07.45 - 08.30  REGISTRATION
08.30 - 08.40  WELCOME & CHAIRPERSON’S OPENING REMARKS FOR DAY ONE

08.40 - 08.15  Biomanufacturing 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
• Combining the NGM mode with modular, expandable facility design and automation

09.50 - 10.40  COFFEE BREAK & MEETINGS

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 - 12.05  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 / Processing
• 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

11.55 - 12.25  Integrated bioprocess robustness enabled by data science and model based tools
• Identify, monitor and control variations along the process chain
• Identify the right harvesting time point to ensure robust downstream processing
• Stability upstream processes by using tunable promoters and model-based control algorithms to allow constant product quality and real continuous processing

12.25 - 12.55  Advancing late stage cell culture concept and leveraging platform knowledge
• Risk assessment in Late Stage process development
• Scale down models – Production bioreactor and beyond
• Advancing Process Characterization Studies
• Towards Late Stage Knowledge Management

12.55 - 13.45  NETWORKING LUNCH
Downstream Processing

13.45 - 14.20

Process validation using Latin Hypercube Sampling
- Method for design of experimental robustness studies
- Used in late stage validation to document parameter ranges
- Test of probable conditions as opposed to worst case
- Model free data analysis (e.g. control charts)

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 strategies
- 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

Panel Discussion: Development and implementation of an industry competitive first-in-human CMC strategy
- The time from candidate selection until the first human administration is key for competitiveness
- An integrated approach across divisions
- Achieving this goal is focusing on the platformization of the early development stream

16.00 - 18.00

COFFEE BREAK & MEETINGS

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

Primary packaging solutions for biotech drugs
- Make personalised medicine a reality with R&D pipeline with biotech-based drugs
- Pay special attention to all the steps along the development process and value chain
- Protect the drug product throughout the shelf life to efficient processing and enable safe and easy drug administration
- Understand all aspects of primary packaging starting with purity of the raw materials to final container with drug product and administration
- Reduce the risk of drug container interaction and ensure safe and easy drug administration

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
08.30 - 08.35
CHAIRPERSON’S OPENING REMARKS FOR DAY TWO AND SUMMARY OF DAY ONE

08.35 - 09.10
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

09.10 - 09.45
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

10.25 - 10.45
COFFEE BREAK & MEETINGS

09.50 - 10.25
Downstream Purification and Automation Strategies for Microbial Expressed Proteins
- Microbial expression
- Downstream process development
- High Throughput Development
- Automation and parallelization
- Interdependencies between upstream and downstream development

10.45 - 12.15
10.45 - 11.15
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

11.15 - 11.45
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

11.45 - 12.15
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

12.15 - 13.05
NETWORKING LUNCH
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<th>Time</th>
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| 13.05 - 13.40 | Process development and manufacturing of Antibody Drug Conjugates | • Process development and challenges for different ADC platforms  
• Strategies for ADC manufacturing  
• Control of product heterogeneity  
• Improvement for future processes |
| 13.40 - 14.15 | Implementation and validation of a single-use mixing system for virus inactivation with solvent / detergent | • Virus inactivation by solvent Detergent treatment  
• Single Use System  
• Scale-down model for S/D Virus inactivation  
• Steps of the validation (temperature mapping; Homogeneity study; ...)  
• Impact of the EU Reach regulatory authority on S/D IV processes |
| 14.20 - 14.50 | Digitising the entire Validation Life Cycle: a productivity leap | • Traditional paper/hybrid manual validation processes are not efficient, not cost effective, not scalable and with high risks  
• Digital and paperless has become a strategic focus, driven by data integrity concerns and compliance risks  
• > 60% of global Pharma/ Biotech companies are actively looking to digitize the entire Validation Lifecycle  
• Learn first-hand experienced how a leading global Biotech considered, evaluated, implemented and scaled its eVal solution across its entire organisation  
• With detailed results, ROI and considerable cost & productivity savings |
| 15.00 - 15.30 | Next generation manufacturing for expanding portfolio of biologics | • Hybrid Model  
• Modular and single-use technologies  
• Flexible fed-batch cell culture  
• High-performance purification  
• Single pass TFF (SPTFF) |
| 14.50 - 15.00 | COFFEE BREAK | |
| 15.30 - 16.00 | Open Panel Discussion: With next gen manufacturing technologies and processes and strategies emerging what gains are being realised for profitability, productivity and quality in future facilities? | • Assessing the benefits and drawbacks of the latest manufacturing technology trends  
• How Single-use equipment can help achieve performance improvements, both for downstream purification and for manufacturing productivity overall  
• Process and Product Considerations for Flexible Manufacturing  
• How Process Technology Platforms can be used to Optimize areas and parameters in upstream processing and automation opportunities to improve productivity and quality  
• Process intensification strategies in USP and DSP shortening process time |
| 16.00 | CHAIRPERSON'S CLOSING REMARKS | |
| 16.05 | CLOSE | |