Bio Talk US

Biological Manufacturing Excellence

14th - 15th May 2020
Boston, USA

Global Manufacturing Strategies

08.00 - 08.40 REGISTRATION

08.40 - 08.50 WELCOME & CHAIRPERSON'S OPENING REMARKS FOR DAY ONE

08.50- 09.25

Factory of the Future 1 – Technology Innovations to Expedite Global Biologics Development
- State-of-the-art technology platforms have been established to expedite global biologics development from discovery to commercialization.
- Technology innovations will be highlighted for improving development efficiencies and reducing timelines from DNA to IND from a typical duration of 18 months to 7-9 months.
- Technology Innovations also are being used for reducing the manufacturing costs by implementing the next generation continuous bioprocessing solution with ultra-high productivity.

Ralf Otto, COO, Rentschler Biopharma SE & CEO, **Rentschler Biopharma Inc** (Invited)

09.25 - 10.00

How to exit a commercial roller bottle process and fix the quality attributes for a complex protein. A joined Up- and Downstream Approach.
- 2nd Gen Process Development (from roller bottles into bioreactors) for a complex non mab like protein
- Significant Yield Increase and Cost Reduction
- Joined Up- and Downstream approach to keep Quality Attributes within commercial range
- Challenges during Upscale and Lessons Learned

Leopold Grillberger, Head of Downstream Process Development, **Takeda**

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

Mitchell Tai, Principal Scientist, **Bristol-Myers Squibb**

10.00 - 10.50 COFFEE BREAK & MEETINGS

10.50 - 11.40

Late stage cell culture and leveraging platform knowledge
- In phase III cell culture, scientists must consider ways to optimize cell-culture conditions while maintaining productivity, quality and consistency
- In addition to optimization, one must consider how to maintain these attributes when scaling-up, scaling-down and in tech transfer
- In this presentation, we will outline the hurdles scientists may face in late stage cell culture and how automation platforms can help navigate these challenges

11.40 - 12.40

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
- Microbial Process Development and Production

11.40 - 12.10

The Evolution of Bioprocess Filtration Single Use Automation: From the Laboratory Bench to the Final Package
- Why automating a single use bioprocess leads to increased process efficiency and reduces risks.
- Overview of Parker Hannifin-the worlds leading motion and control company- and our offering in single use automation for bioprocessing applications.
- How small-scale automation can be used to ensure scale up accuracy and filter performance at cGMP level.
- The Parker SciLog FD- Automating bulk filtration and dispensing applications. The strategic benefits of automating this process.
- Parker SciLog Automated NFF Systems – optimise, control and simplify NFF processes.

12.10 - 12.40

Fibro chromatography: Ultrafast purification platform addressing mAb purification bottlenecks
- First truly Single-use Protein A capture chromatography technology
- Case study data of Pilot scale purification
- Process scale opportunities for the future explored

12.40 - 13.30 NETWORKING LUNCH

	Downstream Processing	Upstream Processing
13.30 - 14.05	**Simulation Tools in Biotechnology** • Implementation of modelling and simulation tools in biotechnology • What can biotechnology learn from the automotive industry? • First steps towards an "Insilico Process Development" • Examples of the biotech industry (e.g. Chromatography Modelling) **Dr. Peter Schwan,** Senior Expert Downstream , **BayerTechnologies**	**Challenges and opportunities during mammalian cell culture process development through to clinical manufacture** • Overcoming upstream hurdles during project progression • Case studies from development through to manufacture • Working to accelerated timelines • Collaborative approach required to ensure success **Wai Lam Ling,** Sr. Principal Scientist/Group Director, **Merck & Co.**

Please note: agenda and speakers are subject to change

	Downstream Processing	Upstream Processing
14.05 - 14.40	**Next generation downstream process – manufacturing of biologics in a continuous way** • Fully connected continuous downstream process for monoclonal antibodies • Integrated advanced analytical tools for real time monitoring • Complete single use setup and increased flexibility • Reduced costs and environmental impacts • High productivity **Chen Wang,** Director of Purification Development, Process Sciences, **Abbvie**	**Challenges during the Development of a High Cell Density (HCD) Continuous Upstream Process and Evaluation of an Ambr15 Perfusion-Mimic model** • Impact of the quality and quantity of cryopreserved cells • Development of media able to support high cell density cultures • Availability of rapid analytical tools which are capable to measure CQAs at small harvest quantities • Micro control of a continuous cell culture process • Minor equipment failure leads to serious impact on performance • Challenges and importance of PAT during small scale runs
14.40 - 15.15	**Impurity Control Strategies and Challenges in Impurity Reduction Studies** • Different impurity control strategies • Pro's and con's for different strategies • Case study: Antifoam reduction study • Technical and analytical challenges met in reduction study **Yi Liu,** Senior Scientist DSP, **Bayer**	**Success stories and learnings building a strong upstream manufacturing platform** • How to cope with growing variability in molecule formats • Transferring knowledge from research to development to production • Fast to clinic • Seamless transition to GMP and commercial • Beyond fed-batch **Ting Guo, Ph.D.**, Scientist, **Amgen**
15.15 - 16.05	**COFFEE BREAK & MEETINGS**	
16.05 - 17.35	**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 • Microbial Process Development and Production	16.05 - 16.35 **The future of Protein A affinity chromatography** • Process intensification by resin design • Very high productivity • Minimal buffer consumptionCost effective purification • Salt tolerant IEX resins for high resolution applications 16.35 - 17.05 **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 17.05 - 17.35 **Designing "Quality by Design"** • QbD represents a heavy workload, takes time and costs a lot. However, benefits largely outweigh the costs • QbD is not a goal in itself, it is only a methodology that support a reliable process development, leading to process robustness, understanding and increase safety for patients • The presentation will illustrate a coupole of case studies that « demistify QbD » and highlight advantages of designing QbD as an integral part of process initial development and lifecycle
17.40 - 18.15	**Factory of the Future 2 – The future of pharmaceutical production using the example of the GSK Marburg Site transformation** • Trends in the pharmaceutical market. What challenges do (bio-) pharmaceutical producers in Germany have to face? • The Marburg Transformation – "Turning old into new" • Development of a vaccines manufacturing platform – Was all this planned? • Criteria for long-term competitiveness	
18.15	**CHAIRPERSON'S CLOSING REMARKS AND END OF DAY ONE**	
18.20	**NETWORKING DRINKS RECEPTION**	

DAY TWO

08.30 - 08.35 **CHAIRPERSON'S OPENING REMARKS FOR DAY TWO AND SUMMARY OF DAY ONE**
Natraj Ram, Senior Director, Biologics Process Development, Alkermes

08.35 - 09.10

Factory of the Future 3 – Plant Design Philosophy and Technology Transfer Strategy for a Large Scale Commercial Monoclonal Antibody Process
- Design Basis for a new facility to manufacture a large volume commercial Mab
- Utilizing Data Management and Digital tools as part of facility design concept
- Outlining a complex node to node technology transfer
- Validation strategy to meet an aggressive timeline

Anu Bansal, Director Manufacturing Science and Technology, **Genentech**

Downstream Processing

Upstream Processing

09.15 - 09.50

Bioprocessing in the digital age – paving the path towards industry 4.0 through smart digital technologies for biopharma
- Challenges in digitalization and big data analytics in biopharma
- Enabling role of domain knowledge versus standard statistics
- Potential for value creation based on advanced modelling technologies as well as their integration with sensors and robotic platforms
- Industrial use cases for the successful implementation of smart digital technologies for biopharma

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

09.50 - 10.25

Vaccine development and manufacturing in the era of acceleration and Industry 4.0
- Significant demand and pressure on vaccine industry prompts faster adoption of new technologies
- Industry 4.0 presents opportunities in every aspects of the vaccine life cycle
- Challenges to initiate and sustain transformation for vaccine development and manufacturing
- A fine balance between acceleration and transformation
- Case studies on development and implementation

Complete single-use upstream workflow from process development to clinical manufacturing to rapidly advancing biologics programs
- Single-use high-throughput bioreactor systems greatly increase development capability and efficiency
- Detailed bioreactor characterization effort enables seamless scale-up and process transfer from high-throughput mini-bioreactors to clinical scale at 2,000 L
- Streamlined workflow leads to rapid and efficient FIH process development
- Potential acceleration to late stage development and characterization using the same single-use equipment and methodology

10.25 - 10.50 **COFFEE BREAK & MEETINGS**

10.50 - 12.20

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10.50 - 11.20

High Productivity Harvest- Intensify and displace clarification in Fed Batch cell culture
- How can I gain from process intensification with the least effort?
- Should I retrofit my facility to become continuous or not?
- Is it possible to introduce intensification changes in late clinical or post commercial phases?

11.20 - 11.50

Improving single use bioreactor design and process development
- Improve performance and control when operating under these special conditions
- Impacts of enhanced energy transfer-Implementing bottom heat exchange, alternate impeller positions, and considering agitation dissipation rates
- How new technology improves equipment utilisation, scheduling efficiency, inventory logistics, and reactor harvest consistency?

11.50 - 12.20

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

12.20 - 13.10 **NETWORKING LUNCH**

	Process Development	Upstream Processing
13.10 - 13.45	**Biologics process intensification during development and production** • Process intensification strategies for mAbs • Continuous versus semi-continuous versus fed-batch • Plant design • Adaptations of regular facilities for process intensification **John Mattila,** Director Purification Process Development, **Regeneron**	**The Evolution of a Next Generation, High-Intensity Manufacturing Process – A Pfizer Update** • The evolution of a Boehringer Ingelheim, Pfizer collaboration design of an intensified, next generation manufacturing process • The evolution from a proof of concept system through GMP design considerations is a significant challenge • New integrated skid (iSKID) assimilates, prototype system increases process efficiency • They system integrated iSKID is capable of 24-hour, unmanned operation, delivering superior daily productivity to traditional batch processing in a low bioburden environment • Learnings from the prototype system play a significant role in the design of a GMP bioprocess manufacturing system **Michael O'Connor,** Senior Engineer, **Pfizer** **John Galyas,** Senior Associate Scientist, **Pfizer**
13.50 - 14.25	**Process development approaches to continuous capture and connected downstream** • Retrofitting a discrete fed-batch process into a continuous capture / connected downstream process • Strategies and challenges in process characterization • Case study **Sarwat Khattak,** Senior Engineer III, **Biogen**	**Bio-Process Fermentation optimization: the CPV added value** • Continued process verification basis • Data driven decision-making • Incoming materials monitoring in upstream areas of bioprocess • Example of process optimization starting by routine trending activities and cross-functional team work
14.25 - 15.00	**Parallelized DSP steps with a single-skid at pilot-scale: manufacturing strategies, buffer platforms and equipment integration** • We performed advanced trials of a pilot-scale equipment allowing several DSP steps to be performed at the same time • The strategy employed was: multi-column capture step, followed by an automated viral inactivation step, followed by a depth filtration step paired with an ion exchange chromatography step • We also tested several features of the equipment to apply different buffer platform strategies: 1X buffers, in-line dilution and an advanced inline buffer conditioning **Nicolas-Julian Hilbold,** Associate Scientist, PhD – Bioprocess Technology and Innovation, **Merck**	**Monitoring the scale-up of a biopharmaceutical cell culture process using Raman spectroscopy at 2000 L scale in a GMP environment** • Raman spectroscopy • Biopharmaceutical • Fed-batch • GMP • Chemometric model development
15.00 - 15.20	**COFFEE BREAK**	
15.20 - 15.55	**Factory of the Future 4 – Technical trends and concepts in modern bioprocessing facilities** • Hybrid solutions • Digital strategies and automation • Process intensification • Buffer handling **Stefan Schmidt,** COO – Head of Operations, **BioAtrium**	
15.55	**CHAIRPERSON'S CLOSING REMARKS**	
16.00	**CLOSE**