ORAL SESSIONS

Session 1: Continuous Culture to Capture

Chairs: **Martina Micheletti**, University College London (UCL), United Kingdom
Thomas Ryll, Immunogen, USA

This session will address emerging and enabling technologies in the area of high density continuous mammalian cell culture, cell retention devices, and linkage to the initial capture step of the product. Studies focusing on the challenges associated with high cell density culture, such as the use of highly concentrated media and the cell retention device limitations, and those aiming at improving the perfusion performance while ensuring consistent product quality are encouraged. Key questions we wish to debate in the session include: Can scale-down studies efficiently support the optimization of media consumption and improvement of cell densities? What are the challenges associated with continuous process integration down to the capture step? Can single-use technology facilitate the integration of the different process steps in a cost-effective way, ensuring long term reliability and supporting target product titers? In this session we encourage submissions addressing topics such as:

- Scalability and robustness of cell retention devices with lessons learnt from implementation in clinical/commercial facilities
- Concentrated versus diluted media streams and strategies
- Scale down modeling of continuous culture and capture sequences for process characterization and validation
- Capture step performance in context of variable feed streams
- Linkage of continuous culture to non-chromatographic capture technologies
- Dynamic control approaches for culture, linkage and capture step, process analytical technologies
- Experimental and modelling comparisons of perfusion strategies with fed-batch, concentrated fed-batch and perfusion-supported fed-batch approaches
- Cell age challenges and product quality consistency with continuous operation

Session 2: Continuous Purification and Drug Product Sequences

Chairs: **Manuel Carrondo**, iBET, Portugal
Art Hewig, Amgen, USA

This session will focus on critical aspects of “Continuous Purification and Drug Product Sequences”, including but not limited to emerging and enabling technologies, strategic technological considerations, as well as scale-down development processes and tools aimed at delivering comparable performance to at scale operations. Potential areas of interest are chromatography, filtration, viral clearance/inactivation, formulation, and drug product generation. Submitters are also encouraged to present topics not directly related to biopharmaceuticals or other biologicals in an effort to draw inspiration and create analogies from fields outside of bioprocessing, eventually including 3D drug product printing, spray drying, as well as continuous filtration and crystallization.

Session 3: End-to-end Continuous Biomanufacture

Chairs: **Massimo Morbidelli**, ETH Zurich, Switzerland
Rohan Patil, Sanofi, USA

As end-to-end continuous manufacturing in the biopharmaceutical industry gains momentum, development of key upstream and downstream technologies and integration approaches for these technologies are evolving. This session will highlight development efforts on technologies that enable end-to-end continuous biomanufacturing. These can include case studies on lessons learned from other sectors and industries, design criteria for continuous biomanufacturing, challenges for handling perturbations during continuous operations, design and execution of viral clearance studies, continuous viral inactivation (low pH and others), PAT, process monitoring and analyses of cyclic data generated during continuous operations, technologies for continuous lyophilization or drug product manufacturing, etc.

Session 4: Predictive Continuous QbD Case Studies

Chairs: **Naz Karim**, Texas A & M University, USA
Dorothee Ambrosius, Boehringher Ingelheim Pharma, Germany

This session will address questions regarding application of QbD concepts or tools in continuous bioprocess development and manufacturing, including scale-down, PAT, chemometrics, modeling and control. We encourage contributions that address the following topics:

- Case studies dealing with implementation of various features of QbD
- Case studies dealing with successes and failures of QbD. Do we see/expect specific challenges for continuous mode production?
- Effective implementation of PAT and other technologies to improve product quality and reduce batch-to-batch variability.
- Application of modeling frameworks and integrated control strategies in continuous manufacturing of biopharma products.
- Use of multivariate statistical analysis in QbD.
- Impact of QbD approach on process characterization studies.
- Role of QbD in taking a product to market in minimal time.

Session 5: Business Case for Facilities of the Future

Chairs: **Nigel Titchener-Hooker**, University College London (UCL), United Kingdom
Thomas Sauer, Sanofi, Germany

We invite talks that present business cases comparing the feasibility of traditional versus continuous facilities of the future across a range of scenarios and sectors. For this session, we would appreciate any contribution that helps shed light on the following questions:

- What is driving decisions for traditional versus continuous processes beyond company-specific considerations or product-specific needs? How big does the financial driver have to appear for ICB to win out?
- What is the balance between CAPEX and OPEX in such decisions? How much of this is not related to single-use/disposable versus stainless steel?
- Are there cases where both approaches have been compared using similar technology background (e.g. both modes using disposable technologies)?
- Are there flexible approaches to allow that both modes are executable in a facility and how much does this flexibility contribute to the attractiveness of the business case?
- Are there any known cut-off criteria that drive decisions towards ICB or stainless steel respectively? Will ICB change the paradigm that stainless steel approaches are obligatory for large volume mAbs?
- Does ICB provide enough flexibility for fast-to-market approaches?

Session 6: Continuous Biomanufacture Beyond CHO or Proteins

Chairs: **Chris Love**, MIT, USA
Uwe Gottschalk, Lonza, Switzerland

Many advances enabling the continuous production of recombinant proteins by mammalian hosts like CHO cells have been realized. The benefits of integrated and continuous production should extend to other areas of biomanufacturing as well. For recombinant proteins, alternative hosts such as microbes can offer additional advantages for simplifying or integrating unit processes such as downstream purifications. Furthermore, the emerging challenges of producing complex biologic products like cell-based therapies or gene therapies present new opportunities to examine and develop best practices for establishing consistency and quality of products, as well as efficiencies in capital requirements where and when localized manufacturing may be required. This session will explore these frontiers for continuous biomanufacturing beyond the conversion of existing production platforms to continuous operations.