BioTalk US
Biological Manufacturing Excellence

15th - 16th May 2019
Boston, US

Global Manufacturing Strategies

DAY ONE

07.45 - 08.30 REGISTRATION

08.30 - 08.40 WELCOME & CHAIRPERSON'S OPENING REMARKS FOR DAY ONE

08.40 - 09.15

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
- Combing the NGM mode with modular, expandable facility design and automation

09.50 - 10.40 COFFEE BREAK & MEETINGS

	Next-Gen Technology	Upstream Processing
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	**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
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	**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
11.55 - 12.55	**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** **Using systematic tools to expedite PC and maximise reliability of PPQ campaigns** • Emphasising the science of the control strategy • Focuses attention on critical process understanding • Efficient, thorough, and useful process characterisation designs • Confidence that equipment controls are optimized • Maximise reliability for PPQ, PAI, commercial manufacturing **12.25 - 12.55** **Future trends perspectives and insights on biomanufacturing** • Major market trends, market growth and new modalities • Risk factors in biomanufacturing • Capacity planning: new approaches and technologies • Process intensification

12.55 - 13.45 NETWORKING LUNCH

Downstream Processing

Upstream 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)

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

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

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

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

Panel Discussion: Development and implementation of an industry competitive first-in-human CMC strategy
- The timing 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

15.40 - 16.30 COFFEE BREAK & MEETINGS

16.30 - 18.00

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

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

DAY TWO

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

Process Development

Biosimilars

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

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

10.25 - 10.45 **COFFEE BREAK & MEETINGS**

10.45 - 12.15

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

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**

Process Development

Biosimilars

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

Biosimilars – Differentiation as a success factor
- Regulators Perspective
- Biosimilar Landscape
- Differentiators for success:
  - Manufacturing considerations
  - Technical Development Considerations
  - Interchangeability
  - Portfolio Selection

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

Using SPOT™ Technology in our CHOBC® Platform and our USP Modulation toolbox to reduce cost of goods for Biosimilar Development
- SPOT™ technology in our CHOBC® platform
- Upstream process modulation to meet CQAs
- Costs of Goods reduction
- Metabolic Engineering of Cell Lines

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 Lifecyle
- 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

14.50 - 15.00 **COFFEE BREAK**

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)

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**