDEES:

Have an updated COVID-19 vaccination and wear a mask in public spaces at the event.

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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 and interactive discussions and activities to maximize the learning experience. These Training Seminars are led by experienced instructors who will focus on content applicable to your current research and provide important guidance to those new to their fields.

Training Seminars Will Be Offered In-Person Only

TUESDAY, MARCH 14 | 08:30 - 17:10
WEDNESDAY, MARCH 15 | 08:30 - 10:30

TS1: Introduction to Bioprocessing

Instructor:

Sheila Magil, PhD, Vice President, CMC & Quality, Elevation Oncology

CHI's Introduction to Bioprocessing training seminar offers a comprehensive survey of the steps needed to produce today's complex biopharmaceuticals, from early development through commercial. The seminar begins with a brief introduction to biologic drugs and the aspects of protein science that drive the intricate progression of analytical and process steps that follows. We then step through the stages of bioprocessing, beginning with the development of cell lines and ending at scaling up for commercial production. The seminar also explores emerging process technologies, facility design considerations and the regulatory and quality standards that govern our industry throughout development. The important roles of analytical methods at all stages of development as well as formulation and stability assessments in developing and gaining approval for a biopharmaceutical are also examined. This 1.5-day class is directed to attendees working in any aspect of industry, including scientific, technical, business, marketing or support functions, who would benefit from a detailed overview of this field.

WEDNESDAY, MARCH 15 | 14:05 - 17:40
THURSDAY, MARCH 16 | 08:30 - 15:20

TS2: Design of Experiments (DOE) for Bioprocess Analysis

Instructor:

Marcello Fidaleo, PhD, PEng, Associate Professor, University of Tuscia

Today, leaders in the biopharmaceutical industry are increasingly adopting Quality by Design (QbD), a systematic approach to development that, starting from predefined requirements, emphasizes the understanding of products and processes, as well as the ability to control them. The effectiveness of QbD is evidenced by its wide application in the pharmaceutical field and beyond. The benefits of QbD can be further enhanced by combining this approach with design of experiments (DoE), a method that helps reduce the cost of acquiring new knowledge through statistically designed experiments. This training seminar will present DoE as a tool to support QbD, focusing on the practical application of DoE methods through the use of lectures, JMP statistical software (SAS Institute) and bioprocess case studies.

INSTRUCTOR BIOGRAPHIES

Sheila Magil, PhD, *Vice President, CMC & Quality, Elevation Oncology*

Sheila Magil has over 40 years of experience in quality and analytical method development for biologics, peptides and small molecules. Her expertise includes quality assurance, protein and peptide biochemistry and analytical development. She was formerly Senior Manager of Analytical Development and Quality Control at Biomeasure, Inc., and previously held positions at Waratah Pharma, Alkermes, Bion and HHMI at Massachusetts General Hospital. Dr. Magil has implemented quality systems and has managed external analytical and QC activities for multiple biopharmaceutical products. Dr. Magil holds a PhD in Biochemistry from the University of Minnesota.

Marcello Fidaleo, PhD, *PEng, Associate Professor, University of Tuscia*

Marcello Fidaleo is an associate professor at the University of Tuscia (Italy), where he teaches unit operations and design and analysis of experiments for the food and biotechnology industry. He is also a teaching fellow at the Biomanufacturing Training and Education Centre of North Carolina State University (Raleigh, USA) where he teaches a class on DoE for Bioprocess Characterization and Optimization. Marcello has about fifteen years of experience in design of experiments and data modeling in the field of membrane separation, enzymatic, microbial and chemical processes. He is the author of more than 50 scientific papers published on peer reviewed journals and has been a scientific consultant for companies operating in the fields of chemistry, biotechnology and food. Marcello holds a master's degree in chemical engineering from the Sapienza University of Rome and a doctorate in food biotechnology from the University of Tuscia.

"A really great event. I really like the chance to look back on all the presentations, even if they are running in parallel."

Takeda

PLENARY KEYNOTES

WEDNESDAY, 15 MARCH: 11:15 – 12.20

EMERGING MODALITIES, PLATFORMS, AND TECHNOLOGIES – FROM mRNA TO PROTEINS

KEYNOTE PRESENTATION: Overcoming CMC and Supply Chain Challenges for mRNA Technologies

Gregory Troiano, Chief Manufacturing Officer, mRNA Center of Excellence, sanofi

Thanks to the rapid development of mRNA vaccines for COVID-19, the industry now has the momentum and resources to overcome many of the early CMC challenges and realize its enormous potential. This presentation will discuss the strategies in place to overcome CMC and supply chain challenges for mRNA technologies already and future innovations primed to take it to the next level.

KEYNOTE PRESENTATION: Affinity Proteins for Biotechnological and Medical Purposes

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

Affinity proteins are crucial for life, for building structures, performing reactions, and for signaling purposes. In life sciences and medicine, affinity proteins are used to generate knowledge, but also for diagnostic and therapeutic purposes. This talk will cover how antibodies and small affinity molecules can be used to map the human proteome, develop diagnostic tools for *in vivo* visualization as well as efficiently purify therapeutics based on antibodies.

BIOGRAPHIES

Gregory Troiano, *Chief Manufacturing Officer, mRNA Center of Excellence, sanofi*

Greg serves as Chief Manufacturing Officer at Translate Bio, a sanofi company, where he is responsible for strategic oversight for all aspects of cGMP CMC operations, including clinical supply, analytical testing, quality, and engineering. Prior to TBio, Greg was VP of Technology and Chief Engineer at Seer, a life sciences and health data company using nanotechnology for proteomics and biomarker discovery. Prior to Seer, Greg was VP of Nanomedicine Development and Manufacturing within Pfizer's Pharmaceutical Sciences group, leading the development and manufacturing of novel nanoparticle drug products. Over his 20+ year career in the drug delivery field, Greg had various roles leading the pharmaceutical development of complex formulations, including numerous nano- and microparticle based systems.

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

Sophia Hober is Professor of Molecular Biotechnology at KTH, Stockholm, Sweden. The focus of her current research group is development of predictable and robust systems for protein purification and detection by protein design and various selection methodologies. Her key scientific achievements include design and development of gene fusion systems for selective ion-exchange purification and improvements of the alkaline tolerance of protein A for industrial purification of IgG (currently a product sold by GE-Health care). Also, a novel ligand for affinity purification of proteins has been developed that display a calcium dependent binding, enabling mild elution from the column. Moreover, small bispecific protein domains with ability to strongly and selectively bind to two different proteins recently have been developed for use in diagnostic and therapeutic applications.

TRACK KEYNOTE AND FEATURED SPEAKERS

Stream 1: Upstream

Yves Durocher, PhD, Research Officer & Head, Mammalian Cell Expression, National Research Council Canada

Gyun Min Lee, PhD, Professor, Cell and Developmental Biology, KAIST, Korea

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

Daniel G. Bracewell, PhD, Professor, Bioprocess Analysis, Biochemical Engineering, University College London, United Kingdom

Stream 2: Downstream

KEYNOTE PRESENTATION

James Reilly, Associate Director, Regeneron Pharmaceuticals Inc.

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

Kaihui Hu He, PhD, Laboratory Head, Microbial Platform DSP, Global CMC Development, Sanofi

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

Stream 3: Gene Therapy

James Warren, PhD, Vice President, Pharmaceutical Development, Ultragenyx Pharmaceutical

Jorge F. Haller, PhD, Director, Process & Analytical Development, Prevail Therapeutics, a Wholly Owned Subsidiary of Eli Lilly and Company

Ayda S. Mayer, PhD, Executive Director, Vector Core, REGENXBIO, Inc.

Andrea C.M. Rayat, PhD, Chair & Lecturer, Biochemical Engineering, University College London

Stream 4: Cell Therapy

Vered Caplan, CEO, Orgenesis, Inc.

Florence Salmon, PhD, Vice President, Regulatory Affairs and Preclinical Development, Ridgeline Discovery

Michael Delahaye, Director, Team Leader Cell Therapy Bioprocessing, AstraZeneca

Janet Glassford, PhD, Expert Quality Assessor, MHRA

Stream 5: Analytics and Formulation

Dan Bach Kristensen, PhD, Principal Scientist, Symphogen, Denmark

Arun Alphonse Ignatius, PhD, Director, Drug Product Sciences, Macrogenics, Inc., USA

Christine Carapito, PhD, Co-Head of the BioOrganic Mass Spectrometry Laboratory, CNRS Research Director, University of Strasbourg, France

Yunus Saricay, PhD, Specialist, Research & Development, Byondis B.V., The Netherlands

Cambridge Healthtech Institute's 6th Annual | **14 - 15 MARCH 2023 ALL TIMES CET**

Cell Culture and Bioproduction

Emerging Technologies, Improved Process Control, and New Opportunities

TUESDAY 14 MARCH

7:00 Registration and Morning Coffee

ADVANCES IN PROCESS CONTROL

8:25 Chairperson's Remarks

Moritz von Stosch, PhD, Chief Innovation Officer, Datahow, Switzerland

8:30 Monitoring Morphological and Dielectric Properties of Cells during a Bioprocess

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

Optical and dielectric technologies allow continuous monitoring of mammalian cells without manual sampling or labeling, as well as cell counts the methods provide data on the state of the cells. For example, optical methods can determine the changing morphology associated with the loss of viability. Capacitance measurements can determine changes in cytoplasmic conductivity indicative of the first stages of nutrient deprivation. These methods allow fine control during bioproduction processes.

9:00 Closed Loop Control for Achieving Optimum Productivity

Christoph Herwig, PhD, Head of Research Area Bioprocess Technology, TU Vienna, Austria

Continuous bioprocessing not only needs automation to control conditions, but control strategies to optimize productivity. This holds true for mammalian and microbial expression systems, in which the metabolic load to the cells may increase over time. This contribution will show digital twin-based control strategies how to achieve optimum specific productivity of recombinant protein production.

9:30 Smart PAT – Shifting Quality Control to the Shop-Floor

HAMILTON

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

Biopharma production quality controls are traditionally performed off-line in the lab. This impacts the process's productivity. A shift towards smart in-line Process Analytical Technology (Smart PAT) is required to improve it. This involves:

- New real-time measurement technologies to measure PAT Critical Process Parameters and Key Performance Indicators during the process
- Progressing digitalization to enable innovative process analytics, advanced process control and asset management

9:45 Sponsored Presentation (Sponsor Opportunity Available)

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

10:45 KEYNOTE PRESENTATION: Production of SARS-CoV-2 VLP in CHO Cells

Yves Durocher, PhD, Research Officer & Head, Mammalian Cell Expression, National Research Council Canada

Few commercial vaccines are manufactured in CHO cells. We show that CHO cells are amenable to manufacture subunit vaccines, as exemplified with the SARS-CoV-2 trimeric spike antigen. We also show that engineered CHO cells can generate high levels of enveloped VLPs harboring very high density of trimeric spikes at their surface, representing another prospective vaccine candidate. CHO cells show strong manufacturability potential and should be considered for next-generation vaccines.

CELL CULTURE MEDIA OPTIMISATION

11:15 Best Practices for Media Optimization

Antoine Piednoir, Scientist, Upstream Process Development, UCB, Belgium

At UCB, we employ a range of strategies for cell culture media optimization, and these have been evolved over time to minimize cost and resources and to meet important internal deadlines. The presentation will share our learnings from these experiences and recommend best practices for our industry colleagues working on similar projects.

11:45 *In silico* Media Optimization

Rui M. Oliveira, PhD, Associate Professor, Systems Biology & Engineering, Chemical Engineering & Biochemistry, Nova School of Science and Technology, Portugal

Hybrid modelling tools were developed for *in silico* culture media design with minimal wet lab activity requirements. A genome-scale model (GEM) of CHO -K1 cells was combined with empirical information deduced from principal component analysis (PCA) of historical data. The resulting hybrid model was applied for semi-automatic implementation of custom culture media feeds. A key advantage of the hybrid approach is the ability to "learn from experience."

12:15 Enabling Real-Time Process Control: Automated Glucose Feeding Based on Online Measurement

908devices

Nick Randall, Bioprocessing Product Manager, 908 Devices

Faster development cycles, intensified processes, and automation of process control are key-initiatives in biotherapeutics manufacturing. However, offline analytics requiring manual intervention are commonly used to monitor critical and time-sensitive process parameters. We describe a new automated approach for optimal growth and production, leveraging sensitive, online (sample-free) monitoring of glucose & lactate with automated feed control, and its impact on growth/viability, lower metabolite, and improved PQA.

12:45 Networking Lunch (Sponsor Opportunity Available)

MODELLING AND MACHINE LEARNING IN UPSTREAM PROCESSING

13:45 Chairperson's Remarks

Mark Duerkop, CEO, Novasign GmbH, Austria

13:50 Can Genetic Algorithms and Machine Learning Improve the Quality of a Mammalian Manufacturing Platform?

Marco Cardinali, AI/ML Engineer, GlaxoSmithKline, Italy

Machine learning models used in mammalian cell cultures can leverage both historical and real-time data, with the final goal to ensure a consistent product output quality and optimised process operation. We will show how a state-of-the-art model can design optimal experimental setups in an active learning scenario, bringing an improvement both in the quality of the data produced by experiments, and in the yield and robustness of the process itself.

14:20 Continuously Accelerating Process Development with Machine Learning Supported Knowledge Transfer

Moritz von Stosch, PhD, Chief Innovation Officer, Datahow, Switzerland

Quality by Design (QbD)-guided bioprocess development is cost effective only if knowledge is transferred from one project to the next (horizontal knowledge transfer) and one scale to the other (vertical knowledge transfer). We developed a novel hybrid machine-learning method to allow model processes across scales, projects, and products. This method retains and transfers knowledge, reducing experiments across scales and for the development of a process of a new product.

14:50 Talk Title to be Announced

4TE™

Speaker to be Announced

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

15:40 Hybrid Modeling, Digital Twins and Advanced Process Control: Status Quo, Pitfalls, and Solution Paths to Accelerate Bioprocess Development

Mark Duerkop, CEO, Novasign GmbH, Austria

Sufficient process understanding in the QbD concept is a cumbersome task. Hybrid modeling and advanced design space screening methods reduce the required experimental effort to reduce overall development timelines. Conserving process understanding in these models enables model transfer from early-stage development until manufacturing. The presentation will cover model-assisted process characterization, process optimization, implementation of soft-sensors, and a model predictive control showcase for different cell lines.

OPPORTUNITIES IN PRECISION FERMENTATION AND CELLULAR AGRICULTURE

16:10 Agriculture in a Bioreactor Needs More than a Beefed-Up CHO-Bioprocess

Andy Racher, PhD, CTO, HigherSteaks, United Kingdom

Following the launch of Eat Just's chicken nuggets, bioreactor-grown meat is now available at commercial outlets in Singapore. Other companies, using different species, are developing technologies for manufacturing meat. Creating pork is more than simply using a high-intensity CHO-process to grow porcine cells. This talk discusses challenges the nascent industry faces, learnings from the CHO-world, and where new thinking is needed if cell-based meats are to find space in supermarket aisles.

16:40 Future of Cheese: The Evolution from Cows to a Fully Digitized Casein Production Platform

Eva Sommer, PhD, CEO & Founder, Fermify, Austria

Bioprocesses for large-scale protein production are generally known to be labor-intensive, time-consuming and inefficient in the usage of assets. To ensure commercial viability of protein manufacturing for food application– such as precision fermentation-derived caseins for human consumption – it is essential to rethink the entire bioprocess design, from GRAS strain engineering to lean downstream processing as well as a smart conceptual design that leads to a tremendous CAPEX reduction.

17:10 Sponsored Presentation *(Opportunity Available)*

17:40 Welcome Reception in the Exhibit Hall with Poster Viewing

18:45 Close of Day

WEDNESDAY 15 MARCH

8:00 Registration and Morning Coffee

OPTIMISING UPSTREAM PROCESSING

8:25 Chairperson's Remarks

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

8:30 FEATURED PRESENTATION: Digitalisation of Cell Culture Operations Enabling Better Clone Selection and Scale-Up

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

This research outlines the development of a data-driven methodology to enhance lead clone selection that not only considers the available titre concentration and product quality information but also leverages the significant untapped data resource containing all the available offline, online and metadata. To help automate this selection process the research outlines the use of a simple natural-language-generation (NLG) algorithm to summarises the large volume of information into a human-readable report.

9:00 Across Scales: An Integrated Robotic Cultivation Platform for Accelerated Bioprocess Development

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

KIWI-biolab enables the efficient development and optimisation of bioprocesses on a robotic platform with parallel bioreactor systems of different sizes, analytical instruments and a mobile laboratory robot. The focus is on well-controlled, parallel, miniaturised fed-batch cultivations with fully integrated sample analysis and mathematical, model-based decision-making to feed-back control the ongoing experiments for maximum knowledge gain. The power and opportunities of the platform are demonstrated by several industrially relevant recombinant processes.

9:30 Strategies for Resolving Sustainability Issues with Single-Use Plastics

Olivier Cousin, PhD, Head, GSK Vaccines MSAT Environmental Sustainability, GlaxoSmithKline, Belgium

Environmental impact and plastic waste management is a sensitive topic for the pharma industry during the evaluation of changes in manufacturing processes. New SUT could represent a disruptive cluster of technologies compared to the more embedded Stainless-Steel Systems or classical technologies as well. In this essay we purpose a supporting methodology that can give an aid to decision-making illustrated via specific vaccines' business cases.

10:00 Talk Title to be Announced

Speaker to be Announced

cytiva

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

PLENARY SESSION: EMERGING MODALITIES, PLATFORMS, AND TECHNOLOGIES – FROM mRNA TO PROTEINS

11:15 Chairperson's Opening Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

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Gregory Troiano, Chief Manufacturing Officer, mRNA Center of Excellence, sanofi

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

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12:20 Transition to Sessions

12:30 Talk Title to be Announced

Speaker to be Announced

cytiva

13:00 Networking Lunch (Sponsor Opportunity Available)

14:00 Close of Cell Culture and Bioproduction Conference

Cambridge Healthtech Institute's 5th Annual | **15 - 16 MARCH 2023 ALL TIMES CET**

Cell Line Development

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

WEDNESDAY 15 MARCH

10:30 Registration Open

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12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

CELL ENGINEERING

14:00 Chairperson's Remarks
Arnaud Poterszman, PhD, Research Director, Integrated Structural Biology, IGBMC, France

14:05 Understanding Recombinant Protein Production at Single Cell Resolution
Colin Clark, PhD, Principal Investigator, NIBRT; Associate Professor University College Dublin, Ireland
Single cell omics is a powerful technology for the understanding of biological systems. In this talk, studies from our laboratory focused on capturing chromatin accessibility, gene expression, and protein abundance from monoclonal antibody CHO cell lines will be presented. Single cell omics platforms and computational approaches for data analysis will also be discussed.

14:35 Modification of Lipid Metabolism in Chinese Hamster Ovary Cells for Enhanced Recombinant Protein Production
James Budge, PhD, Postdoctoral Researcher, Industrial Biotechnology, University of Kent, United Kingdom
Lipid metabolism plays a key role in cellular processes central to achieving high recombinant protein titres. Processes such as secretion, cell division, and endoplasmic reticulum size and function are highly dependent on lipids and their metabolism. In this approach, we have used genetic engineering techniques to optimise lipid metabolism in CHOK1-SV cells which has been successful in expanding the endoplasmic reticulum and enhancing recombinant protein titres between 1.5 and 9-fold.

15:05 KEYNOTE PRESENTATION: A Cell Engineer's Perspective on Platform Technology for the Production of Therapeutic Proteins
Gyun Min Lee, PhD, Professor, Cell and Developmental Biology, KAIST, Korea
Biotech companies have their own platform technologies for the efficient production of therapeutic proteins. The superiority of a platform is determined by its ability to rapidly produce large quantities of high-quality therapeutic proteins. A next-generation platform employs CHO host cells engineered to overcome bottlenecks and negative effects on productivity and CRISPR/Cas9-mediated targeted integration combined with recombinase-mediated cassette exchange for rapid cell line generation.

15:35 Talk Title to be Announced
Speaker to be Announced

ATUM

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

16:40 Top-Down Strategies for the Preparation and Characterization of Human Macromolecular Assemblies: Insights from Genome Editing Approaches
Arnaud Poterszman, PhD, Research Director, Integrated Structural Biology, IGBMC, France
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.

17:10 Development of an Inducible rAAV-Producer Cell Line
Sofia Zaichick, PhD, Lead Researcher, Gene Therapy Program, Pathology and Laboratory Medicine, University of Pennsylvania, USA
There is a need for a better and more cost-effective method for rAAV production to meet the high demand in the gene therapy field. We address this issue by creating an inducible rAAV producer HEK293 cell line that does not need further transient transfection with plasmid DNA or infection with a helper virus.

17:40 Sponsored Presentation *(Opportunity Available)*

18:15 Close of Day

THURSDAY 16 MARCH

8:00 Registration and Morning Coffee

OPTIMISING CELL LINE DEVELOPMENT

8:25 Chairperson's Remarks
Philip Probert, PhD, Technology Lead, CPI, United Kingdom

8:30 Accelerated Cell Line Engineering Using Multiplexed, Targeted Integration
Lars Keld Nielsen, PhD, Scientific Director, Novo Nordisk Foundation Center for Biosustainability, DTU, Denmark
The availability of the CHO and Chinese Hamster genomes together with advances in mammalian genome editing has renewed interest in using systems and synthetic biology to guide rational strain design. In this talk, we will present recent work on model-based design strategies, efficient multigene genome editing, as well as multi-omics characterization. We will highlight outstanding challenges that need to be resolved before a CHO Biofoundry can be fully realized.

9:00 Cell Line Development in Biologics Discovery and Development
Bernd Voedisch, PhD, Principal Scientist II, Novartis Pharma AG, Switzerland
The presentation will highlight the components of the cell systems employed for generations of research cell lines and CHO manufacturing cell lines, and recent developments aiming at enhancing the quality and titer of produced complex biotherapeutic proteins.

Cell Line Development

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

9:30 Leveraging a Transposase-Mediated Semi-Targeted Transgene Integration System to Enable WARP Speed Development of a Monoclonal Antibody

Nikolas Zeh, PhD, Postdoctoral Researcher, Cell Biology, Cell Line Development, Bioprocess Development Biologicals, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Cell line development (CLD) represents a central part of a biologics development process. Hence, accelerating the CLD process would have substantial impact on overall timelines. Integration of the semi-targeted integration (STI) technology into our CLD platform enabled manufacturing of a therapeutic antibody at 2,000L scale in less than 3 months. Next, by using a clonally derived production cell line, a process with ~5g/L was implemented in less than 9 months.

10:00 Talk Title to be Announced

Speaker to be Announced

10:15 Application of Efficient sStrategies for the dDevelopment of More Complex BIotherapeutics

Fay Saunders, PhD, Director of Mammalian Cell Culture Process Development, FUJIFILM Diosynth Biotechnologies

The Apollo™X expression system and associated technologies provide versatile solutions that are compatible with a diverse range of biotherapeutics such as Bispecific and Fc-fusion molecules. We demonstrate that the system has the ability to express these proteins efficiently. The inherent complexity of these molecules means that product quality assessments during development can be challenging. FUJIFILM Diosynth Biotechnologies has developed methods to support this analysis which allows a streamlined development process.

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

11:00 New CHO Host Cell Line: Genetic Reporter for Fast Productivity Assessment

Katarzyna Sobkowiak, PhD, Associate Scientist, Biopharma, Merck Serono SA, Switzerland

Chinese hamster ovary cells are commonly used for therapeutic proteins production. Major challenge of cell line development is to obtain stable high-producing clones. Therefore, we set out to develop new CHO host cell line that would be selected based on the growth characteristics as well as productivity and secretion potential. To assess cell productivity and secretion capabilities, we used genetic reporter that allowed us for high-throughput screen of CHO cells.

11:30 Anticipated Cell Line Selection in Biopharmaceutical Process Development through Machine Learning on Metabolomics and Process Dynamics

Pierantonio Facco, PhD, Associate Professor, University of Padova, Italy

The identification of productive cell lines is of paramount importance in the development of bioprocesses. Metabolomics and process data provide valuable information for cell line selection to study their relationship with product quality attributes. Machine learning exploits the dynamic information on metabolomics and process data to support the selection of highly productive cell lines and to identify biomarkers that are related to cell productivity during bioprocess development and scale-up.

12:00 Strategies for Fast Cell Line Development

Stefan Wieschalka, Scientist, Early Stage Bioprocess Development, Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

In-licensing of molecules may come along with unforeseen challenges. In this study, we observed product fragmentation using a cell line from an in-licensing partner. To ensure clinical supply, root causes and solutions were investigated, including fast generation of a new cell line. Transposase-mediated semi-targeted transgene integration facilitated the identification of stable producer pools in a competitive project timeline. Thus, fast cell line development can tackle CMC difficulties, without stretching timelines.

12:30 Go beyond Titer and Select Top Producers with Favorable Quality Attributes within 5 Days of Cloning

Speaker to be Announced, Berkeley Lights

Despite a growing need for earlier information on quality and manufacturability, initial clone screening in mammalian CLD continues to focus on selection for growth and titer. Yet the fastest-growing and highest-producing clones may not secrete a product with the appropriate quality attributes. The Berkeley Lights Opto CLD workflow accelerates early CLD by integrating high throughput cell sorting, cloning, culture, productivity, growth, and product quality assays into a single, five-day automated process.

13:00 Networking Lunch (Sponsor Opportunity Available)

13:45 Chairperson's Remarks

Pierantonio Facco, PhD, Associate Professor, University of Padova, Italy

13:50 Systems and Synthetic Biology to Define Limiting Genes and Tune Their Expression

Johan Rockberg, PhD, Professor, Antibody Technology and Directed Evolution, KTH Royal Institute of Technology, Sweden

Biopharmaceutical and AAV production in CHO/HEK293 challenges their translational, secretional, and metabolic boundaries. We show the importance of ER-mitochondria signaling to fulfill energy demand of secreted products. Further, we exemplify how systems and synthetic biology can be used to define limiting genes and tune their expression improving activity of therapeutic enzymes 100-fold by OMICS and engineered TIS and regulatory elements for precise expression.

CELL-FREE SYNTHESIS

14:20 Development of a Manufacturing Platform with Analytical Toolkit for mRNA-Based Products

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

mRNA based products represent a novel emerging modality with the potential to treat the previously untreatable. This talk will outline and present case data on the development of a flexible and scalable manufacturing process for mRNA-LNP products. This will include the development of the analytical toolkit to support process development and manufacture, which encompasses biochemical, structural and biological activity assays for product characterisation.

14:50 FEATURED PRESENTATION: Cell-Free Protein Synthesis of Virus-Like Particles

Daniel G. Bracewell, PhD, Professor, Bioprocess Analysis, Biochemical Engineering, University College London, United Kingdom

Virus-like particles (VLPs) have proven potent vaccines. However, their complex self-assembly can make their development challenging. Here we describe progress in the use of *E. coli* cell-free synthesis platforms to expedite these activities for this product class. Two examples will be given: picornavirus-like particle vaccine candidates stabilized by N-myristoylation and universal influenza vaccine candidates based on tandem-core hepatitis B core antigen VLPs.

15:20 Close of Summit

Cambridge Healthtech Institute's 6th Annual | **14 - 15 MARCH 2023 ALL TIMES CET**

Advances in Recovery and Purification

Optimizing DSP, Reducing Costs, Accelerating Development

TUESDAY 14 MARCH

7:00 Registration and Morning Coffee

PLATFORMING COMPLEX BIOLOGICS

8:25 Chairperson's Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

8:30 KEYNOTE PRESENTATION Precision Medicine for Cancer Treatment Leveraging Industrialized, Robust and Simple Bispecific Antibody Platform: Learnings from a 10-Year Journey

James Reilly, Associate Director, Regeneron Pharmaceuticals, Inc.

Cancer is a leading cause of death worldwide, accounting for almost 10 million deaths in 2020. Regeneron has a bispecific immuno-oncology platform technology, where the patient's immune system is activated to recognize and eliminate cancer cells, that has shown substantial potential across cancer types. This presentation outlines key learnings from a 10-year journey whereby these bispecific antibodies have become readily available industrialized therapeutics amenable to meeting a global demand.

9:00 FEATURED PRESENTATION Implementation of Purification Platform for Nanobody Molecules – Lessons Learned

Kaihui Hu He, PhD, Laboratory Head, Microbial Platform DSP, Global CMC Development, Sanofi

Nanobody molecules, a type of single-domain antibody, are an attractive drug class thanks to their therapeutic versatility and production advantages. In our Microbial Platform Downstream Processing team, Nanobody molecules from microbial fermentation extracts are handled by a classical multi-step process entailing Capture, Intermediate, Polishing Purification, and Ultrafiltration-Diafiltration steps. Tailored processes and adaptations have been made to reduce impurities and multimerizations to accommodate demands in clinical development.

9:30 Talk Title to be Announced

Speaker to be Announced

Pfanstiehl

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

DOWNSTREAM PROCESSING FOR COMPLEX BIOLOGICS

10:45 Downstream Processing of DuoBody and HexaBody Antibody Formats

Rick Hibbert, PhD, Senior Director, Head of CMC Science and Technologies, Genmab BV

Genmab's DuoBody platform is a versatile technology for generating bispecific antibodies via a post-production exchange process. The HexaBody platform allows for the creation of potent therapeutics by promoting hexamer formation on the cell surface for enhanced complement-mediated cytotoxicity. These platforms are used to create next-generation antibody therapeutics. Case studies describe the downstream processing strategies that are utilized to control the process at research and manufacturing scale.

11:15 Development of a High-Throughput Purification Workflow within the Constraints of a Containment Facility

Daniel Melotte, PhD, Scientist II, Downstream Development, IPSEN Biopharm Ltd.

Developing commercial processes for potent molecules is highly challenging due to processes requiring containment facilities to isolate the product from the operator. Standard high-throughput screening platforms are not viable due to the limited space within these highly controlled containment facilities. This project aimed to configure and program an ÄKTA Pure to establish an automated method to process multiple bioreactor samples through multiple purifications and buffer conditioning steps in containment.

11:45 Real-Time Aggregate Detection during Cation Exchange Bind-and-Elute Chromatography for Optimised Pooling: A BioPhorum Proof-of-Concept Collaboration

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

An industry-wide team consisting of 18 companies from pharmaceutical manufacturers and suppliers organised by BioPhorum is working on a proof of concept for controlling product collection during bind-and-elute cation exchange chromatography of monoclonal antibodies. The analytical technique of choice is real-time multi-angle light scattering (RT-MALS) which is used for aggregate monitoring. This talk will summarize the project setup, challenges encountered, the experimental design developed by the team, and initial results.

12:15 Talk Title to be Announced

Speaker to be Announced

MERCK

12:45 Networking Lunch (Sponsor Opportunity Available)

ADVANCING RECOVERY AND PURIFICATION

13:45 Chairperson's Remarks

David O'Connell, PhD, Lecturer in Biotherapeutics, School of Biomolecular & Biomedical Science, University College Dublin

13:50 Cell-Tolerant Radial Affinity Chromatography

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

Biopharmaceutical proteins (e.g., monoclonal antibodies) are important therapeutic medicines for different human diseases such as oncology. In this presentation, the USP bioreactor will be directly integrated into the DSP capture column so that the expressed monoclonal antibody can be directly purified on the capture step consisting of a disposable cell Tolerant Radial Affinity Chromatography (cTRAC) column and the cells efficiently removed as waste in closed disposable bags.

14:20 3D Visualization and Characterization of Chromatographic Packed Bed and Individual Bead Structure

Thomas F. Johnson, PhD, Senior Research Fellow, Biochemical Engineering, University College London

In this study, high resolution X-ray computed tomography is applied to visualise and characterise internal geometry of packed beds and individual beads made of agarose, cellulose and ceramics. Pixel sizes from 3 µm to 32 nm enabled resolution of detailed features to analyse properties including porosity and available surface area, with positional based analysis able to identify physical phenomena such as wall effects.

14:50 Talk Title to be Announced

Jessica Chow-Hubbertz, Lab Head DSP, Bioprocess Engineering, SANOFI

GORE

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

IMPROVING RECOVERY AND PROCESS UNDERSTANDING

15:40 Development of Purification Procedures for Engineered 10kDa Scaffolds from a Novel Selection Platform

David O'Connell, PhD, Lecturer in Biotherapeutics, School of Biomolecular & Biomedical Science, University College Dublin

This talk describes two directions toward therapeutic developments: 1) design and production of proprietary protein libraries based on a small and stable scaffold with a screening procedure that has identified specific binders against difficult-to-drug targets, and 2) approaches to (a) producing a candidate drug-

protein at scale and (b) high-throughput production method development for candidates from selections for functional screening rounds are described using tagless, affinity tag-based, and twin IEX approaches.

16:10 Multi-Product Protein A Resin Reuse for Biopharmaceutical Products

Stanislas Helle, PhD, Postdoc Researcher, Chemical Sciences, University of Limerick

The overall purpose is to compare the performance of a resin reused to process a single product stream with the same mAb select Sure protein A resin type reused to process two product streams. Here, we developed the experimental design to determine if the same yield and quality of product can be obtained compared to keeping the resin dedicated to the one product stream only.

16:40 CSL112 Process Characterization: A Modern Process Development Approach Implementing QbD Principles

Jonathan Eras, PhD, Senior Manager, Process Development R&D, CSL Behring

A modern process development approach implementing QbD principles will be presented which is very relevant to ensure process understanding

17:10 Sponsored Presentation *(Opportunity Available)*

17:40 Welcome Reception in the Exhibit Hall with Poster Viewing

18:45 Close of Day

WEDNESDAY 15 MARCH

8:00 Registration and Morning Coffee

CONTINUOUS DOWNSTREAM PROCESSING

8:25 Chairperson's Remarks

Jose Paulo B. Mota, PhD, Professor, Chemical & Biochemical Engineering, University Nova de Lisboa

8:30 Digital UF-DF-UF Twin: How to Successfully Design This Crucial Bioprocess Step

Maximilian Krippl, PhD, Head of DSP Modeling, Novasign GmbH

Ultra- and diafiltration is a critical step in virtually every bioprocess. Due to various membrane interactions, it can be difficult to fully recover the product which leads to low yields and higher overall process costs. By introducing controlled process variations, hybrid modeling helps to identify the best suited process conditions with few experiments. We present a UF-DF-UF model to predict and describe product and membrane specific filtration processes.

9:00 Recent Advances in Model-Based Design and Optimization of Downstream Processing of Biopharmaceuticals

Jose Paulo B. Mota, PhD, Professor, Chemical & Biochemical Engineering, University Nova de Lisboa

We discuss how continuous multicolumn chromatography for downstream processing can be designed for improved performance using model-based state-of-the-art optimisation tools. The aim is not only to maximize process throughput but also to reduce solvent consumption, increase product concentration and, if possible, reduce the number of steps of the operating cycle. Concrete examples of the increased productivities and cost savings benefits of using optimised continuous multicolumn chromatography are given.

9:30 Latest Developments in Continuous Downstream Processing: Updates from CODOBIO

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

The CODOBIO consortium consists of nine industry partners, eight universities, one research organisation, a regulatory institution and a business consultancy, and has developed a research and training programme including relevant scientific/technical and transferable skills trainings. This presentation will review the cutting-edge science and future industrial applications of the findings.

10:00 Talk Title to be Announced

Speaker to be Announced

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

PLENARY SESSION: EMERGING MODALITIES, PLATFORMS, AND TECHNOLOGIES – FROM mRNA TO PROTEINS

11:15 Chairperson's Opening Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: Overcoming CMC and Supply Chain Challenges for mRNA Technologies

Gregory Troiano, Chief Manufacturing Officer, mRNA Center of Excellence, sanofi

Thanks to the rapid development of mRNA vaccines for COVID-19, the industry now has the momentum and resources to overcome many of the early CMC challenges and realize its enormous potential. This presentation will discuss the strategies in place to overcome CMC and supply chain challenges for mRNA technologies already and future innovations primed to take it to the next level.

11:50 PLENARY PRESENTATION: Affinity Proteins for Biotechnological and Medical Purposes

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

Affinity proteins are crucial for life, for building structures, performing reactions, and for signaling purposes. In life sciences and medicine, affinity proteins are used to generate knowledge, but also for diagnostic and therapeutic purposes. This talk will cover how antibodies and small affinity molecules can be used to map the human proteome, develop diagnostic tools for *in vivo* visualization as well as efficiently purify therapeutics based on antibodies.

12:20 Transition to Sessions

12:30 Talk Title to be Announced

Speaker to be Announced

13:00 Networking Lunch (Sponsor Opportunity Available)

14:00 Close of Advances in Recovery and Purification Conference

Cambridge Healthtech Institute's 6th Annual | **15 - 16 MARCH 2023 ALL TIMES CET**

Intensified and Continuous Processing

Improving Process Intensification, Monitoring, and Control

WEDNESDAY 15 MARCH

10:30 Registration Open

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12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

END-TO-END CONTINUOUS PROCESSING

14:00 Chairperson's Remarks
Stefan R. Schmidt, MBA, PhD, COO & Head, Operations, BioAtrium AG

14:05 KEYNOTE PRESENTATION: End-to-End Integrated and Continuous Monoclonal Antibody Manufacturing
Richard D. Braatz, PhD, Edwin R. Gilliland Professor, Chemical Engineering, Massachusetts Institute of Technology
A fully instrumented testbed is described for the end-to-end, integrated, and continuous manufacturing of monoclonal antibodies. The testbed consists of parallel bioreactors, simulated moving bed chromatography systems for capture and polishing, bespoke viral inactivation, and a MAST auto-sampling system. Experimental results are compared with a digital twin for continuous runs lasting 30 to 60 days each, which include variations in metabolites and glycosylation profiles in designed experiments.

14:35 Smart Tools for High Cell Density Perfusion Culture Process
Veronique Chotteau, Associate Professor, Director of AdBIOPRO, Centre for Advanced Bioproduction by Continuous Processing, Industrial Biotechnology, KTH Royal Institute of Technology
We have created an approach for optimization of mammalian cell perfusion process by smart substrate targeted feeding, providing high cell growth, viability, productivity, and low byproducts. This work is supported by scale-down bioreactors fully operated in perfusion: stirred tank bioreactor of 200 mL and ERBI bioreactor of 2 mL. For the substrate optimization (e.g., glucose, amino acids) it leans on design of experiment or digital twin approaches.

15:05 Intensified and Continuous Processing
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.

15:35 Talk Title to be Announced
Speaker to be Announced

MERCK

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

COMMERCIAL-SCALE CONTINUOUS PROCESSING

16:40 FEATURED PRESENTATION: Highly Flexible Future-Proof Bioprocess Facility – Understanding Shift in Requirements from Development to Commercialization for Continuous Manufacturing
Lara Fernandez-Cerezo, PhD, Associate Principal Scientist, Merck
Standard batch monoclonal antibody biologics manufacturing processes are costly and time-consuming. A switch to intensified continuous processing enables much higher productivity. Lessons learned from initial continuous manufacturing clinical productions at Merck have been directly leveraged and used to project process, automation, and analytical requirements for next-generation commercial facilities. Facility design strategies including modularity, flexibility, 'lights-out operation,' and reduced scale have become key concepts for future highly automated and intensified processes.

17:10 Intensification Strategies: Multiple Dimensions at Different Stages for Higher-Throughput
Stefan R. Schmidt, MBA, PhD, COO & Head, Operations, BioAtrium AG
Processes can be intensified at all scales and all dimensions and are not limited to commercial production only. However, that requires implementing approaches to achieve "more, with less effort, faster" already at the beginning. This presentation gives a comprehensive overview of strategies how to integrate process intensification through the whole product life cycle. The opportunities from early development to continuous process improvements will be summarized in this talk.

17:40 Talk Title to be Announced
Sebastian Thürmann, PhD, Product Management, Tosoh Bioscience

TOSOH

18:15 Close of Day

THURSDAY 16 MARCH

8:00 Registration and Morning Coffee

SUSTAINABLE APPROACHES TO BIOPROCESSING

8:25 Chairperson's Remarks
Andrew Sinclair, President & Founder, BioPharm Services Ltd., United Kingdom

8:30 Predicting Performance and Sustainability Based on Process Intensification and Geography
Andrew Sinclair, President & Founder, BioPharm Services Ltd., United Kingdom
The latest process models evaluate facility efficiency (doses per unit volume of cleanroom), PMI, and total energy efficiency. Pre-release versions were used by process intensification team in NIIMBL to support sustainability assessments.

Intensified and Continuous Processing

Improving Process Intensification, Monitoring, and Control

In this talk, comparisons are made between standard fed-batch processes and intensified process options that include perfusion and continuous downstream operations and considers the impact of facility locations.

9:00 Sustainable Metrics for Biopharmaceutical Production

Felix Dieringer, PhD Student, Responsible Process Design, Takeda

This presentation examines recent developments of green chemistry and sustainability metrics with a focus on the biopharmaceutical industry.

9:30 Chelation Technology, a Simple and Effective Solution to Remove Copper from CSL's Human Albumin Product

Robin Das Gupta, PhD, Team Lead, PPD Process Development, CSL Behring

CSL Behring manufactures albumin in various concentrations. Interestingly, higher albumin concentrations showed sediments, with copper sulphide (CuS) being the main component; low copper concentrations (= 0.2mg/kg) significantly delay sediment formation. One method to remove CuS is the chelation of metal ions by chelating agents. Usage of EDTA and a new chelator (EDDS) decreased proteolytic activity and improved binding capacity. Additionally, stability studies demonstrated that these chelators delayed sediment formation significantly.

10:00 Talk Title to be Announced

Speaker to be Announced

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

SMART BIOPROCESSING

11:00 The Role of Digitalization in Continuous Processing of Therapeutic Proteins

Massimo Morbidelli, PhD, Professor, Department of Chemistry, Materials and Chemical Engineering, Politecnico di Milano, President, DataHow AG

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

To sustain the rapid expansion of biopharmaceuticals while 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 toward consistent product quality and high throughput. However, digitalization is the keystone to express their full potential as it allows a model-based process control, to reduce the time-to-market and costs, and to fulfill the QbD guidelines.

11:30 Implementing the Lab of the Future – Pain or Gain?

Sandra Krause, Lab Engineer, Biodevelopment Microbial Platform, sanofi

Digital Transformation is one of the keywords in the beginning of the 21st century. Companies, including biotech and pharma, now push forward to keep pace with customer needs and competitors. Here, we describe the pitfalls, pains, and gains in preparing, transforming, and executing digitalization in our labs, as part of sanofi's global digital transformation.

12:00 Digital Transformation in BioPharma Manufacturing: Current Business, Organizational, and Technological Challenges-- and Opportunities

Michael Sokolov, PhD, Co-Founder and COO, DataHow AG, Lecturer, ETH Zurich

Pharma manufacturing is still mostly focusing on the exploration phase of digital technology. The major goal of this presentation is to identify major drivers and challenges for digitalization and digital transformation in pharma manufacturing. Three main perspectives, namely technology, organization, and culture, as well as management and business strategy, will be highlighted. The results are based on extensive collaboration with several tens of pharma, biotech, and CDMO companies.

12:30 Talk Title to be Announced

Speaker to be Announced

13:00 Networking Lunch (Sponsor Opportunity Available)

PROCESS CONTROL AND MODELLING

13:45 Chairperson's Remarks

Michael Sokolov, PhD, Co-Founder and COO, DataHow AG, Lecturer, ETH Zurich

13:50 Modeling & Simulation as One Key Element in Next-Generation CMC

Johannes Scheiblauer, Fellow, Automation & Control, Innovation & Technology Sciences, Pharmaceutical Sciences, R&D, Takeda

Several enabling technologies change the way we do pharmaceutical development: automation and digitalization, modeling and simulation. But especially the latter are not silver bullets, and it is important to have a closer look: why and when one might use them, which factors support a successful and sustainable implementation, and what it means for an organization to embrace these new ways of work.

14:20 Continuous Biologics Manufacturing at CPI: Past, Present, and Future

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 projects. Process analytical technology (PAT) is becoming increasingly important in biologics manufacturing. In this talk, I will discuss previous and current projects involving continuous manufacturing and the use of novel process analytical technologies (PATs).

14:50 Benefits of Microbial Continuous Processing

Julian Kopp, PhD, Postdoc Researcher, Chemical & Environmental & Biological Engineering, Vienna University of Technology

State-of-the-art recombinant protein production with microbials is conducted in fed-batch cultivation. Switching to continuous processing would impose small-footprint manufacturing and increase the space-time yield compared to fed-batch processing. Still, industry and research struggle in achieving long-term microbial cultivations with stable productivity. Within this presentation, I will address reasons for fluctuating productivity in continuous processes, and discuss opportunities and how to overcome these challenges.

15:20 Close of Summit

Cambridge Healthtech Institute's 4th Annual | **14 - 15 MARCH 2023 ALL TIMES CET**

Gene Therapy CMC and Analytics

Improving the Analysis, Control, and Quality of Gene Therapies

TUESDAY 14 MARCH

7:00 Registration and Morning Coffee

CMC AND TECHNICAL DEVELOPMENT STRATEGIES

8:25 Chairperson's Remarks
Christine Le Bec, PhD, Head, CMC Gene Therapy, Sensorion

8:30 KEYNOTE PRESENTATION Challenges and Opportunities in Gene Therapy Technical Development
Markus Haindl, PhD, Global Head, Gene Therapy Technical Development, Roche Diagnostics GmbH

9:00 FEATURED PRESENTATION: Analytical Comparison of AAV Manufactured by Triple-Plasmid Transfection/HEK293 and Double-Baculovirus Infection/SF9 Processes
Jorge F. Haller, PhD, Director, Process & Analytical Development, Prevail Therapeutics, a Wholly Owned Subsidiary of Eli Lilly and Company
Comparability between triple-plasmid transfection/HEK293 adherent and double-baculovirus infection/Sf9 suspension manufacturing processes was evaluated for AAV9 with the same transgene. Both processes yield viral capsid proteins with identical mass, comparable safety, strength, and biological activity. Differences in the impurity profiles, which are inherent to the processes, were observed. Overall, the double-baculovirus infection/Sf9 process was able to upscale AAV production and deliver a comparable AAV product to the triple-plasmid transfection/HEK293 adherent process.

9:30 Talk Title to be Announced
Speaker to be Announced

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

IMPROVING PRODUCT QUALITY THROUGH IN-DEPTH CHARACTERISATION

10:45 Novel Approaches to Analyse AAVs and Lentiviruses Using BLI and Flow Virometry
Felix F. Fuchsberger, PhD, Scientist, Takeda
Advances in analytical approaches have the potential to gather novel information about gene therapy vectors and characterize the same better. Here, I will be talking about the application of biolayer interferometry (BLI) to characterize adeno-associated virus (AAV) to antibody binding. Additionally, I will be talking about flow virometry which is emerging due to more sensitive instruments for the analysis of larger vectors like lentiviruses.

11:15 AAV Genome Integrity: Going Deep with Nanopore Sequencing and Multiplex Digital PCR
Peter Andorfer, PhD, Development Scientist, Gene Therapy, Takeda
In gene therapy a better understanding of the AAV content, in terms of transgene integrity and unwanted DNA contaminations, is fundamental to achieve the best possible therapy outcome and reduce the risk of side effects. Nanopore long read sequencing and multiplex digital PCR are two state-of-the-art technologies, which enable a detailed analysis of the DNA cargo and can help to improve the production process towards better gene therapy products.

11:45 Characterization of Dual AAV Vector Otoferlin
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 Usher Syndrome type 1. Since the Otoferlin gene is large and exceeds the AAV packaging capacity, two AAV vectors have been developed. The product characterization of the dual vectors will be presented.

12:15 Sponsored Presentation (Sponsor Opportunity Available)

12:45 Networking Lunch (Sponsor Opportunity Available)

IMPROVING PRODUCT AND PROCESS CHARACTERISATION

13:45 Chairperson's Remarks
Markus Haindl, PhD, Global Head, Gene Therapy Technical Development, Roche Diagnostics GmbH

13:50 Viral Safety: The Need for a Wholistic Approach
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.
Because there are limited options to apply viral reduction or elimination steps in the manufacture of viral vectors, viral control becomes more important. As a consequence, viral testing likely needs to be more comprehensive. Multiple orthogonal methods increase the chances of detection and examples of viral contamination events will be presented.

14:20 New Chromatographic Approaches for Payload and Capsid Characterization in AAVs
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. We will also show that multidimensional approaches offer additional possibilities for automation and reduced sample consumption.

14:50 Talk Title to be Announced
Speaker to be Announced

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

LINKING ANALYTICS TO PROCESS DEVELOPMENT

15:40 KEYNOTE PRESENTATION: Expanding AAV Manufacturability Toolbox for Early-Phase Programs and beyond
Ayda S. Mayer, PhD, Executive Director, Vector Core, REGENXBIO, Inc.
The presentation will summarize the efforts of REGENXBIO's Vector Core team to produce pre-clinical AAV material for pipeline programs and platform development. Implementation of high-throughput production and manufacturability assessments through evaluation of process titers and product quality, combined with continuous efforts to improve production processes through multiple work-streams, including cell line development, plasmid optimization, and early phase process development, have led to improvements in overall AAV yields exceeding 40-fold.

16:10 Addressing Challenges for Production and Analysis of AAV Vectors
Helen Young, PhD, Manager, Synthetic & Mammalian Upstream, CPI
Developing high-yielding, scalable, and commercially viable processes for AAV manufacture, with associated analytical methods for assessing the CQAs, presents challenges. Here, we present work being performed at CPI to address some of the upstream challenges, including development of an intensified N-1

seed train step to reduce inoculum requirements. Further, we discuss some of the approaches we have been working on for full and empty capsid determination, including mass photometry.

16:40 CMC Strategies for Gene Therapies
Christiane Niederlaender, PhD, Vice President, Technical CMC, Parexel

17:10 Interactive Discussions
Interactive 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. For in-person events, the facilitator will lead from the front of the room while attendees remain seated. 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 Discussion page on the conference website for a complete listing of topics and descriptions.

BREAKOUT DISCUSSION: Ensuring Product Quality through Analytics
Tony Bou Kheir, PhD, Head, Analytical Development and QC, Purespring Therapeutics

17:40 Welcome Reception in the Exhibit Hall with Poster Viewing

18:45 Close of Day

WEDNESDAY 15 MARCH

8:00 Registration and Morning Coffee

ADVANCING PROCESS DEVELOPMENT, OUTSOURCING AND CARGO DELIVERY

8:25 Chairperson's Remarks
Hemant Kumar, PhD, Chief Manufacturing and Technology Officer, Genprex, Inc.

8:30 Managing Headwinds Due to CDMO's M&A Activities and Its Impact on Gene Therapy Companies and Innovation
Hemant Kumar, PhD, Chief Manufacturing and Technology Officer, Genprex, Inc.
Dramatic increase in mergers and acquisitions within the global CDMO market has raised concerns about delays in bringing the disruptive innovative gene therapy target development and delays in clinical trials. This has encouraged CDMOs to provide integrated services to advance drug development but has become a financial burden on the clinical-stage companies.

9:00 Advancing Process Development for Gene Therapies
Florian Leseigneur, Head, Process Development, Dinaqor
Alignment of upstream and downstream processes and analytical methods from preclinical to GMP manufacturing reduces time to market and de-risks drug development. The use of standardized assays for the characterization of preclinical vectors provides critical insights on potency, identity, and purity, and strengths the value of PoC and IND-enabling studies performed with those vectors.

9:30 Expanding AAV Cargo Delivery Capacity
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 one of the most versatile gene therapy platforms. However, AAV vectors have a small packaging capacity impairing delivery of therapeutic genes over 3.5 kb in size. This limits their use in the treatment of innumerous genetic diseases. Herein dual AAV co-delivery strategies are discussed, namely the use of protein trans-splicing systems, to deliver larger genes.

10:00 Talk Title to be Announced
Speaker to be Announced

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

PLENARY SESSION: EMERGING MODALITIES, PLATFORMS, AND TECHNOLOGIES – FROM mRNA TO PROTEINS

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

11:20 PLENARY PRESENTATION: Overcoming CMC and Supply Chain Challenges for mRNA Technologies
Gregory Troiano, Chief Manufacturing Officer, mRNA Center of Excellence, sanofi
Thanks to the rapid development of mRNA vaccines for COVID-19, the industry now has the momentum and resources to overcome many of the early CMC challenges and realize its enormous potential. This presentation will discuss the strategies in place to overcome CMC and supply chain challenges for mRNA technologies already and future innovations primed to take it to the next level.

11:50 PLENARY PRESENTATION: Affinity Proteins for Biotechnological and Medical Purposes
Sophia Hober, PhD, Professor, School of Biotechnology, KTH Royal Institute of Technology
Affinity proteins are crucial for life, for building structures, performing reactions, and for signaling purposes. In life sciences and medicine, affinity proteins are used to generate knowledge, but also for diagnostic and therapeutic purposes. This talk will cover how antibodies and small affinity molecules can be used to map the human proteome, develop diagnostic tools for *in vivo* visualization as well as efficiently purify therapeutics based on antibodies.

12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

14:00 Close of Gene Therapy CMC and Analytics Conference

"The most valuable meeting in the bioprocessing field"

Celonic AG

Cambridge Healthtech Institute's 4th Annual | **15 - 16 MARCH 2023 ALL TIMES CET**

Gene Therapy Manufacturing

Improving Viral Vector Production, Yield and Supply

WEDNESDAY 15 MARCH

10:30 Registration Open

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12:20 Transition to Sessions

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch (Sponsor Opportunity Available)

OPTIMISING VIRAL VECTOR PROCESS DEVELOPMENT

14:00 Chairperson Remarks
James Warren, PhD, Vice President, Pharmaceutical Development, Ultragenyx Pharmaceutical

14:05 Manufacturing Strategies for Viral Vector Gene Therapies
Rajiv Gangurde, PhD, CTO, SparingVision

14:35 High-Throughput Technologies in AAV Production
Hugo F. Rojas, PhD, Lead Scientist, Upstream Process Development, uniQure
In this talk, we aim at discussing challenges and opportunities to accelerate process development of AAV-gene therapies, by leveraging concepts of scale-down models and high-throughput experimentation

15:05 KEYNOTE PRESENTATION: Bioprocess Engineering Strategies to Enhance Productivity and Yield of the Pinnacle Producer Cell Line Platform, Enabling High Productivity at 2000L Scale
James Warren, PhD, Vice President, Pharmaceutical Development, Ultragenyx Pharmaceutical
Ultragenyx has developed the Pinnacle PCL producer cell line platform for rAAV product development which is readily scalable to 2000L and has successfully supported multiple clinical gene therapy programs. Bioprocess engineering strategies have been applied to significantly improve productivity and yield, now achieving levels approaching 1E12 gc/ml or greater. The improved Pinnacle PCL platform will be implemented for the manufacturing of an rAAV product to treat Duchenne's Muscular Dystrophy.

15:35 Sponsored Presentation *(Opportunity Available)*

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

INCREASING TITRES

16:40 Process Optimization for AAV Production – Ensuring High Titer from Lab Scale to Manufacturing Scale
Susanne Heider, PhD, Lead, Gene Therapy, Upstream, Takeda
Adeno-associated viruses (AAVs) are currently one of the viral vectors of choice for gene therapy. High titers are necessary to ensure the desired outcome, therefore process optimization has a strong focus on yield improvement. The Upstream tested conditions for enhancing titers through ideal process conditions, the Downstream worked on keeping titers high whilst removing impurities and concentrating the vectors. Together, we established a process feasible for manufacturing at large scales.

17:10 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
The biopharmaceutical industry is looking at the concepts of intensification and integration to create more efficient processes. In this presentation, we will provide an overview of the use of perfusion bioreactors to integrate AAV harvesting and clarification processes. Continuous chromatography will then be presented as a tool for AAV capture. Finally, the two examples will be examined for their potential to link upstream and downstream processes.

17:40 Interactive Discussions
Interactive 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. For in-person events, the facilitator will lead from the front of the room while attendees remain seated. 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 Discussion page on the conference website for a complete listing of topics and descriptions.

18:15 Close of Day

THURSDAY 16 MARCH

8:00 Registration and Morning Coffee

RECOVERY AND PURIFICATION OF VIRAL VECTORS

8:25 Chairperson's Remarks
Cristina C. Peixoto, PhD, Head Downstream Process, Animal Cell Technology, iBET Instituto de Biologia Experimental Tecnologica

8:30 High-Resolution Displacement Anion Exchange Chromatography for the Separation of Empty, Partial, and Full AVVs
Ohnmar Khanal, PhD, Senior Scientist, Technical Development, Downstream and Drug Product Development, Spark Therapeutics
Partial AAV capsids are heterogeneous and difficult to separate from full AAV capsids. We demonstrate unparalleled separation of empty, partial, and full capsids with single- and multi-column anion exchange displacement chromatography.

9:00 Mechanistic Modeling for Empty and Full Adeno-Associated Viral Capsid Separation

Vijesh Kumar, PhD, Lead Scientist, Technology Development Downstream & Drug Product, Spark Therapeutics, Inc.

Developed a mechanistic anion exchange chromatography column model to expedite late phase process development for empty and full capsid separation. Modeling the transport of a large molecule, such as rAAV, in chromatography resin is very challenging and was overcome using an advance general rate model, which included variable surface diffusion.

9:30 Use of Anion Exchange Chromatography in Weak Partitioning Mode to Provide High Empty AAV Capsid Removal and Product Yields

Sian Davies, Scientist, MSAT Downstream Process Dev, MeiraGTx

Scalable methods of full capsid enrichment have often come at the cost of product recovery, thereby increasing the COGS. Here we would like to show that understanding of the AEX chromatography design space led to the identification of weak partitioning mode as an alternative to bind-and-elute. Results show that a full capsid ratio of >80% and a product yield >50% can be robustly achieved when utilizing this method of chromatography.

10:00 Sponsored Presentation *(Opportunity Available)*

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

LENTIVIRAL, ONCOLYTIC VIRUS PROCESS DEVELOPMENT

11:00 Evolving Approaches to Viral Vector Manufacturing Development

Carol Knevelman, PhD, Vice President, Head, Process R&D, Oxford Biomedica

Oxford Biomedica (OXB) is a pioneer in developing products based on viral vectors. To meet the forecast vector demand for gene and cell therapies, OXB has evolved strategies to develop the next-generation manufacturing processes to yield higher vector quantities, suitable product quality attributes, and acceptable cost of goods in order to advance development of a diverse product portfolio including Lenti, Adeno and AAV products which currently present significant challenges.

11:30 FEATURED PRESENTATION: Turning Challenges to Opportunities in Membrane-Based Downstream Processes: Learning from Biologics to Pathfinding for Improved Viral Vector Recovery

Andrea C.M. Rayat, PhD, Chair & Lecturer, Biochemical Engineering, University College London

12:00 Single-Step Rapid Chromatographic Purification Process for Clinical Stage Oncolytic VSV-GP

Saurabh Gautam, PhD, Principal Scientist and Lab Head, Bioprocess Development, Viral Vectors, and Vaccines, ViraTherapeutics, Boehringer Ingelheim

The traditional tools used for protein-based therapeutics often come short in the case of viruses. This is particularly the case when the virus is used for oncolytic purposes rather than as a vaccine wherein the administered dosages are several-fold lower. The work presented will focus on our efforts in developing novel chromatographic purification techniques complemented with extensive characterization of our virus using a suite of analytics.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch (Sponsor Opportunity Available)

mRNA PRODUCTION AND MANUFACTURING

13:45 Chairperson's Remarks

Oliver Spadiut, PhD, Associate Professor, Integrated Bioprocess Development, Vienna University of Technology (BOKU)

13:50 Gene Therapy Using Emerging mRNA Technology

Qian Ruan, PhD, Vice President, Tech Operations and Manufacturing, Arcturus Therapeutics, Inc.

mRNA is emerging as a new class of drug that has the potential to play a role in protein replacement therapies. Arcturus has established mRNA/LNP technology platform and applied to rare diseases treatments.

14:20 Production and Purification of Archaeal Lipids for Enhanced mRNA Delivery

Oliver Spadiut, PhD, Associate Professor, Integrated Bioprocess Development, Vienna University of Technology (BOKU)

The use of liposomes and lipid nanoparticles (LNPs) as efficient vehicles for the transport and delivery of APIs is impressively being demonstrated in the ongoing COVID-19 pandemic. Still, current formulations suffer from several drawbacks. I present a scalable strategy for production, purification, and use of very special lipids from extremophilic Archaea for mRNA delivery. Using these lipids in formulations, the transfection efficiency of mRNA could be enhanced more than 80-fold.

14:50 Benefits of Microbial Continuous Processing

Julian Kopp, PhD, Postdoc Researcher, Chemical & Environmental & Biological Engineering, Vienna University of Technology

State-of-the-art recombinant protein production with microbials is conducted in fed-batch cultivation. Switching to continuous processing would impose small-footprint manufacturing and increase the space-time yield compared to fed-batch processing. Still, industry and research struggle in achieving long-term microbial cultivations with stable productivity. Within this presentation, I will address reasons for fluctuating productivity in continuous processes, and discuss opportunities and how to overcome these challenges.

15:20 Close of Summit

"A great opportunity to meet and connect with leaders in the field and long-time collaborators"

BOKU

Cambridge Healthtech Institute's 5th Annual | **14 - 15 MARCH 2023 ALL TIMES CET**

Cell Therapy Manufacturing

Optimise Scale-Up Strategies and Achieve Commercial Success

TUESDAY 14 MARCH

7:00 Registration and Morning Coffee

ADVANCED MANUFACTURING PROCESSES

8:25 Chairperson's Remarks

Sanjin Zvonic, PhD, Vice President, Business Development & Practice Expert, Dark Horse Consulting

8:30 The Challenges of Developing Bespoke Technologies to Close and Automate Complex Cell Therapy Manufacturing Processes

Toby Proctor, EngD, Head of Manufacturing Science and Technology, Achilles Therapeutics

9:00 Manufacturing Enhancements with a Focus on Robustness, Quality, and Speed of TCR T Product Release

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. Manufacturing improvements implemented enhance key features of the cell product. Continuous enhancements are in progress in preparation of later-stage clinical trials.

9:30 Talk Title to be Announced

Speaker to be Announced

9:45 Presentation to be Announced

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

10:45 A Consortium Investigation for the Implementation of PATs for Immunotherapy Manufacturing

John Churchwell, PhD, Associate Lead Scientist, Cell & Gene Therapy Catapult

There are longstanding challenges in the commercialisation of ATMPs that can be addressed by the implementation of process analytical technologies (PATs). Cell and Gene Therapy Catapult (CGTC) has led a consortium project with 23 collaborators to investigate the application of PAT and advanced analytics for a T cell immunotherapy process. We will describe results from the online, in-line, and at-line PATs employed and discuss the different applications and implementations.

11:15 Integrated Manufacturing for Autologous and Allogenic Cell Therapeutics

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

Cell therapies require chemical gene synthesis, plasmid DNA fermentation, along with viral vector design and production, isolation of human T cells from the patient or allogenic T cells, propagation of the T cells and transfection with the viral vector. Or coupling monoclonal antibodies to the surface of the T cell to target the tumor cell. An end-to-end supplier for required manufacturing technologies is advisable and will facilitate the process chain.

11:45 PANEL DISCUSSION: Advanced Manufacturing Processes

Moderator: Sanjin Zvonic, PhD, Vice President, Business Development & Practice Expert, Dark Horse Consulting

Panelists:

Toby Proctor, EngD, Head of Manufacturing Science and Technology, Achilles Therapeutics

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

John Churchwell, PhD, Associate Lead Scientist, Cell & Gene Therapy Catapult

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

12:15 Talk Title to be Announced

Speaker to be Announced

12:45 Networking Lunch (Sponsor Opportunity Available)

ADVANCED MANUFACTURING PROCESSES (CONT.)

13:45 Chairperson's Remarks

Michael Leek, PhD, Executive Chairman & Founder, TC BioPharm Ltd.

13:50 KEYNOTE PRESENTATION: Decentralized Manufacturing and POCare Processing Platform

Vered Caplan, CEO, Orgenesis, Inc.

A roadmap to enabling cell and gene therapies (CGTs) in an affordable and accessible format at the point of care. The Orgenesis Point-of-Care (POCare) Platform enables a globally harmonized pathway for CGTs to reach large numbers of patients at the point of care at reduced costs through a data centric approach supporting scalable, and decentralized production. OMPULs (Orgenesis Mobile Production Units and Labs) are autonomous production units allowing rapid global deployment.

14:20 Challenges to Commercialisation of Allogeneic Cell Therapies

Michael Leek, PhD, Executive Chairman & Founder, TC BioPharm Ltd.

Many observers correctly regard cell therapies as an exciting new area of medicine. Despite encouraging clinical data, many of the challenges faced in the 1980's when companies like ATS and Organogenesis were developing the first cell-based products still exist. We are still grappling with logistics of shipping such products from clean room to clinic, regulatory uncertainty from region-to-region, donor-to -donor variation of allogeneic products, and high cost of goods.

14:50 Sponsored Presentation *(Opportunity Available)*

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

15:40 End-to-End Automation Platform for the Manufacture of Complex Organoid-Based Implants

Ioannis Papantoniou, PhD, Associate Professor, Skeletal Biology & Engineering Research Center, Catholic University Leuven

Organoid-based implant manufacturing may enable the production of complex 3D ATMP implants able to revolutionise defect regeneration and restore organ function. Engineering such complex ATMPs requires manufacturing technologies that can provide a robust backbone for phenotypic changes but also for increase in size. A novel integrated and fully automated biomanufacturing platform will be showcased allowing the automated transition from single cells to organoids and finally to organoid-based 3D implants.

16:10 Biological Raw Material Sourcing for an Early Stage ATMP and Considerations for Late Stage Clinical Development

Sidonie Karlsson, Head of Manufacturing, Amniotics

Amniotics has developed a MSC cell therapy for treatment of inflammatory lung diseases, currently tested in a Phase I clinical trial. The process uses multiple raw materials of biological origin, e.g., as source material (MSCs from amniotic fluid), sorting antibody, culture medium, detachment enzyme. Quality requirements, suitability for manufacturing of Phase I clinical material and supply issues are discussed here, as well as regulatory aspects and considerations for further development.

16:40 A Translational Services Business Model on the Grounds of Public Cell and Tissue Banking

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

Cell and tissue banks are establishments adhering to strict quality management standards and regulations, and we advocate its prominent role to enhance the value of donated Substances of Human Origin in innovative Advanced Therapy Medicinal Products. To achieve this, we have created a platform for collaboration

with academic and industrial developers, supporting a range of activities from bioprocess design and Good Manufacturing Practice validation, to early phase I/II clinical trials.

17:10 Interactive Discussions

Interactive 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. For in-person events, the facilitator will lead from the front of the room while attendees remain seated. 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 Discussion page on the conference website for a complete listing of topics and descriptions.

17:40 Welcome Reception in the Exhibit Hall with Poster Viewing

18:45 Close of Day

WEDNESDAY 15 MARCH

8:00 Registration and Morning Coffee

IMPACT OF BIG PHARMA

8:25 Chairperson's Remarks

Michael Delahaye, Director, Team Leader Cell Therapy Bioprocessing, AstraZeneca

8:30 FEATURED PRESENTATION: Harnessing the Capabilities of Big Pharma to Drive Cell Therapy

Michael Delahaye, Director, Team Leader Cell Therapy Bioprocessing, AstraZeneca

LARGE-SCALE WORKFLOWS AND CRYOPRESERVATION

9:00 Development of an Allogenic Mesothelin CAR T Cell Therapy Production Process with a Representative Scale-down Model

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

CAR T cell therapy success in solid tumors has been limited due to the lack of tumor-specific antigens, to tumor heterogeneity, and to the immuno-inhibitory nature of the tumor microenvironment. To address these challenges, we engineered CAR T cells that use the tumor-specific mesothelin antigen as a discriminatory target and have enhanced therapeutic properties. Its manufacturing method uses a representative small-scale model that led to a new large-scale workflow.

9:30 Strategies for Cryopreservation and Banking of iPS Cells and Their Derivatives

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.

10:00 Sponsored Presentation *(Opportunity Available)*

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

PLENARY SESSION: EMERGING MODALITIES, PLATFORMS, AND TECHNOLOGIES – FROM mRNA TO PROTEINS

11:15 Chairperson's Opening Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: Overcoming CMC and Supply Chain Challenges for mRNA Technologies

Gregory Troiano, Chief Manufacturing Officer, mRNA Center of Excellence, sanofi

Thanks to the rapid development of mRNA vaccines for COVID-19, the industry now has the momentum and resources to overcome many of the early CMC challenges and realize its enormous potential. This presentation will discuss the strategies in place to overcome CMC and supply chain challenges for mRNA technologies already and future innovations primed to take it to the next level.

11:50 PLENARY PRESENTATION: Affinity Proteins for Biotechnological and Medical Purposes

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

Affinity proteins are crucial for life, for building structures, performing reactions, and for signaling purposes. In life sciences and medicine, affinity proteins are used to generate knowledge, but also for diagnostic and therapeutic purposes. This talk will cover how antibodies and small affinity molecules can be used to map the human proteome, develop diagnostic tools for *in vivo* visualization as well as efficiently purify therapeutics based on antibodies.

12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

14:00 Close of Cell Therapy Manufacturing Conference

"A Great place to connect with industry peers and discover the latest innovations"

Locus Cell Co., Ltd.

"Great!"

BMS

Cambridge Healthtech Institute's 5th Annual | **15 - 16 MARCH 2023 ALL TIMES CET**

Cell Therapy CMC and Analytics

Implementing New Technologies and Enhancing Analytical Strategies

WEDNESDAY 15 MARCH

10:30 Registration Open

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12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

CMC & EMERGING ANALYTICAL METHODS

14:00 Chairperson's Remarks
Christiane Niederlaender, PhD, Vice President, Technical CMC, Parexel

14:05 CMC Challenges and Opportunities for Cell and Gene Therapies
Paulo Fernandes, PhD, Associate Director Cell & Gene Therapy Technologies, Technology Operations & Global Tech Development, Orchard Therapeutics
Developing next generation products to release current bottlenecks in CGT. Technical overview on CMC strategies for real CGT products, presentation of actual scientific data showing the progress done to release current bottlenecks in the manufacture and COGs of CGT products. The critical points in the CMC strategy for CGT products, with real examples. Current bottlenecks in the manufacture of CGT products and development areas to focus on.

14:35 A Consortium Investigation for Extensive Analytical Characterisation of T Cell Immunotherapy Processes
Rhys Macown, PhD, Lead Scientist, Cell & Gene Therapy Catapult
There are longstanding challenges in the commercialisation of ATMPs that can be addressed by the implementation of process analytical technologies (PATs). Cell and Gene Therapy Catapult has led a consortium project with 23 collaborators to investigate the application of PAT and advanced analytics for a T cell immunotherapy process. We will discuss the extensive approach we applied to analytical characterisation of the process and the opportunities and challenges it presented.

15:05 Cell Sorting and Analytical Development Considerations for GMP Manufacture of Cell Therapies
Harish Adoni, Scientist, Analytics Cell Therapy, ElevateBio
Over the past decade, the development of cell therapies has gained significant momentum. Processes executed in a hospital setting such as the isolation of tumor infiltrating lymphocytes (TILs), transformed clones of hematopoietic stem cells (HSCs), or other rare cells, are challenging to replicate in a cGMP environment. We will discuss the cell sorting process and analytical development considerations when implementing fluorescence activated cell sorting (FACS) in a cGMP environment.

15:35 Sponsored Presentation *(Opportunity Available)*

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

16:40 Establishment of Process Intensification and Automated Process Control Strategies for CAR-T Production
Qasim A. Rafiq, PhD, Associate Professor, Biochemical Engineering, University College London

17:10 PANEL DISCUSSION: CMC & Emerging Analytical Methods
Moderator: Christiane Niederlaender, PhD, Vice President, Technical CMC, Parexel
Panelists:
Paulo Fernandes, PhD, Associate Director Cell & Gene Therapy Technologies, Technology Operations & Global Tech Development, Orchard Therapeutics
Rhys Macown, PhD, Lead Scientist, Cell & Gene Therapy Catapult
Harish Adoni, Scientist, Analytics Cell Therapy, ElevateBio
Qasim A. Rafiq, PhD, Associate Professor, Biochemical Engineering, University College London

17:40 Interactive Discussions
Interactive 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. For in-person events, the facilitator will lead from the front of the room while attendees remain seated. 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 Discussion page on the conference website for a complete listing of topics and descriptions.

18:15 Close of Day

THURSDAY 16 MARCH

8:00 Registration and Morning Coffee

OPTIMISING COMPARABILITY STRATEGIES

8:25 Chairperson's Remarks
Christopher Bravery, PhD, Consulting Regulatory Scientist, Advanced Biologicals Ltd.

8:30 KEYNOTE PRESENTATION: Implementing Risk-Based Approaches for Cell Therapies
Florence Salmon, PhD, Vice President, Regulatory Affairs and Preclinical Development, Ridgeline Discovery
Genetically modified cells are remarkably complex medicinal products that require risk-based manufacturing and control strategies to meet regulatory expectations. Nonetheless, changes are inevitable at each stage of development of cell therapies, sometimes late or even post-approval. Comparability is therefore a key exercise and should be accounted for from the very beginning. Having the right analytical and regulatory tools at hand at the right time is the key to success.

9:00 Life-Cycle Comparability Approaches for Genetically Modified

Cell Therapy CMC and Analytics

Implementing New Technologies and Enhancing Analytical Strategies

Cells

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

The frequently short development timelines for cell and gene therapies mean that comparability is often considered too late during the implementation of process changes. The talk outlines key considerations that ensure that an appropriate comparability plan can be put in place and executed, and that can be adapted throughout the product lifecycle.

REGULATORY CONSIDERATIONS

9:30 Regulatory Strategies for Cell Therapy

Raj Puri, MD, PhD, Executive Vice President, Regulatory Strategy and Translational Medicine, Iovance Biotherapeutics

Tumor-infiltrating lymphocytes (TIL) are circulating cytotoxic and helper T cells that have infiltrated a tumor, recognize tumor-specific neoantigens unique to each patient, and mediate tumor cell death. TIL cell therapy involves the adoptive transfer of billions of polyclonal, patient-specific TIL recovered from a patient's tumor tissue that are amplified and reinvigorated using a proprietary process. I will discuss unique opportunities and challenges in TIL cell therapy manufacturing, logistics, and development.

10:00 Ensuring Quality of Cell Therapy Products

Maura Kibbey, PhD, Director, Biologics Marketing, USP

Assessment of cell therapy quality from raw materials to final product is critical to ensuring their safety and efficacy. Lack of standards for cell therapy has slowed down product development since the path and tools to commercialization are not clear. USP continues to publish best practices and methods that support their innovation. Existing standards as well as new work related to plasmid DNA and rapid microbial methods will be shared.

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

11:00 FEATURED PRESENTATION: Common Issues Identified with Cell Therapy Applications

Janet Glassford, PhD, Expert Quality Assessor, MHRA

This presentation will outline common issues relating to cell therapy applications from the perspective of a quality assessor with over a decade of experience as an MHRA assessor and as a former EMA expert. Updated information regarding UK specific regulatory routes and scientific guidance will also be provided.

11:30 Achieving Global Regulatory Harmonization and Centralized QA in a Decentralized Model

Chaya Mazouz, Vice President, Quality (IL) & Global Regulatory Affairs, Orgenesis, Inc.

Decentralized manufacturing (DCM) has the potential to facilitate accessibility of cell and gene therapies. A regulatory framework is required to enable the development of point of care (POCare) manufacturer providing control measures equivalent to those currently in place for medicinal products, ensuring that POCare products have appropriate quality, safety, and efficacy attributes. The regulatory system is proposed to be based on a Control Site – the primary focus of regulatory authorities.

12:00 Sterility Control for Cell Therapies from a Regulatory Perspective

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

The nature of cell therapy products means they cannot be terminally sterilised or even sterile-filtered; this puts a greater onus on other aspects of sterility control. This talk will discuss how a holistic approach is needed to ensure safety of these products, including facilities, testing and methods of sterilisation.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch (Sponsor Opportunity Available)

NOVEL PLATFORMS, RISK ANALYSIS, AND MACHINE LEARNING

13:45 Chairperson's Remarks

Ricardo Baptista, PhD, CTO, Alder Therapeutics

13:50 Development of a Novel Costimulatory Platform to Improve Adoptive Cell Therapies

John Bridgeman, PhD, Director, Cell Therapy Research, Instil Bio

Utilizing a novel platform to overcome poor endogenous costimulation and leverage the diverse TCR repertoire of TILs while amplifying antitumor activity.

14:20 Raw Materials and Reagents Supply to Develop Scalable Manufacturing Processes – Considerations for Pluripotent Stem Cell Therapies

Ricardo Baptista, PhD, CTO, Alder Therapeutics

Evaluation of critical raw materials should start at early stages of product cycle. This talk will focus on risk analysis and mitigation strategies to support process and analytical development for the manufacture of allogeneic therapies from pluripotent stem cells.

14:50 Replacing Manual Gating of Flow Cytometry Data in Cell Therapy Manufacturing

Ryan Brinkman, Managing Director, Cytapex Bioinformatics, Inc; Distinguished Scientist, BC Cancer; Professor, Medical Genetics, UBC

We have developed the best performing automated approach for cell population identification in the peer-reviewed literature. It consistently achieves up to 94% accuracy, and is in use by pharma for clinical studies and cell therapy manufacturing. Looking to the future our preliminary data supports that machine learning will exceed even this, providing a scalable solution for all users of the technology.

15:20 Close of Summit

"Great to meet industry and academia colleagues in the same place. I strongly believe this event will lead to new synergies and strengthen our efforts towards a more efficient and sustainable biopharmaceutical sector."

3M

Cambridge Healthtech Institute's 4th Annual | **14 - 15 MARCH 2023 ALL TIMES CET**

Analytics and Characterisation

Emerging Technologies for New Biotherapeutic Modalities and Improved Process Control

TUESDAY 14 MARCH

7:00 Registration and Morning Coffee

EXPANDING THE USABILITY AND APPLICATIONS OF MS

8:25 Chairperson's Remarks

Yunlong Zhao, PhD, Staff Scientist, Analytical Chemistry, Regeneron Pharmaceuticals, USA

8:30 LC/MS for Host Cell Protein Monitoring and Characterization

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

It is well known that some HCPs with very little abundance have a strong impact on product quality. Understanding how HCPs escape the purification process and the detection of those HCPs is a prerequisite for developing a suitable HCP depletion process. Here, we assess our research on methods for detection of low abundant HCPs by MS/MS and compare different methods to enrich HCP levels in samples.

9:00 A New Affinity CE-MS Approach to Assess Antibody-Fc Receptor Interaction

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

Monoclonal antibodies consist of a mixture of different proteoforms (e.g. glycoforms) with potentially different functionalities. mAbs activate the immune response via binding to Fc receptors. Common approaches, such as SPR, provide an overall affinity response for all mAb proteoforms. In this presentation, we want to show an innovative approach based on sheathless CE-MS to study relative affinities of different mAb proteoforms in mixtures towards the FcRn and FcγRIIa receptors.

9:30 Talk Title to be Announced

Speaker to be Announced

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

10:45 Developing Protein Interaction Analysis by Chemical Crosslinking and Mass Spectrometry into a Diagnostic Tool

Franz Herzog, PhD, Professor and Head, Mass Spectrometry, Bioanalytics, FH Krems University of Applied Sciences, Germany

Chemical crosslinks identified by mass spectrometry have been widely applied to study the architectures of protein complexes and networks even in organelles and whole cells. The quantification of crosslinks will provide information on the mechanism of protein complexes like binding affinities and interfaces. Capturing changes in protein interactions in samples like biopsies will aid understanding the molecular basis of diseases at the system level and the classification of disease types.

11:15 Automated Iterative LC-MS/MS (HCP-AIMS) for Therapeutic Protein Development

Yu Huang, PhD, Staff Scientist, Analytical Chemistry, Regeneron Pharmaceuticals, Inc., USA

To meet the challenges in host cell protein (HCP) analysis during drug development, especially downstream process development, which entails fast turnaround time and robustness while identifying high level of HCPs and their clearance trend for further purification development, we have developed HCP-automated iterative MS (HCP-AIMS): It is a simple, automated, and robust HCP analysis workflow with deep and unbiased identification and relative quantification capability.

11:45 KEYNOTE PRESENTATION: Addressing Challenges in Sample Preparation and Chromatographic Performance of MS-Based MAM Workflows

Dan Bach Kristensen, PhD, Principal Scientist, Symphogen, Denmark

Peptide mapping by LC-MS, and the related Multi-Attribute Method (MAM), are powerful and well-established tools for mapping and quantitation of quality attributes at the amino acid level in biopharmaceutical development. Here, alternative MAM workflows based on automatic hands-off digestion are presented, which significantly 1) reduced the number of missed cleavages compared to established workflows, and 2) radically reduce chromatographic peak tailing and carry-over of hydrophobic peptides.

12:15 Talk Title to be Announced

Speaker to be Announced

12:45 Networking Lunch (Sponsor Opportunity Available)

EMERGING METHODS AND INSTRUMENTS

13:45 Chairperson's Remarks

Franz Herzog, PhD, Professor and Head, Mass Spectrometry, Bioanalytics, FH Krems University of Applied Sciences, Germany

13:50 Preclinical *in vitro* Studies on Parameters Governing Immune Complex Formation

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

The success of biotherapeutics is often challenged by the undesirable events of immunogenicity in patients. Immunogenicity is often associated with formation of immune complexes (ICs) as a triggering point. We have performed an in-depth study to evaluate factors, which govern formation of ICs using classical and state-of-the-art analytical methods. An overview of the study, the critical method performance aspects, and an overarching evaluation of the obtained results will be presented.

14:20 Knowing More from Less: A Microfluidic Analytical Toolbox for the Monitoring of Bioprocesses

Inês Fernandes Pinto, PhD, Postdoctoral Researcher, KTH, Sweden

The development of miniaturized systems with automation of analytical methods represents an attractive approach to achieve a better understanding of cell culture processes. In this context, we developed a novel microfluidics-based modular system to be coupled to a mAb-producing mammalian cell bioreactor aiming at performing (1) multiplexed immunodetection of relevant proteins, (2) evaluation of glycosylation profile of the target mAb, and (3) analysis of amino acids using microchip capillary electrophoresis.

14:50 Talk Title to be Announced

Speaker to be Announced

15:20 Refreshment Break in the Exhibit Hall with Poster Viewing

15:40 Identifying Product-Related Impurities with TRIFLE

John Hales, PhD, Biochemical Engineering, University College London, United Kingdom

Time-resolved intrinsic-fluorescence-lifetime extraction (TRIFLE) is an emerging analytical technology for quantifying product and impurities in real-time. TRIFLE can be used to identify and quantify biophysically-similar proteins even when there is overlap in their chromatographic elution profiles. I will discuss examples of TRIFLE being used to identify product and product-related impurities for different modalities, including mAbs and viral vectors, and I will introduce our work on another analytical technology: virus lasers.

16:10 LC-MS and LC-IM-MS Software for Analysis of Glycopeptides and Released Glycans in Bioprocessing

*Ian Walsh, PhD, Senior Staff Scientist, Bioprocessing Technology Institute (A*STAR), Singapore*

Analytics and Characterisation

Emerging Technologies for New Biotherapeutic Modalities and Improved Process Control

A significant burden in biomanufacturing is the characterization of glycans and glycopeptides on biopharmaceuticals. To address the need for customized software to handle multi-attribute data arising from combinations of liquid chromatography, ion mobility, and mass spectrometry (LC-IM-MS), two semi-automated software programs for released glycan and glycopeptide characterization and quantitation are described. Both programs can identify glycans/glycopeptides more accurately and quicker compared to other methods.

16:40 Glycine Additive Facilitates Site-Specific Glycosylation Profiling of Biopharmaceuticals by Ion-Pairing Hydrophilic Interaction Chromatography Mass Spectrometry

Yunlong Zhao, PhD, Staff Scientist, Analytical Chemistry, Regeneron Pharmaceuticals, USA

Glycine as a signal-boosting additive solves the dilemma between excellent peak separation and sufficient MS sensitivity for glycopeptide analysis using regular-flow ion-paring HILIC-MS. Here, we present showcases where this platform was applied to support early and late stages of biopharmaceutical development, including quick glycosylation profiling of monoclonal antibody and fusion proteins, discovery of atypical glycosylation sites of low occupancy in monoclonal antibody, and targeted-based subclass-specific IgGs N-glycosylation profiling in serum.

17:10 Interactive Discussions

Interactive 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. For in-person events, the facilitator will lead from the front of the room while attendees remain seated. 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 Discussion page on the conference website for a complete listing of topics and descriptions.

Session Header

17:10 Presentation to be Announced

17:40 Welcome Reception in the Exhibit Hall with Poster Viewing

18:45 Close of Day

WEDNESDAY 15 MARCH

8:00 Registration and Morning Coffee

ANALYTICAL SUPPORT FOR PRODUCT QUALITY MONITORING AND CONTROL

8:25 Chairperson's Remarks

Christine Carapito, PhD, Co-Head of the BioOrganic Mass Spectrometry Laboratory, CNRS Research Director, University of Strasbourg, France

8:30 MAM (Multi-Attribute Methods) in Process Characterization and Control

Dietmar Reusch, PhD, Director, Development Analytics, Roche, Germany

Multi-attribute monitoring (MAM) by LC-MS has gained increased interest from Biopharma companies to replace multiple traditional assays in the control system. In this presentation, we will provide Roche/Genentech's perspective on the practical considerations and strategies for MAM use in quality control and replacement of traditional assays, including target attribute selection, new peak detection for stability studies, and bridging strategies to justify traditional assays replacement with MAM.

9:00 FEATURED PRESENTATION: Advanced Sample Preparation, LC-MS/MS and Data Processing Workflows for Host Cell Protein Impurities Quantification

Christine Carapito, PhD, Co-Head of the BioOrganic Mass Spectrometry Laboratory, CNRS Research Director, University of Strasbourg, France

The quantification of individual host cell proteins (HCP) is a major analytical challenge that bottom-up proteomics workflows need to address. The implementation of new standards for robust and accurate quantification of HCP will be presented. The potentialities of Data Independent Acquisition coupled with ion mobility separation will be assessed on various latest-generation instrumental platforms. Finally, benefits of using innovative artificial intelligence algorithms for data processing will be highlighted.

9:30 The Role of CQAs for Product Quality Control from Manufacturing to Shelf Life

Dirk Haubert, PhD, Analytical Project Lead, Biologics, Novartis Pharma AG, Switzerland

Product quality is controlled at all stages of the manufacturing process, at release, and on stability. Criticality assessment of each quality attribute provides the basis for defining the required level of control. By combining available knowledge of the molecule's degradation behavior with understanding how the individual steps of the manufacturing process impact CQAs, a smart control strategy can be developed allowing for manufacturing flexibility without compromising quality and safety.

10:00 Talk Title to be Announced

Speaker to be Announced

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

PLENARY SESSION: EMERGING MODALITIES, PLATFORMS, AND TECHNOLOGIES – FROM mRNA TO PROTEINS

11:15 Chairperson's Opening Remarks

Margit Holzer, PhD, Owner, Ulysse Consult

11:20 PLENARY PRESENTATION: Overcoming CMC and Supply Chain Challenges for mRNA Technologies

Gregory Troiano, Chief Manufacturing Officer, mRNA Center of Excellence, sanofi

Thanks to the rapid development of mRNA vaccines for COVID-19, the industry now has the momentum and resources to overcome many of the early CMC challenges and realize its enormous potential. This presentation will discuss the strategies in place to overcome CMC and supply chain challenges for mRNA technologies already and future innovations primed to take it to the next level.

11:50 PLENARY PRESENTATION: Affinity Proteins for Biotechnological and Medical Purposes

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

Affinity proteins are crucial for life, for building structures, performing reactions, and for signaling purposes. In life sciences and medicine, affinity proteins are used to generate knowledge, but also for diagnostic and therapeutic purposes. This talk will cover how antibodies and small affinity molecules can be used to map the human proteome, develop diagnostic tools for *in vivo* visualization as well as efficiently purify therapeutics based on antibodies.

12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

14:00 Close of Analytics and Characterisation

Cambridge Healthtech Institute's 4th Annual | **15 - 16 MARCH 2023 ALL TIMES CET**

Formulation and Stability

New Technologies, Big Data Tools, and Formulating New Modalities

WEDNESDAY 15 MARCH

10:30 Registration Open

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12:20 Transition to Sessions

12:30 Sponsored Presentation (Sponsor Opportunity Available)

13:00 Networking Lunch (Sponsor Opportunity Available)

FORMULATION OF INNOVATIVE BIOTHERAPEUTICS

14:00 Chairperson's Remarks
Shahid Uddin, PhD, Director, Drug Product, Formulation & Stability, Immunocore, United Kingdom

14:05 Developability Assessment of Biologics and Formulation of Novel Molecules
Shahid Uddin, PhD, Director, Drug Product, Formulation & Stability, Immunocore, United Kingdom
Biologics are challenging molecules that require extensive characterisation for them to be developed. Formulation plays a key role in enhancing the stability profile of biologics, but to risk mitigate late-stage development, studies such as developability are critical to ensure manufacturable candidates are advanced. The presentation will focus on the importance of developability during drug development and touch on a novel class of molecules that require unique approaches to deliver.

14:35 Development and Formulation of ACE2-Fc Fusion Proteins as Broadly Active Antivirals
Hristo Svilenov, PhD, Associate Professor, Ghent University, Belgium
The ACE2-Fc fusion proteins are biotherapeutic candidates that can potently neutralize viruses using the ACE2 receptor to infect cells. In this presentation, I will discuss considerations for the development, analytical characterization, and formulation development of engineered ACE2-Fc drug candidates.

15:05 Mechanistic Understanding of Biologics Formulations through Higher-Order Structure Analysis and Simulations
Paul Dalby, PhD, Professor, Biochemical Engineering, University College London, United Kingdom
Protein formulation remains challenging. By combining mutations, reformulations, and presentations in liquid or solid-state, a wide range of products were generated and characterised using higher order structure analyses (LC-MS, NMR) and simulations. Case studies from established products through to novel antibody coformulations reveal specific mechanisms governing conformational stability, dynamics, and aggregation. This understanding should lead to better prediction of potential mutations and formulations for new proteins.

15:35 Talk Title to be Announced
Speaker to be Announced
MERCK

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

16:40 Nano-Enabled Formulations for Improved Stability, Safety, and Efficacy of Therapeutics
Iris L. Batalha, PhD, 'La Caixa' Junior Leader, Institute for Bioengineering of Catalonia (IBEC), Spain
The nanoformulation of therapeutics has gained new momentum with the COVID-19 pandemic. By allowing the rational design of complex architectures and the incorporation of bio-responsive and targeting moieties, nanoformulations have the potential to improve the clinical outcomes of free drugs and navigate biological barriers that are disease-specific and sometimes heterogeneous across patient populations. This talk will give an overview of my recent work using nanocarrier-mediated combination therapy for bacterial infections.

17:10 KEYNOTE PRESENTATION: A Tale of Visible Proteinaceous Particles in a Monoclonal Antibody
Arun Alphonse Ignatius, PhD, Director, Drug Product Sciences, Macrogenics, Inc., USA
Visible proteinaceous particles are a potential patient safety concern. Control of visible particles remains a challenge for pharmaceutical scientists and drug product manufacturers. Health authorities have emphasized a holistic risk-based approach for control of visible particulates during development, scale-up, and commercial manufacturing. Herein, an overview of control strategy for visible proteinaceous particles incorporating a semi-quantitative method for visual inspection will be discussed.

17:40 Interactive Discussions
Interactive 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. For in-person events, the facilitator will lead from the front of the room while attendees remain seated. 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 Discussion page on the conference website for a complete listing of topics and descriptions.

18:15 Close of Day

THURSDAY 16 MARCH

8:00 Registration and Morning Coffee

MODELLING AND MACHINE LEARNING IN FORMULATION DEVELOPMENT

8:25 Chairperson's Remarks
Paul Dalby, PhD, Professor, Biochemical Engineering, University College London, United Kingdom

8:30 Predicting Excipient Mixtures in Liquid and Lyophilized Formulations – Advances and Remaining Challenges

Formulation and Stability

New Technologies, Big Data Tools, and Formulating New Modalities

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

Still today, excipients and excipient mixtures within liquid and lyophilized biopharmaceutical formulations are mainly identified based on excipient screening, or heuristic approaches. Especially predictive modeling approaches are thus desirable to identify excipients and excipient mixtures based on a minimal set of experimental data. This allows to access mutual interactions of multi-excipient systems and to determine the optimal excipient mixture for a given liquid/lyophilized formulation in an early development stage.

9:00 Towards Combining Automation and Machine Learning in Formulation Development

Dominik Zürcher, Researcher, Biochemical Engineering, ETH Zurich, Switzerland

Formulating successful therapeutic proteins requires laborious optimization of multiple biophysical properties in a vast design space. In combination with time- and cost-efficient experimentation, artificial intelligence is emerging as a powerful tool to accelerate the optimization of formulations. This talk highlights our efforts to develop high-throughput technologies to assess interfacial stability and provides an example of their synergistic application with machine learning to find optimal buffer conditions for a target protein.

9:30 Predictive Model for Rational Design of Nanomedicine Formulations

Silvia Acosta Gutiérrez, PhD, Beatriu de Pinós Fellow and Computational Lead, Molecular Bionics Lab, Institute for Bioengineering of Catalonia (IBEC), Spain

We have derived a predictive model for nanomedicines (polymersomes)-cell association. Our model considers the nanomedicine interaction with the cell glycocalyx, shedding light on the effect of this barrier on polymersomes' binding and viral attachment to the cell. Experimental validation of the model shows that the nanomedicine/viral-cell binding energy is a highly non-linear function. Our model enables the rational design of phenotypic nanomedicines, allowing us to tune their cell avidity.

10:00 How to Avoid and Model Aggregation of Antibodies during Freezing and Thawing

Miguel Rodrigues, PhD, Professor, Co-Founder, R&D, SmartFreez, Lda

The aggregation of antibodies below freezing temperature was accessed using two strategies, freeze-thaw cycles with different cooling rates and under supercooled states (without freezing), by isochoric cooling. The results were interpreted with computational fluid dynamics modelling (of freeze-thaw) and aggregation modelling (with extended Lumry-Eyring approach). The contribution of cold denaturation on antibodies aggregation was evident in the two cases, revealing important considerations to improve formulation and process development of biologics.

10:15 Sponsored Presentation *(Opportunity Available)*

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

STABILITY CHALLENGES

11:00 FEATURED PRESENTATION: Evaluation of Relationship between Conformational and Chemical Stability, and Protein Binding of Monoclonal Antibody and Antibody-Drug Conjugates for Forced Degradation Studies

Yunus Saricay, PhD, Specialist, Research & Development, Byondis B.V., The Netherlands

Forced degradation studies (FDS) are performed to identify the potential degradation pathways of biopharmaceuticals. By implementing new technologies, we have established a strategy to extend our understanding of the relationship between chemical and structural modifications and protein binding for a monoclonal antibody and an antibody-drug conjugate as a part of an FDS. Our data reveal that chemical modifications can play more critical role in product functionality than 3D conformational changes.

11:30 Heterogeneity of Protein Aggregates and Immunogenicity

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

Protein aggregates may accelerate an immune response towards the therapeutic product, which has impact on efficacy and patient safety. We developed a platform for the analysis of insulin aggregates with selected characteristics. We connected size, structure, and chemical modifications of the aggregates to their immunogenicity potential *in vitro* and *in vivo*. The results show that micron-sized aggregates with highly altered structure were the most immunogenic species.

12:00 Survey of In-Use Handling Aspects of Protein Drugs

Ulla Elofsson, PhD, Associate Professor & Senior Scientist, Health and Life Science, Chemical Process and Pharmaceutical Development, RISE Research Institutes of Sweden AB

What do we know so far about the in-use handling of protein drugs? Which are the steps and the stressors involved in the handling between release from the manufacturer to their administration and use? And who are the people involved? These are questions that are addressed in this literature survey.

12:30 Sponsored Presentation *(Opportunity Available)*

13:00 Networking Lunch (Sponsor Opportunity Available)

CHALLENGES AND SOLUTIONS

13:45 Chairperson's Remarks

Tobias Werk, PhD, CEO, Bionter AG, Switzerland

13:50 Dipolar Interactions and Protein Hydration in Highly-Concentrated Antibody Formulations

Patrick Garidel, PhD, Head, Process, Purification and Pharma Development, Biopharma, Boehringer Ingelheim Pharma GmbH, Germany

Molecular protein-protein interaction (PPI) mechanisms in high-concentrated protein systems are of fundamental importance for the rational development of monoclonal antibody (mAb) formulations. A direct extrapolation of physicochemical properties obtained from measurements at a low protein concentration of the corresponding properties at a high protein concentration is highly questionable. Here, protein hydration, protein dipole moment, and protein-protein interactions were studied in protein concentrations up to 1.3 mM using dielectric relaxation spectroscopy.

14:20 Emerging Methods to Support Drug Product Formulation Development

Tobias Werk, PhD, CEO, Bionter AG, Switzerland

Traditional particle monitoring processes consume the majority of all sample volume during stability studies. An optimization of processes and workflow may allow preservation of more than 90% of the sample volume or allow 10 times more insights during early pharmaceutical development. I will present a case study that shows – if we are up to slightly change our processes – how we can truly bring formulation development to another level.

14:50 Overcoming Barriers for Drug Delivery to the Eye

Karen Peynshaert, PhD, Postdoctoral Researcher, Biochemistry and Physical Pharmacy, Ghent University, Belgium

Retinal diseases, both inherited and acquired, lie at the root of severe vision impairment which affects millions of patients worldwide. While industry and academia are exploring a plethora of cell and gene therapy products, several ocular drug delivery barriers hinder their effective delivery to the retina. Smart design of nanoparticles and/or controlled modulation of the barriers involved could therefore offer a significant therapeutic benefit.

15:20 Close of Summit

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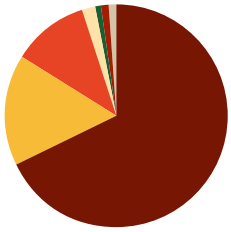
2022 Attendee Demographics



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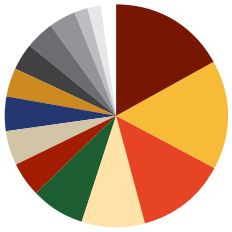

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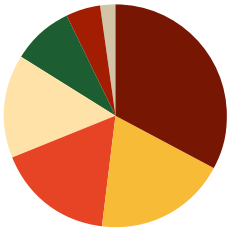

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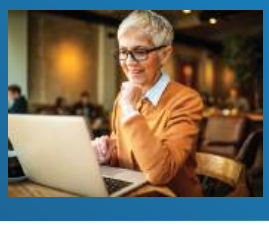

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250 First Avenue, Suite 300, Needham, MA 02494 • Healthtech.com • Phone: 781-972-5400 • Fax: 781-972-5425