SESSIONS

DAY ONE - 24/10/2023

Fast, insight driven process development with hybrid modeling and knowledge transfer

11:00 - 11:30
Mixing The Perfect Cell Culture

Using advanced transfer learning methods, we can quickly develop processes by understanding how they behave across different scales and products. Hybrid models are particularly useful because they combine data with process knowledge, making the development process more cost-effective as less experiments are required. We will showcase a new method for learning across different products and how it can be applied in digital twins to aAgendaccelerate process development.

Participants

Alessandro Butté - CEO, DataHow

Reactor simulations made accurate, fast and easy

11:30 - 12:00
Mixing The Perfect Cell Culture

In the car industry, different variants of cars were crashed to determine the safest configuration. Nowadays, the optimization for crash safety is done on the computer, and one car is crashed to validate the simulation. The same should be true for scale-ups in the biotech industry: Based on a reactor characterization in the lab scale, a computer simulation can determine the ideal process parameters for the production-scale reactor. One batch determines the validity of the simulation-based scale-up. The production is started immediately afterward. All the intermediate scale-up volumes are skipped, thereby reducing the experimental load and the time-to-market. In this presentation, you will see how close we are to this vision.

Participants

Christian Witz - CEO, SimVantage

Business Continuity Management in the Biologic Industry Supply Chain: an Industry Best Practice Approach

12:00 - 12:30
Mixing The Perfect Cell Culture

Both before and throughout the recent COVID pandemic, preparedness to ensure business continuity in the event of supply disruption has been paramount to ensure the continued availability of patient therapies and uninterrupted business operations. The BioPhorum 'Best Practice Guide to Business Continuity Management in the Biologic Supply Chain' is based on ongoing industry collaboration with subject matter experts and provides consensus recommendations to enhance the resilience of the biologics industry. It provides a framework based on internationally recognized standards. By systematically implementing these principles, which can be adapted to the scale and breadth of any individual company, companies can improve their business continuity management systems, supporting industry growth and meeting regulatory requirements. This presentation shares how the guide promotes a consistent approach throughout the supply chain, benefiting patients, companies, and the industry as a whole, and details how to use the associated questionnaire and evaluation tool. Companies supporting the biologics supply chain are strongly encouraged to review existing practices alongside the proposed recommendations, in order to ensure effective management of disruptions, improve communication within the supply chain, and ultimately benefit patients, companies, and the industry as a whole.

Participants

Sonia Schwantes, MBA - Director, Product & Innovation, NewAge AdvantaPure

Susan Neenan - Sr Director, Supplier & Material Risk Quality, AstraZeneca

Lunch Break

12:30 - 13:30

Detergent-based viral inactivation: A Case Study Demonstrating Enhanced Monoclonal Antibody Purification

13:30 - 14:00
Purifying Your Product

Virus inactivation is a critical operation in therapeutic protein manufacturing. Low pH buffers are a widely used strategy to ensure robust enveloped virus clearance. However, aggregation of certain protein products at low pH presents a challenge. One of the classical methods for viral inactivation (VI) is the detergent treatment step in the manufacturing of various drug modalities, including antibodies, plasma-derived products, and AAV. Additionally, detergent-based processes can be performed upstream of downstream steps, thereby increasing the viral safety of the overall process. In this presentation, we will discuss the application of a novel biodegradable detergent to enhance VI while in compliance with the regulation. An extensive study with different model viruses demonstrated its capability of providing >6.5 Log of viral inactivation and high virus-killing kinetics independent of operational temperatures (4 ºC to RT). Other benefits of using this detergent include no environmental toxicity, and no impact on product stability or process performance. This detergent can easily be removed from the product and detected by a simple analytical assay.

Participants

Nandu Deorkar, PhD - Senior Vice President, Research & Development – Biopharma Production, Avantor

Optimizing the Harvest Step to Better Integrate Upstream and Downstream (De-bottlenecking for Downstream Processing)

14:00 - 14:30
Purifying Your Product

Participants

Alois Jungbauer - Professor, Dept. of Biotechnology, University of Natural Resources and Life Sciences

Membrane chromatography in biopharmaceutical manufacturing

14:30 - 15:00
Purifying Your Product

There is a widely recognized need to transform biopharmaceutical development and manufacturing to reduce costs, increase the flexibility of equipment and facilities to accommodate an extremely diverse and changing portfolio of products. This presentation will focus on recent developments in membranes as alternatives to column chromatography for product capture and purification in a wide variety of different applications including protein therapeutics, vaccines and cell and gene therapy.

Participants

Cristiana Boi - Associate Professor, Alma Mater Studiorum, Università di Bologna

SESSIONS

DAY ONE - 24/10/2023

Mitigating HCP Risks throughout the Product Life Cycle

15:00 - 15:30
Purifying Your Product

Based on product development and the manufacturing experience, many examples are known where HCPs could severely impact patient safety. Therefore, the tight control of HCPs is an important issue for many product classes. The removal and control as well as the characterization of HCPs are important measures to guarantee high quality and safe biomedicines. This primary goal is supported by EU and US guidelines providing effective tools to circumvent hurdles during the licensing process. State-of-the-art control strategies during product development and throughout the product life cycle are required to be implemented. An HCP risk assessment should complement the studies. In this presentation, the understanding of the regulatory decisions will be facilitated by case studies.

Participants

Erika Friedl - Hematology Cell and Gene Therapy (HZG) Senior Quality Expert, Paul-Ehrlich-Institut

NEW Planova™ S20N filter: “Superior” filtration performance, “Secure” virus removal, and “Simplified” post-use integrity test

15:30 - 16:00
Purifying Your Product

Significant effort has been made to launch the novel Planova filter—Planova S20N—using superior regenerated cellulose with improved pressure resistance to meet challenges in the production of biopharmaceuticals. Planova S20N does not require the Gold Particle Test (GPT) due to resistance to high pressure, similar in its concept to Planova BioEX, making process development experiments optimal in terms of efficiency and cost. Planova S20N shows higher throughput, robust virus removal capability, and stable protein filterability at higher operating pressures while achieving stable filtration over a wide range of solution conditions, inherited from Planova 20N. The characteristics and the results of internal studies will be discussed in this presentation.

Participants

Achraf Jazi - Product Manager, Asahi Kasei Bioprocess Europe

Vegan Cheese – Essential ingredients to set up a scalable and economic manufacturing process

16:00 - 16:45
Purifying Your Product

There is a huge need to produce vegan cheese, which has the same taste and stretchiness as the classical one. However it needs to reach cost parity. Fermify is developing in fully digitalized continuous production platform to achieve scalability and cost effectiveness. This contribution will identify the main ingredients…such as the unique combination of continuous biomanufacturing, digital twins and PAT paired with bioprocess technology domain knowledge.

Participants

Christoph Herwig - Co-Founder and CPO at Fermify GmbH, Lisalis GmbH

Drinks Reception at BioProduction Lounge - Commencing 5pm

17:00 - 18:00

SCHEDULE

DAY ONE - 24/10/2023

TIME	MIXING THE PERFECT CELL CULTURE	PURIFYING YOUR PRODUCT
11:00	**11:00** - Fast, insight driven process development with hybrid modeling and knowledge transfer **11:30** - Reactor simulations made accurate, fast and easy	
12:00	**12:00** - Business Continuity Management in the Biologic Industry Supply Chain: an Industry Best Practice Approach **12:30** - Lunch Break	**12:30** - Lunch Break
13:00		**13:30** - Detergent-based viral inactivation: A Case Study Demonstrating Enhanced Monoclonal Antibody Purification
14:00		**14:00** - Optimizing the Harvest Step to Better Integrate Upstream and Downstream (De-bottlenecking for Downstream Processing) **14:30** - Membrane chromatography in biopharmaceutical manufacturing
15:00		**15:00** - Mitigating HCP Risks throughout the Product Life Cycle **15:30** - NEW Planova™ S20N filter: “Superior” filtration performance, “Secure” virus removal, and “Simplified” post-use integrity test
16:00		**16:00** - Vegan Cheese – Essential ingredients to set up a scalable and economic manufacturing process
17:00	**17:00** - Drinks Reception at BioProduction Lounge - Commencing 5pm	**17:00** - Drinks Reception at BioProduction Lounge - Commencing 5pm

SESSIONS

DAY TWO - 25/10/2023

Challenges for bio/pharmaceutical manufacturing 2023 and beyond

11:30 - 12:15
Manufacturing Strategy, Business Strategy & Environmental Considerations

Even though the bio-pharmaceutical market is expected to grow significantly in the next few years, there are challenges on the horizon. Specifically,

- Labor shortages
- Sustainable sourcing
- Adoption and training on new technologies
- How to efficiently work with Regulatory authorities (To quickly get products to the patient)
- How to flexibly use or transform older facilities, i.e. mono-facilities conversions to multiproduct facilities.

The most successful companies will be able to sculpt their strategy and remain agile to take advantage of industry trends.

Participants

Georgia Sloboda - Senior Director, CMC, Latham Biopharm Group

Patrick Falvey - Principal Consultant, Latham Biopharm Group

Biologics Approval & Accelerated Pathways in China

12:15 - 12:45
Manufacturing Strategy, Business Strategy & Environmental Considerations

Topics:

• Fast-track registration pathways in China

• Special registration procedures in China

• Imported drugs for urgent clinical use & real world clinical data

• Case studies

China's drug registration process has undergone significant reforms aimed at simplifying application procedures and aligning with international standards since its membership in the ICH in 2017. This presentation explores China's accelerated pathways and pilot programs for drug registration, with a focus on urgent clinical use, rare diseases, pediatrics, breakthrough therapies, and more. It covers the definitions, procedures, requirements, and timelines associated with each pathway, accompanied by case studies highlighting successful registrations and imports. Attendees will gain valuable insights into leveraging these policies for faster market access to China.

Participants

April Wang - Senior Regulatory Affairs Manager, Accestra Consulting

Creating the largest E2E CDMO network to change the future of Biologics Market Supply

12:45 - 13:15
Manufacturing Strategy, Business Strategy & Environmental Considerations

In the dynamic landscape of healthcare, ensuring patient access to medicines is paramount. FUJIFILM Diosynth Biotechnologies is taking a leading role in transforming the biomanufacturing landscape through rapid expansions and a bold network strategy. In this presentation the COO & EVP of Large Scale Manufacturing, Kenneth Bilenberg, will highlight cutting-edge strategies that not only enhance the efficiency and rapid scalability of production but also implements an unprecedented prioritization of people and culture throughout the organization.

FUJIFILM Diosynth Biotechnologies is on a rapid expansion journey unlike anything seen before in the market. By focusing on people & culture, implementing a modular cloning approach, and keep trust and delivery at the forefront, we not only rapidly scale our manufacturing capabilities across US and Europe, but also expand to be able to flexibly meet our clients' needs end to end – covering the entire value chain.

With sustainability and as true Partners for the Planet, we are very ambitious about scaling responsibly both from a climate and a community perspective. We truly believe that through trust and empowerment, our brilliant people will continue to grow and deliver excellent quality and service to our clients. Everyone we partner with can feel this trust and culture when collaborating with our amazing people – we truly build Partnerships for Life.

Participants

Kenneth Bilenberg - COO and Executive Vice President, Large Scale Business Unit, FUJIFILM Diosynth Biotechnologies

Lunch Break

13:15 - 14:15
Manufacturing Strategy, Business Strategy & Environmental Considerations

Implementing PAT in the GMP Space

14:15 - 14:45
Manufacturing Strategy, Business Strategy & Environmental Considerations

Process analytical technologies are typically studied at lab scale prior to commercial manufacturing deployment. Consequently, compromises may have to be made when trying to match one set of process parameters while disregarding the other for a desired attribute. In this talk, Mohamed will discuss personnel training for data analytics, deployment and troubleshooting of errors even with automated process control similar to training pilots to take advantage of autopilot.

Participants

Mohamed Noor, PhD - Digitalization Manager, National Institute for Bioprocessing Research and Training (NIBRT)

Unprecedented Post-Approval Production Cell Line Change of a Bevacizumab Biosimilar with the NMPA

14:45 - 15:15
Manufacturing Strategy, Business Strategy & Environmental Considerations

An unprecedented post-approval production cell line change for a bevacizumab biosimilar is presented. Cell line changes are considered to have a relatively high potential risk to product safety and efficacy. Therefore, such changes are often done before pivotal studies during clinical trials. The post-approval regulatory requirements for significant cell line changes are often ambiguous. There are currently no published examples of a post-approval cell line change. This case study demonstrates a three-way analytical and non-clinical comparability study strategy, which utilizes sophisticated analytical methods, allowing successful approval of a post-approval cell line change with the National Medical Products Administration (NMPA).

Participants

Sun Chau Siu - Executive Director, Head of Technical Operations, Altruist Biologics

Bring Your Laptop - Data How Workshop: QbD guided model-based process development

15:15 - 16:00
Manufacturing Strategy, Business Strategy & Environmental Considerations

- How to move from traditional workflows to model-based development activities
- Insight how process model-based process development works
- Relation between model-based process development and QbD

Participants

Alessandro Butté - CEO, DataHow

SESSIONS
DAY TWO - 25/10/2023

Navigating Pharmacovigilance in China

16:00 - 16:30
Manufacturing Strategy, Business Strategy & Environmental Considerations

Topics:

• Overview of China PV framework

• Updates on China's GVP policies

• China's GVP requirements

• Best practices for compliance with China's GVP requirements and authority inspection key points

• Tips and pitfalls

• Q&A session

The field of pharmacovigilance in China is characterized by its dynamic and fast-changing nature. As the country becomes increasingly important for pharmaceutical companies, it is crucial to stay informed about the latest regulatory developments to ensure compliance and safety. This essential pharmacovigilance session is designed to guide participants through the intricacies of compliance in China, providing valuable insights into Good Pharmacovigilance Practices (GVP) and post-market pharmacovigilance operations.

Participants

Marylene Zhan - Senior PV Manager, Accestra Consulting

Using QbD and DOE to identify critical process parameters as they relate to operating ranges at manufacturing scale

16:30 - 17:00
Manufacturing Strategy, Business Strategy & Environmental Considerations

The use of Quality by Design (QbD) and Design of Experiments (DOE) during process development is key to transparent risk management and maintaining safety, efficacy, and efficiency. An important step is identifying critical process parameters (CPPs) to ensure that a product meets defined quality goals. Regeneron will define strategies for identifying CPPs that emphasizes the relationship between studied ranges and manufacturing operating ranges.

Participants

Rachel Erwin - Process Development Engineer, Regeneron

SCHEDULE

DAY TWO - 25/10/2023

TIME	MANUFACTURING STRATEGY, BUSINESS STRATEGY & ENVIRONMENTAL CONSIDERATIONS
11:00	**11:30** - Challenges for bio/pharmaceutical manufacturing 2023 and beyond
12:00	**12:15** - Biologics Approval & Accelerated Pathways in China **12:45** - Creating the largest E2E CDMO network to change the future of Biologics Market Supply
13:00	**13:15** - Lunch Break
14:00	**14:15** - Implementing PAT in the GMP Space **14:45** - Unprecedented Post-Approval Production Cell Line Change of a Bevacizumab Biosimilar with the NMPA
15:00	**15:15** - Bring Your Laptop - Data How Workshop: QbD guided model-based process development
16:00	**16:00** - Navigating Pharmacovigilance in China **16:30** - Using QbD and DOE to identify critical process parameters as they relate to operating ranges at manufacturing scale

State of the Industry: Global Trends and Future Opportunities for Cell and Gene Therapies

11:00 - 11:45
Novel Modality Manufacturing Challenges & Solutions

- Evaluating the future of the industry:
- Product types – What are the best/ most promising modalities entering the field?
- Therapeutic areas – beyond oncology indications
- Emerging technological advances
- Manufacturing capacity and expertise - Do we have expertise in newer areas and capacity to scale up?
- Regulatory acceptance and expectations for new technologies / next generation products

Participants

Tony Hitchcock - Independent Consultant, AGH Bioconsulting

Moving Beyond 'Difficult-to-Manufacture': Designing Bioproduction Systems Fit for Next-Generation Products

11:45 - 12:15
Novel Modality Manufacturing Challenges & Solutions

Biopharmaceutical development is not limited by our ability to design products that work, but rather by our capability to make them. This talk will discuss how we move beyond the undesirable situation where many promising molecular formats are considered too difficult to manufacture. With a particular focus on the implementation of synthetic biology technologies, I will present new approaches for designing bioproduction systems that are fit for the manufacture of complex, engineered next-generation products.

Participants

Adam Brown, Ph.D. - Associate Professor of Biopharmaceutical Engineering, University of Sheffield

Optimization bispecific antibodies downstream processing: seeking homodimer removal

12:15 - 12:45
Novel Modality Manufacturing Challenges & Solutions

Bispecific antibodies (BsAbs) have gained significant attention in the field of therapeutics due to their ability to simultaneously target multiple disease-related antigens. However, the production and purification of BsAbs present unique challenges compared to traditional monoclonal antibodies. One critical downstream processing step in the production of bispecific antibodies is the removal of unwanted homodimers, which can affect the efficacy and safety of the final product. In Polpharma Biologics, optimized downstream processing strategies were developed for BsAbs biosimilars with a specific emphasis on homodimer removal.

Participants

João Henrique Picado Madalena Santos - Scientist, DSP Department, Polpharma Biologics

SCHEDULE

DAY THREE - 26/10/2023

TIME	NOVEL MODALITY MANUFACTURING CHALLENGES & SOLUTIONS
11:00	**11:00** - State of the Industry: Global Trends and Future Opportunities for Cell and Gene Therapies **11:45** - Moving Beyond 'Difficult-to-Manufacture': Designing Bioproduction Systems Fit for Next-Generation Products
12:00	**12:15** - Optimization bispecific antibodies downstream processing: seeking homodimer removal