BioTalk US
Biological Manufacturing Excellence

19th - 20th & 22nd - 23rd October, 2020, EST

A GMS Live Virtual Platform

Global Manufacturing Strategies

Day 1
Monday 19th October, 2020

All times are in EST

Session 1 - Upstream Processing

10.00 Introduction and Welcome by GMS

10.05 **Moving from intensified fed-batch to an integrated continuous process**

- Case study evaluation of a molecule evaluated both in an intensified fed-batch process and in a perfusion integrated with continuous capture process.
- Perfusion optimization using operational parameters and cell culture media design
- Delivering a target product quality profile with perfusion in consideration of historical product quality data
- Residence time distribution characterization in a perfusion process integrated with continuous capture
- Economics of stainless-steel intensified fed-batch versus a single use integrated continuous format

Sarwat Khattak, Senior Engineer III, Biogen

10.30 **Considerations in developing replacement media for legacy media and demonstrating comparable process performance or product quality**

- MVDA
- Chemically-defined media development
- Cell culture process development
- Biologics production

Wai Lam Ling, Senior Principal Scientist, Merck & Co.

10.55 **Technology Spotlight/Case Study** ThermoFisher SCIENTIFIC

11.15 **Roundtable Discussion:**

Late stage cell culture and leveraging platform knowledge

- How can we optimize cell-culture conditions while maintaining productivity, quality and consistency in phase III?
- How can we maintain these attributes when scaling-up, scaling-down and in tech transfer?
- Outlining the hurdles faced in late stage cell culture and how automation platforms can help navigate these challenges

12.00 Closing Statement

12.05 Close

Session 2 - Downstream Processing

14.00 Introduction and Welcome by GMS

14.05 **Streamline Downstream Process Characterization to Accelerate Late Stage Development for Process Performance Qualification**

- Process characterization (PC), a lengthy process required for performance qualification
- QbD Approach for process characterization study design
- Various study approaches and statistical data analysis tools evaluated to shorten timeline
- Streamline PC methodology for mAb platform to accelerate late stage development
- A mAb case study presented, challenges and bottle necks identified, future solutions provided with lesson learned

Yi Liu, Ph.D. Senior Scientist DSP, Bayer US, LLC

14.30 **Downstream FIH Process Development for Non-Platform Molecules**

- FIH platform downstream process to fit F2FIH timeline
- Key challenges for FIH drug substance process development
- Downstream process development on non-platform molecules
- Case study
- Moving forward

Yan Chen, Associate Director, Downstream Bio-Process Development, Bristol-Myers Squibb

14.55 **Using Diatomaceous earth (DE) for biotechnology processes** FILTROX

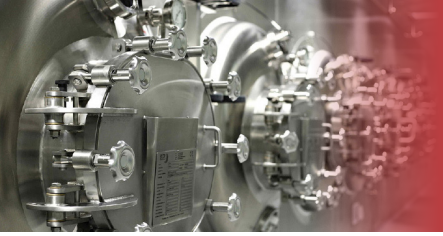
15.15 **Roundtable Discussion:**

How can new midstream (clarification) technologies improve the downstream process? Optimized midstream processes for biotechnology liquids.

- How to optimize clarification to improve further downstream process?
- What are the benefits and drawbacks of the latest clarification technologies trends?
- Clarification of plasmid DNA, mAb`s, viral vectors from biotechnology liquids
- Process and product robustness through midstream application
- How to reduce clarification steps by replacing centrifuges and other technologies

16.00 Closing Statement

16.05 Close



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Day 2
Tuesday 20th October, 2020

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Session 3 - Smart Factory

10.00 Introduction and Welcome by GMS

10.05

Next-generation bio-manufacturing capabilities and state-of-the-art technologies at Amgen Rhode Island

- Accelerating the transformation of our pipeline to deliver the next generation of medicines for patients and achieving long term competitiveness
- Increased bulk production through next-generation biomanufacturing platforms incorporating advanced manufacturing technologies, single use, digitalization and material sciences
- Greater flexibility, speed and efficiency to manufacture multiple medicines simultaneously
- Smaller manufacturing footprint offering environmental benefits such as reduced water consumption and energy and lower levels of carbon emissions

Ben Dionne, Director Process Development, Amgen

10.30

Process intensification strategies for modern bioprocessing facilities

- Approaches to eliminate manual steps in USP and to establish high cell density processes
- Strategies to combine DSP unit operations
- Intelligent buffer management solutions
- Digitization and PAT to enhance process control

Stefan Schmidt, COO, BioAtrium

10.55 Technology Spotlight/Case Study PerkinElmer

11.15 Roundtable Discussion:

Applying Innovative Smart Chromatography Tools for Purification and Recovery of Biomolecules

- What resin characteristics will need to be considered or required to meet future manufacturing challenges?
- Where will the science be focused on for resin development?
- Challenges for biosimilar development
- Should we reconsider how we develop purification processes?
- Future smart concepts of Chromatography

12.00 Closing Statement

12.05 Close

Session 4 - Technology Transfer

14.00 Introduction and Welcome by GMS

14.05

End-to-End Engagement and Tools to Ensure Successful Tech Transfers

- Discuss Amgen's comprehensive approach to ensure right-first-time tech transfer
- End to end tech transfer process evaluating raw materials, process design and control, facility fit, PPQ/Process Validation, and continued process verification
- Modelling and tools to reduce cost and risks while accelerating tech transfer
- Digital transformation shifting document driven to data driven tech transfer

Chae Han, Principal Engineer, Amgen

14.30

Novel and Innovative Characterization Methodology to Optimize Scale Up Strategies for Bioreactors

- Oxygen Transfer Rate
- Improving the Standard Measuring Method
- Reactor Scale Up/Down
- Optimizing Cell Culture Processes

Vivek Bhatnagar, Director Biopharm R&D, Teva Pharm

14.55 Technology Spotlight/Case Study Rentschler Biopharma

15.15 Roundtable Discussion:

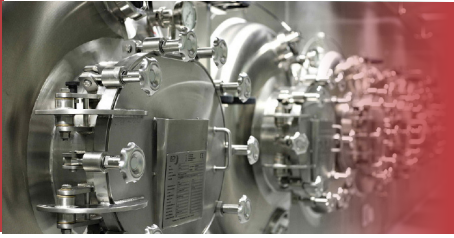
Technology Innovations to Expedite Global Biologics Development

- A discussion on the State-of-the-art technology platforms established to expedite global biologics development from discovery to commercialization.
- Which technology innovations currently deployed highlighted improving development efficiencies and reducing timelines from DNA to IND?

16.00 Closing Statement

16.05 Close

Please note: agenda and speakers are subject to change



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Day 3
Thursday 22nd October, 2020

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Session 5 - Downstream Processing

10.00 Introduction and Welcome by GMS

10.05 **Scale down model qualification (SDMQ) of continuous capture – A comparison study between a continuous and discrete approach**

- Novartis BioFuture Process
- DSP continuous capture concept
- Discrete SDMQ approach for process characterisation
- Continuous SDMQ approach
- Case study - Comparison of process and quality data of the two SDMQ approaches

Jonathan Seidel, Scientist, Late Stage Downstream Process Development, Novartis

10.30 **Stretching the Boundaries of Continuous Operations for a Multiproduct ICB Facility of the Future**

- Background: An Integrated Bioprocess for Continuous Capture at Late Stage and Commercial
- Opportunities for Facility and Process Intensification Beyond Continuous Capture
- Potential Benefits of an End-to-End ICB Process
- Special Focus on Continuous Virus Inactivation

Chad Varner, Scientist, Purification Process Development, Sanofi

10.55 **Developing a scalable closed and connected mAb process** cytiva

11.15 **Roundtable Discussion:**

Strategies for intensified antibody purification

- What are the main drivers for looking at downstream process intensification and how does the choice of upstream mode (fed batch/perfusion) impact mAb capture strategy? Examples: Costs/ Facility footprint/throughput/Productivity
- Where do you see the main opportunities for improvements and intensification in the antibody purification polishing steps? Examples: Flow through steps / 2 step vs 3 steps/ connected vs straight-through / emerging technologies
- What are your thoughts on the future drivers for mAb purification and enabling technologies for the next 5-10 years

12.00 Closing Statement

12.05 Close

Session 6 - CMC & Technology Transfer

14.00 Introduction and Welcome by GMS

14.05 **Post-approval Lifecycle Management Strategies for Biopharmaceuticals**

- Post-approval CMC changes for biopharmaceuticals: what are the drivers, where do changes typically take place, what are the main obstacles & regulatory expectations
- CMC changes: a shift of paradigm demanding greater flexibility
- CMC Lifecycle Management: the risk & cost of getting it wrong
- Strategies and tools to optimize the post-approval Lifecycle Management of Biologics
- Case studies and FAQs

Philippe Baumgartner, Head of Biologics CMC, Global Manufacturing Sciences, Takeda

14.30 **Fine-Tuning Process Development, Scale-up and GMP Manufacturing of a Novel ADC Technology Platform**

- Overview of Complex Supply Chain Architecture for ADC Manufacturing
- QbD-based Strategy to Process Validation of Key Process Parameters
- Process Scale-up Case Studies
- Brief clinical update Mersana's Dolaflexin ADC XMT-1536

Daniel Custar, Associate Director, CMC Drug Substance, Mersana Therapeutics

14.55 **Technology-Enabled Chinese Market Access and Tech Transfer** Pfizer CentreOne

15.15 **Roundtable Discussion:**

The Need for Speed: Maturing the Tech Transfer Business Processes to Achieve On-time Readiness for Clinical Drug Substance Manufacture

- The scope and cadence of clinical tech transfers into the Large Scale Manufacturing
- How can we Evaluate and established Tech Transfer business process?
  - Defining the inputs required for successful tech transfer
  - How can we identify the bottlenecks and challenges?
  - How can we map the risk profile?
- What are your experiences of implementing improvements to achieve speed and mitigate manufacturing readiness risks and yield improvement?

16.00 Closing Statement

16.05 Close

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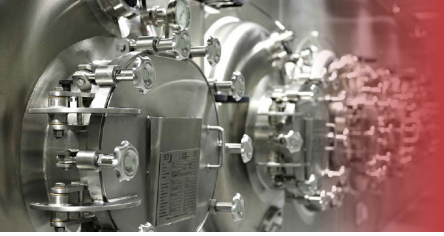

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Day 4
Friday 23rd October, 2020

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Session 7 - Downstream Processing

10.00 Introduction and Welcome by GMS

10.05

Digitalization from Past to Future - Process Development and Tech Transfer
- Use of in silico plant model to guide process definition and linkage of process parameters to quality and performance attributes
- Evolution of predictive model database and use of retrospective data to design prospective studies to enhance predictability
- Potential to scale-up with data lake
- Use cases with complex molecules

John Mattila, Director Purification Process Development, Regeneron Pharmaceuticals, Inc

10.30

CFD Enabled Process Modeling in Bioprocess Development to Improve Process Understanding and Guide Process Transfer
- Potential benefits of building CFD models in biological upstream and downstream process R&D
- Multiphase CFD models that used to be challenging to solve now can be tackled with the investment in modeling infrastructure and novel CFD approach
- Case study on the discrete bubble model in bioreactor characterization
- Case study on stratified buffer mixing model
- Model verification and lifecycle strategy discussion

Lei Cao, Principal Scientist, Bioprocess Development, AbbVie Worcester

10.55

The Parker SciPure Filter and Dispense-A single use automated system for enclosed bulk filtration and filling

11.15

Roundtable Discussion:

The Evolution of Bioprocess Filtration Single Use Automation: From the Laboratory Bench to the Final Package
- Single use implementation will be taken to the next level through automation. But how far can we go?
- How do you ensure scale up accuracy and filter performance at cGMP level?
- How can we enable a fully automated single-use filtration?
- platform to improve efficiency, and performance of the system?
- Future outlook on and technology innovations

12.00 Closing Statement

12.05 Close

Session 8 - Upstream Processing

14.00 Introduction and Welcome by GMS

14.05

Utilization of computational fluid dynamics (CFD) to guide scale up of cell culture bioreactors
- CFD allows for a first principle numerical analysis approach to scale-up and transfer bioprocesses
- Single-phase simulations were performed on BI Fremont bioreactors and media mixing vessels at different scales to estimate power number at different agitation speeds (P/V)
  - o Consistent power number in the turbulent regime was demonstrated
  - o Scale-down models were developed and verified through experimental and CFD results
- The CFD power numbers have been implemented at BIFI to calculate P/V in order to provide more accurate prediction for scale-up and transfer for BIFI bioprocesses

Dominique Monteil, Senior Scientist Cell Culture, Process Science, Boehringer Ingelheim

14.30

Platform Process Development of the Next Generation CHO Expression System in Pfizer
- Development of a high-fidelity, dual site-specific integration (SSI) system to enhance site-specific targeting efficiency and specificity
- Metabolic engineering of amino acid pathways of CHO cells to reduce the production of inhibitory factors in fed-batch cultures and improve cell culture process performance
- Enable rapid and cost-effective project progression during biopharmaceutical process development

Ravali Ragu, Principal Scientist, Pfizer

14.55 **Technology Spotlight/Case Study**

15.15

Roundtable Discussion:

With new upstream and downstream processing technologies emerging what gains will this have on profitability, productivity, and quality in future facilities?
- What are the benefits and drawbacks of the latest manufacturing technology trends?
- How can single-use equipment help to achieve performance improvements for UPS and DSP and for manufacturing productivity overall?
- Process and Product Considerations for Flexible Manufacturing
- How can Process Technology Platforms can be used to Optimize areas and parameters in upstream processing?

16.00 Closing Statement

16.05 Close