08.40 - 09.15

**Biomachining of the future – Which technologies for the benefit of the patient?**

- Major transformation of BioManufacturing and emerging new and game-changing technologies, such as continuous E2E manufacturing, disposable equipment and digital plants
- Which new technologies are just “passing fads” and which game-changing technologies will bring real benefit and added value to the patient?
- Technologies are sometimes incompatible or contradictory, e.g. disposable technology, requiring more manual handling, and plant digitalisation, aiming at self-driving operations
- Is there a “one-size fits all” biomanufacturing plant of the future? Should the biotech industry work towards a common technology platform similar to that developed by the semi-conductor industry a few decades ago?

09.15 - 09.50

**Integrating next-gen processes, technologies and operations to modernise biomanufacturing**

- The growth of biologic therapeutics demands innovations in biomanufacturing to supply drug products in a more reliable and faster manner
- Modernised approach to biomanufacturing with Next-Gen Manufacturing (NGM) integrations
- Combing the NGM mode with modular, expandable facility design and automation

10.40 - 11.15

**Validation of next gen depth filter technology in a commercial downstream process**

- Current situation
- Proposed situation
- Small scale development
- Upscaling and Large scale validation
- Conclusion and take home messages

11.20 - 11.55

**Disposable technology applications to support an evolving product pipeline**

- Introduction of high potency Bispecific to standard product portfolio
- Conventional cleaning methods not feasible
- Design of disposable manufacturing options for 100% of upstream downstream unit operations
- Develop calibration philosophy for disposable instruments
- Deliver capability within 8months to support clinical trial program

11.55 - 12.25

**One to One Meetings**

- Downstream/Upstream Process Technology Platforms
- Specialised cell culture media
- Single-use & Disposable Technologies
- Smart Manufacturing Technologies - Technology Transfer
- Facility Management & Integration
- Capacity & Facility Design
- Multi product facilities
- Energy & Operational Efficiency
- Lean/Transformational Change - Operational Excellence
- Continuous Improvement / Manufacturing Excellence
- PAT & MES / Automation and Process Control Excellence
- QbD
- Quality Assurance & Quality Systems
- Regulation - Rapid Release Testing
- Finance / Inward & Foreign Investment
- cGMP - Contract, External Manufacturing Services
- Biogenerics/ Biobetters
- Personalised Medicines
- Cell & Gene Therapy
- Fill and finish
- Cold chain

12.25 - 12.55

**Future trends perspectives and insights on biomachining**

- Major market trends, market growth and new modalities
- Risk factors in biomachining
- Capacity planning: new approaches and technologies
- Process intensification
Downstream Processing

13.45 - 14.20
Overcoming mAb manufacturing process challenges for high concentration drug substance to facilitate subcutaneous administration
- UF/DF recovery flush strategy to enable high yields
- Targeting expiency concentrations in UF/DF processes
- UF/DF pressure limitations due to high viscosity
- Sterile filtration challenges at high protein concentrations
- Stability considerations at high concentration drug substance

14.25 - 15.00
Downstream development and scale-up challenges for high-titer cell culture processes
- Minimal in-process pool volume and load adjustment/preparation
- Robust impurity clearance and risk-based development considerations
- Manufacturing facility fit and process development considerations
- Scale-dependent challenges and model-assisted solutions

15.05 - 15.40
Evaluation of different continuous chromatography systems for continuous capture
- The leading tool for transition to continuous biomanufacturing
- Different continuous chromatography technologies are currently available in the market, which differ in configuration, control elements
- Each technology comes with different benefits and limitations, selection of one can be based on requirements and feasibility
- Comparison of different systems with feasibility data and operational aspects

Upstream Processing

13.45 - 14.20
Streamlining the Technical Operation Platform to Accelerate Biologics Development and Reduce Manufacturing Cost
- Improvement of technical platform including cell line, cell culture media, and purification framework
- Harmonization of core platform including cell culture, purification, and analytics
- Implementation of automated high-throughput operation
- Best practices in scaling and technology transfers

14.25 - 15.00
Novel Methods to Ensure pH Comparability Globally Independent of Scale and Outlook for Manufacturing
- Discuss pH as CPP and relevant parameter in scale up, SDM and process transfer
- Problem statement for sample based pH offline measurement
- Presentation of a novel method to ensure pH comparability globally independent of scale
- Discuss implementation into manufacturing and outlook

15.05 - 15.40
Development of An Intensified Manufacturing Process for Single-Use Clinical Manufacturing Facility
- New clinical manufacturing suite in Devens site has been built with the intention of implementing a hybrid continuous manufacturing model that can increase monoclonal antibody output
- In the upstream process, a perfusion process has been developed for the seed train to increase cell densities of fed-batch process, reduce cadence and enhance annual antibody output. The perfusion seed train implemented the use of capacitance probes to control perfusion rate and minimize media utilization
- Accompanying high density fed-batch process, a new platform media has been developed for basal and feed to enhance productivities
- A clone selection workflow has also been adapted to accommodate the transition to a high density fed-batch process from the previous fed-batch platform approach

16.30 - 17.00
A new generation of Agarose Beads
- Next generation resin for downstream processing
- Advanced resin technology for continuous and batch manufacturing
- Increased process productivity & economy
- Ultra-high capacities on Protein A resin above 80 g/l

17.00 - 17.30
Alluvial-filtration as effective method to remove cells and HCP’s
- Effective and robust single-use method
- Linear scalable from development to process
- Combined method to remove cells and HCP’s
- Replacing centrifuge and other technologies for midstream
- Step reduction for midstream applications

17.30 - 18.00
Integrated Microbial Process Development: Overcoming Developability Challenges
- Novel biopharmaceutical formats pose unique development challenges. Strategies for successful development need to holistically consider all aspects of biopharmaceutical processes such as expression strategies, novel unit operations, automated high-throughput process development, as well as scale-up and transfer from bench to large-scale manufacturing. We present our holistic approach based on a HTPD toolbox to leverage the complexity of manufacturing development for non-platform biotherapeutics. Integration of the whole process is also discussed

18.05 - 18.35
Open Panel Discussion:
Technical life-cycle management and post-market authorisation changes
- Technical Life-cycle management activities and ICH Q12, more upfront planning required
- Post-market authorization changes, flexible manufacturing networks, however maintaining complexity at a reasonable level
- Treatment access for larger population groups, Biosimilars, and Cost pressure on Biologic

18.35
CHAIRPERSON’S CLOSING REMARKS AND END OF DAY ONE

18.45
NETWORKING DRINKS RECEPTION
### Project acceleration and breakthrough designation for biologics: Effect on early and late stage CMC development
- Strategies for streamlining CMC packages
- Minimising changes during development
- Front-loading versus fast to IND
- Accelerating/Compressing late stage development
- Effect of flexible plants, disposables and continuous processing

### Current innovative bioprocess technologies
- Continuous integrated production of therapeutic proteins
- Design and optimization of perfusion bioreactors
- Continuous chromatography in capture and polishing
- Development of a supervisory control system for an integrated continuous biomanufacturing process

### Implementation of Design Space Strategy to Control Product Quality during Large Scale Purification of Therapeutic Proteins
- Lot-to-lot resin variability – Case study
- Process control strategy
- Regulatory considerations

### Challenges in developing a biosimilar monoclonal antibody
- To reach biosimilarity is a technical challenge
- Biosimilars stimulate innovation
- Biosimilars push for a decrease in costs
- Biosimilars push for an increase in quality

### End-to-End Processing of Biopharmaceuticals – Options for scale-up and/or scale-out strategies
- End-to-end processing may embrace batch, continuous or hybrid technologies
- Single-use technologies enable proven scale-up and then scale-out
- Significant productivity improvements may be achieved through effective process design
- Using a toolbox approach to develop and scale-up a process enables productivity improvements across a broad range of advanced biologics modalities

### Chromassette®: A stackable chromatography cassette enabling next-generation bioprocessing
- A stackable, single-use and pre-packed chromatography cassette with a supported bed (Chromassette®) is a novel product concept in DSP, addressing the current key challenges in manufacturing
- Chromassette combines the separation capabilities of chromatography resins with the convenience of a pre-packed, modular cassette as shown in a range of application examples

### A Robust and Stable Molecularly Imprinted Polymers for Bioprocessing
- Molecularly imprinted polymers (MIPS) have broad application as affinity reagents in sensing, diagnostics, analysis and separation
- MIPS are synthetic alternatives to antibodies – they are robust and stable and can operate in extreme physicochemical conditions
- Viable alternative for purification of biotherapeutics with potential for extensive reuse
- With significantly lower production costs, our initial testing indicates the potential to transform the antibody purification process
- We are developing a MIP alternative to Protein A, available for licensing from 2019
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<th>Time</th>
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<td>13.05 - 13.40</td>
<td><strong>Process Development</strong>&lt;br&gt;<strong>Biosimilars</strong>&lt;br&gt;<strong>Using SPOT™ Technology in our CHOBC® Platform and our USP Modulation toolbox to reduce cost of goods for Biosimilar Development</strong>&lt;br&gt;&lt;br&gt;<strong>Process development and manufacturing of Antibody Drug Conjugates</strong>&lt;br&gt;• Process development and challenges for different ADC platforms&lt;br&gt;• Strategies for ADC manufacturing&lt;br&gt;• Control of product heterogeneity&lt;br&gt;• Improvement for future processes</td>
<td>&lt;br&gt;<strong>Biosimilars – Differentiation as a success factor</strong>&lt;br&gt;• Regulators Perspective&lt;br&gt;• Biosimilar Landscape&lt;br&gt;• Differentiators for success: Manufacturing considerations Technical Development Considerations Interchangeability Portfolio Selection&lt;br&gt;&lt;br&gt;<strong>Implementation and validation of a single-use mixing system for virus inactivation with solvent / detergent</strong>&lt;br&gt;• Virus inactivation by solvent Detergent treatment&lt;br&gt;• Single Use System&lt;br&gt;• Scale-down model for S/D Virus inactivation&lt;br&gt;• Steps of the validation (temperature mapping; Homogeneity study; ...)&lt;br&gt;• Impact of the EU Reach regulatory authority on S/D IV processes&lt;br&gt;&lt;br&gt;<strong>Digitising the entire Validation Life Cycle: a productivity leap</strong>&lt;br&gt;• Traditional paper/hybrid manual validation processes are not efficient, not cost effective, not scalable and with high risks&lt;br&gt;• Digital and paperless has become a strategic focus, driven by data integrity concerns and compliance risks&lt;br&gt;• &gt; 60% of global Pharma/ Biotech companies are actively looking to digitize the entire Validation Lifecycle&lt;br&gt;• Learn first-hand experienced how a leading global Biotech considered, evaluated, implemented and scaled its eVal solution across its entire organisation&lt;br&gt;• With detailed results, ROI and considerable cost &amp; productivity savings&lt;Br&gt;<strong>Next generation manufacturing for expanding portfolio of biologics</strong>&lt;br&gt;• Hybrid Model&lt;br&gt;• Modular and single-use technologies&lt;br&gt;• Flexible fed-batch cell culture&lt;br&gt;• High-performance purification&lt;br&gt;• Single pass TFF (SPTFF)&lt;Br&gt;&lt;br&gt;<strong>Open Panel Discussion:</strong>&lt;br&gt;With next gen manufacturing technologies and processes and strategies emerging what gains are being realised for profitability, productivity and quality in future facilities?&lt;br&gt;• Assessing the benefits and drawbacks of the latest manufacturing technology trends&lt;br&gt;• How Single-use equipment can help achieve performance improvements, both for downstream purification and for manufacturing productivity overall&lt;br&gt;• Process and Product Considerations for Flexible Manufacturing&lt;br&gt;• How Process Technology Platforms can be used to Optimize areas and parameters in upstream processing and automation opportunities to improve productivity and quality&lt;br&gt;• Process intensification strategies in USP and DSP shortening process time</td>
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