17th Annual

Global Bioproduction Summit

February 5 – 6, 2018 | Hilton San Diego Resort & Spa

BOOK NOW

Welcome, you can refine the program by selecting an area of interest below:

Full Program | Day 1 | Day 2 | Program at a Glance

Show All | Upstream | Downstream | Production Quality & Innovation

Day 1 – December, 12 2016 – Monday

7:45-8:35 AM

Registration

8:35-8:40 AM

Chair's Welcome Address

aTyr Pharma

Ashraf Amanullah Ph.D.
Vice President, Biologics Development and Manufacturing, aTyr Pharma

8:40-9:15 AM

Keynote

PRODUCTION QUALITY & INNOVATION

Introducing Flexible Manufacturing into the World of Biotechnology: Constructing the Highly Reconfigurable Facilities of the Future

AMGEN

Leveraging the latest in bioprocessing technology, and plant and process design, Amgen's Singapore facility represents state-of-the-art bio-manufacturing. The new transformative facility promises a simpler, more efficient, more flexible way to make medicines of the future. In this exclusive keynote, Chris Crowell will explore the innovations developed by Amgen in Singapore, and how they are making preparations for their first commercial product launch in 2017.

- Process Performance Qualification Completed 29 Months After Land Acquisition – A Case On The Scale and Speed In Which Single-Use Technologies Can Be Deployed In a Highly Reconfigurable Facility
- Harnessing Your Platform – Key Fundamental Elements and Considerations When Developing a Progressive Plant to Ensure Transformational Elements Are Realized
- The Importance of Building Strong Collaborative Relationships With Suppliers Through Implementation of Robust Supplier Relationship Programmes

> Chris Crowell Ph.D.
> Executive Director, Global Operations
> Amgen

9:15-10:05 AM

Panel

PRODUCTION QUALITY & INNOVATION

The Great Debate: Single Use Systems vs. Stainless Steel

- Where is the optimum balance between speed, quality and cost? What about other considerations such as development stage and geography?
- Supplier management – ensuring consistency and timeliness. What are the key sourcing challenges?
- How to factor in sustainability and "green" concerns?
- Technology capability limits?

Ashraf Amanullah Ph.D.
Vice President, Biologics Development and Manufacturing
aTyr Pharma (Panel Chair)

Ron Ortiz
Director Manufacturing Science and Technology
Pacira Pharmaceuticals, Inc.

Jeremy Young
Director Manufacturing Sciences and Technology
CMC Biologics Inc.

Jonathan K. Romero
Director, Technical Operations
Celgene

Rajesh Krishnan
Director, Process Development
Gilead

10:05-10:55 AM

iSolve Meetings & Refreshment Break

10:55-11:25 AM

Case Study

UPSTREAM

Speed is Good – Bridging the Gap between Upstream & Downstream Processing in Continuous Bio-Manufacturing to Deliver Products On-Time, While Meeting Regulatory Guidelines

- Think Before You Act – Assessing your batch's biological state thoroughly to ensure the implementation of appropriate processes and delivery of samples under a controlled environment

Case Study

DOWNSTREAM

Managing Keystone Contaminants in Downstream Processing

- Soluble chromatin in cell culture harvests interferes directly with IgG purification.
- It reduces capacity, depresses recovery, inflates contamination, and causes aggregation.
- Advance chromatin removal suspends these limitations, removes 5-9 logs of virus and 3-4 logs of endotoxin
- It also enables 2-step purification with better final product quality than traditional 3-step platforms

- Implementing the appropriate quality risk management principles to determine the lowest level of acceptable risk, without negatively impacting your product or equipment
- "Yes, your training process CAN be more effective" – combining TQR's and re-assessing the task at hand, to shorten the average training period and start reviewing electronic records sooner
- Reducing cycle times – A case study on Merck's 150-day-lead-time reduction

Lisa A. Sykes
Director of Global Quality Operations
Merck

Pete Gagnon
Vice President, Process Sciences
Avid BioServices a subsidiary of Peregrine Pharmaceuticals, Inc.

11:25-11:30 AM

Please Move to Your Next Session

11:30-12:00 PM

Solution Spotlight

UPSTREAM

Integrating the Pharmaceutical Manufacturing Process and Quality Organizations to Drive Right First Time Performance

The growth and complexity of modern manufacturing networks, together with the increasing focus by regulatory agencies on data integrity and product quality, are driving the need for data-driven collaboration across manufacturing process and quality organizations, including outsourced operations (CMO's). A high level of data integrity is required so the business can trust its own operational metrics, and so that regulators and customers can trust the quality of the manufacturer's products. Right first time performance requires easy access and automated contextualization of process and quality data from multiple disparate data sources, to understand process performance, minimize variability, and identify science-based process improvements. This presentation will describe how leading companies are achieving these objectives with a validated, high-integrity data-centric collaboration system that span organizations to identify, implement, document, and monitor process performance that minimizes risks and boosts the bottom line.

Justin O. Neway
Vice President, Process Production Operations
BIOVIA (Dassault Systèmes)

Solution Spotlight

DOWNSTREAM

From Pilot to cGMP Commercial Production in 3 years – Incorporating the Latest Downstream Technology to Reduce Costs Whilst Increasing Yields Using Fluidized Bed Columns with Real-time PAT Control

Presented is the last 3 years' scale-up work from laboratory and pilot scale chromatography to full commercial production of a MAb using a unique, successful, excellent downstream production scale technology with live PAT control that uses fluidised medium. This new slant is shown to increase yields, meet regulations and reduce costs at commercial scale.

- Two 250-litre, 600 mm ID, 800 mm height columns for full cGMP commercial production were commissioned and validated for injectables in July this year, 2016.
- MAb from 1,000's litres of unclarified, un-homogenized, live biomass is fed directly into the column.
- This technology has been scaled-up from laboratory to two variable bed height 1.5 metre tubed, 56 litre columns.
- Eight ultrasound transceivers monitor and by feedback, maintain the fluidised bed to a fixed height, automatically, in real time.

Martin Hofmann
Managing Director
Biotechflow

12:00-12:05 PM

Please Move to Your Next Session

12:05-12:35 PM

Case Study

Case Study

UPSTREAM

From Dinosaur to Bird: Environmentally Friendly and Cost-Effective Manufacturing of Biologics through Integrated Continuous Processes

MERCK

Merck's vision and progress on integrated continuous processes for biologics manufacture Process development with consideration of quality, speed, cost, and environmental sustainability Challenges and solutions for the next-generation of continuous manufacture for biologics

Hao Chen, Ph.D
Director, Process Development & Engineering
Merck & Co Inc.

DOWNSTREAM

Exploration of Protein A like resin for Recombinant Proteins-Combating Impurity challenge associated with Primary Recovery Process

Shire

- Exploring the potential of different affinity ligand for target protein capture and release
- Implementing alternative approaches to improve the efficiency of primary recovery processes
- Exploration of new technology enabling future platform downstream processing

Yong Wang
Head, Early Stage BioProcess Development
Shire Inc

12:35-1:35 PM

Networking Lunch

LUNCH

1:35-2:05 PM

Case Study

PRODUCTION QUALITY & INNOVATION

Managing Manufacturing Network and Technology Strategy for a Diversified Biopharma Development Portfolio

janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

- Technology Innovation Management within Parenteral Technology Platform in Janssen Supply Chain
- Key trends and drivers, supply chain implication and technology response
- How does Modelling, PAT, Process Intensivation, Modularity and Robotics drive value for the future
- Up – Downstream as well as Fill Finish
- Short reflection on the Factory of the future

Timo Simmen
Director Technical Operations
Janssen

Case Study

DOWNSTREAM

Risk Mitigation Through Innovative Filtration Methods

Celgene

- Enhancing Cell removal capabilities while building purification capabilities into the Upstream process Train
- Technologies that bridge upstream and downstream Antibody processes enable a continuous, high capacity, low foot print operations
- Advances in harvest clarification methods and technologies for high cell density and high-titer fed batch or perfusion cultures

Jonathan K. Romero
Director, Technical Operations
Celgene

2:05-2:10 PM

Please Move to Your Next Session

2:10-2:40 PM

Case Study

UPSTREAM

Continuous Process Verification: The journey does not end

Genentech
A Member of the Roche Group

1.Devil is in the details: case study of trouble shooting of mature mMFG process 2.Life cycle approach process verification: Process improvement/adjustment due to raw material variability 3. How practically useful is QBD? 4. Steady state Validation or process Validation? Which is one is the appropriate approach?

Mia Wang
Manager MSAT
Genentech Inc.

Case Study

DOWNSTREAM

In-line Diafiltration (ILDF) – A Practical Solution for Continuous Buffer Exchange and Increased Plant Versatility

REGENERON
science to medicine®

The need for high productivity and cost efficient drug substance manufacturing has led key industry leaders to pursue continuous processing for biologics manufacturing. While continuous upstream processing, such as perfusion bioreactors, have been operated for decades, downstream purification technology and experience has been limited until recent years. The largest technology advancements in downstream have been centered on chromatography steps while progress with ultrafiltration and diafiltration (UF/DF) membrane steps have been limited to single-pass concentrators. With the absence of continuous buffer exchange technology, the UF/DF step must be operated in batch, or semi-batch, mode and is therefore the limiting factor to a fully integrated continuous downstream process.

The introduction of the In-Line Diafiltration (ILDF), using a staged, direct channel buffer injection, is the first opportunity the biopharmaceutical industry has had to implement continuous buffer exchange. This study experimentally characterized the buffer exchange performance of the ILDF prototype under a variety of conditions and shares two case studies of process implementation providing versatility in clinical and commercial production of monoclonal antibodies.

Christopher Cowan, Ph.D.
Senior Staff Engineer, Purification Development,Preclinicial Manufacturing Process Development (PMPD)
Regeneron Pharmaceuticals, Inc.

2:40-2:45 PM

Please Move to Your Next Session

2:45-3:15 PM

Keynote

UPSTREAM

Improving Single Use Bioreactor Design and Process Development – New Research Towards Intensifying Seed-Train and Scale-up Methods Using 5:1 Turn-Down

Operating bioreactor vessels at low working volumes (high turn-down ratio) is often desirable but brings about challenges in regard to mixing, mass transfer, and process control. Research done towards optimizing cell culture has provided methods to 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
- Maximizing your platform – Taking advantage of the unique Thermo Fisher Scientific Drilled Hole Sparge design and implementing a new Cross Flow Sparge into the headspace have yielded reliable mass transfer and cell culture results
- Improving bioprocess production – How new technology improves equipment utilization, scheduling efficiency, inventory logistics, and reactor harvest consistency

> Nephi Jones
> R&D Manager, Advanced Technology
> Thermo Fisher Scientific

3:15-4:15 PM

iSolve Meetings & Refreshment Break

4:15-4:50 PM

Solution Spotlight

PRODUCTION QUALITY & INNOVATION

Cleaning validation: Does your prospective CMO have what it takes to protect your molecule?

- The 5 critical questions to ask every CMO candidate about their cleaning validation program.
- How to assess your candidate's fitness for risk-based decision-making.
- Determining a CMO's ability to meet cleaning validation regulations that vary across the globe.
- Compliance is a spectrum: How to determine if you're a good fit for each other, and why that's important.

> Tyler Johnson
> Validation Section Manager, Drug Product Contract Manufacturing Services
> Pfizer CentreOne

Solution Spotlight

PRODUCTION QUALITY & INNOVATION

Optimizing New Facility Investment to Accelerate Time to Market

- Capital expenses (e.g. new facilities, line expansions, etc.) are undermanaged by the industry and new capital projects are under pressure to accelerate speed to market and/or reduce overall costs
- For biopharma projects, it's often more valuable to increase spending to accelerate than to try to cut costs
- We will discuss specific ways to accelerate capital projects (without sacrificing quality) and how to help your business make the value judgement between acceleration and cost reduction

> Garo Hovnanian
> Associate Principal
> McKinsey & Company

4:55-5:25 PM

Case Study

PRODUCTION QUALITY & INNOVATION

How to Minimise Batch Loss and Accident Rates Through Understanding Human Performance and Appropriate Error Reduction Methodologies Across Upstream and Downstream Processes

- How to tie your error reduction processes in to your company-wide operational excellence initiatives
- Identifying the critical steps in your operations and the appropriate human performance techniques to implement at each one
- Tactical error reduction – analysing processes to decide on the "point of no return"
- Understanding the human behaviours behind the methodology

> Julie Nielson
> Director of Engineering
> Amgen

5.25-5:55 PM

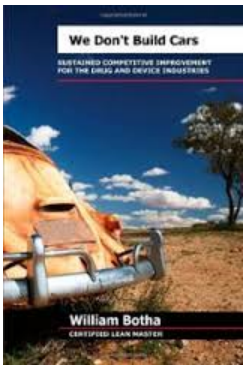
Plenary

PRODUCTION QUALITY & INNOVATION

Revolution Required in Biologics Production

William Botha addresses the rising need for Biologics teams to be faster, more agile, more responsive and certainly lift their quality levels by dissecting the industry's current culture and – using a recent case study – inspirationally provides a proven and effective solution set to those firms ready for the step up. He unpacks the mechanisms underlying culture change and explores the ways in which they can be utilised to fashion your own corporate culture.

> William Botha
> Sensei, Author of the book "We Don't Build Cars – Sustained Competitive Improvement for the Drug and Device Industries"



5:55-6:00 PM

Chair's Closing Remarks

Ashraf Amanullah Ph.D.
Vice President, Biologics Development and Manufacturing, aTyr Pharma

6:00-7:00 PM

Evening Drinks Reception

Day 2 – December, 13 2016 – Tuesday

7:30-8:30 AM

Interactive and Fun Knowledge/Skills Transfer Exercise/Workshop for Biotech Professionals

Delegates required to bring T-Shirts for the exercise, workshop limited to 24 delegates only

William Botha
Sensei, Author of the book "We Don't Build Cars – Sustained Competitive Improvement for the Drug and Device Industries"

7.50-8:30 AM

Registration

8:30-8:35 AM

Chair's Opening Remarks

Jonathan K. Romero
Director, Technical Operations
Celgene

8:40-9:15 AM

Keynote

PRODUCTION QUALITY & INNOVATION

Employing Lean Methodologies to Improve Production Processes and Reduce Cycle Times

- Achieving operational excellence by integrating a full lean manufacturing approach across organisational operations to cut costs
- Introducing lean working methods and six sigma principles to drive productivity levels throughout the organisation
- Decreasing sampling time, documentation and inside testing production to guarantee saving on time and resources
- Implementing performance management systems to review operational key performance indicators (KPIs) and promote operational excellence

Greg Guyer, Ph.D
Global Head & SVP, Biologics Operations and Process Development
Bristol-Myers Squibb

9:15 – 9:20 AM

Please move to your next session

9:20-9:55 AM

Case Study

UPSTREAM

Methodologies for Human Cell Manufacturing from Pluripotent Stem Cells in the Application of Regenerative Medicine

- Where are we going wrong? – Contrasting the scale-up manufacturing of adult cells versus stem cells, and analysing the advantages and disadvantages of both
- A look into novel technologies for the reproducible manufacturing of 1st & 2nd generation, highly-identified, purified products derived from pluripotent stem cells
- Case Study – the unique phenotype of pluripotent-stem-cell-derived cells that could improve the process of tissue repair

Michael D. West PhD.
CEO
BioTime

Case Study

DOWNSTREAM

Leveraging Predictive Modeling to Improve Your Development and Validation Efficiency

- Streamlining The Process of Bringing New Medicine Forward through to its Commercial Launch – A Genentech Case Study
- How to Maximise The Use of Your Data
- A Discussion on Data Integrity Challenges and How to Overcome Them
- IT Support Structures and Beneficial Computational Frameworks That Provide Insightful Information

James Patch
Principal Engineer, Purification Development
Genentech

9:55-10:50 AM

iSolve Meetings & Refreshment Break

10:50-11:25 AM

Case Study

UPSTREAM

Case Study for the Application of Computational Fluid Dynamics for Charac Up of Monoclonal Antibody Production Process

Use of both conventional and computational fluid dynamic (CFD) approaches to develop scale-down, pilot scale models of production bioreactors have resulted in improved process understanding and data driven transfers of late stage processes that take the "art" out of scale-up. Combining predictive scale down models and CFD in our development studies has allowed us to fully characterize ranges of engineering parameters and bioreactor type. These studies yield results that are more informative of how a process will perform at manufacturing scale and promote more robust scale-up. A case study of our approach to scale-up will be discussed.

Michelle LaFond
Director, Bioreactor Scale-Up and Development
Regeneron Pharmaceuticals Inc.

Case Study

DOWNSTREAM

A Universal Manufacturing Platform for Seasonal Flublok Production

Flublok® is a first recombinant influenza vaccine for seasonal influenza manufactured by Protein Sciences Corporation using our BEVS platform. . The production process consists of upstream cell culture and baculovirus infection followed by downstream purification. The downstream process includes extraction, depth filtration, ion exchange column chromatography (IEX), hydrophobic interaction chromatography (HIC), Q- membrane filtration, tangential flow filtration (TFF) and final filtration using a 0.2µm filter.

Current influenza vaccines need to be updated every year because of HA antigenic drift. The commercial Flublok process needs to be optimized for the new antigens. I will present the challenges for the seasonal influenza vaccine production. In addition, I will present results for the constant process and yield improvement such as: 1) Experimental evaluation of column resin lifetime; 2) Experimental determination of

column load limits; 3) Optimization of IEX Elution step by modifying the salt and detergent concentration and revising the volumes of elution fractions; 4) Implementation of Fed-Batch approach to increase the yield of recombinant hemagglutinin (rHA).

Dr. Elena Feshchenko
Associate Director
Protein Sciences Corp

11:25-11:30 AM

Please Move to Your Next Session

11:30-12:05 PM

Case Study

UPSTREAM

Integrating Continuous and Batch Operations for Efficient Initial Clinical Manufacturing of Biopharmaceuticals

Biopharmaceutical manufacturers envision that, as in other industries, continuous processing will provide significant improvement to operations and enable increased global access to medicine. One definition of fully continuous operation is that all inputs, outputs and parameters are at steady state. Konstantinov & Cooney in "White Paper on Continuous Bioprocessing May 20–21, 2014 Continuous Manufacturing Symposium" identified some of the advantages of continuous manufacturing as reduced equipment size, high-volumetric productivity, streamlined process flow, low-process cycle times, and reduced capital and operating cost.

To realize these advantages in an initial clinical manufacturing platform, analysis of individual Unit operations was done in collaboration with contract manufacturer and engineering design partners to define integrated and intensified process options. The mode of operation of each step from vial thaw, through expansions, production culture and purification to product packaging was considered for continuous, transition, periodic or batch operation. This presentation describes the use of deterministic process modelling to guide process definition, prototype assembly and operational testing.

Joseph McLaughlin
Associate Research Fellow, Bioprocess R&D, BRD Mfg
Pfizer

Case Study

DOWNSTREAM

Pre-Packed Chromatography Columns, Use in Large Scale Multi-Product Facility

- Economic drivers to move towards Pre-Packed columns
- Acceptance criteria and methodology for replacing traditional in-house packed columns
- Future of Pre-Packed columns

Carrie Mason
Senior Scientist DSP Team Lead, Mammalian Process Research And Technology
Lonza Biologics

12:05-12:10 PM

Please Move to Your Next Session

12:10-12:45 PM

Case Study

Case Study

UPSTREAM

Scalability Considerations for Technology Transfer Structures, Organizations, and Systems

Technology transfers at a small scale or earlier phases in a project may not need dedicated teams, governance models, or tools. Technology transfers in earlier phase products may only need small tech transfer teams and minimal tools. How to ensure that through the product lifecycle, that the tech transfer you're preparing for is the one you try to execute.

- Overview
- Considerations
- Case Study Examples

Ricardo Ibarra
Senior Process Development Engineer Technology Transfer
Bayer HealthCare

Jasmina Xie
Process Development Engineer Technology Transfer
Bayer HealthCare

PRODUCTION QUALITY & INNOVATION

Understanding the Process – Value-Adding Techniques for Ensured Manufacturing Process Control and Regulatory Compliance

- Do You Pass The Release Criteria? – Trends to look out for to improve your results
- Applying QFD and Statistical Modelling to Confirm Key Process Characteristics for the Successful Delivery of High End Product Quality
- The Importance of Using Real, Continuous Data to Determine the Impact your Manufacturing Process

Ron Ortiz
Director Manufacturing Science and Technology
Pacira Pharmaceuticals, Inc.

12:45-13:45 PM

Networking Lunch

LUNCH

13:45-14:20 PM

Case Study

UPSTREAM

How to Design Your Tech Transfer System to Maintain Consistency During a Complete Site Movement

- Acquisitions, and their challenges – what to do when you find yourself in the midst of a tech transfer with completely different quality systems and manufacturing processes
- The Key Do's and Don'ts
- How data can save you when transferring sites

Case Study

PRODUCTION QUALITY & INNOVATION

Strategy For an Integrated Analytical Development Approach Bridging Development & Manufacturing Activities.

- How to improve the connectivity of the analytical package and the manufacturing?
- Identifying earlier opportunities to build on the life cycle of the analytical package (methods, stability studies and specifications).
- Case Study and Lessons Learned
- Challenges of new technologies and worldwide implications.

Paul Maffuid
Executive Vice President Research and Development
MabVax Therapeutics

Vanessa Auquier, PhD
Analytical Product Owner (Corporate Analytical Sciences)
UCB BioPharma sprl

14:20-14:25 PM

Please Move to Your Next Session

14:25-15:10 PM

Case Study

PRODUCTION QUALITY & INNOVATION

A Pragmatic Enterprise Wide System for QbD Implementation Throughout Product Lifecycle

Shire

ICH and regulatory guidelines have made a compelling case for Quality by Design in pharmaceutical industry. However, organizations struggle with demonstrating a quantifiable value proposition associated with the enhanced approach. A pragmatic and system based approach to QbD, which is right sized for both legacy and new products, will be discussed. Features that allow integration both with internal manufacturing and CMOs will be highlighted. Key metrics that demonstrate the value proposition throughout lifecycle will be presented.

Naveen Pathak
Director Commercial CMC, Manufacturing Science & Technology
Shire Pharmaceuticals

Case Study

DOWNSTREAM

Multiproduct Resin Reuse for Biopharmaceutical Manufacturing

AMGEN

- The current approach of dedicating chromatography resins to a single product can result in substantial underutilization of the resin.
- A proposed methodology for extending resin reuse to multiple products will be described.
- General considerations for designing small-scale chromatographic studies for multiproduct resin reuse will also be described.
- In addition to increasing resin utilization, the proposed approach would reduce column packing, and resin handling and storage requirements.

Rizwan Sharnez
Scientific Director, Process Development
Amgen

Josh Jones
Director Manufacturing
Amgen

15:10-15:15 PM

Please Move To Your Next Session

15:15-16:00 PM

Keynote

PRODUCTION QUALITY & INNOVATION

Strategies for the Future and Evolutionary Trends in BioProcess Development and Production

Bristol-Myers Squibb Company

AMGEN

- What's next? – Market predictions for the future
- Challenges posed by Biosimilars

- Preparing for new manufacturing strategies
- The evolution of personalised medicines
- Areas of investment focus

Joseph McLaughlin
Associate Research Fellow, Bioprocess R&D, BRD Mfg (Session Chair)
Pfizer

Greg Guyer, Ph.D
Global Head & SVP, Biologics Operations and Process Development
Bristol-Myers Squibb

Josh Jones

Hao Chen, Ph.D

16:00-16:10 PM

Chair's Closing Address

MA Business

Mark Allen Group
St Jude's Church
Dulwich Road
London
SE24 0PB
United Kingdom

Switchboard:
+44 (0)20 7738 5454

Email:
mabconferences@markallengroup.com