SESSIONS

MAY 17 - 17/05/2022

Coffee and Registration

07:30 - 08:20
General Session

Chairperson's Opening Remarks

08:20 - 08:30
Cell Line Development and Engineering - Strauss 2 and 3

Participants

Raja Srinivas - Founder, Asimov

Chairperson's Opening Remarks

08:20 - 08:30
Cell Culture - Strauss 1

Participants

Mark Duerkop - Chief Executive Officer, Novasign

Chairperson's Opening Remarks

08:20 - 08:30
Recovery & Purification - Lehar 1 and 2

Participants

Ger Brophy - Executive Vice President, Biopharma Production, Avantor, USA

Chairperson's Opening Remarks

08:20 - 08:30
Viral Safety - Lehar 3

Participants

David Gemmell - Biomanufacturing Engineer, Merck

Chairperson's Opening Remarks

08:20 - 08:30
Cell & Gene Therapy - Lehar 4

Participants

Volker Huppert - Chief Development Officer, Glycostem Therapeutics

KEYNOTE: Cell Engineering Using Synthetic Biology

08:30 - 09:00
Cell Line Development and Engineering - Strauss 2 and 3

Biopharmaceuticals are mainly produced by CHO cell lines, which face novel challenges due to advances in protein formats, bioprocesses or bioprocess control. My talk will present novel developments from my laboratory exploring synthetic biology for (i) the development of a sensor cell line for automated bioprocess control, (ii) cell line development for continuous bioprocessing exploiting hypoxia, (iii) discovering the cell surfaceome to control cell aggregation and using a blueprint from nature for optimization of CHO production cells.

Participants

Kerstin Otte, PhD - Professor, University of Applied Sciences Biberach

PAT for vaccine manufacturing: integrated upstream and downstream applications

08:30 - 09:00
Cell Culture - Strauss 1

Production of vaccines in response to a global pandemic requires robust and reliable manufacturing processes. The use of process analytical technology (PAT) is key to enhance bioprocess monitoring and control, with in-line measurements on product quantity and quantity, enabling real-time process decision. We will present case studies of PAT implementation for upstream and downstream unit operations of Janssen's Adenovirus-based vaccine manufacturing platform.

Participants

Sarah Touw-Mercier - Senior Scientist, USP, Janssen, Pharmaceutical Companies of Johnson and Johnson

Lifecycling of Hybrid Digital Twins: Strategies to Generate, Adapt and Deploy Digital Twins

08:30 - 09:00
Recovery & Purification - Lehar 1 and 2

Participants

Christoph Herwig, PhD - Full Professor for Biochemical Engineering, Vienna University of Technology, Austria & Senior Scientific Advisor, Körber AG, Austria

Strategies for Upstream Viral Risk Mitigation

08:30 - 09:00
Viral Safety - Lehar 3

- Why upstream viral risks should be mitigated & the cost of contamination
- Developing a risk-based approach to upstream raw material contamination
- Mitigation techniques for high-risk raw materials

Participants

David Gemmell - Biomanufacturing Engineer, Merck

CGT Process Development - Challenges and Avenues

08:30 - 09:00
Cell & Gene Therapy - Lehar 4

We are witnessing the golden time of cell and gene therapy with multiple clinical trials and a significant number of approvals globally. The field is evolving based on the existing technologies, GMP, and Regulatory framework of pharmaceuticals and biologics. The process development and manufacturing challenges are the burning concerns to deliver these products to many patients at affordable cost. The talk will review all the challenges and the potential avenues on CGT process development and manufacturing.

Participants

Hemant Dhamne - Head, Process Development, Gene Therapy Vector Facility, King's College London, UK

KEYNOTE: Transcriptional reprogramming of CHO cells

09:00 - 09:30
Cell Line Development and Engineering - Strauss 2 and 3

Nature has provided us with mammalian cells that can (and are used) as factories for production of the desirable biological therapeutics. However, yield and capacity to make specific products can be limited by the properties of different cell types. Nature also tells us (although we may not fully understand it) that specific cellular properties will enable us to generate better cell factories, properties that can be engineered into existing cells.

Participants

Alan Dickson, Ph.D. - Professor, University of Manchester

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The road to digitalisation of a research lab

09:00 - 09:30
Cell Culture - Strauss 1

During the development phase of biopharmaceuticals large volumes of data are generated in many stand-alone hardware devices. Furthermore, with increasing numbers of projects and need to compress development timelines, high throughput and automation systems are being increasingly used. The resulting high pace of data generation augments error rates thereby risking data integrity. In order to ensure a leaner, more efficient and integral data generation we initiated an “e-Transformation” project. The objective was to increase development lab efficiency by ≥20% through increasing automation and interconnectivity of lab instruments and systems in addition to improving data traceability, extractability and searchability. Through implementation and interconnection of systems and software required within the lab we aim to improve processes and reduce timelines for process development enabling acceleration of biopharmaceutical development.

Participants

Steffie Eggermont - Senior Scientist, UCB

Integrated process modelling and machine-learning in downstream process development

09:00 - 09:30
Recovery & Purification - Lehar 1 and 2

Participants

Cécile Brocard, PhD - Director, Downstream Development, Biopharma Process Science Austria, Boehringer Ingelheim RCV GmbH & Co KG

Advancing Bioprocess Operations From Pressure to Pump: Robustness Of Pump Based Virus Filtration, Including Pressure Ramp-Up Phase

09:00 - 09:30
Viral Safety - Lehar 3

Virus filtration processes are developed, optimized, and validated using constant pressure filtration at small scale, and it is critical that this data is predictive and representative of filter performance both at larger scales and under different operation strategies. While using constant pressure at small scale is convenient and common, manufacturing suites often use pump-driven systems with single-use bags to leverage footprint and workflow advantages. In this study, we demonstrate scalability of the Planova™ 20N virus removal filter to provide consistent performance and viral clearance in pump-driven runs at all filter sizes.

Participants

Mathithas Kandasamy - Senior Product Manager, Asahi Kasei Bioprocess Europe

Development of Viral Vectors for Gene Therapy

09:00 - 09:30
Cell & Gene Therapy - Lehar 4

The use of gene therapy for the treatment of diseases has revolutionized the medical world, showing great promise in providing a new avenue of hope alongside conventional treatment. In this presentation I will provide a brief overview of the field, from historical findings to current advances, with an emphasis on the development of viruses as vectors for the introduction of genetic material into patient’s cells. In this context I will talk about the notable work that Oxford Biomedica has contributed to the field, including its world-leading LentiVector® platform with advancements in cell and vector engineering as well as next-generation bioprocessing technologies.

Participants

Catarina Vieira - Principal Scientist, Oxford Biomedica

The Leap-In Transposase Platform: Past, Present and Future

09:30 - 10:00
Cell Line Development and Engineering - Strauss 2 and 3

Launched only a few years ago, the Leap-In Transposase platform has rapidly become an industry standard technology for the generation of CHO cells for the manufacturing of antibodies and other biologics. This presentation will highlight achievements and case studies of the platform including high titer mAb manufacturing, rapid anti-COVID responses, and some novel, next generation, applications.

Participants

Oren Beske, Ph.D. - Amalgamator of Business and Biology, ATUM

Power up your process control with rapid at line MS-based key nutrient monitoring

09:30 - 10:00
Cell Culture - Strauss 1

As the Biopharma 4.0 movement gains momentum, process intensification and predictive modeling are essential for data-driven decisions that open opportunities for efficiency, strategic planning, and agility within the industry. Past development and optimization of CHO and other mammalian bioprocesses have been relying heavily on DOE approaches and offline measurements. Now with the availability of advanced technologies and more information such as cell genome, we can utilize modeling tools along with at line key nutrient measurements to better understand cell metabolism and guide process in a more efficient and knowledge-based way.

Participants

Graziella Piras Ph.D, - Bioprocessing Segment Marketing Director, 908 Devices

HyPeak (DynaChrom)

09:30 - 10:00
Recovery & Purification - Lehar 1 and 2

Participants

Floris Hooijenga, MBA - Global Commercial Sales Leader, BioProcessing Equipment & Automation, Thermo Fisher

Biological Validation of Column-based Continuous Viral Inactivation

09:30 - 10:00
Viral Safety - Lehar 3

Participants

Moo Sun Hong - Postdoctoral Associate, MIT

Use of a Novel Cell Lysis Buffer for Protection of AAVs and Enhancing Manufacturing Efficiency

09:30 - 10:00
Cell & Gene Therapy - Lehar 4

The manufacturing of recombinant adeno-associated virus (rAAV) for use as gene therapies is a complex process that has proven difficult to scale commercially. During manufacturing, intracellular rAAVs are extracted from the host production cells through chemical and/or mechanical lysis. This step presents various challenges in achieving the optimal yield of highly infectious particles. Avantor has developed a novel cell lysis buffer solution with enhanced properties for the manufacturing of rAAVs, which can lead to increased manufacturing efficiency. In this presentation, we will describe the production and extraction of rAAVs produced in HEK293 cells using this novel cell lysis solution. We will also demonstrate the enhanced protection of the rAAVs against sheer stress when using this cell lysis buffer as compared to traditional methods. Together, the enhanced properties and the ease of use, enable this novel cell lysis buffer to provide a more robust and efficient manufacturing process to produce rAAVs.

Participants

Nandu Deorkar, PhD - Vice President, Research & Development, Avantor

SESSIONS

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Diversity, Equity & Inclusion Coffee Morning

10:00 - 10:30
General Session

BioProcess International Europe is running a Panel Discussion incorporated around the relaxed atmosphere of a coffee and cake on Diversity, Equity and Inclusion in the Biopharma industry to raise awareness of the challenges and successes of the different members of the community. We want to hear from you on your personal experiences within the biopharmaceutical and biotech industry and what your company is doing to improve the recruitment, acquisition and training of people from all walks of life.

Themes that could be covered but not limited to (we want to hear your personal experiences and struggles as well and if you have topics to add we greatly appreciate your involvement)

- What is your personal experience? Positive and/or a work in progress: This could be centred around:

- Women in Biotech
- LGBTQ+ Workplace Inclusion
- Being a Foreign-born worker
- Having a young family
- Inclusive Leadership
- Work-Life Balance
- Disability Inclusion
- Hiring an Inclusive workforce

- What is your company doing to improve diversity, equity and inclusion among company atmosphere, recruitment, acquisition and training for all?

- Do you get the support you need?

- What more could your company or other companies be doing in this space? What would you like to see?

Participants

Hemant Dhamne - Head, Process Development, Gene Therapy Vector Facility, King's College London, UK

KEYNOTE: Modifying RNA epigenetics to improve the production of recombinant products

10:30 - 11:00
Cell Line Development and Engineering - Strauss 2 and 3

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

Participants

Niall Barron - Principal Investigator, NIBRT

Development and Qualification of a Representative Small-Scale Model for recombinant protein manufacturing in Perfusion

10:30 - 11:00
Cell Culture - Strauss 1

Small scale models (SSM) (synonym used: scale down model (SDM)) are widely used in the biopharmaceutical industry for process development and optimization, scale-up, technology transfer, process characterization, process validation, and resolution of deviations encountered during manufacturing throughout a product's life cycle. A qualification of the SSM (SSMQ) is required by the regulatory authorities in order to use SSM for (1) performance of DoE; (2) new raw material qualification studies (3) investigation of manufacturing deviations. However, carrying out SSMQ is challenging due to the lack of clear guidance and alignment on acceptable industry standards. Moreover, there is minimal industrial experience and scientific literature on SSMQ for continuous processes. To address these challenges, the USP Development team generated an approach for qualification of SSM for continuous process. This method allows demonstration of equivalency between two different continuous processes (based on perfusion) in two different scales for the following parameters: (1) Cells growth profile; (2) Metabolism related parameters; (3) Productivity; (4) Product quality.

Participants

Barak Hajaj - Head of USP Development, Ferring

Evaluating Liposome Sterile Filtration Through Applying Complementary 3D Imaging Techniques

10:30 - 11:00
Recovery & Purification - Lehar 1 and 2

Participants

Dan Bracewell, Ph.D. - Professor, Chemical Engineering, University College London

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Pathogen Safety by Design

10:30 - 11:00
Viral Safety - Lehar 3

Pathogen safety by design applies principles of quality by design to developing virus reduction capacity into purification processes for biologics. Pathogen safety experts are involved at all steps of the development cycle from definition of the Quality Target Product Profile, collaborative development of the operating space, performance of risk assessments to setting control strategies. The power of using design of experiments in development of specific virus reduction unit operations will be demonstrated.

Participants

Tobias Schraeder - Manager, Virus Validation, Global Pathogen Safety (GPS), CSL Behring Innovation GmbH

Design of a Central Workflow Platform for AAV-Manufacturing Process Development

10:30 - 11:00
Cell & Gene Therapy - Lehar 4

We present an E2E platform that supports the entire bioprocess development workflow starting from registering a therapeutic virus, tracking the plasmids and host cell lines used for AAV production, and managing the process steps of plasmid purification, transfection, and production, as well as the purification of the viral vectors. All analytical data coming from various instruments are automatically associated to the intermediates and products of each process step. The design of this novel platform enables significant efficiency and quality gains in process development.

Participants

Jana Hersch - Scientific Consultant, Genedata

KEYNOTE: How to Train Your Cell

11:00 - 11:30
Cell Line Development and Engineering - Strauss 2 and 3

Based on emerging "-omics" datasets our perception of CHO as the "workhorse of the biopharmaceutical industry" has successively shifted from a nicely working black box to a biological system governed by multiple complex regulatory layers. While the high mutational frequency has been seen as the source of phenotypic variation for decades, the impact of epigenetics and its significance for shaping phenotypes has only recently been addressed. Here, our current understanding of epigenetic regulation in CHO is discussed, including available options to harness and manipulate this network to nudge CHO cells towards a specific phenotype.

Participants

Nicole Borth - Professor, BOKU University and Austrian Center of Industrial Biotechnology

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Collaborative Innovation Addresses New CHO Manufacturing Needs from Media to Clarification

11:00 - 12:00
Cell Culture - Strauss 1

We will explore a workflow featuring three best in class technologies to enable the future of bioprocessing by promoting process compression and intensification. Upstream technologies continue to intensify through CHO media optimisation and bioreactor design. This results in higher cell densities and ultimately higher titer. While novel bioprocessing purification solutions have emerged to overcome the higher contaminant and impurities levels, we will specifically demonstrate how a next-gen CHO media and single use bioreactor (S.U.B) will allow us to achieve process compression by offering high turn-down ratio for seed-train efficiency and flexibility. This combined with novel single-use chromatographic clarification solution will enable highly intensified and robust biopharmaceutical purification processes of the future.

Participants

Geoffroy Malherbe - EMEA Single-Use Technologies Sr Sales Manager, Thermo Fisher Scientific

Hani El-Sabbahy - Bioprocess Applications Specialist, 3M

Monitoring Protein Aggregate Content During Bind-and-Elute Chromatographic Purification: Towards A Proof of Concept

11:00 - 11:30
Recovery & Purification - Lehar 1 and 2

Participants

Daniel Some - Principal Scientist, Wyatt Technology Corp, USA, (A Representative of Biophorum Working Group)

Production Sterility for Batch and Continuous Virus Filtration Processes

11:00 - 11:30
Viral Safety - Lehar 3

Participants

Aernout Martens - Group Leader-Product Manager, Pall Coorporation

Developing a Control Strategy for Full to Empty AAV Particles

11:00 - 11:30
Cell & Gene Therapy - Lehar 4

Characterising the population of full, empty, and intermediate AAV vector particles continues to be a challenge. A number of methods are available for monitoring of this quality attribute. In the early stages of product development it can be difficult however to discern which are most appropriate for product quality control. Furthermore, industry wide benchmarking is hampered by lack of well characterised physical standard(s). This presentation will summarise Gyroscope's approach to building a control strategy for this crucial quality attribute and ongoing work in the CGT community to improve available methods.

Participants

Franz Schnetzinger - VP QC and CMC Analytical Development, Gyroscope Therapeutics

CHO Media Panel Assessment: A Case Study

11:30 - 12:00
Cell Line Development and Engineering - Strauss 2 and 3

Creating highly productive clonal cell lines for Monoclonal Antibody (mAb) production is time-consuming, labor-intensive, and costly, since achieving consistent cell culture performance requires careful screening, selection, and optimization of media formulations and feed.
As a part of the GibcoTM Cell Line Development Partner Program, using the ExpiCHO-S cells offered by Thermo Fisher, Menarini Biotech will be able to speed up cell line development process timelines. Tweleve proprietary chemically defined media and five feeds were tested on recombinant single cell clones generated with the FreedomTM ExpiCHO-S TM Kit . With this work, it will be possible to identify combinations of medium/feed capable of ensuring high productivity (higher than 2 g/L) while maintaining a high standard of quality attributes. This will enable the team to generate recombinant cell lines for mAb production, significantly reducing the time required for the production of stable clones while simplifying the process steps.

Participants

Noemi Moroni - Process Development Upstream Team Leader, Menarini Biotech, Italy

Increased Viral Clearance in Downstream Process Manufacturing Through Use of Novel Purification Resins and Additives

11:30 - 12:00
Recovery & Purification - Lehar 1 and 2

Downstream processing of monoclonal antibodies, which involves multiple chromatographic purification, buffer exchange, and viral inactivation steps, remains the major bottleneck in the manufacturing of these biologic molecules. The evaluation and selection of proper materials and reagents during process development is crucial in developing and optimizing a robust purification process that ensures that in-process impurities from upstream production are removed. In this presentation, we will discuss the development of a novel affinity chromatography resin, PROchievA. We will show that PROchievA provides enhanced purification of monoclonal antibodies and when used in combination with select additives, enhances the removal of impurities such as host cell protein, DNA, and viruses. Furthermore, we will show how PROchievA provides increased purification of Fc-fusion proteins, and when properly utilized in conjunction with subsequent downstream purification steps, can lead to improvement in overall manufacturing process efficiency of mAbs.

Participants

Nandu Deorkar, PhD - Vice President, Research & Development, Avantor

Accelerating Viral Clearance Studies: A Multi-Virus Approach

11:30 - 12:00
Viral Safety - Lehar 3

Participants

Anja Tessarz, PhD - Scientific Specialist, Viral Clearance, Biologics Testing Solutions, Charles River Laboratories

Purify small drug volumes better – GMP manufacturing of viral vectors

11:30 - 12:00
Cell & Gene Therapy - Lehar 4

Purification of small drug volumes like adeno-associated viruses (AAVs) can be tricky, especially when bringing these processes to clinical production. One of the main challenges is that few purification technologies are designed for small drug volumes. In this presentation, we'll take a closer look at new technologies for GMP manufacturing of AAVs and how they can address the challenges in purification of these therapeutics.

Participants

Sushma Nayak Teichert - Global Product Manager, Cytiva

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Multi-Column Chromatography for Early-Stage Process Development

12:00 - 13:10
Sponsored Luncheon Presentation 1

Join Sartorius for a spot of lunch whilst we present an overview of the BioSMB PD system – the multi-column chromatography for early-stage process development. Unlike batch chromatographic processing, which relies on a single large column, the BioSMB PD system can process from 1 to 16 columns.

David Johnson, Head of Chromatography Systems, will highlight and discuss these key points.

- How to Select the Right Technology for your Process: Batch vs. Continuous
- Design for Productivity and Performance
- Reduce Utilisation of Chromatographic Resins
- Increase Application Flexibility
- Reduce Footprint
- Reduce Cleaning and Sanitation Costs
- Scale Up and Down

Participants

David Johnson - Team Lead Chromatography Systems Product Management, Sartorius

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Sponsored Luncheon Presentation by Cytiva: Chromatography modeling trends: Digital twins and more

12:00 - 13:10
Sponsored Luncheon Presentation 2

Mechanistic modeling offers unparalleled efficiency in process development. In silico interrogation of a process provides complete flexibility in evaluating process conditions and extrapolating outside of calibration conditions, ultimately generating profound process understanding and increased productivity. Cytiva supports emerging modeling groups with training and consultancy, as well as with powerful tools, such as pre-characterized columns and sophisticated modeling software for synthesizing digital twins in silico. In this talk, we'll show how digital twins can intensify downstream process development by enabling many thousands of experiments to be simulated based upon sparse experimental data, and we'll look at examples from several industrial case studies. We'll dive into the theory and workflow behind mechanistic modeling of chromatography and explore how natural laws can be used to interpret complex data, understand the underlying phenomena, and simulate processes.

Participants

Nick Whitelock, EngD - Commercial Modelling Specialist, GoSilico, Cytiva

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ChromNeX: a stackable, bed-supported chromatography device enabling intensified downstream processing

12:00 - 13:10
Sponsored Luncheon Presentation 3

ChromNeX is a DSP platform technology comprised of lattice-containing, prepacked chromatography devices that are stackable and will enable intensified as well as next generation manufacturing of biologics by overcoming bottlenecks and optimizing productivity. In this talk, we will present performance comparisons and various applications data with a focus on product quality and productivity.

Participants

Guido Ströhlein, PhD, MBA - Vice President Life Sciences, JSR Micro NV

Chairperson's Remarks

13:10 - 13:15
Cell Line Development and Engineering - Strauss 2 and 3

Chairperson's Remarks

13:10 - 13:15
Cell Culture - Strauss 1

Participants

Mark Duerkop - Chief Executive Officer, Novasign

Chairperson's Remarks

13:10 - 13:15
Recovery & Purification - Lehar 1 and 2

Participants

Ger Brophy - Executive Vice President, Biopharma Production, Avantor, USA

Chairperson's Remarks

13:10 - 13:15
Viral Safety - Lehar 3

Participants

David Gemmell - Biomanufacturing Engineer, Merck

Going beyond the limit: tuning global transcription and translation activity increases recombinant protein secretion in Pichia pastoris

13:15 - 13:45
Cell Line Development and Engineering - Strauss 2 and 3

The yeast Pichia pastoris is well established for heterologous protein production, however, specific productivities are usually tightly coupled to biomass formation. To tackle this issue, we evaluated transcriptomics datasets and identified translation initiation as a main rate-limiting step. Transcriptional regulation was revealed as another cell engineering target.

Both strategies substantially boosted production of recombinant secretory proteins in industrially relevant fed-batch processes, yielding up to 5-fold higher productivities. Besides establishing two novel improved background strains, we will discuss that the capacity of P. pastoris for protein production is not at its limit yet.

Participants

Brigitte Gasser - Professor, BOKU

Raman-based monitoring of amino acids and antibody N-glycosylation in high cell density perfusion culture

13:15 - 13:45
Cell Culture - Strauss 1

Raman spectrum is a very useful process analytical technology (PAT) tool to monitor bioprocesses. Here we present a new approach to provide a dynamic culture environment suitable for the model calibration of the Raman spectrum, obtained during the development of the process. Very accurate monitoring of the cell density, lactate, ammonium and amino acids was obtained in high cell density perfusion cultures at steady-state up to 100 x 1E6 cells/mL. Furthermore the antibody N-glycosylation was predicted in real-time based on Raman spectrum in these cultures. Raman spectroscopy provides an interesting PAT tool for monitoring and control of steady-state perfusion production processes.

Participants

Hubert Schwarz - PhD Student, Cell Technology Group, KTH Royal Institute of Technology

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Development Approach of an Intensified Integrated Continuous Process for Pilot Scale

13:15 - 13:45
Recovery & Purification - Lehar 1 and 2

Participants

Veronique Chotteau, PhD - Associate Professor, Principal Investigator of the Cell Technology group, Dept. Industrial Biotechnology, School of Engineering Sciences in Chemistry, Biotechnology, and Health, KTH (Royal Institute of Technology)

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Considerations for Implementation of Continuous Inline Virus Inactivation

13:15 - 13:45
Viral Safety - Lehar 3

The shift toward connected and continuous mAb processing necessitates development of novel viral inactivation approaches. New incubation chambers have been designed to perform in-line viral inactivation (VI). With these chambers, characterization and operation strategies must be defined to ensure that critical parameters (pH and inactivation time) are controlled and VI performance is robust. Considerations for successful implementation of inline VI will be presented.

Participants

Cindy Delagree - Global Product Manager, Merck Group

Chairperson's Remarks

13:40 - 13:45
Cell & Gene Therapy - Lehar 4

Stable cell lines for large scale lentiviral vector manufacture

13:45 - 14:15
Cell Line Development and Engineering - Strauss 2 and 3

Lentiviral vectors are clinically validated delivery vehicles for gene therapy. However, suppling sufficient quantities of the vector for therapeutic use remains challenging. To overcome some of the limitations of transient transfections GSK has established a stable cell line platform to manufacture clinical grade lentiviral vectors in suspension culture in large bioreactors.

Participants

Sabine Johnson - Investigator, Cell Line Development, GSK

Accelerating upstream development timelines by combining hybrid modelling and advanced design space screening methods

13:45 - 14:15
Cell Culture - Strauss 1

The presentation focuses on the application of hybrid modeling in combination with advanced design space description methods like intensified and model-based Design of Experiments for different cell expression systems, enabling both better process understanding and reduced development timelines. Further, the usage of the same models for soft sensing and control during scale-up will be highlighted.

Participants

Mark Duerkop - Chief Executive Officer, Novasign

AI-ML Based Control Strategies for Control of Downstream Unit Operations in Continuous Manufacturing of mAbs

13:45 - 14:15
Recovery & Purification - Lehar 1 and 2

Participants

Garima Thakur - Researcher, Indian Institute of Technology

Case Study: Manufacturer's Experience of the ICH Q5(A)(R2) Guidelines

13:45 - 14:15
Viral Safety - Lehar 3

- Revision of the ICHQ5A guideline to reflect advances in bioprocessing and analytical technologies has been widely welcomed by industry.
- The European Federation of Pharmaceutical Industries and Associations (EFPIA) assembled representatives to develop a priority and consensus position for the topics planned for revision in the guideline.
- The presentation will summarise the manufacturer's perspective of the main themes for revision in the guideline.

Participants

Marie Murphy - Technical Services Manufacturing Network, Eli Lilly and Company, Ireland, EFPIA

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

13:45 - 14:15
Cell & Gene Therapy - Lehar 4

Participants

Amandine Breton - Associate Director of Cell Process MSAT, Orchard Therapeutics

Localization and structural characterization of random transgene integration of CHO manufacturing clones using next generation sequencing

14:15 - 14:45
Cell Line Development and Engineering - Strauss 2 and 3

In CHO cell line characterization, blotting technologies are commonly used albeit providing limited genetic information. Next generation sequencing holds great promise for strongly facilitating the understanding of CHO cell factories including the localization of integration sites with nucleotide precision and in-depth characterization of the transgene and the surrounding locus. This comprehensive genetic information can be used to support the clone selection process.

Participants

Benjamin Linder - Data Scientist, Boehringer Ingelheim

Advanced simulation of bioreactors

14:15 - 14:45
Cell Culture - Strauss 1

First-physical-principle simulation of (bio-)reactors in production sizes is now possible with the combination of new numerical algorithms and powerful computer hardware. With the simulation of the fluid field and its shear rate, the bubbles and the dissolution of oxygen, the substrate distribution and the temperature field inside the reactor, all factors for the environmental conditions of the cells or microorganisms can be simulated. With the lifelines concept, different reactor sizes or geometries can be compared based on the experience of the cells or microorganisms in the reactor, thus providing a concept for scale-up and reactor characterization based on validated simulations.

Participants

Christian Witz - CEO, SimVantage

Design & Construction of a Truly Continuous and Automated Process Skid for the Production and Purification of a Monoclonal Antibody

14:15 - 14:45
Recovery & Purification - Lehar 1 and 2

Participants

Bernhard Sissolak - Project Manager - End2End – Continuous Integrated Manufacturing, Bilfinger Industrietechnik Salzburg GmbH

Detergent-mediated virus inactivation in biotechnological matrices: More than just CMC

14:15 - 14:45
Viral Safety - Lehar 3

Lipid-enveloped viruses can potentially contaminate medications made from biological materials (e.g. plasma, cell culture-derived proteins), yet are efficiently inactivated by treatment of process intermediates with detergents. While it is well known that detergents form micelles if their concentration exceeds the critical micelle concentration (CMC), it is less clear whether the presence of detergent micelles is indispensable for effective virus inactivation. Further, while CMCs are routinely determined at ~25°C in deionized water, it is unknown to which extent the CMC might differ in biopharmaceutical manufacturing conditions, i.e., in the presence of salts and proteins and at different temperatures.

The present study addressed these issues via force tensiometry measurements. For five distinct detergents, the CMCs were determined in deionized water and two process intermediates relevant for plasma- and cell-derived products. Subsequently, comparative virus inactivation studies – conducted above and below the detergent's CMC – revealed that the formation of micelles is not a prerequisite for virus inactivation.

Participants

Michael Karbiener, PhD - Head of Virological Method & Assay Development at Global Pathogen Safety, Takeda

Platform Approaches for Process Understanding Across Different Biopharmaceutical Sectors: Varying Starting Raw Material in ATMP Processes

14:15 - 14:45
Cell & Gene Therapy - Lehar 4

Participants

Volker Huppert - Chief Development Officer, Glycostem Therapeutics

Improve your cell line development processes through rapid and low volume automated cell counting on the ICONTM instrument with STUDIUSTM data management software

14:45 - 15:15
Cell Line Development and Engineering - Strauss 2 and 3

Cell counting and viability assessments are key parameters for monitoring cell health. The trypan blue assay is the earliest and most widely used method for quantifying live and dead cells. The Viability assay on the ICON instrument uses STUDIUS' artificial Intelligence-based assessment to accurately identify cells when stained with trypan blue. Viability results can be combined with results of the low volume Titer assay, also available on ICON and analysed by the STUDIUS software to produce a measure of protein productivity. The Viability assay requires only 20µL of sample enabling stratification and selection earlier in the process, without using most of your cell culture. This is ideal for use with static plates or suspension culture deep well shaking plates, for both CHO and HEK cell lines. STUDIUS can import clonality results from the Cell Metric and combine them with ICON viability and titer data for fully automated clone selection, as well as track clones from seeding to final selection, providing a consistent audit trail to satisfy regulators. We will outline the importance of accuracy and efficiency when cell counting and outline how the Viability assay on the ICON can enhance your current processes.

Participants

Camilla Domeneghetti - Laboratory Manager, Advanced Instruments

Please Move To Another Track

14:45 - 15:15
Cell Culture - Strauss 1

Contribution to the Global Virus Safety Against Emerging Viruses

14:45 - 15:15
Recovery & Purification - Lehar 1 and 2

Since the publication of the EMA assessment on viral safety of plasma-derived and urine-derived medicinal products with respect to ZIKA virus in 2016, various independent studies have been published confirming the effectivity of virus filtration for removal of ZIKA virus. Similar efforts have been undertaken for the emerging viruses Mayaro-virus and Chikungunya-virus, which both belong to the Semliki-Forest Complex and in reaction to the outbreak of Sars-CoV-1 in 2003 as well as Sars-CoV-2 in 2019. Here outlined are experiments done with commercial virus filters and virus filters that have been manufactured with customized pore sizes in order to characterize the approximate size of viruses in solution. Furthermore demonstrated is that the current practices in the purification of Plasma-Derived Medicinal Products (PDMDs) provide sufficient safety layers for the protection of patients receiving these against the emerging viruses presented herein.

Participants

Sebastian Teitz - Scientific Coordinator, Asahi Kasei Bioprocess Europe

A Quality by Design Approach to Viral Clearance: Predicting LRV through the Use of non-Infectious MVM and RVLP Surrogates

14:45 - 15:15
Viral Safety - Lehar 3

To determine viral clearance efficacy of biomanufacturing steps, viruses are "spiked" into in-process solutions, processed and analyzed for reduction. Due to the infectivity of these viruses, studies are conducted in BSL-2 facilities. Costs and logistics limit analysis during process development. Discussed in the presentation are results from several studies that utilized a non-infectious Mock Virus Particles (MVP's) as MVM and RVLP surrogates. The results demonstrate the feasibility and value of adding viral clearance predication to a QbD process optimization approach.

Participants

Alla Zilberman, Ph.D. - VP Technical Marketing, Cygnus Technologies, LLC

SESSIONS

MAY 17 - 17/05/2022

Next-Generation Transfection Reagent for High Yield, Large Scale and Cost-Effective AAV Manufacturing

14:45 - 15:00
Cell & Gene Therapy - Lehar 4

The number of ATMP therapeutic-based medicines for inherited genetic disorders is in constant growth, with a global 32% increase in new clinical trials in the last 4 years. ATMPs have demonstrated their success with already more than ten approved for commercialization. The success of AAV as the most promising viral vector for gene therapy is due to low immunogenicity, broad tropism and non-integrating properties. One major challenge for translation of promising research to clinical development is the manufacture of sufficient quantities of AAV. Transient transfection of suspension cells is the most commonly used production platform, as it offers significant flexibility for cell and gene therapy development. However, this method presents some limitations in large scale bioreactors: inadequate transfection protocol, reduced transfection efficiency and lower productivity. To address this concern, we present data on a novel transfection reagent showing: i) increased AAV titers, ii) improved transfection protocol for large scale bioreactors, iii) reproducibility of viral titers at different production scale and iv) customer data. The aforementioned optimized parameters make this novel transfection reagent ideal for cell and gene therapy developers by combining the flexibility of transient transfection with scalability and speed to market.

Participants

Guillaume Freund - Scientific Support Manager, Polyplus-transfection

HIP-Vax®: Solving the GMP Capacity Shortage for Viral Vector Production

15:00 - 15:15
Cell & Gene Therapy - Lehar 4

Transformational change is needed in gene therapy manufacturing. By means of bioprocess intensification, the shortage in viral vectors could be reduced. The highly intensified manufacturing platform, HIP-Vax, has proven to support high cell densities, increase product concentration, and as a result lowers the cost of goods. This presentation includes a viral vector case study.

Participants

Angelique Lemckert - Technical Lead, Batavia Biosciences

Networking Refreshment Break

15:15 - 15:50
General Session

Chairperson's Remarks

15:50 - 16:00
General Session

Participants

Nadine Ritter, Ph.D. - President and Analytical Advisor, Global Biotech Experts, LLC

Keynote Address: Process Control Strategy, Residual Uncertainty, and the Myth of Fingerprints

16:00 - 17:00
Plenary Session - Strauss 2 and 3

Definition and management of process control strategies are central to biopharmaceutical development, manufacturing, and global regulatory oversight. Despite advances in data management, increased understanding of dependence and variation, and accommodation of risk based, patient centered specifications by international regulatory authorities, approaches to process control in biopharmaceutical manufacturing remains very similar to that used for decades, increasingly expending energy and rhetoric on minimizing lists of pass/fail tests. This talk will suggest that the twin concepts of management of residual uncertainty and totality of the evidence are foundational to modern regulatory landscapes, that fingerprint approaches to process definition, transfer, and amendment are in fact inappropriate for the day, and offer the provocation that new tools are needed to focus on management of uncertainties rather than continued refinement of measures that may not be relevant to reproducible patient outcomes.

Participants

Jeffrey Baker - Senior Fellow, NIIMBL, Senior Strategy Advisor of CBI, MIT, former Deputy Director, Office of Biotechnology Products, CDER, US FDA

Cocktail Reception and Grand Opening of Exhibit & Poster Hall

17:00 - 18:30
General Session

SCHEDULE

MAY 17 - 17/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	VIRAL SAFETY - LEHAR 3
07:00				**07:30** - Coffee and Registration						
08:00	**08:20** - Chairperson's Opening Remarks **08:30** - CGT Process Development - Challenges and Avenues	**08:20** - Chairperson's Opening Remarks **08:30** - PAT for vaccine manufacturing: integrated upstream and downstream applications	**08:20** - Chairperson's Opening Remarks **08:30** - KEYNOTE: Cell Engineering Using Synthetic Biology			**08:20** - Chairperson's Opening Remarks **08:30** - Lifecycling of Hybrid Digital Twins: Strategies to Generate, Adapt and Deploy Digital Twins				**08:20** - Chairperson's Opening Remarks **08:30** - Strategies for Upstream Viral Risk Mitigation
09:00	**09:00** - Development of Viral Vectors for Gene Therapy **09:30** - Use of a Novel Cell Lysis Buffer for Protection of AAVs and Enhancing Manufacturing Efficiency	**09:00** - The road to digitalisation of a research lab **09:30** - Power up your process control with rapid at line MS-based key nutrient monitoring	**09:00** - KEYNOTE: Transcriptional reprogramming of CHO cells **09:30** - The Leap-In Transposase Platform: Past, Present and Future			**09:00** - Integrated process modelling and machine-learning in downstream process development **09:30** - HyPeak (DynaChrom)				**09:00** - Advancing Bioprocess Operations From Pressure to Pump: Robustness Of Pump Based Virus Filtration, Including Pressure Ramp-Up Phase **09:30** - Biological Validation of Column-based Continuous Viral Inactivation

SCHEDULE

MAY 17 - 17/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	VIRAL SAFETY - LEHAR 3
10:00	**10:30** - Design of a Central Workflow Platform for AAV-Manufacturing Process Development	**10:30** - Development and Qualification of a Representative Small-Scale Model for recombinant protein manufacturing in Perfusion	**10:30** - KEYNOTE: Modifying RNA epigenetics to improve the production of recombinant products	**10:00** - Diversity, Equity & Inclusion Coffee Morning		**10:30** - Evaluating Liposome Sterile Filtration Through Applying Complementary 3D Imaging Techniques				**10:30** - Pathogen Safety by Design
11:00	**11:00** - Developing a Control Strategy for Full to Empty AAV Particles **11:30** - Purify small drug volumes better – GMP manufacturing of viral vectors	**11:00** - Collaborative Innovation Addresses New CHO Manufacturing Needs from Media to Clarification	**11:00** - KEYNOTE: How to Train Your Cell **11:30** - CHO Media Panel Assessment: A Case Study			**11:00** - Monitoring Protein Aggregate Content During Bind-and-Elute Chromatographic Purification: Towards A Proof of Concept **11:30** - Increased Viral Clearance in Downstream Process Manufacturing Through Use of Novel Purification Resins and Additives				**11:00** - Production Sterility for Batch and Continuous Virus Filtration Processes **11:30** - Accelerating Viral Clearance Studies: A Multi-Virus Approach

SCHEDULE

MAY 17 - 17/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	VIRAL SAFETY - LEHAR 3
12:00							**12:00** - Multi-Column Chromatography for Early-Stage Process Development	**12:00** - Sponsored Luncheon Presentation by Cytiva: Chromatography modeling trends: Digital twins and more	**12:00** - ChromNeX: a stackable, bed-supported chromatography device enabling intensified downstream processing	
13:00	**13:40** - Chairperson's Remarks **13:45** - Controlling Manufacturing Processes in Pre-Commercial and Commercial Autologous Cell & Gene Therapy Products	**13:10** - Chairperson's Remarks **13:15** - Raman-based monitoring of amino acids and antibody N-glycosylation in high cell density perfusion culture **13:45** - Accelerating upstream development timelines by combining hybrid modelling and advanced design space screening methods	**13:10** - Chairperson's Remarks **13:15** - Going beyond the limit: tuning global transcription and translation activity increases recombinant protein secretion in Pichia pastoris **13:45** - Stable cell lines for large scale lentiviral vector manufacture			**13:10** - Chairperson's Remarks **13:15** - Development Approach of an Intensified Integrated Continuous Process for Pilot Scale **13:45** - AI-ML Based Control Strategies for Control of Downstream Unit Operations in Continuous Manufacturing of mAbs				**13:10** - Chairperson's Remarks **13:15** - Considerations for Implementation of Continuous In-line Virus Inactivation **13:45** - Case Study: Manufacturer's Experience of the ICH Q5(A)(R2) Guidelines

SCHEDULE

MAY 17 - 17/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	VIRAL SAFETY - LEHAR 3
14:00	**14:15** - Platform Approaches for Process Understanding Across Different Biopharmaceutical Sectors: Varying Starting Raw Material in ATMP Processes **14:45** - Next-Generation Transfection Reagent for High Yield, Large Scale and Cost-Effective AAV Manufacturing	**14:15** - Advanced simulation of bioreactors **14:45** - Please Move To Another Track	**14:15** - Localization and structural characterization of random transgene integration of CHO manufacturing clones using next generation sequencing **14:45** - Improve your cell line development processes through rapid and low volume automated cell counting on the ICONTM instrument with STUDIUSTM data management software			**14:15** - Design & Construction of a Truly Continuous and Automated Process Skid for the Production and Purification of a Monoclonal Antibody **14:45** - Contribution to the Global Virus Safety Against Emerging Viruses				**14:15** - Detergent-mediated virus inactivation in biotechnological matrices: More than just CMC **14:45** - A Quality by Design Approach to Viral Clearance: Predicting LRV through the Use of non-Infectious MVM and RVLP Surrogates
15:00	**15:00** - HIP-Vax®: Solving the GMP Capacity Shortage for Viral Vector Production			**15:15** - Networking Refreshment Break **15:50** - Chairperson's Remarks						

SCHEDULE

MAY 17 - 17/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	VIRAL SAFETY - LEHAR 3
16:00					**16:00** - Keynote Address: Process Control Strategy, Residual Uncertainty, and the Myth of Fingerprints					
17:00				**17:00** - Cocktail Reception and Grand Opening of Exhibit & Poster Hall						

SESSIONS

MAY 18 - 18/05/2022

Coffee and Registration

07:30 - 08:20
General Session

Chairperson's Opening Remarks

08:20 - 08:30
General Session

Keynote Address: Accelerating CMC: the future of process development is in silico

08:30 - 09:00
Plenary Session - Strauss 2 and 3

Simulation for in silico process development is becoming a viable option to reduce the time needed for chemicals, manufacturing, and control (CMC) activities and increase process understanding. Advances in analytics and modeling — and their application to biopharmaceutical products — are driving efforts to transform process development. In this session, you'll gain insight on how to apply simulation in your CMC activities, including case studies of the successful use of simulation in biopharmaceutical process development.

Participants

Per Lidén - Digital Product Management Leader, Cytiva

Keynote Address: Process Intensification Pall Bioprocessing - Monoclonal Antibodies and Viral Vectors

09:00 - 09:30
Plenary Session - Strauss 2 and 3

Participants

Marc Bisschops, Ph.D. - Vice President MSAT, Pall Life Sciences, Holland

Plenary Panel Discussion: Cell & Gene Therapy CMC : An Innovation or Iteration in Biotech Principles and Practice?

09:30 - 10:00
Plenary Session - Strauss 2 and 3

1. Clearly Cell and Gene Therapy is the bright shiny object on the biotech landscape these days and for very important reasons! As I listen to discussions, however, I am hearing two narratives: "Cell & Gene Therapy is a disruptive technology that will require novel manufacturing and control approaches to provide health care solutions to patients in a timely way and we all have to work together to write the new How-To Manual for this modality." and "Cell & Gene Therapy is a new application of established principles of practice—raw materials still have to be fit for purpose, equipment still needs to be qualified, cleaned, and maintained, assays and processes still need to have predictable outcomes, intermediates and products with stability issues still have to be managed --- but from a CMC perspective it is not so much a disruptive technology as the next iteration of established principles of practice." What are your thought about an apparent tension between innovative and iterative? These are clearly new clinical therapies but is this revolutionary or evolutionary manufacturing?
2. As you look at the Cell and Gene Therapy landscape and reflect upon hurdles to commercialization, what do you see as the main manufacturing hurdles or the areas with the most unmet needs? Engineering and equipment? Assays and analytics? Quality Management Systems? Regulatory clarity? Manufacturing capacity? What's one thing you need but don't have that could be highly impactful?

Participants

Moderator: Nadine Ritter, Ph.D. - President and Analytical Advisor, Global Biotech Experts, LLC

Panelist: Yasser El-Sherbini - Consultant, Biopharma Excellence

Panelist: Dirk Böhm - VP, Head CGT CMC & RA, Bayer

Panelist: Jenny Ann Prange - Head of GMP Production, Chief Scientific Officer and Co-Founder, MUVON Therapeutics AG

Panelist: Amandine Breton - Associate Director of Cell Process MSAT, Orchard Therapeutics

Networking Refreshment Break in the Exhibit & Poster Hall

10:00 - 10:55
General Session

Improving the efficacy and productivity of recombinant biologics produced in CHO cells by genome editing

10:15 - 10:45
Product Stage - Exhibit Hall

The glutamine synthetase (GS) gene in CHO cells was inactivated by genome editing techniques. A congenital GS mutation, R324C, which causes glutamine deficiency in human, was evaluated as an attenuated selection marker for CHO cell line development. A panel of new GS mutants were created as potential selection markers. Using this selection system, CHO cell lines were generated to produce a fucosylated rituximab, trastuzumab and GA101.

Participants

Song Zhiwei, Pre-record - Senior Principal Scientist, A*STAR

Chairperson's Remarks

10:55 - 11:00
Cell Line Development and Engineering - Strauss 2 and 3

Chairperson's Remarks

10:55 - 11:00
Cell Culture - Strauss 1

Participants

Steffie Eggermont - Senior Scientist, UCB

Chairperson's Remarks

10:55 - 11:00
Recovery & Purification - Lehar 1 and 2

Participants

Dan Bracewell, Ph.D. - Professor, Chemical Engineering, University College London

Chairperson's Remarks

10:55 - 11:00
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Christian Witz - CEO, SimVantage

Chairperson's Remarks

10:55 - 11:00
Cell & Gene Therapy - Lehar 4

Participants

Jenny Ann Prange - Head of GMP Production, Chief Scientific Officer and Co-Founder, MUVON Therapeutics AG

SESSIONS

MAY 18 - 18/05/2022

Bring Product Quality Assessment into Early Clone Selection with Opto™ Cell Line Development

11:00 - 11:30
Cell Line Development and Engineering - Strauss 2 and 3

CHO cell line selection is a painful bottleneck in biotherapeutic development, particularly for complex molecules like bispecifics. The Opto™ CLD workflow on the Beacon® system accelerates early CLD by integrating high throughput cell sorting, cloning, culture, productivity, growth, and product quality assays into a single, 5-day automated process. Hear about capabilities of on-chip detection that pinpoints best clones early on.

Participants

Simon Margerison - Director, Customer Application Support, Berkeley Lights Inc

From Chemically to Functionally Defined Cell Culture Media

11:00 - 11:30
Cell Culture - Strauss 1

To move beyond chemically to functionally defined cell culture media platform, we integrated a multitude of innovative approaches and advanced technologies (analytics and modelling) in our media development processes, by combining and synergizing them into a single, global and cross-functional media platform. Elimination and substitution of critical components and concurrent focus on optimization of essential raw materials (e.g. vitamins, trace metals, amino acids) and processing parameters, resulted in a high performing, innovative and very robust media formulation. Furthermore, the new functionality and flexibility moves the media platform away from process dedicated versions to a fully characterized, general version which can be applied for various process steps including batch, fed-batch and continuous processes to also reduce raw material changes and variability in the commercial application.

Participants

Andreas Unsoeld - Head of Cell Culture Media, Boehringer Ingelheim

Scale Dependent Aspects of a High Throughput Purification Strategy for Upstream Process Characterization

11:00 - 11:30
Recovery & Purification - Lehar 1 and 2

Upstream process characterization aims to understand the impact of process parameter variations on quality attributes. To enable the measurement of certain quality attributes, the upstream harvest material must be purified. For complex proteins, the purification process required to achieve sufficient product purity is often a lengthy, multi-step process.To increase efficiency, a high-throughput microscale process was developed especially for this purpose. Several scale-dependent aspects had to be considered to obtain comparable results between micro-scale and manufacturing-scale parameters.

Participants

Gregor Bramberger - Senior Scientist, Biologics Process Development, Takeda

Performance Evolution & Lessons Learned in Tech Transfer from Development to Commercial Scale

11:00 - 11:30
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Amir Goudarzi, PhD - Head, Process Engineering, BCMS, UCB

Panel Discussion: Future Outlook for Gene Therapy - mRNA vs Viral Vectors

11:00 - 11:30
Cell & Gene Therapy - Lehar 4

Participants

Moderator: Hemant Dhamne - Head, Process Development, Gene Therapy Vector Facility, King's College London, UK

Panellist: David Loong - Senior Consultant, Novel Modalities Asia Pacific, Bioprocessing Strategy, Merck Process Solutions, Singapore

Panellist: Amélie Boulais - Manager of Market Entry Strategy, Separation Technologies, Sartorius

Advantages and challenges of utilising cell free expression for the production of neurotoxins

11:30 - 12:00
Cell Line Development and Engineering - Strauss 2 and 3

Cell-free expression shows excellent potential as a future expression platform across the industry. However, the technology has historically been used for small scale protein expression for research purposes, and thus, there are still many unknowns for process scalability. Here we discuss a process developed to produce recombinant neurotoxins using cell-free expression technology; this process was scaled to 2L in stirred tank bioreactors and shows the potential for further scale-up.

Participants

Cillian Paget - Senior Process Development Scientist, Ipsen Biopharm

Enhance cell culture productivity and product quality profile using media development

11:30 - 12:00
Cell Culture - Strauss 1

- How can media development support process intensification ?
- Case study 1 : Use of innovative compounds to control product quality profile
- Case study 2 : Bioreactor yields increase thanks to volume reduction and associated challenges

Participants

Valentine Chevallier - Scientist, Upstream Process Development, UCB

Improving Antibody Fragment Capturing in Batch and Continuous Processing

11:30 - 12:00
Recovery & Purification - Lehar 1 and 2

Downstream processing of mAb fragments typically starts with capturing by protein L affinity chromatography. In this talk performance parameters of several Protein L chromatography media will be compared and their influence on process economics will be evaluated. Further, we will demonstrate how transferring from a conventional batch mode to continuous affects the productivity of the antibody fragment capturing process.

Participants

Jonas Wege - Application Specialist, Tosoh Bioscience

SESSIONS

MAY 18 - 18/05/2022

Leveraging Real-Time Data Visualization in Manufacturing for Process Improvement and Troubleshooting

11:30 - 12:00
Manufacturing Strategy & Industry 4.0 - Lehar 3

The data & digital revolution is taking place throughout pharma and biotech industries. New technologies and systems are set to alter the way traditional processes and facilities are currently driven. As organizations broaden their digital footprint, new opportunities and challenges come to play. This talk will discuss digitalization initiatives in commercial manufacturing focusing on the human factors, regulatory constraints, opportunities & roadblocks on the path to digitalization of biotech manufacturing facilities.

Participants

Francisca Gouveia, Ph.D - Innovation Data & Digital Lead, Novartis

Analytical Methodologies for Gene Therapy Products

11:30 - 12:00
Cell & Gene Therapy - Lehar 4

The aim of this presentation is to provide an overview of the major analytical methods used for the development and release of gene therapy products. Beyond this broad overview, we will discuss the following methods in slightly more detail:

- Vector genome quantification using droplet digital PCR (ddPCR)
- Vector particle quantification using an ELISA-based method
- Purity determination by capillary electrophoresis
- Relative quantification of capsid subspecies using AUC

Participants

Robert Pletzenauer - Head of Gene Therapy Analytics, Takeda

Optimized Expression Systems for Increased Productivity in CHO DG44 Based Cell Line Development

12:00 - 12:30
Cell Line Development and Engineering - Strauss 2 and 3

Participants

Rathangadhara Nammalwar - Manager, Cell Line Development, Protein Based Therapeutics, Sartorius

Computational simulation as a predictive tool for bioreactor design and performance

12:00 - 12:30
Cell Culture - Strauss 1

Shorter timelines, fast scale-up and a focus on time to market are of increasing importance in the biopharma industry. In addition, process intensification together with broader use of perfusion processes and non-mammalian expression systems put new requirements on designing high performing bioreactors. In this study, we have leveraged computational fluid dynamics (CFD) to design and select the agitator and sparger for a next generation bioreactor. Further we have used simulations to predict and minimize the shear stress and concentration gradients in the bioreactor.

Participants

Andreas Castan, PhD - Director Strategic Technologies, Cytvia

Addressing today's challenges in antibody therapeutic workflows

12:00 - 12:30
Recovery & Purification - Lehar 1 and 2

The global market for antibody therapeutics is rising rapidly and newer, engineered modalities such as bi-specific antibodies and antibody fragments are entering clinical studies in record numbers. Protein A chromatography is widely adopted for the purification of therapeutic monoclonal antibodies (mAbs). However, with the development of novel modalities, downstream process scientists are forced looking into alternative solutions to expand their antibody purification toolbox.

In this talk, our field application scientist will discuss novel purification approaches to streamline manufacturing of antibody-based therapeutics. In addition, we'll go into further detail on how affinity chromatography could benefit your antibody polishing process.

Participants

Michael Andesner - Staff Scientist, Field Applications, Purification, Thermo Fisher

Approach Industry 4.0 implementation with a Global Product Strategy

12:00 - 12:30
Manufacturing Strategy & Industry 4.0 - Lehar 3

Addressing Industry 4.0 for your company is not a product oriented purpose, but rather an overall strategy in which aligned products are sitting. There are as many products, functions, strategies as companies, focus has to remain on what do I want to achieve as part of 4.0, who can help me the best, what it means as Opex and Capex. The right investments in turn help shape the digital maturity journey of companies. In this talk we will attempt to put into perspective the digital maturity journey and then identify a few use cases that our products can help you move up the maturity curve.

Participants

François Balbin - Customer Application Systems, Software and Automation, Merck

Quality by Design for Adeno-associated Virus AAV Products

12:00 - 12:30
Cell & Gene Therapy - Lehar 4

Participants

Marc Bisschops, Ph.D. - Vice President MSAT, Pall Life Sciences, Holland

Networking Luncheon in the Exhibit & Poster Hall

12:30 - 13:00
General Session

Cell Line Development and Plasmid Optimization to Improve AAV Titers

12:30 - 13:00
Product Stage - Exhibit Hall

In this presentation, we will introduce the efforts at REGENXBIO to adapt our HEK293 host cell lines from adherent to suspension and further improve AAV productivity of cell lines by multiple cloning efforts. Furthermore, to improve AAV titers, we made a sequential modification of our helper plasmid. By combining the new cell lines and new helper plasmids, we improved our overall transient yield >20-fold while maintaining the product quality.

Participants

Ping Liu, Pre-record - Associate Director, Cell Line Development, Regenex Bio

SESSIONS

MAY 18 - 18/05/2022

Advance Small Volume Purification with the ÄKTA™ ready 450 Single-use Chromatography System

13:00 - 13:10
Live Labs

If you're purifying small drug volumes, you may feel stuck between large, single-use systems and stainless-steel systems with time-consuming clean-and-reuse protocols. Join this Live Lab Presentation to learn how ÄKTA ready™ 450, our new single-use chromatography system, can help you with small-scale manufacturing.

The system offers:

- Low flow rate and hold-up volume that ensure efficient purification of small drug quantities in a GMP environment.
- Support for closed processing that reduces contamination risk significantly.
- Simple flow kit installation and the integrated sensors that support fast changeover between products, and consistency in manufacturing.

Meeting Buffer Demand

13:10 - 13:20
Live Labs

The changing face of the biopharmaceutical industry has brought about an increased need for flexibility and adaptability, with developments in upstream processing resulting in higher product yields, and with multi-product facilities becoming commonplace. In addition to this there is always the ever-present call manufacturers to reduce costs without compromising the essential facets of quality and safety.

Process intensification, specifically higher cell culture titers, has increased the volume of buffer required and magnified the challenges posed by traditional buffer preparation. The extensive and varied range of biotherapeutics currently being developed has led to significantly different process demands, and the necessity for biomanufacturing facilities to cope with processes that may be vastly different in scale. This has a direct impact on the number of process buffers required.

The good news is that the pain points associated with buffer preparation can now be addressed efficiently through the advancement of well-designed automated technologies. Our understanding of the bottlenecks in buffer management that hinder production, enables us to partner with you to attain a robust buffer management strategy that encompasses preparation, mixing, storage, and a just-in-time solution at the point of use.

Join us on booth #62 to discover the Allegro™ Buffer Management System.

Modify. Intensify. Amplify – A Definition of Process Intensification

13:20 - 13:30
Live Labs

Take a tour of the intensified solutions Sartorius has to offer for upstream or downstream unit operations that will result in increased overall productivity of your process or facility. Our Technologies, which high-throughput tools for process development and scalable, flexible manufacturing solutions, combined with our team of expert application scientists, help manufacturers succeed on their PI journey.

Maximize bioreactor analysis with Nova Biomedical's BioProfile® Online Sampler, partnered with FLEX2

13:30 - 13:40
Live Labs

Nova's FLEX2 Online Autosampler (OLS) provides fully automated sampling from virtually all culture systems from single-use bench scale bioreactors to large production bioreactors. When connected to an OPC-compatible control system, FLEX2 with OLS provides real-time data transmission for automated sampling, analysis, and feedback control of all measured parameters. The OLS can connect up to 10 vessels and setup time for a full bench of 10-bioreactors can be completed in less than 20 minutes. The increased data-density can facilitate process intensification and improved perfusion process control.

Visit us at stand 65.

Chairperson's Opening Remarks

13:40 - 13:45
Cell Line Development and Engineering - Strauss 2 and 3

Chairperson's Opening Remarks

13:40 - 13:45
Cell Culture - Strauss 1

Participants

Christian Witz - CEO, SimVantage

Chairperson's Opening Remarks

13:40 - 13:45
Recovery & Purification - Lehar 1 and 2

Participants

Dan Bracewell, Ph.D. - Professor, Chemical Engineering, University College London

Chairperson's Opening Remarks & Market Situation Analysis

13:40 - 13:55
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Robert Brooks, Ph.D. - Supply Partner Phorum Leader and Operations Team Member, Biophorum

Cell-Free protein synthesis of monoclonal antibodies and a novel cell-free glycosylation pattern

13:45 - 14:15
Cell Line Development and Engineering - Strauss 2 and 3

Cell-free protein synthesis (CFPS) is an emerging field that facilitates rapid protein expression and characterisation enabling high-throughput screening prior to large scale cell-based expression. Protein based therapeutics are predominantly predominantly produced in mammalian cell-based expression systems, primarily Chinese hamster ovary (CHO). CHO cells are known to perform human-like glycosylation makingthema an ideal CFPS platform. This presentation will focus on evaluating the performance of an in-house CHO CFPS for the production of monoclonal antibody targets. Finally, a novel modular strategy to modify the glycosylation pattern will also be presented.

Participants

Elli Makrydaki, PhD - Research Associate, Chemical Engineering, Imperial College London

Strategy to monitoring raw materials variability across the value chain

13:45 - 14:15
Cell Culture - Strauss 1

Participants

Paolo Grisostomi - Senior Engineer, Biogen

Combining Knowledge management and Risk management to Accelerate Development

13:45 - 14:15
Recovery & Purification - Lehar 1 and 2

Participants

Joey Studts - Director of Downstream Development, Boehringer Ingelheim Pharma GmbH & Co. KG

SESSIONS

MAY 18 - 18/05/2022

NIIMBL-BioPhorum buffer stock blending system vision, collaboration, design and outcome

13:55 - 14:20
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Jeff Johnson - President, Biotech Design, LLC

Chairperson's Opening Remarks

14:10 - 14:15
Cell & Gene Therapy - Lehar 4

Participants

Ger Brophy - Executive Vice President, Biopharma Production, Avantor, USA

Recent Advances in Cell Line Engineering of the Moss Physcomitrium patens for Biopharmaceutical Production

14:15 - 14:45
Cell Line Development and Engineering - Strauss 2 and 3

Roughly 20 years ago first attempts have been made to use moss as a protein production platform. Ever since, the chassis has been engineered in perspective of a humanized glyco-profile and higher productivity. The biggest breakthrough came with codon optimization tremendously increasing productivity more than 10-fold. By means of metabolic engineering to optimize energy supply we were able to further boost productivity. Next level up is anticipated with establishing automation to facilitate finding the rare super-producer.

Participants

Christian Sievert - Head of Strain Development, Eleva Biologics

Digital Twins and robotic experimental facilities for bioprocess development

14:15 - 14:45
Cell Culture - Strauss 1

Lab automation and computational experimental tools are changing bioprocessing and biopharma. Nevertheless, the biggest hurdles for autonomous development of bioprocesses are still to be tackled. Efficient data management tools, Machine Learning solutions tailored to the characteristics of bioprocesses (dynamics, high complexity, nonlinearity of the system, etc.), process control strategies that exploit parallel cultivations in High Throughput Facilities, and Active Learning algorithms that plan and operate optimal experiments. We will discuss the latest advances in this direction and its potential applications.

Participants

Annina Kemmer - PhD Student, High Throughput Bioprocess Development group, Chair of Bioprocess Engineering, Technische Universität Berlin

Enabling Expedited Development of Complex Bispecific Antibodies

14:15 - 14:45
Recovery & Purification - Lehar 1 and 2

Participants

Florian Schelter - Principal Scientist, DS Technical Development Lead, Pharma Technical Development Europe, Roche Diagnostics GmbH

Innovations in Residual DNA Testing for Gene Therapy

14:15 - 14:45
Cell & Gene Therapy - Lehar 4

Participants

Ilaria Scarfone, PhD - Field Application Specialist, Pharma Analytics, Thermo Fisher

Efficient raw material management for improving bioprocess throughput and flexibility

14:20 - 14:45
Manufacturing Strategy & Industry 4.0 - Lehar 3

There has been significant change across the biomanufacturing industry over the last couple of decades, as increased complexity of biologics and a growing focus on smaller patient populations have led to a greater need for process flexibility and efficiency as well as cost control. As productivity has improved as a result, so too have titers and other areas of process development. Typical biologic manufacturing consumes hundreds of raw materials including media, supplements, single-use systems, process chemicals, filters, resins, and excipients. Buffers are one of the largest constituents by volume used in the production of most modern biopharmaceutical products. The various compositions of buffers used across a biopharma manufacturing facility requires inflexible & cost-inefficient infrastructure for support and has several contamination risks. Any deviation from the standard in these raw materials typically requires significant micro-management to resolve, resulting into prosecution delays and losses.

While buffer in-house manufacturing is an established method specifically for larger volumes, the adoption of hydrated, pre-made liquid buffers and buffer concentrates is a cost-, time- and resource-saving as well as risk mitigating alternative for multi-batch facilities or small-scale manufacturing of mAbs and novel therapeutics.

These single use liquid formulations when combined with innovative new technologies like in-line dilution can help reduce facility footprint, labor hours and overall cost-of-goods. This presentation will give an overview of the challenges in raw material management with a risk/benefit analysis of liquid handling options to overcome some of these issues.

Participants

Nandu Deorkar, PhD - Vice President, Research & Development, Avantor

SESSIONS

MAY 18 - 18/05/2022

Industrial production of therapeutic proteins using a CHO cell expression system

14:45 - 15:00
Cell Line Development and Engineering - Strauss 2 and 3

Mammalian cell lines, particularly Chinese Hamster Ovary (CHO) cells, are important host cells for the industrial production of pharmaceutical-grade proteins, owing to their capacity to facilitate correct folding, assembly and post-translational modification of the produced protein.

Our speech will introduce:

1. The role and development of the CHO cell line industrial protein expression.
2. The key differences between HEK and CHO cell lines as platforms for industrial protein expression.
3. How GenScript's proprietary TurboCHO cell platform performs as a protein expression platform.

Participants

Monica Zhang - Field Application Scientist, EU division, Genscript Biotech

Cell culture intensification from seed train to the N bioreactor for step change capacity increases

14:45 - 15:15
Cell Culture - Strauss 1

XCell ATF® Systems are the most established and successful technology for cell culture intensification. Increasing VCD with cell retention in seed train and N bioreactors delivers more product in less time from vial to harvest. Through application development, the XCell ATF® Technology can be utilized in both fed-batch and perfusion modes. Case studies describing a 10-20X yield increase per N bioreactor run, a 10X product cost reduction and a 30% facility output will be discussed.

Participants

Charles Hill - Field Applications Scientist, Repligen

High Performance and Stability with GMP Ready Prepacked CHT Process-Scale Columns

14:45 - 15:00
Recovery & Purification - Lehar 1 and 2

In this session, we will present GMP ready prepacked CHT™ Ceramic Hydroxyapatite Media column performance data. This will include HETP and asymmetry data that show excellent column performance post shipping tests over a range of column diameters. The data indicates column bed stability with no headspace formed. Cycling and pressure data will be presented. The columns are designed specifically for CHT Media and used for the production-scale manufacturing of biologics. These columns are newly launched by Bio-Rad Laboratories (CHT Media manufacturer) and offer a cost-effective solution to “pack in place” designs.

Participants

Sharon Bola - Global Product Manager, Bio-Rad Laboratories

Accelerating upstream process development with direct CQA and media analysis feedback

14:45 - 15:15
Manufacturing Strategy & Industry 4.0 - Lehar 3

Real-time product attribute and spent media information is important to upstream bioprocess optimization, analysis results are often lagging by weeks. Engineers can now take decisions faster by producing their own at-line quality data, accessible workflows coupling small bioreactors like Sartorius Ambr systems to Waters’ BioAccord LC-MS system. Drug quality and yield can be maximized, and downstream impurities minimized. Development is accelerated from weeks to days, saving resources from multiple optimization cycles.

Participants

Nick Pittman - Marketing Manager, Global Biopharmaceutical Business, Waters Limited

Aseptic Fluid Transfer Considerations in Gene Therapy Applications

14:45 - 15:15
Cell & Gene Therapy - Lehar 4

CPC will lay the framework of some of the challenges gene therapy manufacturers face, reasons for adoption of single-use systems for flexible and modular manufacturing operations.

You will also learn about some of the key benefits and differences in tube welding and connectors and where each might be best suited in your gene therapy processes.

Participants

Eoin Dolan - Applications Development Manager - CGT, Colder Products Company

A CHO platform for the rapid production of vaccine antigens: From Wuhan to FrankenSpikes

15:00 - 15:15
Cell Line Development and Engineering - Strauss 2 and 3

The recent COVID19 pandemic showed that current protein production technologies for subunit protein antigens are insufficient to meet the global demand for these critical molecules. Using optimized CHO based technologies, we developed scalable, GMP-compliant, chemically defined processes for production of SARS-COV-2 Spike antigens. Within weeks we were able to produce grams quantities of fully active and stabilized SARS-COV-2 Spike protein trimers. Vaccination with the SARS-CoV-2 spike-trimer induced high antibody titers in animals and provided exceptional sensitivity and specificity in diagnostic tests. These observations highlight the potential of CHO cells for manufacturing of potent sub-unit vaccines at low cost and large scale.

Participants

Paco Pino - Director Research and Development, ExcellGene

Simplify and Accelerate Downstream Process Development of AAV

15:00 - 15:30
Recovery & Purification - Lehar 1 and 2

Participants

Marcus Peiker - Platform Development Specialist, Sartorius

Networking Refreshment Break in the Exhibit & Poster Hall

15:30 - 16:00
General Session

SESSIONS

MAY 18 - 18/05/2022

Developability - Early Preparation for a Successful Product

15:30 - 16:00
Product Stage - Exhibit Hall

Drug discovery and development of a new therapeutic is a time consuming and expensive process. A developability assessment is used to evaluate and de-risk potential therapeutics in the very early stages of development. To determine the liabilities of a protein therapeutic we seek to understanding the physical and chemical stability as well as determining compatibility with the established manufacturing process and proposed administration method. Incompatibilities may be mitigated through process customization and formulation; however, this can lead to timeline delays and greater cost of goods. As part of our developability assessment at Sanofi, we have established a strategy to test manufacturability and device compatibility which will be described and illustrated with a few case studies.

Participants

Sarah Auclair, Pre-record - Scientist, Sanofi

Improving the efficacy and productivity of recombinant biologics produced in CHO cells by genome editing

16:00 - 16:30
Cell Line Development and Engineering - Strauss 2 and 3

The glutamine synthetase (GS) gene in CHO cells was inactivated by genome editing techniques. A congenital GS mutation, R324C, which causes glutamine deficiency in human, was evaluated as an attenuated selection marker for CHO cell line development. A panel of new GS mutants were created as potential selection markers. Using this selection system, CHO cell lines were generated to produce afucosylated rituximab, trastuzumab and GA101.

Participants

Song Zhiwei, Pre-record - Senior Principal Scientist, A*STAR

Bioreactor automation and intelligent control for robust and high yielding processes

16:00 - 16:30
Cell Culture - Strauss 1

Understanding the culture environment within bioreactors is essential for developing robust, high yielding processes. We will explore using advanced process control and predictive modelling in mammalian cultures to automate and optimise bioreactor feeding and control strategies. A series of case studies will cover topics including utilising integrated PAT tools for automated at-line feeding and using machine learning to control and refine bioreactor set points.

Participants

Bethany Kerr - Team Leader, Upstream Development, CPI

Analysis of Depth Filter Performance Using Breakthrough Studies and Confocal Microscopy and its Interaction with Protein A Resin Lifetime

16:00 - 16:30
Recovery & Purification - Lehar 1 and 2

Participants

Maria Parau - PhD Student, Biochemical Engineering, University College London

BioPhorum approach to the registration of innovative raw materials using quality by design (QbD) principles

16:00 - 16:25
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Isabelle Lequeux - Regulatory program Lead, BioPhorum

Translation and Automation Hurdles for Cell Therapies

16:00 - 16:30
Cell & Gene Therapy - Lehar 4

Participants

Jenny Ann Prange - Head of GMP Production, Chief Scientific Officer and Co-Founder, MUVON Therapeutics AG

Partnerships Panel Discussion

16:25 - 17:00
Manufacturing Strategy & Industry 4.0 - Lehar 3

This Panel will discuss the critical need for increased partnership and collaboration between biomanufacturer companies and suppliers providing the key raw materials and services that support the manufacturing process. You will hear speakers from the earlier part of the session answer questions on the importance of building closer relationships based on openness and trust is in improving operational excellence in the inbound supply chain. The panelist are experienced subject matter experts in inbound supply chain matters and will present major supply partners and biomanufacturer viewpoints and regulatory aspects that are important for continuous improvement for the inbound supply chain.

Participants

Moderator: Robert Brooks, Ph.D. - Supply Partner Phorum Leader and Operations Team Member, Biophorum

Panelist: Isabelle Lequeux - Regulatory program Lead, BioPhorum

Panelist: Jeff Johnson - President, Biotech Design, LLC

Panelist: Nandu Deorkar, PhD - Vice President, Research & Development, Avantor

Panelist: Vikki Ponting - Security of Supply Manager, Cytiva

Development of the expression platform for BEAT bispecific antibody expression

16:30 - 17:00
Cell Line Development and Engineering - Strauss 2 and 3

Ichnos Biosciences developed BEAT bispecific antibody format employs expression of two modified heavy chains and a common light chain to achieve nearly perfect heterodimeric antibody expression. The heterodimer form is present in ≥95% of expressed species and the BEAT format enables one step purification of the heterodimer. Here, we present the improvements in cell line development platform for the expression of BEAT bispecific antibodies covering the vector systems, transfection, and clone enrichment with Splicelect technology.

Participants

Jana Frank - Team Leader, Ichnos Sciences

Please Move To Another Track

16:30 - 17:00
Cell Culture - Strauss 1

One-Step Clarification, Capture and Recovery Process of Antibodies from Very-High Cell Densities Using Magnetic Beads

16:30 - 17:00
Recovery & Purification - Lehar 1 and 2

Participants

Nils Brechmann - PhD Student, Cell Technology group, Dept. Industrial Biotechnology, School of Engineering Science in Chemistry, Biotechnology, and Health, Royal Institute of Technology (KTH)

Current Landscape of CAR T Cell Manufacturing Process Development

16:30 - 17:00
Cell & Gene Therapy - Lehar 4

Participants

Gerardo Santiago Toledo - Senior Scientist, Process Development, Autolus Ltd.

Offsite Cocktail & Refreshment Party

17:00 - 20:00
General Session

SCHEDULE

MAY 18 - 18/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	LIVE LABS	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	PRODUCT STAGE - EXHIBIT HALL	RECOVERY & PURIFICATION - LEHAR 1 AND 2
07:00				**07:30** - Coffee and Registration					
08:00				**08:20** - Chairperson's Opening Remarks			**08:30** - Keynote Address: Accelerating CMC: the future of process development is in silico		
09:00							**09:00** - Keynote Address: Process Intensification Pall Bioprocessing - Monoclonal Antibodies and Viral Vectors **09:30** - Plenary Panel Discussion: Cell & Gene Therapy CMC : An Innovation or Iteration in Biotech Principles and Practice?		
10:00	**10:55** - Chairperson's Remarks	**10:55** - Chairperson's Remarks	**10:55** - Chairperson's Remarks	**10:00** - Networking Refreshment Break in the Exhibit & Poster Hall		**10:55** - Chairperson's Remarks		**10:15** - Improving the efficacy and productivity of recombinant biologics produced in CHO cells by genome editing	**10:55** - Chairperson's Remarks

SCHEDULE

MAY 18 - 18/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	LIVE LABS	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	PRODUCT STAGE - EXHIBIT HALL	RECOVERY & PURIFICATION - LEHAR 1 AND 2
11:00	**11:00** - Panel Discussion: Future Outlook for Gene Therapy - mRNA vs Viral Vectors **11:30** - Analytical Methodologies for Gene Therapy Products	**11:00** - From Chemically to Functionally Defined Cell Culture Media **11:30** - Enhance cell culture productivity and product quality profile using media development	**11:00** - Bring Product Quality Assessment into Early Clone Selection with Opto™ Cell Line Development **11:30** - Advantages and challenges of utilising cell free expression for the production of neurotoxins			**11:00** - Performance Evolution & Lessons Learned in Tech Transfer from Development to Commercial Scale **11:30** - Leveraging Real-Time Data Visualization in Manufacturing for Process Improvement and Troubleshooting			**11:00** - Scale Dependent Aspects of a High Throughput Purification Strategy for Upstream Process Characterization **11:30** - Improving Antibody Fragment Capturing in Batch and Continuous Processing
12:00	**12:00** - Quality by Design for Adeno-associated Virus AAV Products	**12:00** - Computational simulation as a predictive tool for bioreactor design and performance	**12:00** - Optimized Expression Systems for Increased Productivity in CHO DG44 Based Cell Line Development	**12:30** - Networking Luncheon in the Exhibit & Poster Hall		**12:00** - Approach Industry 4.0 implementation with a Global Product Strategy		**12:30** - Cell Line Development and Plasmid Optimization to Improve AAV Titers	**12:00** - Addressing today's challenges in antibody therapeutic workflows

SCHEDULE

MAY 18 - 18/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	LIVE LABS	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	PRODUCT STAGE - EXHIBIT HALL	RECOVERY & PURIFICATION - LEHAR 1 AND 2
13:00		**13:40** - Chairperson's Opening Remarks **13:45** - Strategy to monitoring raw materials variability across the value chain	**13:40** - Chairperson's Opening Remarks **13:45** - Cell-Free protein synthesis of monoclonal antibodies and a novel cell-free glycosylation pattern		**13:00** - Advance Small Volume Purification with the ÄKTA™ ready 450 Single-use Chromatography System **13:10** - Meeting Buffer Demand **13:20** - Modify. Intensify. Amplify – A Definition of Process Intensification **13:30** - Maximize bioreactor analysis with Nova Biomedical's BioProfile® Online Sampler, partnered with FLEX2	**13:40** - Chairperson's Opening Remarks & Market Situation Analysis **13:55** - NIIMBL-BioPhorum buffer stock blending system vision, collaboration, design and outcome			**13:40** - Chairperson's Opening Remarks **13:45** - Combining Knowledge management and Risk management to Accelerate Development

SCHEDULE

MAY 18 - 18/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	LIVE LABS	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	PRODUCT STAGE - EXHIBIT HALL	RECOVERY & PURIFICATION - LEHAR 1 AND 2
14:00	**14:10** - Chairperson's Opening Remarks **14:15** - Innovations in Residual DNA Testing for Gene Therapy **14:45** - Aseptic Fluid Transfer Considerations in Gene Therapy Applications	**14:15** - Digital Twins and robotic experimental facilities for bioprocess development **14:45** - Cell culture intensification from seed train to the N bioreactor for step change capacity increases	**14:15** - Recent Advances in Cell Line Engineering of the Moss Physcomitrium patens for Biopharmaceutical Production **14:45** - Industrial production of therapeutic proteins using a CHO cell expression system			**14:20** - Efficient raw material management for improving bioprocess throughput and flexibility **14:45** - Accelerating upstream process development with direct CQA and media analysis feedback			**14:15** - Enabling Expedited Development of Complex Bispecific Antibodies **14:45** - High Performance and Stability with GMP Ready Prepacked CHT Process-Scale Columns
15:00			**15:00** - A CHO platform for the rapid production of vaccine antigens: From Wuhan to FrankenSpikes	**15:30** - Networking Refreshment Break in the Exhibit & Poster Hall				**15:30** - Developability - Early Preparation for a Successful Product	**15:00** - Simplify and Accelerate Downstream Process Development of AAV

SCHEDULE

MAY 18 - 18/05/2022

TIME	CELL & GENE THERAPY - LEHAR 4	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	LIVE LABS	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	PRODUCT STAGE - EXHIBIT HALL	RECOVERY & PURIFICATION - LEHAR 1 AND 2
16:00	**16:00** - Translation and Automation Hurdles for Cell Therapies **16:30** - Current Landscape of CAR T Cell Manufacturing Process Development	**16:00** - Bioreactor automation and intelligent control for robust and high yielding processes **16:30** - Please Move To Another Track	**16:00** - Improving the efficacy and productivity of recombinant biologics produced in CHO cells by genome editing **16:30** - Development of the expression platform for BEAT bispecific antibody expression			**16:00** - BioPhorum approach to the registration of innovative raw materials using quality by design (QbD) principles **16:25** - Partnerships Panel Discussion			**16:00** - Analysis of Depth Filter Performance Using Breakthrough Studies and Confocal Microscopy and its Interaction with Protein A Resin Lifetime **16:30** - One-Step Clarification, Capture and Recovery Process of Antibodies from Very-High Cell Densities Using Magnetic Beads
17:00				**17:00** - Offsite Cocktail & Refreshment Party					

SESSIONS

MAY 19 - 19/05/2022

Coffee and Registration

07:30 - 08:20
General Session

Chairperson's Opening Remarks

08:20 - 08:30
General Session

Keynote Address: SARS-CoV-2 and the seasonal Coronaviruses: global spread as deduced from antibodies in plasma supply

08:30 - 09:00
Plenary Session - Strauss 2 and 3

Plasma pools and immunoglobulin (IG) lots manufactured thereof contain pathogen epidemiological information on many thousands of plasma donors in different geographic locations, making them highly informative tools for the investigation of circulating or emerging viruses. Coronaviruses have been circulating globally for centuries, which is reflected in the neutralizing antibody content in lots of IG. The rapid emergence of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) enabled real-time tracking of appearance of antibodies with specificity against this novel virus in plasma pools and IG lots fractionated thereof and the introduction of highly immunogenic COVID-19 vaccines increased these titers rapidly and significantly.

This antibody monitoring informs on circulating and emerging viruses and also aids IG replacement therapy, as passive immunization through IGs is the most important protection for patients with immunodeficiencies and therefore needs to contain the appropriate regional antibody spectrum.

Participants

Maria Farcet, PhD - Head of Cell Culture, Virus Models & Serology at Global Pathogen Safety, Takeda

Keynote Address: Building a Digital Data Backbone to Improve BioPharma Lifecycle Management (BPLM)

09:00 - 09:30
Plenary Session - Strauss 2 and 3

With the acquisition of Skyland Analytics, IDBS combined manufacturing data management with process development data management to create the industry's first end-to-end, cloud-based platform that addresses BioPharma Lifecycle Management (BPLM) challenges. By creating a persistent, dynamic data backbone throughout the biopharma lifecycle, data can flow seamlessly across internal and external teams, sites, and partners as well as up and down the process. This enables insights to be shared that accelerate process understanding and ensure product quality, supporting the development of more scalable, robust, and higher yielding processes.

Participants

Alberto Pascual - Director, Data Science & Analytics, IDBS

Process Intensification in the Biopharma Industry - Improving Efficiency of Protein Manufacturing Processes from Development to Production Scale

09:30 - 10:00
Plenary Session - Strauss 2 and 3

Process intensification strives for more efficient conversion of raw materials into products while minimizing resource usage.

We present intensification techniques and process sequences that deliver synergistic benefits like increasing space-time yields, shortening production runs, or saving numerous days in cell expansion.

Combining highly productive perfusion with continuous downstream purification promises improved yields and production economics, especially for advanced, often labile molecules.

Since many techniques readily extend to other protein and viral vector based biotherapeutics, intensification can be regarded as key pillar enabling fast, cost-efficient development and production of biopharma products.

Participants

Gerben Zijlstra, Ph.D - External Collaboration Manager, Sartorius

Networking Refreshment Break in the Exhibit & Poster Hall

10:00 - 10:40
Cell Line Development and Engineering - Strauss 2 and 3

Networking Refreshment Break in the Exhibit & Poster Hall

10:00 - 10:40
Cell Culture - Strauss 1

Networking Refreshment Break in the Exhibit & Poster Hall

10:00 - 10:40
Recovery & Purification - Lehar 1 and 2

Networking Refreshment Break in the Exhibit & Poster Hall

10:00 - 10:40
Manufacturing Strategy & Industry 4.0 - Lehar 3

Chairperson's Opening Remarks

10:40 - 10:45
Cell Line Development and Engineering - Strauss 2 and 3

Participants

Bernd Voedisch - Lab Head R & D, Novartis

Chairperson's Opening Remarks

10:40 - 10:45
Cell Culture - Strauss 1

Chairperson's Opening Remarks

10:40 - 10:45
Recovery & Purification - Lehar 1 and 2

Participants

Jae Sly - Chief Business Officer, LigaTrap Technologies

Chairperson's Opening Remarks

10:40 - 10:45
Manufacturing Strategy & Industry 4.0 - Lehar 3

From Transfection to FIH in 6 Months: How Advances in Cell Line Development Enabled Manufacturing of Monoclonal Antibodies at Unprecedented Pace

10:45 - 11:15
Cell Line Development and Engineering - Strauss 2 and 3

Participants

Moritz Schmidt - Labhead Molecular Biology, Boehringer Ingelheim

SESSIONS

MAY 19 - 19/05/2022

Use of semi-automation during Cell line development for RUBY Bispecific antibodies

10:45 - 11:15
Cell Culture - Strauss 1

Bispecific antibodies (bsAb) have great therapeutic potential and are capable of inducing novel mechanisms of action that are beyond what can be achieved with monoclonal antibodies alone. Alligator Bioscience has developed RUBY, a novel bsAb platform that allows for streamlined generation of new bsAb from any 2 monoclonal antibodies. Here, I will present the approach Alligator Bioscience has chosen for effective cell line generation and I will illustrate the benefit of semi-automation of various parts of the workflow in order to increase efficiency and minimize risk. In addition, I will also present data demonstrating that RUBY molecules have excellent manufacturability potential.

Participants

Dietmar Weilguny - Principal Scientist, Alligator Bioscience

Measuring Across the Process Chain for Solutions in Process Intensification: Using a Combination of PAT, Data Science & Digital Twins

10:45 - 11:15
Recovery & Purification - Lehar 1 and 2

Participants

Christoph Herwig, PhD - Full Professor for Biochemical Engineering, Vienna University of Technology, Austria & Senior Scientific Advisor, Körber AG, Austria

eBR MES from AS-IS to Go-live in biopharma industry

10:45 - 11:15
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Reut Kornasio, Ph.D - Production Manager - MES/eBR, Recovery and Purification at Bio-Technology General Israel (a Ferring Company)., Ferring Pharmaceuticals

Approaches towards minimizing cell line development timelines

11:15 - 11:45
Cell Line Development and Engineering - Strauss 2 and 3

Reducing timelines to the clinic is crucial in making innovative medicine available to patients as early as possible. Development of a production cell line is on the critical path to achieve this goal. Several case studies will be presented which demonstrate from which angles we approach this issue without compromising on product quantity and quality.

Participants

Jan Schouten - Principal Scientist, Byondis

Faster scale up by leveraging wireless 3D sensor technology

11:15 - 11:45
Cell Culture - Strauss 1

Reliable scaling of cell culture processes presents a critical bottleneck for the pharmaceutical industry. One of the major challenges in scaling up a new process is the difference between the cell's growth environment in the lab compared to the pilot and production scale bioreactors and being able to adjust the process condition accordingly. Gathering comprehensive equipment characterization data at an early phase of process development can significantly reduce the risk of issues and batch failure, and subsequently, speed up the process up-scaling phase.

To support more advanced process and equipment characterization, Freesense has developed an in-reactor sensor technology for single use bags and steel bioreactors to provide 3D data on the culture condition from the whole internal volume of the bioreactor, which is not possible using traditional inline sensors. The technology consists of a wireless sensor technology that follows the flow in the bioreactor and determine flow, temperature, pH and dissolved oxygen. We present a case study on effective equipment characterization and process validation during scaling up a mammalian cell culture into a 5000L bioreactor. It was demonstrated how this technology can provide detailed information about the mixing performance, heterogeneity of the critical process parameters (CPP), presence of poorly mixed zones and gas transfer performance within the process operation conditions.

Participants

Tue Rasmussen, PhD - CEO, Freesense, ApS

Implementation of Tech for Digitalization Transformation – Successes, Lessons Learned, and Impact on Project Workflow

11:15 - 11:45
Recovery & Purification - Lehar 1 and 2

Participants

Gang Wang - Principal Scientist/Lab Head, Late Stage Downstream Process Development at Boehringer Ingelheim, Boehringer Ingelheim

Overcoming R&D Data Integrity and Lab Quality Issues for CMC Studies

11:15 - 12:15
Manufacturing Strategy & Industry 4.0 - Lehar 3

Participants

Nadine Ritter, Ph.D. - President and Analytical Advisor, Global Biotech Experts, LLC

SESSIONS

MAY 19 - 19/05/2022

Application of gene editing technologies to improve biotherapeutic manufacturing

11:45 - 12:15
Cell Line Development and Engineering - Strauss 2 and 3

Gene editing tools such as the CRISPR-Cas9 system have gained traction over the last few years in the bioproduction space where they have been used to genetically enhance capabilities in host cells routinely used in the industry, including Chinese Hamster Ovary (CHO), or Human Embryonic Kidney (HEK) cells. However, executing gene editing projects in a successful and reliable manner still remains a challenge due to a lack of well-defined gene editing pipelines and workflows.

Horizon's technical expertise includes robust pipelines and tools established to isolate, identify and characterize edited knockout (KO) or knock-in (KI) clones in many different cell types including CHO and HEK293 cells. Recently, we have incorporated into our portfolio new and highly specific CRISPR-based gene editing technologies that provide full freedom-to-operate and eliminate the need to secure independent commercial licenses. We will show data from several gene editing projects where the gene(s) of interest have been successfully targeted with high efficiency, irrespective of the gene copy number. We have also successfully generated various knock-in edits using different strategies and will present data showing successful knock in of DNA fragments ranging from 1kb to 13kb, exemplifying the capability of the platform in integrating potentially complex gene structures.

In addition to targeting single genes, we have developed a strategy for multiplex gene editing with high efficiencies, where multiple loci are targeted simultaneously. The ability to edit multiple genes is particularly important for the development of improved host cell lines. Here we will show the successful editing of 4 different genes and the different validations that we have performed.

Participants

Delphine Cougot - Senior Manager, Horizon Discovery

Raman PAT to Enable Real-Time Upstream Bioprocess Monitoring and Continuous Control

11:45 - 12:15
Cell Culture - Strauss 1

In bioprocessing, Raman spectroscopy is recognized as an integral part of the PAT strategy to ensure a pre-defined final product quality and performance. In this study, we demonstrate Raman combined with chemometrics as a key solution for inline and real-time monitoring of CQAs for upstream processes. A Robust growth of CHO cell culture is then achieved through process automation.

Participants

Fabien Caron - Product Manager, Process Solutions, Merck

Navigating the diverse antibody pipeline with chromatography ligand innovations

11:45 - 12:15
Recovery & Purification - Lehar 1 and 2

Antibodies are the largest class of biotherapeutics today and are likely to remain so in the future. As this class grows, so does its diversity — projects in preclinical stages through to commercial manufacturing increasingly involve variants such as bispecifics, conjugates, or fragments. Platform approaches have eased the development of purification protocols for many monoclonal antibodies (mAbs) on the market, but selecting purification schemes can be challenging for antibody variants given the wide range in the pipeline. We'll discuss how to select resins for capture steps to achieve selectivity and purification outcomes using established and new ligand innovations.

Participants

Jesper Hansson - Staff Research Engineer, R & D, Cytiva

New solutions for reducing complexity and increasing automation in stable cell line development

12:15 - 12:30
Cell Line Development and Engineering - Strauss 2 and 3

Cell line development (CLD) to produce monoclonal antibodies, complex proteins and gene therapies is a time-consuming and resource-intensive process. With the demand for faster and more advanced medical solutions on the rise, it's more important than ever before to reduce the time it takes to get from DNA sequence to GMP master cell bank. At CYTENA, we performed a validation study with the UP.SIGHTTM, our single-cell dispenser for more efficient cloning, assurance of clonality and plate imaging. The UP.SIGHT uses nozzle images and an innovative 3D Full Well Imaging method that images the entire volume of each well and ultimately achieves a documented probability of clonality >99.99%. Furthermore, we developed a new automation work cell designed to screen hundreds of clones without user interaction, enabling confluency, cell count, viability, fed-batch suspension culture and mAb titer screening at the push of a button.

Participants

Julian Riba - CEO, Cytena

Networking Luncheon in the Exhibit & Poster Hall

12:15 - 13:25
Cell Culture - Strauss 1

Networking Luncheon in the Exhibit & Poster Hall

12:15 - 13:25
Recovery & Purification - Lehar 1 and 2

Networking Luncheon in the Exhibit & Poster Hall

12:15 - 13:25
Manufacturing Strategy & Industry 4.0 - Lehar 3

Networking Luncheon in the Exhibit & Poster Hall

12:30 - 13:25
Cell Line Development and Engineering - Strauss 2 and 3

Chairperson's Remarks

13:25 - 13:30
Cell Line Development and Engineering - Strauss 2 and 3

Participants

Bernd Voedisch - Lab Head R & D, Novartis

Chairperson's Remarks

13:25 - 13:30
Cell Culture - Strauss 1

Participants

Mark Duerkop - Chief Executive Officer, Novasign

Chairperson's Remarks

13:25 - 13:30
Recovery & Purification - Lehar 1 and 2

Participants

Jae Sly - Chief Business Officer, LigaTrap Technologies

Chairperson's Remarks

13:25 - 13:30
Vaccines Manufacturing - Lehar 4

SESSIONS

MAY 19 - 19/05/2022

Cell Line Development and Plasmid Optimization to Improve AAV Titers

13:30 - 14:00
Cell Line Development and Engineering - Strauss 2 and 3

In this presentation, we will introduce the efforts at REGENXBIO to adapt our HEK293 host cell lines from adherent to suspension and further improve AAV productivity of cell lines by multiple cloning efforts. Furthermore, to improve AAV titers, we made a sequential modification of our helper plasmid. By combining the new cell lines and new helper plasmids, we improved our overall transient yield >20-fold while maintaining the product quality.

Participants

Ping Liu, Pre-record - Associate Director, Cell Line Development, Regenex Bio

Production Bioreactor scale-up and scale-down verification during a fast track project

13:30 - 14:00
Cell Culture - Strauss 1

While developing a manufacturing process for the production of a biopharmaceutical product, the small scale model used to support process ranges should be representative to the manufacturing scale process. A case study will be presented by Byondis which highlights the challenges in tech transfer to large scale and subsequently qualifying the small scale model used during development.

Participants

Deborah Hol - Principal Scientist Upstream Processes, Byondis

Twin-column Continuous Chromatography (MCSGP) for Oligonucleotide Purification

13:30 - 14:00
Recovery & Purification - Lehar 1 and 2

Participants

Thomas Müller-Späth, PhD - Director R&D, YMC ChromaCon

The importance of vaccine development and manufacturing in low and middle income countries in a pandemic situation

13:30 - 14:00
Vaccines Manufacturing - Lehar 4

As majority of population of World lives in low and middle income countries vaccine development and manufacturing becomes very important. Further as their income is low or middle vaccine availability at affordable cost can result in better coverage. The vaccine availability itself is and issue however company like Serum Institute of India Pvt Ltd., is doing it by going in for affordable innovation.

Participants

Satish Ravetkar - Executive Director, Serum Institute of India Pvt. Ltd

A modular assembly system for rapid and scalable construct generation

14:00 - 14:30
Cell Line Development and Engineering - Strauss 2 and 3

Rapid and flexible construct generation at scale is one of the most limiting first steps in the majority of drug discovery projects. Construct turnaround time and cost can be heavily reduced by adopting modular DNA design principles and automation. To this end we have designed a robust, multi- module golden gate based cloning platform combined with a software tool that performs fragmentation and codon optimization of long coding sequences in an automated manner. Using this platform, we: i) generated constructs for SarsCoV2 protein reagents, ii) automated and parallelized assemblies iii) built modular libraries of chimeric antigen receptors (CARs) variants.

Participants

David Öling - Associate Principal Scientist, AstraZeneca

Intensification of a high yield fed-batch cell culture process for commercial biologics production

14:00 - 14:30
Cell Culture - Strauss 1

Metabolic efficiency and cellular productivity of a mammalian cell culture was improved with lactate feeding. The induced lactate consumption substituted for glutamate catabolism and consequently reduced ammonia build-up. A direct correlation between increased monoclonal antibody titers and reduced ammonia levels was shown.

Participants

Sylvain Gros - Upstream Engineer, Manufacturing Sciences, Biogen

Harnessing the Power of mRNA, an Overview of Manufacturing and Purification Strategies

14:00 - 14:30
Recovery & Purification - Lehar 1 and 2

Participants

David Gemmell - Biomanufacturing Engineer, Merck

Boost your Vaccine Manufacturing: Accelerating for a Rapid Response

14:00 - 14:30
Vaccines Manufacturing - Lehar 4

The clinical promise of mRNA therapeutics and vaccines is clear, but their novelty also brings new challenges to the manufacturing process. Compared to monoclonal antibodies or viral vectors, cell-free mRNA production is faster, but processes related to plasmids, in vitro transcription, purification, and lipid nanoparticles (LNPs), add challenges. In this presentation, we'll discuss strategies and technologies for advancing and accelerating vaccine manufacturing and look how to address challenges to develop a robust, optimized, scalable, and integrated mRNA manufacturing process.

Participants

Katarina Stenklo - Enterprise Solutions Commercial Activation Leader, Cytiva

CHO fed-batch strategies to rapidly increase mAb titers by 100% without sacrificing product quality

14:30 - 14:45
Cell Line Development and Engineering - Strauss 2 and 3

Biopharma must constantly innovate to address manufacturing challenges associated with newer and complex protein therapeutics. In cell line development, both flexibility and early process solutions play critical roles for addressing manufacturing demands.

Selexis will illustrate how they boosted protein titers by 100% in 14 days through an intensified cell culture approach that utilizes different fed-batch process solutions.

Participants

Séverine Fagète, PhD - Vice President, Cell Line Development Services, Selexis SA

SESSIONS

MAY 19 - 19/05/2022

What's New -Corning product solutions for up-scaling of adherent cell culture.

14:30 - 15:00
Cell Culture - Strauss 1

A major challenge for manufacturing adherent cells for advanced therapies or viral vector production is producing the large quantities of cells needed in a cost-effective manner. In this presentation we will introduce Corning's new bioprocess products like our Ascent™ FBR System, a fixed bed bioreactor system designed to combine the benefits of adherent bioproduction platforms with the scale and automation of suspension manufacturing systems, and our HYPER Technology, including closed system HYPERStack® cell culture vessels, providing a significantly enhanced growth surface area compared to traditional cell culture vessel of comparable footprint, saving time, space and cost.

Participants

Anette Funfak, PhD - Field Application Scientist EMEA, Corning

Dowstream Viral Clearance of mAbs: Are Continuous Processes as Effective as Batch?

14:30 - 15:00
Recovery & Purification - Lehar 1 and 2

Viral safety is a Critical Quality Attribute for mAbs purified by Protein A chromatography.

Murine Minute Virus (MMV)-spiking experiments were performed at small scale on BioSC™ Lab in order to compare multicolumn (SMCC process) vs batch-column chromatography.

It was confirmed that viral clearance was similar in both cases, securing the use of multi-columns for downstream processing.

The presentation will also include an overview of the largest setting of the BioSC™ platform.

Participants

Christophe Egrot - Sales Manager LPLC, EMEA, Sartorius

mRNA Manufacturing: Removing Bottlenecks in Process Development and Manufacturing

14:30 - 15:00
Vaccines Manufacturing - Lehar 4

In vitro-transcribed messenger RNA-based therapeutics represent a relatively novel and highly efficient class of drugs. Current clinical efforts encompassing mRNA – based drugs are directed to three categories: mRNA vaccine, mRNA therapy and protein replacement therapy. As mRNA vaccine became the frontrunners to fight the COVID-19 pandemic, challenges surrounding their process development and manufacturing became readily apparent:

1. mRNA manufacturing is not yet a platform approach. Standardized products along the processes are needed.
2. mRNA is a relatively large molecule, which leads more challenges for downstream purification. mRNA is intrinsically unstable and prone to degradation.
3. High raw material cost is limiting mRNA commercialization.

This presentation provides a detailed overview of current mRNA manufacturing approaches, summarize the latest findings in cost of goods, highlight challenges and recent successes, and offer perspectives on the future of mRNA manufacturing

Participants

Amélie Boulais - Manager of Market Entry Strategy, Separation Technologies, Sartorius

CMC Strategy to take Bispecifics from DNA to IND in 13 Months

14:45 - 15:15
Cell Line Development and Engineering - Strauss 2 and 3

Lonza has applied it's 35 years of CMC experience in Biologics to develop an end-to-end comprehensive DS/DP DNA to IND strategy in 13 months. This presentation will highlight key approaches and technologies that enable this timeline. Case study examples will be shared for application in vector, process, analytic and formulation development of bispecific molecules during pre-clinical development.

Participants

Alice Harrison - Director, Global Technical & CMC, Analytics, Lonza

Networking Refreshment Break in the Exhibit & Poster Hall

15:00 - 16:00
Cell Culture - Strauss 1

Networking Refreshment Break in the Exhibit & Poster Hall

15:00 - 16:00
Recovery & Purification - Lehar 1 and 2

Networking Refreshment Break in the Exhibit & Poster Hall

15:00 - 16:00
Vaccines Manufacturing - Lehar 4

Networking Refreshment Break in the Exhibit & Poster Hall

15:15 - 16:00
Cell Line Development and Engineering - Strauss 2 and 3

Cell Line Development for Biologics R&D

16:00 - 16:30
Cell Line Development and Engineering - Strauss 2 and 3

Participants

Bernd Voedisch - Lab Head R & D, Novartis

Challenges to manufacture vaccines targeting speed, scale and access

16:00 - 16:30
Vaccines Manufacturing - Lehar 4

Since January 2020 vaccine developers around the world have undertaken measures to deliver safe and efficient vaccines to combat the pandemic. We have seen unprecedented efforts to make vaccines available across the globe at shortest possible time, accelerating timelines and taking multiple actions at risk. This presentation will address work within the CMC field to meet the COVAX motto: Speed, Scale, Access.

Participants

Anna Särnefält - CMC Lead, CEPI

High Throughput Technologies in USP Bioprocessing

16:30 - 17:00
Cell Line Development and Engineering - Strauss 2 and 3

In this talk we aim at discussing challenges and opportunities to accelerate process development of AAV-gene therapies, by levaring concepts of scale down models and high-throughput experimentation

Participants

Hugo F. Cueto-Rojas - USP Lead Scientist, uniQure

Trends in Vaccine Manufacturing That are Accelerating Innovation

16:30 - 17:00
Vaccines Manufacturing - Lehar 4

The COVID pandemic along with advances related to the Industry 4.0 have enabled greater agility in vaccine manufacturing. The evolution from dedicated manufacturing facilities for a single vaccine to customizable and adaptable manufacturing infrastructures will enable fast and efficient set-up of multi-modal productions. In this presentation, we will review a variety of trends and innovative solutions for closed processing, modular facilities, and future platform manufacturing.

Participants

Jerome Dalin - EMEA Core Modalities Strategy operationalization – Senior Consultant – Bioprocessing, Merck Life Science

SCHEDULE

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TIME	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	VACCINES MANUFACTURING - LEHAR 4
07:00			**07:30** - Coffee and Registration				
08:00			**08:20** - Chairperson's Opening Remarks		**08:30** - Keynote Address: SARS-CoV-2 and the seasonal Coronaviruses: global spread as deduced from antibodies in plasma supply		
09:00					**09:00** - Keynote Address: Building a Digital Data Backbone to Improve BioPharma Lifecycle Management (BPLM) **09:30** - Process Intensification in the Biopharma Industry - Improving Efficiency of Protein Manufacturing Processes from Development to Production Scale		

SCHEDULE

MAY 19 - 19/05/2022

TIME	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	VACCINES MANUFACTURING - LEHAR 4
10:00	**10:00** - Networking Refreshment Break in the Exhibit & Poster Hall **10:40** - Chairperson's Opening Remarks **10:45** - Use of semi-automation during Cell line development for RUBY Bispecific antibodies	**10:00** - Networking Refreshment Break in the Exhibit & Poster Hall **10:40** - Chairperson's Opening Remarks **10:45** - From Transfection to FIH in 6 Months: How Advances in Cell Line Development Enabled Manufacturing of Monoclonal Antibodies at Unprecedented Pace		**10:00** - Networking Refreshment Break in the Exhibit & Poster Hall **10:40** - Chairperson's Opening Remarks **10:45** - eBR MES from AS-IS to Go-live in biopharma industry		**10:00** - Networking Refreshment Break in the Exhibit & Poster Hall **10:40** - Chairperson's Opening Remarks **10:45** - Measuring Across the Process Chain for Solutions in Process Intensification: Using a Combination of PAT, Data Science & Digital Twins	
11:00	**11:15** - Faster scale up by leveraging wireless 3D sensor technology **11:45** - Raman PAT to Enable Real-Time Upstream Bioprocess Monitoring and Continuous Control	**11:15** - Approaches towards minimizing cell line development timelines **11:45** - Application of gene editing technologies to improve biotherapeutic manufacturing		**11:15** - Overcoming R&D Data Integrity and Lab Quality Issues for CMC Studies		**11:15** - Implementation of Tech for Digitalization Transformation – Successes, Lessons Learned, and Impact on Project Workflow **11:45** - Navigating the diverse antibody pipeline with chromatography ligand innovations	

SCHEDULE

MAY 19 - 19/05/2022

TIME	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	VACCINES MANUFACTURING - LEHAR 4
12:00	**12:15** - Networking Luncheon in the Exhibit & Poster Hall	**12:15** - New solutions for reducing complexity and increasing automation in stable cell line development **12:30** - Networking Luncheon in the Exhibit & Poster Hall		**12:15** - Networking Luncheon in the Exhibit & Poster Hall		**12:15** - Networking Luncheon in the Exhibit & Poster Hall	
13:00	**13:25** - Chairperson's Remarks **13:30** - Production Bioreactor scale-up and scale-down verification during a fast track project	**13:25** - Chairperson's Remarks **13:30** - Cell Line Development and Plasmid Optimization to Improve AAV Titers				**13:25** - Chairperson's Remarks **13:30** - Twin-column Continuous Chromatography (MCSGP) for Oligonucleotide Purification	**13:25** - Chairperson's Remarks **13:30** - The importance of vaccine development and manufacturing in low and middle income countries in a pandemic situation
14:00	**14:00** - Intensification of a high yield fed-batch cell culture process for commercial biologics production **14:30** - What's New -Corning product solutions for up-scaling of adherent cell culture.	**14:00** - A modular assembly system for rapid and scalable construct generation **14:30** - CHO fed-batch strategies to rapidly increase mAb titers by 100% without sacrificing product quality **14:45** - CMC Strategy to take Bispecifics from DNA to IND in 13 Months				**14:00** - Harnessing the Power of mRNA, an Overview of Manufacturing and Purification Strategies **14:30** - Dowstream Viral Clearance of mAbs: Are Continuous Processes as Effective as Batch?	**14:00** - Boost your Vaccine Manufacturing: Accelerating for a Rapid Response **14:30** - mRNA Manufacturing: Removing Bottlenecks in Process Development and Manufacturing

SCHEDULE

MAY 19 - 19/05/2022

TIME	CELL CULTURE - STRAUSS 1	CELL LINE DEVELOPMENT AND ENGINEERING - STRAUSS 2 AND 3	GENERAL SESSION	MANUFACTURING STRATEGY & INDUSTRY 4.0 - LEHAR 3	PLENARY SESSION - STRAUSS 2 AND 3	RECOVERY & PURIFICATION - LEHAR 1 AND 2	VACCINES MANUFACTURING - LEHAR 4
15:00	**15:00** - Networking Refreshment Break in the Exhibit & Poster Hall	**15:15** - Networking Refreshment Break in the Exhibit & Poster Hall				**15:00** - Networking Refreshment Break in the Exhibit & Poster Hall	**15:00** - Networking Refreshment Break in the Exhibit & Poster Hall
16:00		**16:00** - Cell Line Development for Biologics R&D **16:30** - High Throughput Technologies in USP Bioprocessing					**16:00** - Challenges to manufacture vaccines targeting speed, scale and access **16:30** - Trends in Vaccine Manufacturing That are Accelerating Innovation

SESSIONS

MAY 20 - 20/05/2022

Coffee and Registration at the Courtyard Marriott First Floor

09:00 - 10:00
General Session

CDMO Oversight in Biomanufacturing

10:00 - 12:00
CDMO Oversight in Biomanufacturing - Room Messe 1

Session 1: CDMO Selection
• Introduction
• CDMO selection model and process
• Case study and exercise 1

Session 2 :Contract Negotiation
• Different contractual documents
• QTQ / MSA / WPA
• Batch pricing
• Exercise 2

Session 3: Tech Transfer
• Tech transfer : what and why ?
• Formal TT : regulatory / documents / information transfer
• Risk management in TT
• Types of TT & conclusions
• Case study and exercise 3

Session 4 : On-going manufacturing
• Organisational models and interactions
• Regular production
• Audits and Campaign Reviews
• Exercise 4

Session 5: Interactions during Life Cycle
• When to make changes
• Activities outsourced to CMOs
• Implementing improvements

Session 6: Managing different interests
• Different Interests at stake
• Dealing with the human factor
• Negotiating or Collaborating
• Case study and Exercise 5

Conclusions

Participants

Thomas Chattaway - Senior Life Science Consultant, Independent

Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding

10:00 - 12:00
Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding - Room Messe 2

Pharma 4.0 is the perceived enabler to accelerate the product life cycle, ensure swift process validation, avoid fail batches and optimize productivity. However, for this, process understanding, the link between CPPs, CQAs and KPIs, need to be identified and deployed, which is still unresolved in industrial practice. This is due to the complexity of the data sources, the missing methods of data contextualization and due to the interactivity of a multitude of unit operations. The commonly accepted hypothesis is that sound data science and digital twin approaches along Pharma principles will be a success factor in this endeavor.

Course Outline:
Hands-on learning of basic principles and best practices performing data analytics and data management for integrated bioprocesses. Bring your own laptop. You will perform exercises on bioprocess data management and analytics using the web-based educational software tool PAS-X Savvy®. Methods and best practices embedded in workflows based on data science ad digital twins, using case studies and hands-on exercises. Designed for the biopharmaceutical and industrial biotech industry.

Digital Bioprocess Lab/ Plant: Best practices for bioprocess data management
- Data Management Workflows
- Handling Data of different frequencies and dimensionality
- Monitoring & Trending, raw data visualization
- Inspecting your data for outliers

Bioprocess data analytics: Best practices
- Setting process phases
- Conversion of raw data to reliable feature based information
- Integrated Process Analysis over multiple unit operations
- Root Cause Analysis of process variability
- CPV and Golden Batch Analysis

Digital twins for CMC knowledge capture and process control
- Workflows for generation of digital twins
- Applications of digital twins in efficient experimental designs
- Applications of digital twins for process prediction and control
- Integrated process modelling for a robust control strategy

Participants

Christoph Herwig, PhD - Full Professor for Biochemical Engineering, Vienna University of Technology, Austria & Senior Scientific Advisor, Körber AG, Austria

Lukas Marschall - Principal Consultant, PAS-X Savvy, Körber Pharma Software

Single-Use Technologies for Cell and Gene Therapies

10:00 - 12:00
Single-Use Technologies for Cell and Gene Therapies - Room Messe 3

Overview: An Introduction to Single-Use Technologies and the specific attributes
and quality needs when implementing Single-Use Technologies in Cell and Gene
Therapy Manufacturing. BPI's training workshop will focus on the importance and the implementation of Single- Use technologies in production of manufacturing facilities.

The format of the course includes valuable and unbiased classroom instruction by industry expert James Dean Vogel, P.E. With Mr. Vogel's assistance, course participants will experience the latest Single-Use products first hand during the lab portion of the course.

Topics include:
• Brief Review of Cell and Gene Production Methods and Regulatory Considerations
• Single-Use Bioprocess Equipment - Materials of Construction
• Single-Use Advantages and Disadvantages
• Single-Use Requirements for Cell and Gene Therapies and Risks
• Single-Use Components available for Hands-On Demonstration
• Attendees range from end-users, suppliers, sales and regulatory personnel who have a general understanding of the SUT industry and want to experience Single-Use products hands on!

Participants

James Dean Vogel - Founder and Director , The BioProcess Institute

SESSIONS

MAY 20 - 20/05/2022

Principles and Practices of CMC Analytics for Cell and Gene Therapy

10:00 - 12:00
Principles and Practices of CMC Analytics for Cell and Gene Therapy - Room Messe 4

Course Objective: This quick but comprehensive tutorial will provide an overview of the regulatory and quality principles that guide the analytical studies for all biological products, with emphasis on the specific elements applicable to complex MODALITIES such as gene and cell therapy. Emerging best practices in analytical methods for characterization, comparability, release and stability testing of gene and cell therapy will be presented. The rationale behind the requirements, with supporting references, will be provided. Attendees to this class will receive electronic copies of all reference guidances and publications discussed in the class.

Course Outline:
• Overview of CMC analytical regulatory deliverables for all biological products
• Specific additional guidances applicable to analytics of gene and cell therapy products
• Core principles of analytical characterization, comparability and control of complex biological products
• Practices for establishing the right 'analytical tool kit' for gene and cell therapy products
• Challenges in establishing product reference standards for use with complex biologics
• Emerging horizontal method standards for use with gene and cell therapy product analytical methods
• Key elements of compendial and non-compendial analytical methods lifecycles for biological products
• Quality requirements for documentation and data integrity of gene and cell therapy analytical studies
• Interactive Q&A with class speaker

Participants

Nadine Ritter, Ph.D. - President and Analytical Advisor, Global Biotech Experts, LLC

Luncheon served in the First Floor Foyer

12:00 - 13:00
CDMO Oversight in Biomanufacturing - Room Messe 1

Luncheon served in the First Floor Foyer

12:00 - 13:00
Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding - Room Messe 2

Luncheon served in the First Floor Foyer

12:00 - 13:00
Single-Use Technologies for Cell and Gene Therapies - Room Messe 3

Luncheon served in the First Floor Foyer

12:00 - 13:00
Principles and Practices of CMC Analytics for Cell and Gene Therapy - Room Messe 4

CDMO Oversight in Biomanufacturing

13:00 - 14:30
CDMO Oversight in Biomanufacturing - Room Messe 1

Participants

Thomas Chattaway - Senior Life Science Consultant, Independent

Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding

13:00 - 14:30
Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding - Room Messe 2

Participants

Christoph Herwig, PhD - Full Professor for Biochemical Engineering, Vienna University of Technology, Austria & Senior Scientific Advisor, Körber AG, Austria

Lukas Marschall - Principal Consultant, PAS-X Savvy, Körber Pharma Software

Single-Use Technologies for Cell and Gene Therapies

13:00 - 14:30
Single-Use Technologies for Cell and Gene Therapies - Room Messe 3

Participants

James Dean Vogel - Founder and Director , The BioProcess Institute

Principles and Practices of CMC Analytics for Cell and Gene Therapy

13:00 - 14:30
Principles and Practices of CMC Analytics for Cell and Gene Therapy - Room Messe 4

Participants

Nadine Ritter, Ph.D. - President and Analytical Advisor, Global Biotech Experts, LLC

Coffee Break served in the First Floor Foyer

14:30 - 15:00
CDMO Oversight in Biomanufacturing - Room Messe 1

Coffee served in the First Floor Foyer

14:30 - 15:00
Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding - Room Messe 2

Coffee served in the First Floor Foyer

14:30 - 15:00
Single-Use Technologies for Cell and Gene Therapies - Room Messe 3

Coffee served in the First Floor Foyer

14:30 - 15:00
Principles and Practices of CMC Analytics for Cell and Gene Therapy - Room Messe 4

CDMO Oversight in Biomanufacturing

15:00 - 16:00
CDMO Oversight in Biomanufacturing - Room Messe 1

Participants

Thomas Chattaway - Senior Life Science Consultant, Independent

Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding

15:00 - 16:00
Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding - Room Messe 2

Participants

Christoph Herwig, PhD - Full Professor for Biochemical Engineering, Vienna University of Technology, Austria & Senior Scientific Advisor, Körber AG, Austria

Lukas Marschall - Principal Consultant, PAS-X Savvy, Körber Pharma Software

Single-Use Technologies for Cell and Gene Therapies

15:00 - 16:00
Single-Use Technologies for Cell and Gene Therapies - Room Messe 3

Participants

James Dean Vogel - Founder and Director , The BioProcess Institute

Principles and Practices of CMC Analytics for Cell and Gene Therapy

15:00 - 16:00
Principles and Practices of CMC Analytics for Cell and Gene Therapy - Room Messe 4

Participants

Nadine Ritter, Ph.D. - President and Analytical Advisor, Global Biotech Experts, LLC

SCHEDULE

MAY 20 - 20/05/2022

TIME	CDMO OVERSIGHT IN BIOMANUFACTURING - ROOM MESSE 1	DATA MANAGEMENT AND PREDICTIVE ANALYTICS FOR SOUND PHARMA 4.0 PROCESS UNDERSTANDING - ROOM MESSE 2	GENERAL SESSION	PRINCIPLES AND PRACTICES OF CMC ANALYTICS FOR CELL AND GENE THERAPY - ROOM MESSE 4	SINGLE-USE TECHNOLOGIES FOR CELL AND GENE THERAPIES - ROOM MESSE 3
09:00			**09:00** - Coffee and Registration at the Courtyard Marriott First Floor		
10:00	**10:00** - CDMO Oversight in Biomanufacturing	**10:00** - Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding		**10:00** - Principles and Practices of CMC Analytics for Cell and Gene Therapy	**10:00** - Single-Use Technologies for Cell and Gene Therapies
11:00					
12:00	**12:00** - Luncheon served in the First Floor Foyer	**12:00** - Luncheon served in the First Floor Foyer		**12:00** - Luncheon served in the First Floor Foyer	**12:00** - Luncheon served in the First Floor Foyer
13:00	**13:00** - CDMO Oversight in Biomanufacturing	**13:00** - Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding		**13:00** - Principles and Practices of CMC Analytics for Cell and Gene Therapy	**13:00** - Single-Use Technologies for Cell and Gene Therapies
14:00	**14:30** - Coffee Break served in the First Floor Foyer	**14:30** - Coffee served in the First Floor Foyer		**14:30** - Coffee served in the First Floor Foyer	**14:30** - Coffee served in the First Floor Foyer
15:00	**15:00** - CDMO Oversight in Biomanufacturing	**15:00** - Data Management and Predictive Analytics for Sound Pharma 4.0 Process Understanding		**15:00** - Principles and Practices of CMC Analytics for Cell and Gene Therapy	**15:00** - Single-Use Technologies for Cell and Gene Therapies