SESSIONS

ON DEMAND SESSIONS - 19/09/2021

Process intensification, Way to achieving extreme biologics volumetric productivity

On demand

Participants

Xiao Pan, PhD - Director of Bioprocessing, GenScript ProBio

Expanding facility capacity through seed train and N bioreactor intensification

On demand

Participants

Charles Hill - Field Applications Scientist, Repligen

Advanced chromatography system design increases yield and reduces deviations

On demand

Participants

Steven Cates - Chief Technology Officer, Repligen

New Data: A Better Way to Run CHO Cell Culture Experiments

On demand

The bench-scale bioreactor has been the workhorse of Chinese hamster ovary (CHO) cell culture process development for decades. However, running benchtop bioreactors requires significant resources, infrastructure, and staffing. Tubing assembly, sterilization, calibration, and other setup activities can take hours to days. Tear down, cleaning, and deactivation are similarly burdensome. There are potentially large associated costs to prepare or purchase media, carry seed trains, and maintain facilities. Most critically, running bioreactors may be an inefficient use of staff hired to focus on innovation, experiment design, and complex data analysis â€" and not for daily sampling and monitoring trends. At the same time, consistent and expert laboratory operations remain essential to generating reproducible and reliable data.

To address these challenges, Culture Biosciences built a 250-mL bioreactor system that runs off site and in the cloud. Culture Biosciencesâ€™ high-throughput bioreactor infrastructure can reproducibly execute CHO cell culture experiments with scalable results. The data presented here should give confidence to upstream bioprocess engineers that Culture Biosciencesâ€™ cloud lab can be an effective resource for generating high-quality data to develop, optimize, and scale their cell culture processes. With access to more bioreactor capacity than ever before and advanced analytical software to generate insights faster, teams working with Culture Biosciences can spend more of their time focusing on what matters most: delivering quality bioproducts.

Key Takeaways:

Learn about a more efficient way to run cell culture experiments
See data showing how Culture Biosciences built a scalable and reproducible 250-mL cloud bioreactor system for cell culture development
Find out how upstream bioprocess scientists can use Culture Biosciencesâ€™ bioreactor system and real-time data visualizations to get faster insights and get their product to market more quickly.

Participants

Deborah Pascoe - Vice President of Operations, Culture Biosciences

Manufacturing CRISPR RNPs for Clinical Applications

On demand

David Yoder, Ph.D., Aldevron Senior Manager of Product Strategy, discusses how Aldevron has defined the optimal conditions for complexing, characterizing, and storing CRISPR RNPs created using the companyâ€™s research and GMP manufactured CRISPR/Cas proteins.

Participants

David Yoder - Senior Manager of Product Strategy, Aldevron

A TRANSFORMATIONAL PLATFORM THAT TRANSCENDS THE LIMITS OF LEGACY PROTEIN PRODUCTION TECHNOLOGIES- Dyadic Thermophilic Filamentous Fungus (C1 platform) Recombinant Production of Glycoprotein Antigen Vaccines, Antibodies & Other TherapeuticProtein Product - Mark Emalfarb, Dyadic International Inc, CEO"

3:20am - 4:20am

Participants

Mark Emalfarb - Chief Executive Officer, Dyadic International Inc

In-process control for pDNA production

4:20am - 4:50am

Global demand for pDNA production is at an all time high, due to increased need from Gene Therapy ramp-up. pDNA, as an enabling product, is critical in production of mRNA, AAV and other therapeutic vectors. Increasing yield and purity in the production of pDNA is a vital step in meeting such demand. Supporting reliable in-process control during pDNA purification, PATfix pDNA analytical platform is enabling rapid process development and optimization while providing a reliable analytical platform for production runs.

Participants

Blaž Bakalar - Product manager, BIA Separations a Sartorius company

Development and scale up of a manufacturing process for novel oral delivery of a traditional IV treatment

4:50am - 5:20am

Based in the UK, CPI is an RTO providing support to biopharmaceuticals and other advanced manufacturing industries often through multi-organisation collaborative programmes. A recent CPI collaborative project has been to support development of a treatment for the debilitating condition, Inflammatory Bowel Disease (IBD). Currently mAbs can be used to treat IBD such as Ulcerative Colitis and Crohn's. However, due to poor physiochemical stability, monoclonal antibodies (mAbs) are limited to parenteral delivery which can result in less than 1% of the drug reaching the target diseased site, limiting the efficacy of the treatment.

Through an Innovate UK funded collaboration, CPI was been working with Intract Pharma, a company offering novel oral delivery technologies in development of scalable manufacturing process for an innovative oral mAb treatment to IBD.

This case study demonstrates the breadth of CPI's capabilities and will update on the status of project in providing treatments for this debilitating disease

Participants

Julia Leach - Senior Scientist, Analytical, Centre for Process Innovation Limited

Forced degradation workflows in late Discovery: making the feasible routine

5:20am - 5:50am

Our biologics early development group brings forced degradation to the later part of Discovery pipeline screening efforts. To be successful, we have miniaturized the process of forced degradation by focusing on mass spectrometry as our main analytical technique because of its multi attribute cross-examination and broad applicability across biologic formats. Miniaturization and automation allow us to interact with early-stage development projects and perform robust chemical liability risk assessment with ~2 mg of material. For ADC screening, we have developed a homogeneous cross-functional workflow with the small molecule analytics group to integrate analysis of drug-linker surrogates. Combining protein-centered and small molecule analysis allows for a comprehensive, timely and pipeline appropriate risk assessment of biologic candidates to facilitate data driven decision making in late Discovery and early Development.

Participants

Alayna Thompson - Sr Research Scientist II, NBE ARD, AbbVie Inc

SCHEDULE

ON DEMAND SESSIONS - 19/09/2021

TIME	
12:00AM	**On demand** - Process intensification, Way to achieving extreme biologics volumetric productivity
1:00AM	**On demand** - Expanding facility capacity through seed train and N bioreactor intensification **On demand** - Advanced chromatography system design increases yield and reduces deviations **On demand** - New Data: A Better Way to Run CHO Cell Culture Experiments
2:00AM	**On demand** - Manufacturing CRISPR RNPs for Clinical Applications
3:00AM	**3:20am** - A TRANSFORMATIONAL PLATFORM THAT TRANSCENDS THE LIMITS OF LEGACY PROTEIN PRODUCTION TECHNOLOGIES-Dyadic Thermophilic Filamentous Fungus (C1 platform) Recombinant Production of Glycoprotein Antigen Vaccines, Antibodies & Other TherapeuticProtein Product - Mark Emalfarb, Dyadic International Inc, CEO"
4:00AM	**4:20am** - In-process control for pDNA production **4:50am** - Development and scale up of a manufacturing process for novel oral delivery of a traditional IV treatment
5:00AM	**5:20am** - Forced degradation workflows in late Discovery: making the feasible routine

SESSIONS

PRE-CONFERENCE WORKSHOP DAY - 20/09/2021

Coffee and Registration

9:00am - 10:00am

ROOM 257A: Single-Use Technologies for Cell and Gene Therapies

10:00am - 4:00pm
Pre-Conference Workshop - Single-Use Technologies for Cell and Gene Therapies

Overview:

An Introduction to Single-Use Technologies and the specific attributes and quality needs when implementing Single-Use Technologies in Cell and Gene Therapy Manufacturing. BPI's training workshop will focus on the importance and the implementation of Single- Use technologies in production of manufacturing facilities. The format of the course includes valuable and unbiased classroom instruction by industry expert James Dean Vogel, P.E. With Mr. Vogel's assistance, course participants will experience the latest Single-Use products first hand during the lab portion of the course.

Topics include:

- Brief Review of Cell and Gene Production Methods and Regulatory Considerations
- Single-Use Bioprocess Equipment - Materials of Construction
- Single-Use Advantages and Disadvantages
- Single-Use Requirements for Cell and Gene Therapies and Risks
- Single-Use Components available for Hands-On Demonstration

Attendees range from end-users, suppliers, sales and regulatory personnel who have a general understanding of the SUT industry and want to experience Single-Use products hands on!

Instructor:

James Dean Vogel, P.E., Founder and Director,

The BioProcess Institute

Participants

James Dean Vogel - Founder and Director , The BioProcess Institute

ROOM 257B: Principles and Practices of CMC Analytics for Cell and Gene Therapy

10:00am - 4:00pm
Pre-Conference Workshop - Principles and Practices of CMC Analytics for Cell and Gene Therapy

Course Objective: This quick but comprehensive tutorial will provide an overview of the regulatory and quality principles that guide the analytical studies for all biological products, with emphasis on the specific elements applicable to complex modalities such as gene and cell therapy. Emerging best practices in analytical methods for characterization, comparability, release and stability testing of gene and cell therapy will be presented. The rationale behind the requirements, with supporting references, will be provided. Attendees to this class will receive electronic copies of all reference guidances and publications discussed in the class.

Course Outline:

- Overview of CMC analytical regulatory deliverables for all biological products
- Specific additional guidances applicable to analytics of gene and cell therapy products
- Core principles of analytical characterization, comparability and control of complex biological products
- Practices for establishing the right 'analytical tool kit' for gene and cell therapy products
- Challenges in establishing product reference standards for use with complex biologics
- Emerging horizontal method standards for use with gene and cell therapy product analytical methods
- Key elements of compendial and non-compendial analytical methods lifecycles for biological products
- Quality requirements for documentation and data integrity of gene and cell therapy analytical studies
- Interactive Q&A with class speaker

Primary Audience:

- Analytical R&D scientists engaged in development of gene or cell therapy products
- QC analysts performing release and stability testing of biological products
- Process development scientists involved in process changes (eg scale up, process transfer)
- QA reviewers of analytical study protocols and reports for biological products
- Regulatory affairs staff preparing CMC sections for gene and cell therapy products
- Contract organizations conducting analytical testing of complex biologics such as gene and cell therapy products
- Project managers seeking an overview of the analytical strategies necessary for complex biological products

Instructor:

Nadine M. Ritter, Ph.D., President and Analytical Advisor, Global Biotech Experts, LLC

Participants

Nadine Ritter - President and Analytical Advisor, Global Biotech Experts, LLC.

ROOM 253C: Chairperson Opening Remarks

10:20am - 10:30am
Pre-Conference Workshop - Cell Line Development

Participants

Raja Srinivas - Founder, Asimov

ROOM 253C: High-throughput gene editing of CHO-K1 cells using Cas-CLOVER

10:30am - 11:00am
Pre-Conference Workshop - Cell Line Development

CHO cells are commonly used as the workhorse in protein biologic platforms. New advances in gene editing technology have provided the means to efficiently edit mammalian genomes with few off-target effects. We utilized the new gene editing technology, Cas-CLOVER (Demeetra), to edit thirty individual CHO-K1 host cell lines with different characteristics This yielded edited clones that were confirmed by orthogonal methods.

Participants

Tiffany McLamarrah - Scientist, Sanofi

SESSIONS

PRE-CONFERENCE WORKSHOP DAY - 20/09/2021

ROOM 253C: High Throughput Upstream Processing and Quality Analysis via Microfluidic Capillary Electrophoresis

11:00am - 11:30am
Pre-Conference Workshop - Cell Line Development

Characterization and quantification of biologics, such as monoclonal antibodies (mAbs), during production from cell cultures is essential to ensure that critical quality attributes (CQAs) are achieved. Cell culture production teams must determine which of their samples best meet these CQAs before moving to manufacturing. Often, the quality of samples is compromised during production (i.e. low yield, aggregation, fragmentation). Therefore, it is valuable to utilize strong analytical methods and instrumentation to help cell culture teams monitor biologic production and accurately characterize their samples. PerkinElmer provides a suite of instruments and assays that allow researchers to precisely and reproducibly characterize their biologics during and after production. Utilizing capillary gel electrophoresis (CGE) and capillary zone electrophoresis (CZE), PerkinElmer's LabChip® GXII Touch™ Protein Characterization System provides high throughput characterization of proteins and nucleic acids in as little as 42 seconds per sample, delivering data comparable to other methods of quantitation with as much as 70x increase in throughput. The system has been applied to measure yield, purity, aggregation, fragmentation, charge variation, and glycosylation profiles of numerous biological samples, including mAbs and Adeno-associated viruses (AAVs). Altogether, the microfluidic capillary electrophoresis system from PerkinElmer offers quick, accurate and reliable characterization of biologics at any stage of production.

Participants

James Geiger - Field Application Scientist, PerkinElmer, USA

Networking Break

11:30am - 12:00pm
Pre-Conference Workshop - Cell Line Development

ROOM 253C: Cell Line Development and Engineering for Novel Modalities

12:00pm - 12:30pm
Pre-Conference Workshop - Cell Line Development

Novel modalities of Biologics have emerged in many therapeutical areas due to their unique chemical/ physical structure advantages as well as efficacies. However, specific challenges also existed for these types of molecules because of their non-natural structure. A case study will be provided for an unique fusion protein to demonstrate the successful approaches from both cell engineering and process optimization perspectives.

Participants

Lianchun Fan, Ph D., Remote - Live with Q & A - Director of Cellular and Molecular Biology, Bioprocess Development, Abbvie Bioresearch Center

ROOM 253C: Providing increased assurance of clonality and clone stability in production cell lines

12:30pm - 1:00pm
Pre-Conference Workshop - Cell Line Development

The assurance of clonality and clone stability can be achieved through many approaches. Genetic studies including Targeted Locus Amplification technology, gene copy number analysis and high-throughput single cell qPCR together with flow cytometry-based intracellular staining method can provide direct evidence for clonal derivation, homogeneity and genetic stability.

Participants

Lina Chakrabarti - Senior Manager, R & D, Astrazeneca

ROOM 253C: An Integrated Data Approach For More Assured, Decision Making In Cell Line Development.

1:00pm - 1:30pm
Pre-Conference Workshop - Cell Line Development

When selecting techniques for single-cell seeding, capturing evidence for assurance, measuring growth monitoring and assays for lead clone selection, CLD scientists have a wide range of instruments and vendors to consider. Individually, each has its pros and cons in terms of workflow and the quality of the evidence generated for Assurance purposes.
Reporting on the same clone at multiple points in the process offers significant benefits in providing evidence that the colony was clonally derived as is favoured by Regulatory bodies. This can include evidence captured at time of seeding then again at Day0 and subsequent days. Furthermore, linking early titer to cell growth can provide a further level of internal process control as a form of continual verification.
However, when using multiple instruments from multiple vendors, varying levels of data quality, data security and formats generates a weakness in the Quality chain. Furthermore, it can be challenging to adequately control quality of process when consolidating data onto spreadsheets where the risk of â€˜copy and pasteâ€™ errors is high, not to mention time-consuming.
Single instruments that perform multiple aspects of CLD or single-vendor approaches that inherently integrate data under one unifying data management system can strengthen the quality of the data package, minimising risks of errors and save considerable work for lab scientists.
In this presentation a summary of recent developments in multi-assay / multi-time point instruments will be presented and the pros / cons of Single Vendor discussed in the context of the quality of data package delivery and time savings.

Participants

Ray Davis - Consultant, RuffLife Consulting

Lunch

1:30pm - 2:30pm
Pre-Conference Workshop - Cell Line Development

ROOM 253C: Effective Strategies To Help Speed Up Cell Line Development

2:30pm - 3:00pm
Pre-Conference Workshop - Cell Line Development

The generation of cell lines producing therapeutic proteins in pharmaceutical industry is an important step in the process development required for Biologics production. Different procedures and technologies can be used to generate cell lines with high titer and desired product characteristics. Here, we will present some of the challenges in the process and what strategies can be used to overcome them to help speeding up timeline.

Participants

Eva Rubio-Marrero, Ph.D. - Senior Scientist, Bristol Myers Squibb

ROOM 253C: Celltheon SMART Platform for DEPs: Scale-up in 200L Allegro STR

3:00pm - 3:30pm
Pre-Conference Workshop - Cell Line Development

Establishing a platform for developing and manufacturing therapeutic proteins that ensures predictable productivity and product quality will eliminate bottlenecks and in tech transfer. The Celltheon SMART Technology Platform in combination with Pall Biotech's manufacturing equipment addresses bottlenecks in tech transfer by accelerating time from cDNA to RCB within 4 months and ensuring scalability between 3L to 200L pilot scale with a pre-defined upstream and downstream processing platform for monoclonal antibodies and difficult to express proteins. The Celltheon SMART Technology Platform is a scalable mammalian expression system that includes novel expression elements and optimized CT-CHO cells. The Celltheon SMART Technology Platform results in homogenously high-expressing clones that are 4-6 fold higher than cell lines generated from unoptimized platforms and are stable for >121 generation. The Pall Allegro STR single-use bioreactors are optimally engineered to increase kLa and P/V, ensuring that scalability parameters are not limited in commercial production. In this case study, Celltheon demonstrates a workflow established with the Celltheon SMART Technology Platform in developing an RCB followed by scale-up to demonstrate reproducible productivity and product quality from 3L bench-scale bioreactor to pilot scale in the 200L Allegro STR single-use bioreactor.

Participants will learn about:

- Improvements in current mammalian expression platforms for difficult to express proteins (DEPs)
- Cell line development and scalability workflows
- Key features and advantages of using the Allegro STR Bioreactors

Participants

Divya Goel - Technology and Business Development, Celltheon

ROOM 253C: PANEL: Speeding Up Cell Line Development via Workflow Optimization Techniques and Technologies

3:30pm - 4:00pm
Pre-Conference Workshop - Cell Line Development

- Workflow tips to speed up Cell Line Development
- What are the different selection criteria?
- How do bispecific and fusion protein workflows differ to mabs?
- Thoughts on Pools of Clones for Phase 1 and beyond?
- Is the workflow goal clone selection?
- Successes and thoughts on targeted integration?
- What would be your ideal piece of technology?
- Technologies which allow for automation, high-throughput or online monitoring?
- Can resources be reduced?
- How much testing of candidate cell lines?
- Do you do sequence variance analysis early to prevent an unstable cell bank?

Participants

Eva Rubio-Marrero, Ph.D. - Senior Scientist, Bristol Myers Squibb

Tiffany McLamarrah - Scientist, Sanofi

Jean Qiu - Chief Technical Officer, Founder, Nexcelom

Divya Goel - Technology and Business Development, Celltheon

Raja Srinivas - Founder, Asimov

Cytiva Welcome Reception

4:00pm - 5:00pm

Cytiva is excited to meet everyone in person again! To celebrate we are hosting a beer, wine and Bavarian pretzel reception in our Welcome Lounge located outside of registration from 4pm-5pm on Monday, September 20. We look forward to seeing you.

SCHEDULE

PRE-CONFERENCE WORKSHOP DAY - 20/09/2021

Delivered as a Hybrid Event from September 20-30, 2021
Live In-Person Experience Delivered September 20-23
Boston Convention and Exhibition Center

TIME	PRE-CONFERENCE WORKSHOP - CELL LINE DEVELOPMENT	PRE-CONFERENCE WORKSHOP - PRINCIPLES AND PRACTICES OF CMC ANALYTICS FOR CELL AND GENE THERAPY	PRE-CONFERENCE WORKSHOP - SINGLE-USE TECHNOLOGIES FOR CELL AND GENE THERAPIES
9:00AM	**9:00am** - Coffee and Registration	**9:00am** - Coffee and Registration	**9:00am** - Coffee and Registration
10:00AM	**10:20am** - ROOM 253C: Chairperson Opening Remarks **10:30am** - ROOM 253C: High-throughput gene editing of CHO-K1 cells using Cas-CLOVER	**10:00am** - ROOM 257B: Principles and Practices of CMC Analytics for Cell and Gene Therapy	**10:00am** - ROOM 257A: Single-Use Technologies for Cell and Gene Therapies
11:00AM	**11:00am** - ROOM 253C: High Throughput Upstream Processing and Quality Analysis via Microfluidic Capillary Electrophoresis **11:30am** - Networking Break		
12:00PM	**12:00pm** - ROOM 253C: Cell Line Development and Engineering for Novel Modalities **12:30pm** - ROOM 253C: Providing increased assurance of clonality and clone stability in production cell lines		
1:00PM	**1:00pm** - ROOM 253C: An Integrated Data Approach For More Assured, Decision Making In Cell Line Development. **1:30pm** - Lunch		
2:00PM	**2:30pm** - ROOM 253C: Effective Strategies To Help Speed Up Cell Line Development		
3:00PM	**3:00pm** - ROOM 253C: Celltheon SMART Platform for DEPs: Scale-up in 200L Allegro STR **3:30pm** - ROOM 253C: PANEL: Speeding Up Cell Line Development via Workflow Optimization Techniques and Technologies		
4:00PM	**4:00pm** - Cytiva Welcome Reception	**4:00pm** - Cytiva Welcome Reception	**4:00pm** - Cytiva Welcome Reception

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

Coffee and Registration

7:00am - 8:00am

BALLROOM WEST: Conference Opening and Welcome

8:00am - 8:15am
Keynote Session

Participants

Muthiah (Mano) Manoharan, PhD - Senior Vice President of Drug Discovery, Alnylam Pharmaceuticals, Inc.

BALLROOM WEST: Keynote Presentation: RNAi Therapeutics: Past, Present, and (Mostly) Future

8:15am - 9:00am
Keynote Session

As we approach the 20 year anniversary of its first description in mammalian cells, RNAi has now emerged as a whole new class of medicines. With 4 marketed products and over a dozen programs in clinical development, Alnylam aims to continue to harness RNAi therapeutics for human health. An update will be provided on the past, present, and future efforts to bring RNAi therapeutics to patients.

Participants

John Maraganore, PhD, Remote - Live with Q & A - Chief Executive Officer, Alnylam Pharmaceuticals, Inc

BALLROOM WEST: Keynote Presentation: My Long Road from the 2'-5' Oligos to the mRNA Vaccine

9:00am - 9:45am
Keynote Session

Different types of RNA are weapons to fight against viruses. Inhibition of the viral replication can be achieved directly using 2'-5'-linked oligonucleotide that activates RNaseL, which degrades viral RNA. Long double-stranded RNA induce interferon with strong antiviral activity. Vaccination using nucleoside-modified mRNA encoding the viral antigen, and formulated in lipid nanoparticles induces humoral and cellular immune responses and provides protection against viral infection.

Participants

Katalin Karikó, PhD - Senior Vice President RNA Protein Replacement Therapy, BioNTech

Multiple Rooms: Refreshment Break and Morning Technology Workshops

9:45am - 10:25am

9:45-10:25am

Room 257AB: Strategies for stepwise implementation of process intensification (PI) in downstream bioprocessing for existing and new processes/ facilities (BREAKFAST INCLUDED)

As biological product pipelines become diverse, productivity demands and cost pressures are increasing. Future bio-manufacturing facility networks must be flexible to manage varying clinical and commercial molecule demands, accommodate innovative platforms, simplify technology transfers of various molecule types while maintaining a lower capital and operational cost of goods (COGs). Process Intensification (PI) is a practical approach to accelerating drug development, increasing productivity, reducing footprint, and improving quality. The talk defines the market trends, and process/ business needs driving manufacturers to evaluate and implement process intensification. Though the advantages of platform intensification are becoming well known across the industry, this presentation would also cover how a stepwise implementation of process intensification downstream would be best suited for bio manufacturers to significantly enhance productivity and throughput while achieving cost-effectivity in their existing facilities/processes.

Elliot Haimes , Field Applications Specialist for Chromatography, Sartorius

9:55-10:25am

Room 253AB: Rapid AAV titer quantification using a fully automated and scalable dPCR workflow

As gene therapies grow in numbers and scale, core technologies must keep pace with demands by providing the speed and throughput necessary for advancement. The QIAcuity Digital PCR technology exceeds these needs by offering comparable data to existing dPCR methods while delivering the walk-away automation, rapid time to results and unparalleled throughput required in the biomanufacturing environment.

A'Drian Pineda, Sr. Business Development Manager, digital PCR, QIAGEN

Participants

Elliot Haimes - Field Applications Specialist for Chromatography, Sartorius

A'Drian Pineda - Senior Business Development Manager, BioPharma, dPCR, NA, QIAGEN

ROOM 253AB: Chairperson's Remarks

10:25am - 10:30am
Cell Culture and Upstream Processing

Participants

Raja Srinivas - Founder, Asimov

ROOM 258 C: Chairperson's Remarks

10:25am - 10:30am
Recovery & Purification

Participants

Duncan Low - Executive Consultant, Claymore Biopharm

ROOM 210 B: Chairperson's Remarks

10:25am - 10:30am
Manufacturing Strategy & Bioprocessing 4.0

Participants

Chris Gemmiti, Ph.D. - Executive Director of Technical Operations; Head of Early Stage CMC and Product Launch Programs, CRISPR Therapeutics

ROOM 253 C: Chairperson's Remarks

10:25am - 10:30am
Intensified and Continuous Processing

Participants

Priyanka Gupta - Head of Market Entry Strategy, Sartorius

Mandar Dixit - Head of Value Chain Services, Sartorius Stedium Biotech

ROOM 253 C: Chairperson's Remarks

10:25am - 10:30am
Analytical & Quality

Participants

Priyanka Gupta - Head of Market Entry Strategy, Sartorius

Mandar Dixit - Head of Value Chain Services, Sartorius Stedium Biotech

ROOM 210A: Chairperson's Opening Remarks:

10:25am - 10:30am
Cell Therapy

Participants

Shashi Murthy, PhD - Founder & CTO, Flaskworks

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

ROOM 210B: Chairperson's Opening Remarks:

10:25am - 10:30am
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Participants

Chris Gemmiti, Ph.D. - Executive Director of Technical Operations; Head of Early Stage CMC and Product Launch Programs, CRISPR Therapeutics

ROOM 210C: Chairperson's Opening Remarks:

10:25am - 10:30am
In Vivo Gene Therapy

Participants

Jorge Santiago-Ortiz, Ph.D. - Director, Process Development, BioCentriq, USA

ROOM 253AB: Correlation of Online and Offline Techniques to Measure CHO Cell Health for Early Detection and Control of Cell Stress

10:30am - 11:00am
Cell Culture and Upstream Processing

Advances in automated bioreactor sampling and machine learning for imaged-based cell analysis have significantly improved our ability to quantify and monitor changes in cell health for bioprocessing development. Here we describe leveraging multiple methods of measuring cell health including the Canty cell imager with Flownamics SegFlow autosampler, biocapacitance probes, image-based and flow cytometry, and standard trypan blue-based quantitation to develop more representative models for online or at-line monitoring.

Participants

Kyle McHugh - Scientist, Bristol-Myers Squibb

ROOM 258 C: Extracellular Vesicles: Strategies for Their Engineering and Scalable Purification and Fractionation

10:30am - 11:00am
Recovery & Purification

- An overview of extracellular vesicles as tools for drug delivery
- Labelling and loading strategies for extracellular vesicles
- Chromatographic separation of differing extracellular vesicle populations

Participants

Dan Bracewell, Ph.D., Remote - Live with Q & A - Professor of Bioprocess Analysis, University College London

ROOM 210 B: Scale Up & Manufacture of CRISPR Gene Edited Hematopoietic Stem Cell (eHSC) Therapies for AML

10:30am - 11:00am
Manufacturing Strategy & Bioprocessing 4.0

Participants

Sadik H. Kassim - Chief Technology Officer, Vor Biopharma

ROOM 253 C: New Bioprocess Tools and Designs towards the Continuous Purification of Viral Vectors for Gene Therapy

10:30am - 11:00am
Intensified and Continuous Processing

Participants

Stefano Menegatti - Associate Professor, North Carolina State University, USA

ROOM 253 C: New Bioprocess Tools and Designs towards the Continuous Purification of Viral Vectors for Gene Therapy

10:30am - 11:00am
Analytical & Quality

Participants

Stefano Menegatti - Associate Professor, North Carolina State University, USA

ROOM 253AB: Correlation of Online and Offline Techniques to Measure CHO Cell Health for Early Detection and Control of Cell Stress

10:30am - 11:00am
Speed from Gene to Market

Advances in automated bioreactor sampling and machine learning for imaged-based cell analysis have significantly improved our ability to quantify and monitor changes in cell health for bioprocessing development. Here we describe leveraging multiple methods of measuring cell health including the Canty cell imager with Flownamics SegFlow autosampler, biocapacitance probes, image-based and flow cytometry, and standard trypan blue-based quantitation to develop more representative models for online or at-line monitoring.

Participants

Kyle McHugh - Scientist, Bristol-Myers Squibb

Please move to another track

10:30am - 11:00am
Cell Therapy

- Consistent, simple, and cost-effective incorporation into products
- What does it mean for product development?
- What are the quality specifications?

ROOM 210B: Scale Up & Manufacture of CRISPR Gene Edited Hematopoietic Stem Cell (eHSC) Therapies for AML

10:30am - 11:00am
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Participants

Sadik H. Kassim - Chief Technology Officer, Vor Biopharma

ROOM 210C: A Simple and Robust AAV Manufacturing System to Achieve High Titer And Quality Gene Therapy Vector

10:30am - 11:00am
In Vivo Gene Therapy

A basic system introduction, Bac-to-AAV vector system. Manufacturing process and results: a. extra rAAV titer, 100-fold higher than any system so far in the industry, b. simple and fast, c. robust, good quality consistency and d. extra viral safety profile to animal/human cell system. This system is several clinical phase III demonstrated systems and thousands of users are now using this system. This system is simple and robust which delivers to vectors very fast from idea to clinical. The system provides an extra viral safety profile.

Participants

Shenjiang (Shawn) Liu, Remote - Live with Q&A - President & CEO, Avirmax Inc.

ROOM 253AB: Evaluation of an Online PAT Co-Laboratory for Rapid Process Development

11:00am - 11:30am
Cell Culture and Upstream Processing

Accelerated process development requires rapid decision-making capabilities. Current offline sample testing approaches have long data turn-around times (TAT), are expensive and require extensive resources. PAT technology enables real time/right time testing resulting in improved process control and process knowledge while minimizing FTE resources. A cross-functional team comprising upstream, downstream engineers and analytical scientists successfully developed a non-GMP bench scale bioreactor model with online purification and product quality testing. Attributes monitored include process performance, titer, aggregation, charge variants, and post-translational modifications (PTMs). Results from traditional bench scale model (offline methods) were compared to online methods. Comparative results, a 10x reduction in data TAT, and >65% reduction in FTE resources per testing panel was observed compared to conventional testing. This co-laboratory model will be employed for future bench scale and pilot scale development enabling acceleration of product development activities.

Participants

Katrina Janiszewski - Development Specialist II, Takeda

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

ROOM 258 C: Development of ADC Purification Tool Box to Address Manufacturing Challenges

11:00am - 11:30am
Recovery & Purification

Butyl Sepharose HP has been used in ADC purification processes. However, efficient DAR separation can be quite challenging, and processing times are long due to the compressible nature of the resin matrix. To address these challenges, A unique POROS-Ethyl chromatography process was successfully developed to isolate the DAR species of an ADC having the structure of Ab-mc-vc-PABC-MMAE. Given its superior ability to separate DAR species and more favorable pressure-flow properties, POROS-Ethyl is an excellent addition to ADC HIC purification toolbox.

Participants

Dr Lihua Yang, Remote - Live with Q & A - Principal Scientist, Bioprocess Development, AbbVie

ROOM 210 B: Spotlight Presentation - Oxford Biomedica

11:00am - 11:30am
Manufacturing Strategy & Bioprocessing 4.0

ROOM 253 C: On-Line Monitoring of Metabolites and Glycosylation in High Cell Density Perfusion Process

11:00am - 11:30am
Intensified and Continuous Processing

Participants

Veronique Chotteau, PhD, Remote - Live with Q & A - Director, AdBIOPRO - Competence Centre for Advanced Bioproduction by Continuous Process, Sweden

ROOM 253 C: On-Line Monitoring of Metabolites and Glycosylation in High Cell Density Perfusion Process

11:00am - 11:30am
Analytical & Quality

Participants

Veronique Chotteau, PhD, Remote - Live with Q & A - Director, AdBIOPRO - Competence Centre for Advanced Bioproduction by Continuous Process, Sweden

ROOM 253AB: Evaluation of an Online PAT Co-Laboratory for Rapid Process Development

11:00am - 11:30am
Speed from Gene to Market

Accelerated process development requires rapid decision-making capabilities. Current offline sample testing approaches have long data turn-around times (TAT), are expensive and require extensive resources. PAT technology enables real time/right time testing resulting in improved process control and process knowledge while minimizing FTE resources. A cross-functional team comprising upstream, downstream engineers and analytical scientists successfully developed a non-GMP bench scale bioreactor model with online purification and product quality testing. Attributes monitored include process performance, titer, aggregation, charge variants, and post-translational modifications (PTMs). Results from traditional bench scale model (offline methods) were compared to online methods. Comparative results, a 10x reduction in data TAT, and >65% reduction in FTE resources per testing panel was observed compared to conventional testing. This co-laboratory model will be employed for future bench scale and pilot scale development enabling acceleration of product development activities.

Participants

Katrina Janiszewski - Development Specialist II, Takeda

ROOM 210A: Risk Based Approaches to Comparability

11:00am - 11:30am
Cell Therapy

- Comparability burden ranges
- When should you implement a risk-based approach/ how do you make sure you aren't going overboard on what you are doing?
- When is the best time to conduct comparability?
- Considerations when moving from early to late stage processes
- Design of comparability studies, test methods & establishing acceptance criteria

Participants

Silky Kamdar, Remote - Live with Q&A - Manager, BMS

ROOM 210B: Leveraging Platform Technologies for Gene Therapies

11:00am - 11:30am
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Drug development for Gene Therapies can be a complex undertaking. Learn how you can answer key challenges and pain points surrounding manufacturing and commercialization by leveraging proven platform technologies.

Participants

Jessica Carmen, PhD - US Business Development Adviser, Oxford Biomedica, USA

ROOM 210C: Optimisation of AAV Production: Transfection Matters

11:00am - 11:30am
In Vivo Gene Therapy

Participants

Hélène Trottin, Remote - Live with Q&A - Senior Technical Specialist, Process Sciences, Pharmaron

ROOM 253AB: Get More Molecules to the Clinic Faster with Automated Opto™ Cell Line Development

11:30am - 12:00pm
Cell Culture and Upstream Processing

CHO cell line selection represents a painful bottleneck in biotherapeutic development. The Opto™ CLD workflow on the Beacon® system accelerates CLD by integrating cell enrichment, cloning, culture, productivity and quality screening into a single, automated microscale process that generates the highest titer clones in just 5 days. With in-process detection of product aggregation and FDA-accepted monoclonality assurance, Opto CLD can save valuable development time and help de-risk the path to IND

Participants

Renee Tobias - Director CLD Product Management, Berkeley Lights

ROOM 258 C: Mechanistic modeling as a tool to streamline downstream process development, scale-up, and characterization

11:30am - 12:00pm
Recovery & Purification

Computer simulations have become an indispensable tool in many areas over recent decades, including aeronautics and the automotive industry. These dynamic models enable rapid prototyping, increase productivity, and accelerate innovation cycles. Nevertheless, biopharmaceutical process development and characterization mainly rely on a large number of expensive and time-consuming lab experiments. This approach is reaching its limit in the context of diversified development pipelines, greater economic pressures, changing regulatory expectations, and an increased focus on quality by design.

In recent years, the biopharmaceutical industry has started to adapt mechanistic models and digital twins for bioprocesses. This talk will outline the latest advances in applying mechanistic digital twins for chromatography. We will cover a diverse set of applications along the development life cycle, from early phase process definition to trouble shooting of manufacturing processes, while giving practical advice on how to establish modeling tools within an organization.

Participants

John Scibetta - Advanced Chromatography Specialist, GoSilico, now part of Cytiva

Please move to another track

11:30am - 12:00pm
Manufacturing Strategy & Bioprocessing 4.0

ROOM 253 C: Process Intensification: Selection Criteria and Impact on Facility Footprint and Sustainability

11:30am - 12:00pm
Intensified and Continuous Processing

As current biological product pipelines become more diverse, product demand and cost pressures are increasing. To meet these demands, manufacturers often evaluate implementing different elements of process intensification. This can be accomplished by making changes to either a few unit operations, the process, or even the type of facility itself. Intensified manufacturing has the potential to increase productivity, reduce timelines and process footprint, lower cost of goods, and/or unlock additional manufacturing flexibility.

This presentation addresses the drivers for intensified processing and provides a decision criteria matrix to choose the optimum intensified strategy based on the desired annual facility output. The presentation will assess the impact on the overall Cost of Goods by selecting different types of upstream and downstream intensification scenarios.

It will also show how selecting a specific process influences the overall facility footprint for the desired throughput demands. These solutions give multi-product facilities the flexibility to increase annual product output by up to 50%. Finally, the impact of the different types of Intensified processes on energy usage, water usage reported as the PMI index would be addressed as well.

Participants

Mandar Dixit - Head of Value Chain Services, Sartorius Stedium Biotech

Priyanka Gupta - Head of Market Entry Strategy, Sartorius

ROOM 253 C: Process Intensification: Selection Criteria and Impact on Facility Footprint and Sustainability

11:30am - 12:00pm
Analytical & Quality

As current biological product pipelines become more diverse, product demand and cost pressures are increasing. To meet these demands, manufacturers often evaluate implementing different elements of process intensification. This can be accomplished by making changes to either a few unit operations, the process, or even the type of facility itself. Intensified manufacturing has the potential to increase productivity, reduce timelines and process footprint, lower cost of goods, and/or unlock additional manufacturing flexibility.

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Mandar Dixit - Head of Value Chain Services, Sartorius Stedium Biotech

Priyanka Gupta - Head of Market Entry Strategy, Sartorius

ROOM 253AB: Get More Molecules to the Clinic Faster with Automated Opto™ Cell Line Development

11:30am - 12:00pm
Speed from Gene to Market

CHO cell line selection represents a painful bottleneck in biotherapeutic development. The Opto™ CLD workflow on the Beacon® system accelerates CLD by integrating cell enrichment, cloning, culture, productivity and quality screening into a single, automated microscale process that generates the highest titer clones in just 5 days. With in-process detection of product aggregation and FDA-accepted monoclonality assurance, Opto CLD can save valuable development time and help de-risk the path to IND

Participants

Renee Tobias - Director CLD Product Management, Berkeley Lights

ROOM 210A: Engineering of hemopoietic stem cells on the CliniMACS Prodigy®

11:30am - 11:50am
Cell Therapy

The recent successes in gene therapy for the treatment of rare blood disorders such as primary immunodeficiencies and hemoglobinopathies have highlighted the need for manufacturing processes that are robust and scalable in order to make gene therapy for monogenic diseases more applicable to the patients. Here we compare large scale lentiviral transductions performed on the CliniMACS Prodigy® (Miltenyi Biotec) involving hemopoietic stem cells (HSCs), to the "classical" manual transductions that are performed with the open handling steps in terms of efficacy and viability of the end product. Our results indicate that the CliniMACS Prodigy® generates higher transduction rates, combined with high viability compared to the manual process, but most importantly, with significantly lower variability. Thus the CliniMACS Prodigy® represents a closed system able to automatically perform complex processes as successfully as when manual handling steps are performed, but with higher predictability, efficiency and with minimal user interaction. This approach will greatly simplify and improve robustness of the manufacturing process and therefore is expected to promote the notion of automation to hemopoietic stem cell gene therapy.

Participants

Eleni Papanikolaou - Manager Hemapoietic Stem Cell Gene Therapy and Graft Engineering, Miltenyi Biotec, Germany

Please move to another track

11:30am - 12:00pm
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

ROOM 210C: Design, Manufacturing and Analytics of New AAV Reference Materials – A Case Study

11:30am - 11:50am
In Vivo Gene Therapy

Reference standards for gene therapy has been lacking, resulting in poor inter-lab and inter-product comparability. We developed a standardized production protocol and analytics panel for AAV1, AA2, AAV5, AAV6, AAV8 and AAV9 empty and full capsids to facilitate the testing of AAV gene therapy products. The production process and analytical results will be discussed. Lesson learned from this year-long endeavor will also be shared.

Participants

Jeffrey Hung - Chief Commercial Officer, Vigene Biosciences, Inc., USA

ROOM 210A: Custom Assay Development on the Accellix Automated Flow Cytometry Platform

11:50am - 12:05pm
Cell Therapy

To harness the potential of cutting-edge cellular engineering, stringent process controls must be put into place that monitor and measure critical parameters of the cell product at every step, from patient sample acquisition to drug product release. Accellix offers a streamlined flow cytometry workflow solution that couples dried ambient-stable reagents, automated cell sample preparation and data acquisition within a single-use microfluidic cartridge, and customized auto analysis. The combination results in robust multiparametric analysis with 'mix and read' simplicity, enabling standardized process controls for our cell and gene therapy customers.

In this talk we will review the process for developing custom assay kits and automated analysis, as well as provide an example of a custom drug-release assay for a CD19 CAR-T product. Data presented will highlight precision, accuracy and linearity of Accellix assays, demonstrating how the Accellix platform can bring the power of flow cytometry to the manufacturing floor.

Participants

Amanda Trent - Director of Assay Development, Accellix, Inc., USA

ROOM 210C: Mass Spectrometry Support for HCP Elisa In AAV Gene Therapy

11:50am - 12:05pm
In Vivo Gene Therapy

Residual Host Cell Proteins (HCP) are inevitable impurities in any biopharmaceutical product and a critical quality attribute relevant to the safety of gene therapy products. AAV viral vectors are typically manufactured using human cell lines like HEK293, which present a potentially complex proteome background. Contrasting with recombinant proteins purified from cell culture supernatant, the harvest of viral vectors typically relies on cell lysis, meaning the entire proteome may contribute to the HCP load presented to downstream purification processes where purification steps may also be limited in number, impacting the overall capacity to separate the virus product from other protein impurities. Adding to any technical challenges, gene therapy programs are often intended for severe indications, and more likely to be placed on an accelerated development pathway. This time pressure conflicts with the timeline required to develop a product-specific immunoassay, so the use of commercially available generic HCP detection ELISA kits is common practice from early-stage through late-stage viral vector product development. Quantification of HCPs by LC-MS is an unbiased orthogonal approach to ELISA detection wherein peptide standards can be spiked into test articles at defined concentrations providing a quantitative readout of HCP content while also providing for identification of the individual proteins detected. LC-MS is an advantageous strategy to use to report on commercial ELISA kit coverage, guiding refinement of AAV purification strategies on a faster timescale than is possible by product-specific ELISA development.

[HA1] [HA2]

[HA1]Typo in „commercially"

[HA2]English language publication may ask for decimal points instead of commas?

Participants

Andrew Hanneman - Scientific Advisor, Biologics Testing, Charles River Massachusetts, Biologics Division, USA

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

ROOM 258C: How new aseptic filling technologies can support faster clinical trial progress

12:05pm - 12:50pm
Sponsored Luncheon Presentation 1

Aseptic filling is a crucial step in advancing pipeline candidates into the clinic, where hard work in drug substance and drug product development culminates.

Whether you are bringing filling operations in-house or looking for a CDMO, this lunch and learn will help advance your strategy. Join Brendan Bradley from Cytiva and Brent Lieffers with Singota Solutions as they discuss how companies can reach the filling step faster and with less risk, covering the following topics:

How a closed robotic filling process reduces risk in the filling of high-value drug products
The influence of filling technologies on key quality and performance metrics
The benefits of selecting standardized containers and closures
The importance of creating user requirements, specifications, and batch documentation

Participants

Brendan Bradley - Business Development Manager, Aseptic Filling at Cytiva

Brent Lieffers - Senior Director or Operations, Singota Solutions

ROOM 253AB: Continuously improving DSP manufacturing by using JSR Life Sciences latest innovations: Amsphere A+ and ChromNeX

12:05pm - 12:50pm
Sponsored Luncheon Presentation 2

Learn about JSR Life Sciences latest innovations in downstream processing. Amsphere A+ is our new, re-engineered Protein A resin with higher capacity and enhanced NaOH stability for improved utility to deliver high performance affinity separation. ChromNeX is a DSP platform comprised of lattice-containing, prepacked chromatography devices that are stackable and will enable next generation manufacturing of biologics by overcoming bottlenecks and optimizing productivity. In this talk, we will present performance comparisons and various applications data.

Participants

Masayoshi Nagaya - Global Head of Marketing, JSR Life Sciences

ROOM 253C: Process Intensification: Benefits, Challenges and How to Overcome These Challenges

12:05pm - 12:50pm
Sponsored Luncheon Presentation 3

Diverse biological pipelines, varying drug throughput requirements and unpredictable demands are increasing manufacturing and cost pressures. To meet these demands, manufacturers often evaluate different process intensification scenarios. Process intensification is defined as a holistic framework to maximize overall productivity of the unit operation(s), manufacturing process and/or the facility output. Intensified processes have the potential to increase productivity and reduce cost of goods, reduce timelines, footprint and provide greater flexibility in existing facility or substantially reduce facility buildout times.

While there is no one size fits all approach for process intensification, it can offer several benefits depending on the process and facility. However, it requires careful consideration of some of the challenges that may come up. In this presentation, we will present some of the common challenges with intensified processes and how these can be overcome. We will present both upstream and downstream process intensification challenges, including how increased titer affects downstream processing, robust virus clearance validation for continuous downstream, handling varying product profile in continuous harvest obtained from perfusion processes as well as media and buffer management strategies. This presentation will be followed by a panel discussion.

Participants

Priyanka Gupta - Head of Market Entry Strategy, Sartorius

Mandar Dixit - Head of Value Chain Services, Sartorius Stedium Biotech

ROOM 210B: Critical Challenges and Potential Solutions For Successful Cell Therapy Manufacturing Process Development and Technology Transfer

12:05pm - 12:50pm
Sponsored Luncheon Presentation 4

The goal of process development for cell therapy manufacturing is to optimize methods that will enable robust, reliable, and cost-effective production of quality-assured therapeutic cells. In this presentation, we will provide examples of how PBS Biotechâ€™s contract services team solved process challenges associated with scalable expansion of mesenchymal stem cells (MSCs) and induced pluripotent stem cells (iPSCs).

Participants

Breanna Borys - PhD Candidate, PBS Biotech, Inc., USA

Sunghoon Jung PhD - Senior Director of Bioprocess Research & Development, , PBS Biotech, Inc., USA

ROOM 210A: CONSIDERATIONS IN CLARIFICATION OF AAV AND LENTIVIRUS

12:05pm - 12:50pm
Sponsored Luncheon Presentation 5

In recent years, development in the gene therapy industry has grown rapidly, with adeno-associated virus (AAV) and lentivirus (LV) making up two of the largest classes of viral vectors. A key process step in the manufacture of these vectors is clarifying the product from the cell culture. Depth and membrane filters, used widely in the recombinant protein industry, have generally translated well to the gene therapy industry. However, there are some key differences in performance that need to be considered when developing a gene therapy clarification process. In this work we look to optimize clarification processes using depth and membrane filter technologies. We will share data on both AAV and LV, produced in both adherent and suspension cell culture. We look at yield, impurity reduction, and capacity, and how these key outputs are influenced by key input parameters including feed characteristics (e.g. turbidity, cell density, serotype), filter characteristics (e.g. chemistry, pore size) and operating parameters (e.g. recovery procedure, scale). The data will provide insight into which inputs are most impactful to performance and guidance for process development.

Participants

Rajeshwar Chinnawar - Senior R&D Engineer, Pall Corporation, USA

Networking Refreshment Break

12:50pm - 1:25pm

ROOM 253AB: Chairperson's Remarks

1:25pm - 1:30pm
Cell Culture and Upstream Processing

Participants

Al Doig - Manager, BioProcess Technology Group, BDO

ROOM 258C: Chairperson's Remarks

1:25pm - 1:30pm
Recovery & Purification

Participants

Duncan Low - Executive Consultant, Claymore Biopharm

ROOM 258AB: Chairperson's Remarks

1:25pm - 1:30pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

ROOM 253AB: Chairperson's Remarks

1:25pm - 1:30pm
Intensified and Continuous Processing

ROOM 253C: Chairperson's Remarks

1:25pm - 1:30pm
Analytical & Quality

Participants

Li Zang, PhD - Director, Protein Analytics, Abbvie

Chairperson's Remarks

1:25pm - 1:30pm
Speed from Gene to Market

Participants

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

ROOM 210B: Chairperson's Opening Remarks

1:25pm - 1:30pm
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Participants

Mark Davis - Founder & Principal, NegotiumBio, LLC, USA

ROOM 253AB: Using Hybrid Continuous Biomanufacturing Approaches to increase efficiency and decrease cost in the manufacture of Biosimilars

1:30pm - 2:00pm
Cell Culture and Upstream Processing

There has been an increasing trend in developing unit operations that can been utilised in a continuous fashion, although fully continuous end to end operations are not fully realised yet there are opportunities to use these unit operations in a hybrid mode to increase output, reduce footprint and reduce cost of goods. Data from experiments to show effectiveness of these approaches with others concepts for future development.

Participants

Andrew Falconbridge, Remote - Live with Q & A - Vice President of Process Technology and Innovation, Alvotech

ROOM 258C: Challenges and Adventures in Purification Development for Novel Diabody

1:30pm - 2:00pm
Recovery & Purification

- Unique separation and purification challenges are presented by novel diabody format
- Non-platform process development is required to address process and product quality challenges
- A multi-tiered development approach drives development efficiency and quality

Participants

Jian Ren, Ph.D., Remote with Live Q & A - Senior Scientist, AbbVie

ROOM 258AB: Acceleration, Compliance, Uncertainties, Excellence: Lifecycle Turns 4.0 Too

1:30pm - 2:00pm
Manufacturing Strategy & Bioprocessing 4.0

- No other field has higher requirements for acceleration than C&GT and emergency preparedness (viz. ATMPs for pandemics).
- This will come from parallelizing activities and from disruptions in the MS&T model used for clinical and commercial development.
- The regulatory approval and successful launch in record time of a handful of safe and effective COVID-19 vaccines, based on distinct 'technology platforms', shows that biotech products development (e.g., biosimilars) could benefit from the acceleration and disruptions taking place in vaccines and cell & gene therapies space.
- This talk discusses how acceleration and uncertainties management can be built into the current model used to develop ATMPs while delivering high regulatory compliance and operational excellence levels.

Participants

José Menezes, Ph.D., Remote - Live with Q & A - Chairman, 4Tune Engineering

ROOM 253AB: Using Hybrid Continuous Biomanufacturing Approaches to increase efficiency and decrease cost in the manufacture of Biosimilars

1:30pm - 2:00pm
Intensified and Continuous Processing

There has been an increasing trend in developing unit operations that can been utilised in a continuous fashion, although fully continuous end to end operations are not fully realised yet there are opportunities to use these unit operations in a hybrid mode to increase output, reduce footprint and reduce cost of goods. Data from experiments to show effectiveness of these approaches with others concepts for future development.

Participants

Andrew Falconbridge, Remote - Live with Q & A - Vice President of Process Technology and Innovation, Alvotech

ROOM 253C: Clarification Challenges & Solutions for Gene Therapy Downstream Purification Process Development

1:30pm - 2:00pm
Analytical & Quality

Participants

Xiaotong Fu, PhD, Remote - Live with Q & A - Sr. Engineer, Biogen

ROOM 258AB: Acceleration, Compliance, Uncertainties, Excellence: Lifecycle Turns 4.0 Too

1:30pm - 2:00pm
Speed from Gene to Market

- No other field has higher requirements for acceleration than C&GT and emergency preparedness (viz. ATMPs for pandemics).
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- This talk discusses how acceleration and uncertainties management can be built into the current model used to develop ATMPs while delivering high regulatory compliance and operational excellence levels.

Participants

José Menezes, Ph.D., Remote - Live with Q & A - Chairman, 4Tune Engineering

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

ROOM 210A: Strategies for Maximizing MSC-EV Productivity and Lot Size

1:30pm - 2:00pm
Cell Therapy

- What challenges do this next gen product bring?
- Productivity & Cost considerations
- What are the parallels in manufacturing processes between exosomes and cell therapy?
- From a CMC perspective should they be viewed the same way as MSc?

Participants

Jon A. Rowley, Ph.D., Remote - Live with Q&A - Founder & Chief Product Officer, RoosterBio Inc.

ROOM 210B: High Throughput Upstream Processing and Quality Analysis via Microfluidic Capillary Electrophoresis

1:30pm - 2:00pm
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Participants

James Geiger - Field Application Scientist, PerkinElmer, USA

ROOM 253AB: Intensified Perfusion USP for ICB

2:00pm - 2:30pm
Cell Culture and Upstream Processing

Participants

William Napoli - Scientist, Sanofi

ROOM 258C: Challenges and strategies for large-scale production and purification of oncolytic viruses

2:00pm - 2:30pm
Recovery & Purification

- Large-scale production of oncolytic viruses is challenging, especially harvest and downstream purification
- Several critical quality attributes need to be considered
- Improved methods necessary, utilization of e.g. different harvest methods or virus release agents as well as purification methods
- Continuously intensified upstream processes and improved product understanding may require adaptation of DS strategy along the way

Participants

Alexander Brix, Ph.D., Remote - Live with Q & A - Head of Laboratory ATMP II, Boehringer Ingelheim Pharma GmbH & Co. KG

ROOM 258AB: Panel Discussion – Strategies to Accelerate and Optimize Process Development, Production and Time to Clinic for Novel Modalities

2:00pm - 2:30pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Panellist: Henning Gerschewski, Remote - Live with Q & A - VP Manufacturing Science & Technology, Rentschler Biopharma SE

Nadine Ritter - President and Analytical Advisor, Global Biotech Experts, LLC.

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

Andrew Tustian - Director, Regeneron Pharmaceuticals

Anthony Davies, Ph.D. - Founder & CEO, Dark Horse Consulting

ROOM 253AB: Sanofi Case Study: Upstream Continuous Processing

2:00pm - 2:30pm
Intensified and Continuous Processing

Participants

William Napoli - Scientist, Sanofi

ROOM 253C: Product Quality of antibody-based therapeutics direct from cell culture supernatants

2:00pm - 2:30pm
Analytical & Quality

Development and production of innovative biotherapeutics demands bioprocesses that consistently yield a high-quality product. However, current methods to determine product quality do not necessarily capture the actual mix of product and related impurities in cell culture supernatant, but rather what can be captured after purification. We developed a highly-sensitive method that can be applied to the detailed characterization of cell culture supernatants from bioreactors without a falsifying pre-purification step.

Participants

Jose Bonfiglio, Remote - Live with Q & A - Research Fellow, Roche

ROOM 258AB: Panel Discussion – Strategies to Accelerate and Optimize Process Development, Production and Time to Clinic for Novel Modalities

2:00pm - 2:30pm
Speed from Gene to Market

Participants

Panellist: Henning Gerschewski, Remote - Live with Q & A - VP Manufacturing Science & Technology, Rentschler Biopharma SE

Nadine Ritter - President and Analytical Advisor, Global Biotech Experts, LLC.

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

Andrew Tustian - Director, Regeneron Pharmaceuticals

Anthony Davies, Ph.D. - Founder & CEO, Dark Horse Consulting

ROOM 210A: iPSC Processes: Road to Automation and Closed System

2:00pm - 2:30pm
Cell Therapy

Participants

Cenk Sumen - Chief Technology Officer, Stemson Therapeutics

ROOM 210B: bluebird bio Supply Chain Strategy Case Study

2:00pm - 2:30pm
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Participants

Roy Sorek, Remote - Live with Q&A - Director, Quality Assurance, bluebird bio

ROOM 253AB: Manufacturing Next-Generation Multi Domain Protein Pharmaceuticals Using the Leap-In Transposase's Platform

2:30pm - 3:00pm
Technology Workshop 1

Since 1986 when the first protein therapeutics were approved, the field has seen a transition from standard antibodies to complex multidomain molecules engineered for optimal target recognition, pharmacokinetics, biodistribution, and therapeutic function. Increasingly these next generation protein pharmaceuticals consist of three, four or more protein chains resulting in complex and expensive manufacturing. ATUM has discovered, characterized, and engineered multiple orthologous new transposon-transposase pairs that efficiently facilitate the generation of high producing stable cell lines while allowing for an unprecedent control of chain ratios, modifying enzymes and other quality attributes accessible through genome engineering of the cell line. The Leap-In TransposaseÂ® is an engineered enzyme that catalyzes the integration of a transposon and your gene of interest into the target genome. The technology enables a specified sequence of interest to behave as a transposon, a mobile genetic element, which can efficiently transpose between vectors and chromosomes via a â€œcut & pasteâ€? mechanism. During transposition, the Leap-In TransposaseÂ® recognizes transposon-specific inverted terminal repeat sequences (ITRs) located on both ends of the transposon vector and moves the contents from the original sites and efficiently integrates them into alternative chromosomal sites. Using our Leap-In transposaseÂ® technology in combination with the VectorGPSÂ® design platform, and GeneGPSÂ® recoding we can design, synthesize, and transfect several orthogonal synthetic transposons in parallel, each harboring multiple independently controlled, codon-optimized ORFs with altered expression ratios. The presentation will include case studies showcasing how this technology significantly accelerates timelines while simultaneously increasing yield and stability for stable pool and cell-line generation.

Participants

Oren Beske, Ph.D. - Amalgamator of Business and Biology, ATUM

ROOM 258C: Production of Protein Therapeutics in CHO Cells

2:30pm - 3:00pm
Technology Workshop 2

Production of Protein Therapeutics in CHO Cells

The production of recombinant therapeutic proteins requires the use of a host organism. Commonly used host organism for protein production include CHO, E. coli, P. Pastoris, and S. cerevisiae. The popularity of CHO for mammalian cell-based production is mainly due to its capacity for efficient protein folding, and post-translational modifications such as glycosylation compatible with humans at manufacturing scale. There are many therapeutic proteins approved by the FDA which are produced in various CHO cells such as CHO-S, CHO-K1, CHOK1SV, and CHO DG44. The time required to produce a therapeutic protein can add substantial cost to a project. Therefore, much attention has been given to developing CHO platforms that decrease the time necessary to bring a new protein into manufacturing. Cytovance has been working with the FreedomTM CHO-STM expression system for several years and we have developed a platform to enable the rapid generation of clinical material. Some of the data generated by Cytovance in the development of this platform will be presented.

Speaker: Stephanie Wickham, PhD, Sr. Director of Research and Development

Participants

Stephanie Wickham, PhD - Sr. Director of Research and Development, Cytovance Biologics

ROOM 253C: Practical Application of ISO Cell Counting Standards to Improve the Quality of Cell Counting Measurements

2:30pm - 3:00pm
Technology Workshop 4

Practical Application of ISO Cell Counting Standards to Improve the Quality of Cell Counting Measurements

Biological samples range in complexities and require various considerations, formulations, and bioprocessing steps depending on intended utilization. As there are no ground truth reference materials for live cells, determining the accuracy of cell counting becomes challenging. Therefore, to increase the confidence of cell counting results, following the ISO cell counting standards is necessary to ensure the appropriate cell counting methods are selected and evaluated.

In this webinar, we will discuss six key factors impacting the selection of a fit-for-purpose cell counting method and the quality of measurements, as described in the ISO Cell Counting Standard ISO 20391-1:2018 Biotechnology Cell counting Part 1: General guidance on cell counting methods.

1. Determine the intended use of the intended cell counting result
2. Investigate to understand cell sample composition
3. Methodologies of cell population identification
4. Cell counting system considerations
5. Cell counting process optimization
6. Consistent and robust operator training

As a member of the US Technical Advisory Group, led by the National Institute of Standards and Technology (NIST) in collaboration with FDA, we have actively participated and contributed to the development of the ISO Cell Counting Standards 20391-1:2018 Part I and ISO 20391-2:2019 Part II: Experimental design and statistical analysis to quantify counting method performance.

Speaker: Leo Chan PhD, Head of Advanced Technology Research and Development, Nexcelom

Participants

Leo Chan - Head of Advanced Technology Research and Development, Nexcelom

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

ROOM 210A: Scalable and Customizable Solutions for Cell and Gene Therapy Manufacturing

2:30pm - 3:00pm
Cell Therapy

Advancing cell and gene therapy research towards the clinic requires quality reagents to meet the GMP standards. Bio-Techne supports the entire workflow providing solutions for Cell Separation, Cell culture, Genome Editing, Product Release Testing for Cell Manufacturing and Monitoring Efficacy and Toxicity. Bio-Techne also provides options to customize reagents to support a variety of manufacturing process. In this talk we will discuss some of the tools and custom reagent options that will enhance your cell and gene therapy manufacturing processes.

Participants

Nithya Jesuraj - Product Manager, CGT, Bio-Techne, USA

ROOM 210B: Big Solutions Come in Small Packages: Expanding Sterile Connection Technology to Small-Format Product or Process Fluid Volume Transfer Applications

2:30pm - 2:50pm
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

In state-of-the-art cell therapy and gene therapy manufacturing, you're challenged to engineer and operate processes that are robust, reliable and repeatable. Building on the inventiveness of CPC and its AseptiQuik® Series Connectors, the leader in single-use connection technology, the company's new MicroCNX™ Series Connectors provide a modern alternative to the tube welding process. Learn how this new category of aseptic micro-connectors provides a simple, efficient method of connecting tubing for small format assemblies to help manufacturers improve efficiencies, reduce time and total cost, and mitigate risk.

Participants

Jayanthi Grebin - Sr. Business Development Manager CGT, CPC - Colder Products Company

ROOM 210B: Evaluation of novel affinity resin with alkali stable ligand for AAV viral vectors

2:50pm - 3:10pm
Gene Edited Ex Vivo Cell Therapy / In Vivo Gene Therapy

Purification of recombinant AAV viral vectors from cell lysates can be considered a technical challenge especially if the economic burden for commercial manufacturing is considered. Currently available affinity resins for AAV9 purification deliver reasonable reduction in Host Cell Protein (HCP) at relevant binding capacities and yields. However, the inability to use efficient CIP solutions may have a strong impact on the cost of the capture step.

We will present results from a benchmarking study evaluating a commercially available novel affinity resin for purification of AAV9 capsids. The resin was developed for purification of capsids from clarified and concentrated cell lysates. It is (based on) an alkali stable ligand that enables sanitization using NaOH and extensive cycling. The evaluation of the resin will be based on yield, capacity, HCP reduction and reusability. In addition, a comprehensive review of the analytical results obtained from the perspective of different manufacturing scenarios will be provided, including process economics.

Participants

Nagendra Singh, Remote - Live with Q&A - Senior Scientist, Downstream Process Development, Catalent Cell & Gene Therapy, USA

Grand Opening of the Poster & Exhibit Hall and Refreshment Break

3:10pm - 3:55pm

Chairperson's Opening Remarks

3:55pm - 4:00pm
In Vivo Gene Therapy

Participants

Stefano Menegatti - Associate Professor, North Carolina State University, USA

Chairperson's Remarks

4:00pm - 4:05pm
Plenary Session

Participants

Howard Levine, PhD - National Leader, BioProcess Technology Group

ROOM 210A: Selection & Management of Suppliers and Contract Service Providers

4:00pm - 4:20pm
Cell Therapy

- Criteria
- Qualification
- Quality Agreements

Participants

Ruti Goldberg, Remote - Live with Q&A - Compliance and Methods Validations Manager, Pluristem

ROOM 210B: Manufacturing process optimization during early- and late-stage development

4:00pm - 4:30pm
Gene Edited Ex Vivo Cell Therapy

- Development of TCR-engineered T cell therapies against novel targets for solid tumors
- Case study for optimized vein-to-vein time
- Outlook for closed system automated for late-stage development

Participants

Ali Mohamed - Vice President, CMC, Immatics, USA

SESSIONS
CONFERENCE DAY 1 - 21/09/2021

ROOM 210C: Developing an Integrated Manufacturing Process and Platform to Increase Speed to Clinic

4:00pm - 4:30pm
In Vivo Gene Therapy

- At Homology Medicines, we have increased our speed to the clinic by implementing a "plug and play" internal commercial GMP manufacturing process and platform designed to deliver transformative genetic medicines in vivo through multiple modalities, including different approaches to gene therapy and nuclease-free gene editing, across a broad range of genetic disorders.
- Having a well-established and proven platform based on a family of 15 naturally-derived AAVs that enables us to select the best capsid for each target based on the tissue tropism has allowed us to quickly execute multiple programs and support having three clinical programs by the end of this year.
- Formation of the platform was accomplished by early investment in internal Process Development and Manufacturing with methodical Research collaboration on construct design.
- Using the platform process allowed for robust manufacturing up to 2,000L bioreactor scale by limiting differences in process step execution and associated analytics across pipeline candidates; we now have 3,500L of active capacity.
- Deep understanding of vector purity and high-titer impact on process performance was enabled through in-depth analytical characterization across our project platform.
- We have developed more than 40 analytical methods and have a deep internal characterization capability
- We have executed more than 500 constructs and more than 600 unique lots
- Recent data supporting our platform and process have demonstrated:
- Our ability to drive higher productivity and achieve higher quality vector across all scales through a single design change that gives us both transfection improvements, a cleaner vector profile and a more potent vector
- Our new platform formulation that delivers greater stability and allows us to move away from frozen storage to cold storage, which is intended to support our clinical programs and eventually our commercial products
- Continued optimization of our process and platform has yielded greater than 50% efficiencies in subsequent programs.
- This approach has empowered us to quickly and effectively build a robust genetic medicines pipeline, with four development candidates to-date and a fifth one expected by the end of this year from our new gene therapy antibody program (GTx-mAb platform).

Participants

Alex Meola - Scientist II, Downstream Process Development, Homology Medicines

ROOM: Ballroom West Keynote Address - BioManufacturing During a Pandemic When You're Not Making a COVID Vaccine

4:05pm - 4:45pm
Plenary Session

- Biomanufacturing during the pandemic has been challenging, especially for companies that are not making a COVID vaccine. This keynote address will focus on the key challenges and mitigation measures that these companies have performed to keep the flow of life-saving therapies on-line.
- Highlight techniques for keeping manufacturing on track during supply chain shortages
- Discuss the lessons learned from the current pandemic in order to protect biomanufacturers during the next pandemic. Provide an outlook for what the "new normal" will look like

Participants

Charles Sardonini, PhD - Head, Drug Substance Manufacturing for Biologics – Upstream Processing, Sanofi

ROOM 210A: Cell Therapy Raw Materials Customization

4:20pm - 4:40pm
Cell Therapy

Participants

Lili Belcastro - Principal Scientist, Technical Center of Excellence (TCoE) for Cell Therapy Raw Materials, BMS

ROOM 210B: PANEL: Let's Settle the Debate – Can Auto and Allo Therapies Co-Exist

4:30pm - 5:00pm
Gene Edited Ex Vivo Cell Therapy

- Do Allo therapies still have to much risk associated?
- Will auto eventually fade out? Or will there always be a demand for them?
- What needs to change in the current process/ manufacturing of cells to allow for allo success?
- Where are the biggest and most successful stride being seen?

Participants

Jon A. Rowley, Ph.D., Remote - Live with Q&A - Founder & Chief Product Officer, RoosterBio Inc.

Ali Mohamed - Vice President, CMC, Immatics, USA

Armon Sharei - Chief Executive Officer & Founder, SQZ Biotechnologies, USA

Cenk Sumen - Chief Technology Officer, Stemson Therapeutics

ROOM 210C: Mechanistic Modelling for the Production of Recombinant Adeno-Associated Virus via Triple Transfection of HEK293 Cells

4:30pm - 5:00pm
In Vivo Gene Therapy

Case Study

Participants

Tam Nguyen - PhD Candidate, Massachusetts Institute of Technology, USA

ROOM 210A: Fitting Product to Process: Raw Materials Customization for Cell Therapy Manufacturing Success

4:40pm - 5:00pm
Cell Therapy

Participants

Raymond Luke - Associate Director, MS&T, Adaptimmune, USA

ROOM Ballroom West: Plenary Panel Discussion: Achieving supply Chain Continuity to Overcome Supply Chain Disruption Related to COVID-19 Response

4:45pm - 5:30pm
Plenary Session

Participants

Panelist:: Charles Sardonini, PhD - Head, Drug Substance Manufacturing for Biologics – Upstream Processing, Sanofi

Vasell Dillard - Director of Supply Chain, Macrogenics

Jim Marshall - Associate Director, Devens Supply Chain, Bristol-Myers Squibb

Howard Levine, PhD - National Leader, BioProcess Technology Group

Christine Callahan - VP of Supply Chain, Thermo Fisher

ROOM 210B: Quality by Design (QbD) for Adeno-Associated Virus (AAV) Products

5:00pm - 5:30pm
Cell Therapy

The FDA rejected several manufacturers of gene therapy products in 2020 due to insufficient data in the chemistry, manufacturing and controls (CMC) documentation. A key aspect to the CMC documentation of such complex biological products is the application of QbD principles: a rationale of quality being achieved by process design rather than relying on final quality testing alone. This case study gives an example of how QbD can be applied to an AAV gene therapy product.

The four most prominent AAV manufacturing platforms were evaluated: transfection of either 1) adherent or 2) suspension HEK (Human Embryonic Kidney) cells, and infection-based productions through 3) adenovirus infection of HeLa producer cells or 4) baculovirus infection of Sf 9 (Spodoptera frugiperda) insect cells. The process and product related impurities as well as adventitious agents in the AAV reference processes were identified as critical quality attributes (CQA).

A preliminary hazard analysis (PHA) of the quality attributes assessed the criticality based on the effect on patient safety and the level of evidence and likelihood thereof and identified 14 CQAs for the AAV platforms. For each manufacturing step, from media filtration in upstream processing (USP) to final sterile filtration of the AAV drug substance, the relevant CQAs were identified combining literature, industry and in-house data as well as knowledge from subject matter experts at Pall Corporation. Critical material attributes (CMAs) and critical process parameters (CPPs) for each step in the process were evaluated. The QbD assessment was completed with an example of a control and testing strategy. It summarizes methods of CPP and CMA control and provides an overview of possible stages, methods and acceptance criteria for CQA testing.

This work shows that a wide process understanding is already created within the industry despite AAV manufacture being a new field in biopharmaceutical production. Bridging available knowledge allows the mapping of the relevant CQAs affected at each stage of USP and downstream processing (DSP) operation and identify the critical parameters to be controlled for assurance of AAV quality and patient safety. With several approved gene therapies and hundreds of products in the pipeline, industry knowledge is building at an unprecedented pace. At the same time, the regulatory framework is rapidly developing which is increasing confidence in interpreting guidelines and building regulatory maturity within both industry and regulators. Data and detailed process understanding thereby supports the prior knowledge needed to implement risk-based QbD strategies. By combining expert and industry knowledge in this work the authors intend to support the continuous advancement of gene therapy products for the benefit of patients.

Participants

Parth Trivedi M.S. - Team Manager, Pall Corporation, USA

ROOM 210B: Quality by Design (QbD) for Adeno-Associated Virus (AAV) Products

5:00pm - 5:30pm
Gene Edited Ex Vivo Cell Therapy

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Participants

Parth Trivedi M.S. - Team Manager, Pall Corporation, USA

SESSIONS

CONFERENCE DAY 1 - 21/09/2021

Cocktail Reception in the Poster & Exhibit Hall

5:30pm - 7:00pm

End of Day One

7:00pm - 7:05pm

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
7:00AM	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration	**7:00am -** Coffee and Registration

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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8:00AM								**8:00am** - BALLROOM WEST: Conference Opening and Welcome **8:15am** - BALLROOM WEST: Keynote Presenta-												

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
								tion: RNAi Therapeutics: Past, Present, and (Mostly) Future												

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

BioProcess International

Delivered as a Hybrid Event from September 20-30, 2021
Live In-Person Experience Delivered September 20-23
Boston Convention and Exhibition Center

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9:00AM	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:00am -** BALLROOM WEST: Keynote Presentation: My Long Road from the 2'-5' Oligos to the mRNA Vaccine **9:45a**	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops	**9:45am -** Multiple Rooms: Refreshment Break and Morning Technology Workshops

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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								m - Multiple Rooms : Refreshment Break and Morning Technology Workshops												

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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10:00AM	**10:25am** - ROOM 253 C: Chairperson's Remarks **10:30am** - ROOM 253 C: New Bioprocess Tools and Designs	**10:25am** - ROOM 253AB: Chairperson's Remarks **10:30am** - ROOM 253AB: Correlation of Online and Offline Techniques	**10:25am** - ROOM 210A: Chairperson's Opening Remarks: **10:30am** - Please move to another track		**10:25am** - ROOM 210B: Chairperson's Opening Remarks: **10:30am** - ROOM 210B: Scale Up & Manufacture of CRISPR Gene	**10:25am** - ROOM 210C: Chairperson's Opening Remarks: **10:30am** - ROOM 210C: A Simple and Robust AAV Manufactur-	**10:25am** - ROOM 253 C: Chairperson's Remarks **10:30am** - ROOM 253 C: New Bioprocess Tools and Designs		**10:25am** - ROOM 210 B: Chairperson's Remarks **10:30am** - ROOM 210 B: Scale Up & Manufacture of CRISPR Gene Edited		**10:25am** - ROOM 258 C: Chairperson's Remarks **10:30am** - ROOM 258 C: Extracellular Vesicles: Strategies for	**10:30am** - ROOM 253AB: Correlation of Online and Offline Techniques to Measure CHO Cell Health for Early Detection							

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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	towards the Continuous Purification of Viral Vectors for Gene Therapy	to Measure CHO Cell Health for Early Detection and Control of Cell Stress			Edited Hematopoietic Stem Cell (eHSC) Therapies for AML	ing System to Achieve High Titer And Quality Gene Therapy Vector	towards the Continuous Purification of Viral Vectors for Gene Therapy		Hematopoietic Stem Cell (eHSC) Therapies for AML		Their Engineering and Scalable Purification and Fractionation	and Control of Cell Stress								

SCHEDULE

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11:00AM	**11:00am** - ROOM 253 C: On-Line Monitoring of Metabolites and Glycosylation in High Cell Density Perfusion Process	**11:00am** - ROOM 253AB: Evaluation of an Online PAT Co-Laboratory for Rapid Process Development **11:30am** - ROOM	**11:00am** - ROOM 210A: Risk Based Approaches to Comparability **11:30am** - ROOM 210A: Engineering of hemopoietic		**11:00am** - ROOM 210B: Leveraging Platform Technologies for Gene Therapies **11:30am** - Please move to another	**11:00am** - ROOM 210C: Optimisation of AAV Production: Transfection Matters **11:30am** - ROOM 210C: Design,	**11:00am** - ROOM 253 C: On-Line Monitoring of Metabolites and Glycosylation in High Cell Density Perfusion Process		**11:00am** - ROOM 210 B: Spotlight Presentation - Oxford Biomedica **11:30am** - Please move to another track		**11:00am** - ROOM 258 C: Development of ADC Purification Tool Box to Address Manufacturing Challenges **11:30am** -	**11:00am** - ROOM 253AB: Evaluation of an Online PAT Co-Laboratory for Rapid Process Development **11:30am** - ROOM							

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
	11:30am - ROOM 253 C: Process Intensification: Selection Criteria and Impact on Facility Footprint and Sustainability	253AB: Get More Molecules to the Clinic Faster with Automated Opto™ Cell Line Development	stem cells on the CliniMACS Prodigy® **11:50am** - ROOM 210A: Custom Assay Development on the Acellix Automat-		track	Manufacturing and Analytics of New AAV Reference Materials – A Case Study **11:50am** - ROOM 210C: Mass Spectrome-	**11:30am** - ROOM 253 C: Process Intensification: Selection Criteria and Impact on Facility Footprint and Sustainability				ROOM 258 C: Mechanistic modeling as a tool to streamline downstream process development, scale-up, and characteri-	253AB: Get More Molecules to the Clinic Faster with Automated Opto™ Cell Line Development							

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
			ed Flow Cytometry Platform			try Support for HCP Elisa In AAV Gene Therapy					zation									

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
12:00PM	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:05pm** - ROOM 258C: How new aseptic filling technologies can support faster clinical trial progress **12:50p**	**12:05pm** - ROOM 253AB: Continuously improving DSP manufacturing by using JSR Life Sciences latest innova-	**12:05pm** - ROOM 253C: Process Intensification: Benefits, Challenges and How to Overcome These Challenges **12:50pm** -	**12:05pm** - ROOM 210B: Critical Challenges and Potential Solutions For Successful Cell Therapy Manufacturing Process De-	**12:05pm** - ROOM 210A: CONSIDERATIONS IN CLARIFICATION OF AAV AND LENTI VIRUS **12:50pm** - Network-	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break	**12:50pm** - Networking Refreshment Break

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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													m - Networking Refreshment Break	tions: Amsphere A+ and ChromNeX **12:50pm** - Networking Refreshment Break	Networking Refreshment Break	velopment and Technology Transfer **12:50pm** - Networking Refreshment Break	ing Refreshment Break			

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
1:00PM	**1:25pm** - ROOM 253C: Chairperson's Remarks **1:30pm** - ROOM 253C: Clarification Challenges & Solutions for Gene	**1:25pm** - ROOM 253AB: Chairperson's Remarks **1:30pm** - ROOM 253AB: Using Hybrid Continuous Biomanufacturing Ap-	**1:30pm** - ROOM 210A: Strategies for Maximizing MSC-EV Productivity and Lot Size		**1:25pm** - ROOM 210B: Chairperson's Opening Remarks **1:30pm** - ROOM 210B: High Throughput Upstream Process-		**1:25pm** - ROOM 253AB: Chairperson's Remarks **1:30pm** - ROOM 253AB: Using Hybrid Continuous Biomanufacturing Ap-		**1:25pm** - ROOM 258AB: Chairperson's Remarks **1:30pm** - ROOM 258AB: Acceleration, Compliance, Uncertain-		**1:25pm** - ROOM 258C: Chairperson's Remarks **1:30pm** - ROOM 258C: Challenges and Adventures in Purification	**1:25pm** - Chairperson's Remarks **1:30pm** - ROOM 258AB: Acceleration, Compliance, Uncertainties, Excel-							

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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	Therapy Downstream Purification Process Development	proaches to increase efficiency and decrease cost in the manufacture of Biosimilars			ing and Quality Analysis via Microfluidic Capillary Electrophoresis		proaches to increase efficiency and decrease cost in the manufacture of Biosimilars		ties, Excellence: Lifecycle Turns 4.0 Too		Development for Novel Diabody	lence: Lifecycle Turns 4.0 Too								

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CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
2:00PM	**2:00pm** - ROOM 253C: Product Quality of antibody-based therapeutics direct from cell culture supernatants	**2:00pm** - ROOM 253AB: Intensified Perfusion USP for ICB	**2:00pm** - ROOM 210A: iPSC Processes: Road to Automation and Closed System **2:30pm** - ROOM 210A: Scalable		**2:00pm** - ROOM 210B: bluebird bio Supply Chain Strategy Case Study **2:30pm** - ROOM 210B: Big Solutions Come in		**2:00pm** - ROOM 253AB: Sanofi Case Study: Upstream Continuous Processing		**2:00pm** - ROOM 258AB: Panel Discussion – Strategies to Accelerate and Optimize Process Development, Production		**2:00pm** - ROOM 258C: Challenges and strategies for large-scale production and purification of oncolytic viruses	**2:00pm** - ROOM 258AB: Panel Discussion – Strategies to Accelerate and Optimize Process Development, Production						**2:30pm** - ROOM 253AB: Manufacturing Next-Generation Multi Domain Protein Pharmaceuticals Using the Leap-In	**2:30pm** - ROOM 258C: Production of Protein Therapeutics in CHO Cells	**2:30pm** - ROOM 253C: Practical Application of ISO Cell Counting Standards to Improve the Quality of Cell Counting Mea-

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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			and Customizable Solutions for Cell and Gene Therapy Manufacturing		Small Packages: Expanding Sterile Connection Technology to Small-Format Product or Process Fluid Volume				and Time to Clinic for Novel Modalities			and Time to Clinic for Novel Modalities						Transposase's Platform		surements

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
					Transfer Applications **2:50pm** - ROOM 210B: Evaluation of novel affinity resin with alkali stable ligand for AAV viral vectors															

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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3:00PM	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break **3:55pm** - Chairperson's Open-	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break	**3:10pm** - Grand Opening of the Poster & Exhibit Hall and Refreshment Break

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						ing Remarks														

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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4:00PM			**4:00pm** - ROOM 210A: Selection & Management of Suppliers and Contract Service Providers **4:20pm** - ROOM	**4:00pm** - ROOM 210B: Manufacturing process optimization during early- and late-stage development **4:30pm** -		**4:00pm** - ROOM 210C: Developing an Integrated Manufacturing Process and Platform to Increase Speed to Clinic				**4:00pm** - Chairperson's Remarks **4:05pm** - ROOM: Ballroom West Keynote Address - Bio-Manufacturing During										

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

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			210A: Cell Therapy Raw Materials Customization **4:40pm** - ROOM 210A: Fitting Product to Process: Raw Materials Cus-	ROOM 210B: PANEL: Let's Settle the Debate – Can Auto and Allo Therapies Co-Exist		**4:30pm** - ROOM 210C: Mechanistic Modelling for the Production of Recombinant Adeno-Associated Virus via Triple				a Pandemic When You're Not Making a COVID Vaccine **4:45pm** - ROOM Ballroom West: Plenary Panel Discus-										

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CONFERENCE DAY 1 - 21/09/2021

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			tomization for Cell Therapy Manufacturing Success			Transfection of HEK293 Cells				sion: Achieving supply Chain Continuity to Overcome Supply Chain Disruption Related to COVID-19 Response										

SCHEDULE

CONFERENCE DAY 1 - 21/09/2021

BioProcess International

Delivered as a Hybrid Event from September 20-30, 2021
Live In-Person Experience Delivered September 20-23
Boston Convention and Exhibition Center

TIME	ANALYTICAL & QUALITY	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY	GENE EDITED EX VIVO CELL THERAPY / IN VIVO GENE THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	PLENARY SESSION	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	SPONSORED LUNCHEON PRESENTATION 1	SPONSORED LUNCHEON PRESENTATION 2	SPONSORED LUNCHEON PRESENTATION 3	SPONSORED LUNCHEON PRESENTATION 4	SPONSORED LUNCHEON PRESENTATION 5	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 4
5:00PM	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:00pm** - ROOM 210B: Quality by Design (QbD) for Adeno-Associated Virus (AAV) Products **5:30pm** - Cocktail Recep-	**5:00pm** - ROOM 210B: Quality by Design (QbD) for Adeno-Associated Virus (AAV) Products **5:30pm** - Cocktail Recep-	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:00pm** - ROOM 210B: Quality by Design (QbD) for Adeno-Associated Virus (AAV) Products **5:30pm** - Cocktail Recep-	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall	**5:30pm** - Cocktail Reception in the Poster & Exhibit Hall

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			tion in the Poster & Exhibit Hall	tion in the Poster & Exhibit Hall		tion in the Poster & Exhibit Hall														
6:00PM																				
7:00PM	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One	7:00pm - End of Day One

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

Coffee and Registration

7:30am - 8:00am
Keynote Session

Chairperson's Opening Remarks

8:00am - 8:10am
Keynote Session

Participants

Tom Ransohoff - Co-Head Biologicals Franchise, Resilience

ROOM 210BC: Coffee and Registration

8:00am - 8:20am
Cell & Gene Therapy Manufacturing & Commercialization

ROOM Ballroom West: Keynote Address - Impact of the Global Pandemic on Biopharmaceutical Manufacturing: Resilience, Regulation, and Rubber Bands

8:10am - 8:50am
Keynote Session

Participants

Jeffrey C. Baker, Ph.D - Former Deputy Director, Office of Biotechnology Products, CDER, FDA

ROOM 210BC: Chairperson's Opening remarks

8:20am - 8:30am
Cell & Gene Therapy Manufacturing & Commercialization

ROOM 210BC: Azzur Cleanrooms on Demand – Addressing the Buy vs Build Conundrum for Cell and Gene Therapy Manufacturing

8:30am - 9:00am
Cell & Gene Therapy Manufacturing & Commercialization

Recent advances in cell and gene therapies have created a capacity crunch for early phase cGMP manufacturing. The traditional approaches of developing internal manufacturing capability (Build) or reliance on CMO/CDMOs (Buy) takes time and expertise. This talk addresses the build vs buy options for early phase clinical manufacturing and a novel hybrid option designed for acceleration to the clinic will be presented.

Key Takeaways:

- Current industry challenges in terms of cell gene therapy manufacturing capacity and capability.
- Existing options for early phase clinical manufacturing and the challenges (Build vs Buy)
- Azzur's Cleanrooms on Demand hybrid model designed to accelerate cell and gene therapy products

Participants

Ravi Samavedam - President & COO of Azzur Cleanrooms on Demand™, Azzur Group, USA

ROOM Ballroom West: Keynote Address - How Platform Technologies Tested by Ebola Enabled the Development of COVID-19 Neutralizing Antibody Cocktail at Pandemic Speed

8:50am - 9:30am
Keynote Session

Regeneron has developed a rapid response platform for emerging infectious diseases. Proprietary Velocisuite® technologies developed over the past three decades in combination with well-established business processes, deep process and manufacturing knowledge and the Regeneron culture allow rapidly identified and preclinically validated candidate antibodies to move seamlessly to clinical manufacturing. A prominent example of the use of these technologies was the development the REGN-EB3 cocktail of antibodies that have been successfully used in response to outbreaks of the Ebola virus and attained market approval in 2020. This experience base, combined with new innovations and rational risk management, all allowed for the development of Regeneron's REGN-CoV2 neutralizing antibody cocktail at pandemic speed.

Participants

Hanne Bak, Ph.D. - Senior Vice President, Pre-clinical Manufacturing & Process Development, Regeneron Pharmaceutical, Inc.

ROOM 210BC: Charting a new path. Reimagining Automation in Cell Therapy Manufacturing.

9:00am - 9:30am
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Fabian Gerlinghaus - Co-Founder & CEO, Cellares

Networking Refreshment Break in the Exhibit Hall

9:30am - 10:25am
Cell Culture and Upstream Processing

Networking Refreshment Break in the Exhibit Hall

9:30am - 10:25am
Recovery & Purification

Networking Refreshment Break in the Exhibit Hall

9:30am - 10:25am
Manufacturing Strategy & Bioprocessing 4.0

Networking Refreshment Break in the Exhibit Hall

9:30am - 10:25am
Intensified and Continuous Processing

Networking Refreshment Break in the Exhibit Hall

9:30am - 10:25am
Analytical & Quality

Networking Refreshment Break in the Exhibit Hall

9:30am - 10:25am
Speed from Gene to Market

Networking Refreshment Break and Opening of the Exhibit Hall

9:30am - 10:25am
Cell Therapy/ Gene Edited Ex Vivo Cell Therapy

Networking Refreshment Break and Opening of the Exhibit Hall

9:30am - 10:25am
In Vivo Gene Therapy

SESSIONS
CONFERENCE DAY 2 - 22/09/2021

Big Solutions Come in Small Packages: Expanding Sterile Connection Technology to Small-Format Product or Process Fluid Volume Transfer Applications

9:35am - 9:45am
Exhibition Hall Content/ Theater Showcase

In state-of-the-art biopharmaceutical manufacturing, you're challenged to engineer and operate processes that are robust, reliable and repeatable. Building on the inventiveness of CPC and its AseptiQuik® Series Connectors, the leader in single-use connection technology, the company's new MicroCNX™ Series Connectors provide a modern alternative to the tube welding process. Learn how this new category of aseptic, sterile micro-connectors provides a simple, efficient method of connecting tubing for small format assemblies to help manufacturers improve efficiencies, reduce time and total cost, and mitigate risk.

Participants

Troy Ostreng - Senior Product Manager, CPC- Colder Products Company

Improved process performance of selected salts

9:45am - 9:55am
Exhibition Hall Content/ Theater Showcase

Advanced material engineering can have measurable effect in processing performance, for upstream nutrient additives as well as down stream process aids

Participants

Ralf Dieckhoff - VP North America, DPL-US (d.b.a. Dr. Paul Lohmann, Inc.)

Towards a better understanding of plant hydrolysates in cell culture applications

9:55am - 10:15am
Exhibition Hall Content/ Theater Showcase

Hydrolysates have been used to supplement media for many commercial scale bioprocesses, however Chemically Defined Media (CD) is often the preferred platform, primarily due to its perceived defined natured. Plant based hydrolysates are often employed as a nutritional supplement to CD media, however they are not a primary choice due to their undefined nature and variability. FrieslandCampina recognizes these industry concerns and have actively been working / investigating our high performing plant based hydrolysates that are used in cell culture applications. This work has enabled us to develop a deeper understanding of the cellular mechanisms that hydrolysates can impact.
In a study performed in cooperation with John Hopkins University, the CHO pathways that were impacted when CD media was supplemented with hydrolyzed cottonseed (Proyield Cotton CNE50M-UF) were identified, enabling us to understand how this plant hydrolysate created a positive impact with CHO in the system that we used.
Current studies are in progress supplementing various commercially available CD media with soy hydrolysate (Proyield SE50MAF-UF) to determine the effect on growth and production in a CHO cell system.
FCI has further characterized trace mineral variability in soy hydrolysates (Proyield SE50MAF-UF), specifically those that are impactful to cell cultures and has been able to control these within our existing processes enabling us to deliver product that works in a variety of systems.

Participants

Edward Hunter - Technical Sales Support Cell Nutrition, FrieslandCampina Ingredients

Driving next-generation biopharmaceutical production from concept to market: Rentschler Biopharma your trusted CDMO partner

10:15am - 10:25am
Exhibition Hall Content/ Theater Showcase

Translating 50 years of experience and an outstanding track record into lifesaving therapeutics. Tailormade solutions for high-quality bioprocess development and clinical and commercial cGMP manufacturing. Global leader in mammalian cell culture and expert for complex and highly effective biopharmaceuticals.

Participants

Grace Kim - Vice President Business Development North America, Rentschler Biopharma SE

ROOM 253AB: Chairperson's Remarks

10:25am - 10:30am
Cell Culture and Upstream Processing

Participants

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

ROOM 258C: Chairperson's Remarks

10:25am - 10:30am
Recovery & Purification

Participants

Parviz Shamlou - Vice President & Executive Director, Thomas Jefferson University | Jefferson Institute for Bioprocessing

ROOM 258AB: Chairperson's Remarks

10:25am - 10:30am
Manufacturing Strategy & Bioprocessing 4.0

Participants

James Dean Vogel - Founder and Director , The BioProcess Institute

ROOM 253AB: Chairperson's Remarks

10:25am - 10:30am
Intensified and Continuous Processing

Participants

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

ROOM 210BC: Chairperson's Opening Remarks

10:25am - 10:30am
Analytical & Quality

Participants

Marinna Madrid - Co-Founder, Cellino

ROOM 253C: Chairperson's Remarks

10:25am - 10:30am
Speed from Gene to Market

Participants

Al Doig - Manager, BioProcess Technology Group, BDO

ROOM 210BC: Chairperson's Opening Remarks

10:25am - 10:30am
Cell Therapy/ Gene Edited Ex Vivo Cell Therapy

Participants

Marinna Madrid - Co-Founder, Cellino

ROOM 210A: Chairperson's Opening Remarks

10:25am - 10:30am
In Vivo Gene Therapy

Participants

Jorge Santiago-Ortiz, Ph.D. - Director, Process Development, BioCentriq, USA

ROOM 253AB: How PAT is Enabling Continuous Bioprocessing

10:30am - 11:00am
Cell Culture and Upstream Processing

- Real time in-process quality control is critical to ensure consistent product quality in continuous manufacturing
- Key enablers for PAT in continuous processing are in-line analyzers, novel spectroscopic approaches, mechanistic and data-driven models, real time fault detection, and surge tank management
- Continuous manufacturing combined with robust PAT tools can handle the major and minor deviations in process parameters and feed material which inevitably arise over continuous campaigns

Participants

Garima Thakur, Remote-Live with Q & A - Researcher, Indian Institute of Technology

ROOM 258C: Purification of polyclonal Immunoglobulin G from human serum using LigaGuardTM and LigaTrapTM adsorbents

10:30am - 11:00am
Recovery & Purification

We present the fractionation and purification of immunoglobulin G (IgG) from human plasma using a two-column chromatographic process comprising adsorbents LigaGuardTM, which captures non-Ig plasma proteins in flow-through mode, and LigaTrapTM, which isolates IgG in bind-and-elute mode. Two process configurations were evaluated, under optimized buffer composition and column loading. In the first one, plasma was fed to a LigaGuardTM column to capture plasma proteins, the effluent was loaded on the LigaTrapTM column, and the bound IgG was eluted with 63.8% global recovery and 99.7% purity. In the alternative design, the LigaGuardTM column was utilized to polish the LigaTrapTM elution stream, affording 82.3% global recovery and 98.8% purity. Collectively, these results demonstrate the potential of a fully chromatographic process for isolating polyclonal IgG from plasma feedstocks.

Participants

Wen Ning Chu - Postdoctoral Scholar, North Carolina State University

ROOM 258AB: A Town Hall Forum: BioProcess and Single-Use Standardization: What are the Next Steps for the Industry?

10:30am - 11:30am
Manufacturing Strategy & Bioprocessing 4.0

Featuring Updates from Industry and Standards Organizations on Their Current Activities

- Join the conversation and participate in the ongoing discussions regarding standardization of single-use systems and the implications for biologics developers and single use technology providers.
- Lend your voice to the discussions and help drive the biopharma industry to the next level of implementation.

Participants

James Dean Vogel - Founder and Director , The BioProcess Institute

Robert Brooks, Ph.D., Remote - Live with Q & A - Supply Partner Phorum Leader and Operations Team Member, Biophorum

Jeff Carter, Ph.D. - Consumables Product Strategy Leader, Cytiva

James Hathcock, Ph.D. - Senior Director, Regulatory and Validation Strategy, Pall Biotech, Pall Life Sciences

ROOM 253AB: How PAT is Enabling Continuous Bioprocessing

10:30am - 11:00am
Intensified and Continuous Processing

- Real time in-process quality control is critical to ensure consistent product quality in continuous manufacturing
- Key enablers for PAT in continuous processing are in-line analyzers, novel spectroscopic approaches, mechanistic and data-driven models, real time fault detection, and surge tank management
- Continuous manufacturing combined with robust PAT tools can handle the major and minor deviations in process parameters and feed material which inevitably arise over continuous campaigns

Participants

Garima Thakur, Remote-Live with Q & A - Researcher, Indian Institute of Technology

ROOM 210BC: Building an Analytical Toolbox for Potency Testing for Next Generation CARs

10:30am - 10:50am
Analytical & Quality

Participants

Daniel Hui - Associate Director – Product Characterization/Clinical Assay Development, Tmunity Therapeutics

ROOM 253C: The Accelerated Development of Rylaze™(asparaginase erwinia chrysanthemi (recombinant)-rywn): A Case Study in Leveraging Early Investment in Process Development for Late-Stage Success

10:30am - 11:00am
Speed from Gene to Market

Rylaze™, a recombinant Erwinia asparaginase for intramuscular injection for the treatment of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) in patients who have developed hypersensitivity to E. coli-derived asparaginase, was developed through a partnership between Jazz Pharmaceuticals and Ligand Pharmaceuticals (parent company of Pfenex, Inc.) using Pelican Expression Technology™ to address the worldwide shortage of Erwinia-derived asparaginases. This partnership achieved FDA approval for Rylaze™ less than 5 years from the selection of the production strain. Rapid and comprehensive strain selection and an early process development program utilizing the Pelican Expression Technology™ were key to establishing the foundation for late-stage success. This early investment combined with a robust expression platform led to successful scale-up and tech transfer to a cGMP facility to supply the clinical development program. The knowledge gained was leveraged to develop an accelerated risk-based process characterization strategy and successful process performance qualification (PPQ) campaign demonstrating a reliable and robust process capable of delivering consistently high-quality drug substance. The process development strategy was instrumental in ensuring accelerated FDA approval as part of the agency's Real-Time Oncology Review program could be achieved while maintaining CMC product quality standards.

Participants

Chris Woods - Director, Biologics Drug Substance Development, Jazz Pharmaceuticals, Inc

ROOM 210BC: Building an Analytical Toolbox for Potency Testing for Next Generation CARs

10:30am - 10:50am
Cell Therapy/ Gene Edited Ex Vivo Cell Therapy

Participants

Daniel Hui - Associate Director – Product Characterization/Clinical Assay Development, Tmunity Therapeutics

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

ROOM 210A: Measuring the DNA cargo of Adeno-Associated Viruses using nanofluidic resonators

10:30am - 11:00am
In Vivo Gene Therapy

Recombinant Adeno-Associated Viruses (rAAVs) deliver therapeutic DNA for gene therapy.

However, rAAV manufacturing is imperfect, producing a small portion of recombinant viruses with the therapeutic gene. Here, we developed nanofluidic resonators for characterizing rAAV by measuring their mass. We juxtapose our approach with techniques ranging from ddPCR and Analytical Ultracentrifugation to Light Scattering Methods. With our rAAV characterization approach, we aim to enable real-time quality control in continuous rAAV manufacturing.

Participants

Georgios Katsikis - Postdoctoral Associate, Massachusetts Institute of Technology, USA

ROOM 210BC: An Introduction to Cell and Gene Therapy Validation Challenges

10:50am - 11:10am
Analytical & Quality

Participants

Sharif Ahmed, Remote - Live with Q&A - Senior Product Supply Product Lead for rFVIII Products, Bayer Pharmaceuticals, USA

ROOM 210BC: An Introduction to Cell and Gene Therapy Validation Challenges

10:50am - 11:10am
Cell Therapy/ Gene Edited Ex Vivo Cell Therapy

Participants

Sharif Ahmed, Remote - Live with Q&A - Senior Product Supply Product Lead for rFVIII Products, Bayer Pharmaceuticals, USA

ROOM 253AB: N-1 Intensification to Improve Fed-batch Production Processes

11:00am - 11:30am
Cell Culture and Upstream Processing

Technologies such as perfusion have enabled the development of high cell density processes, which can be used to reduce manufacturing cost by shortening fed-batch production bioreactor duration or improve the fed-batch production process by deepening understanding of cell culture metabolism. In this proof-of-concept study, a high cell density culture in N-1 seed bioreactor was implemented to show the feasibility of shortening production bioreactor duration. Spent medium data from this run were then used to identify potential process improvement levers to the current fed-batch production process, which were confirmed experimentally to increase protein production by 20%. This work demonstrates the application of N-1 perfusion to improve upstream fed batch production, efficiency, and robustness.

Participants

Nick Morse - Scientist, Upstream Process Development, Alexion

ROOM 258C: NIIMBL-BioPhorum Buffer Stock Blending System Vision, Collaboration, Design and Outcome

11:00am - 11:30am
Recovery & Purification

Participants

Jeff Johnson - President, Biotech Design, LLC

ROOM 253AB: N-1 Intensification to Improve Fed-batch Production Processes

11:00am - 11:30am
Intensified and Continuous Processing

Technologies such as perfusion have enabled the development of high cell density processes, which can be used to reduce manufacturing cost by shortening fed-batch production bioreactor duration or improve the fed-batch production process by deepening understanding of cell culture metabolism. In this proof-of-concept study, a high cell density culture in N-1 seed bioreactor was implemented to show the feasibility of shortening production bioreactor duration. Spent medium data from this run were then used to identify potential process improvement levers to the current fed-batch production process, which were confirmed experimentally to increase protein production by 20%. This work demonstrates the application of N-1 perfusion to improve upstream fed batch production, efficiency, and robustness.

Participants

Nick Morse - Scientist, Upstream Process Development, Alexion

ROOM 253C: Streamlined ambr250 Product Characterization Using HTP Purification and Automated Data Structuring

11:00am - 11:30am
Speed from Gene to Market

Participants

Luke Cach - Head of Scientific Solutions, Synthace

ROOM 210A: Developing a Fed-Batch process to increase productivity of the Bac/Sf9 Platform

11:00am - 11:30am
In Vivo Gene Therapy

Participants

Krishanu Mathur, Remote - Live with Q&A - CMC, Early & Late Stage Gene Therapy, Voyager Therapeutics, USA

ROOM 210BC: Potency Assay Development for Commercialization

11:10am - 11:30am
Analytical & Quality

Participants

Knut Niss - Chief Technology Officer, Mustang Bio

ROOM 210BC: Potency Assay Development for Commercialization

11:10am - 11:30am
Cell Therapy/ Gene Edited Ex Vivo Cell Therapy

Participants

Knut Niss - Chief Technology Officer, Mustang Bio

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

ROOM 253AB: Commercial Scale Insect Cell Culture: Opportunity and Challenges in a CHO centric world

11:30am - 12:00pm
Cell Culture and Upstream Processing

A strategy for scale up and manufacture of a recombinant protein from Insect Cell Culture (ICC) using a Baculovirus Expression Vector System (BEVS) should be mapped out during the earliest stages of process development. The challenges of recombinant protein expression using ICC/BEVS production systems are different to more commonly used expression systems such as CHO and few vendors have the necessary scale-up experience to perform these assessments. The challenges include overcoming the inherent inconsistency of production media used for ICC, defining the appropriate cell cycling strategy and, most importantly, the defining viral infection strategy. Keeping a line of sight to manufacturing helps to define the manufacturing process and ensure it is reliable and robust.

Participants

Sharyn Farnsworth - Principal Scientist and Upstream Process Development-Cell Culture Group Leader, FUJIFILM Diosynth Biotechnologies

ROOM 258C: A new Protein A resin allowing elution of monoclonal antibodies at pH 5.0

11:30am - 12:00pm
Recovery & Purification

This paper will present data from a new Protein A resin that allows elution of IgG, including IgG of the VH3 family at significantly higher pH compared to regular Protein A resins.

Participants

Fred Ghanem - North America Life Science Manager, Purolite

Hans Johansson, Ph.D. - Global Applications Director, Purolite

ROOM 258AB: Flexible approaches to addressing mRNA vaccine demand

11:30am - 12:00pm
Manufacturing Strategy & Bioprocessing 4.0

mRNA technology and the recent pandemic have upended conventional timelines for vaccine development. As we race to meet todays demand for mRNA vaccines, the future already poses new strategic questions. How will new variants affect demand for vaccines or boosters? How will mRNA vaccine technology evolve? Can todays mRNA manufacturing infrastructure adapt to the future?

In this presentation, we'll discuss strategies for rapid deployment of mRNA manufacturing capacity using a flexible, end-to-end platform approach and modular manufacturing systems. We'll also address multiproduct manufacturing, insourcing vs outsourcing, and batch management.

Participants

Joe Makowiecki - Director of Business Development, Enterprise Solutions, Cytiva

Katarina Stenklo - Enterprise Solutions Commercial Activation Leader, Cytiva

ROOM 253AB: Commercial Scale Insect Cell Culture: Opportunity and Challenges in a CHO centric world

11:30am - 12:00pm
Intensified and Continuous Processing

A strategy for scale up and manufacture of a recombinant protein from Insect Cell Culture (ICC) using a Baculovirus Expression Vector System (BEVS) should be mapped out during the earliest stages of process development. The challenges of recombinant protein expression using ICC/BEVS production systems are different to more commonly used expression systems such as CHO and few vendors have the necessary scale-up experience to perform these assessments. The challenges include overcoming the inherent inconsistency of production media used for ICC, defining the appropriate cell cycling strategy and, most importantly, the defining viral infection strategy. Keeping a line of sight to manufacturing helps to define the manufacturing process and ensure it is reliable and robust.

Participants

Sharyn Farnsworth - Principal Scientist and Upstream Process Development-Cell Culture Group Leader, FUJIFILM Diosynth Biotechnologies

ROOM 210BC: High Throughput Characterization of Antibody, AAV and Cell Therapy Aggregates and Particulate Impurities Using the Aura

11:30am - 12:00pm
Analytical & Quality

In all biological products, distinguishing aggregated API from other particle types matters for understanding the root cause of instability. Until now, subvisible particle characterization methods have been unreliable, slow and require significant sample volume, and have been difficult to use across many workflows. Here, we introduce the Aura, a 96-well, low-volume, high throughput particle imaging system can rapidly size, count, and characterize biological particles and identify them as proteins, non-proteins, cellular aggregates, or other types of molecules. In this talk, we will present 3 case studies: identifying protein aggregates and distinguishing them in from degraded polysorbate components, determining subvisible particle content of AAV formulations at low volumes under different stress conditions, and a thorough particle characterization of cellular therapy products including cell aggregation, viability, and product impurities.

Participants

Bernardo Cordovez - Chief Science Officer and Founder, Halo Labs, USA

ROOM 210BC: High Throughput Characterization of Antibody, AAV and Cell Therapy Aggregates and Particulate Impurities Using the Aura

11:30am - 12:00pm
Cell Therapy/ Gene Edited Ex Vivo Cell Therapy

In all biological products, distinguishing aggregated API from other particle types matters for understanding the root cause of instability. Until now, subvisible particle characterization methods have been unreliable, slow and require significant sample volume, and have been difficult to use across many workflows. Here, we introduce the Aura, a 96-well, low-volume, high throughput particle imaging system can rapidly size, count, and characterize biological particles and identify them as proteins, non-proteins, cellular aggregates, or other types of molecules. In this talk, we will present 3 case studies: identifying protein aggregates and distinguishing them in from degraded polysorbate components, determining subvisible particle content of AAV formulations at low volumes under different stress conditions, and a thorough particle characterization of cellular therapy products including cell aggregation, viability, and product impurities.

Participants

Bernardo Cordovez - Chief Science Officer and Founder, Halo Labs, USA

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

ROOM 210A: Platform Manufacturing Approach for Adeno Associated Virus: Accelerated Time and Cost Saving

11:30am - 12:00pm
In Vivo Gene Therapy

- The demand for viral vectors is expected to increase, fuelled by clinical successes in gene and cell therapy.
- Adeno associated virus (AAV) is one of the key viral vectors used for many gene therapy applications. Availability of several serotypes, favourable tropism for selective tissues and aggressive clinical development timelines have propelled the demand for high-titer AAV and hence the need for rapid process establishment/scale up
- The establishment of a platform approach for the development of processes for viral vector manufacturing, based on triple-transfection technology, will be presented and the benefits, challenges and limitations will also be discussed.

Participants

Elie Hanania, Remote - Live with Q&A - Director of Upstream Process Development, FUJIFILM Diosynth Biotechnologies

Networking Luncheon in the Exhibit & Poster Hall

12:00pm - 1:25pm

Chairperson's Remarks

1:25pm - 1:30pm
Cell Culture and Upstream Processing

Participants

Susan Dana Jones, Ph.D. - SVP, Product Development, Harpoon Therapeutics Inc.

Chairperson's Remarks

1:25pm - 1:30pm
Recovery & Purification

Participants

Parviz Shamlou - Vice President & Executive Director, Thomas Jefferson University | Jefferson Institute for Bioprocessing

Chairperson's Remarks

1:25pm - 1:30pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Parviz Shamlou - Vice President & Executive Director, Thomas Jefferson University | Jefferson Institute for Bioprocessing

ROOM 210A: Chairperson's Opening Remarks

1:25pm - 1:30pm
Analytical & Quality

Participants

Sadik H. Kassim - Chief Technology Officer, Vor Biopharma

ROOM 210A: Chairperson's Opening Remarks

1:25pm - 1:30pm
Cell Therapy

Participants

Sadik H. Kassim - Chief Technology Officer, Vor Biopharma

ROOM 210B: Chairperson's Opening Remarks

1:25pm - 1:30pm
Gene Edited Ex Vivo Cell Therapy

Participants

Knut Niss - Chief Technology Officer, Mustang Bio

ROOM 210C: Chairperson's Opening Remarks

1:25pm - 1:30pm
In Vivo Gene Therapy

Participants

David Dobnik - Scientific Associate, National Institute of Biology, Slovenia

ROOM 253AB: Overcoming the challenges in antibody manufacture using mechanistic modelling and machine learning

1:30pm - 2:00pm
Cell Culture and Upstream Processing

This talk will present advances in the use of mathematical techniques for reducing process development timelines while also increasing product quality with respect to protein glycosylation. It will also showcase how machine learning can be harnessed to guide cell line engineering for targeted glycosylation profiles.

Participants

Cleo Kontoravdi, Remote - Live with Q & A - Professor of Biological Systems Engineering, Imperial College London

ROOM 258AB: Justification of Small-Scale Models: An Industry Perspective

1:30pm - 2:00pm
Recovery & Purification

Participants

Robert Luo, Remote - Live with Q & A - Scientific Director, BioPharm Process Development, GSK

ROOM 258AB: Justification of Small-Scale Models: An Industry Perspective

1:30pm - 2:00pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Robert Luo, Remote - Live with Q & A - Scientific Director, BioPharm Process Development, GSK

Please move to another track

1:30pm - 2:00pm
Analytical & Quality

Please move to another track

1:30pm - 2:00pm
Cell Therapy

ROOM 210B: Is Gene Editing a Gene Therapy or Cell Therapy or both? Where does it fit?

1:30pm - 2:00pm
Gene Edited Ex Vivo Cell Therapy

Participants

Devyn Smith - Chief Operating Officer, Sigilon Therapeutics

ROOM 210C: Challenges for Potency Assay Development for Gene Therapies & the Matrix Approach

1:30pm - 2:00pm
In Vivo Gene Therapy

Participants

Roland Pach, Remote - Live with Q&A - Project Leader, F.Hoffmann-La Roche, Switzerland

Christina Grigoriadou, Remote - Live with Q&A - Senior Scientist, AstraZeneca

ROOM 253AB: Implementing PAT at USP - From Lab to Manufacturing

2:00pm - 2:30pm
Cell Culture and Upstream Processing

Participants

George Zhou, PhD, Remote - Live with Q & A - Associate Principal Scientist, Merck & Co., Inc.

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

ROOM 258AB: Visualizing Manufacturing Data in Real Time and How the Data Relates to Models for the Process

2:00pm - 2:30pm
Recovery & Purification

Participants

Francisca Gouveia, Ph.D, Remote - Live with Q & A - Senior Process Expert, MS&T, Novartis

ROOM 258AB: Visualizing Manufacturing Data in Real Time and How the Data Relates to Models for the Process

2:00pm - 2:30pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Francisca Gouveia, Ph.D, Remote - Live with Q & A - Senior Process Expert, MS&T, Novartis

ROOM 210A: Process Analytical Technologies for Cell Therapies

2:00pm - 2:30pm
Analytical & Quality

Cellular therapies have shown considerable clinical activity in recent years. A goal of CAR-T process development (PD) is to produce consistent drug product. To achieve this goal, PD scientists employ process analytical technologies (PAT) to monitor upstream, downstream, and final product attributes. This talk will focus on how the cell therapy field is leveraging mass spectrometry-based PAT for cell-based therapies.

Participants

Ho-Tak Lau, Remote - Live with Q&A - Senior Scientist, Bristol-Myers Squib

ROOM 210A: Process Analytical Technologies for Cell Therapies

2:00pm - 2:30pm
Cell Therapy

Cellular therapies have shown considerable clinical activity in recent years. A goal of CAR-T process development (PD) is to produce consistent drug product. To achieve this goal, PD scientists employ process analytical technologies (PAT) to monitor upstream, downstream, and final product attributes. This talk will focus on how the cell therapy field is leveraging mass spectrometry-based PAT for cell-based therapies.

Participants

Ho-Tak Lau, Remote - Live with Q&A - Senior Scientist, Bristol-Myers Squib

ROOM 210B: Novel Modalities to Address CAR-T Challenges - NK Cell Case Study

2:00pm - 2:30pm
Gene Edited Ex Vivo Cell Therapy

Participants

Bruno Marques, Remote - Live with Q&A - Head of Process & Product Development, Century Therapeutics

ROOM 210C: Developing Functional Potency Assay for Gene Therapy Products

2:00pm - 2:30pm
In Vivo Gene Therapy

Participants

Arkadi Manukyan - Scientist, Analytical Development, Sanofi, USA

ROOM 253AB: Single-Use Material Selection for Critical Storage Operations in Gene Therapy Development and Scale-up

2:30pm - 3:00pm
Technology Workshop 1

Despite the industry challenges posed by the COVID-19 pandemic, novel gene therapy development has adapted and is returning to the spotlight. With this comes a refocus on the selection of optimal single-use materials for early-phase regulatory compliance. This is particularly important for materials used in storage and cryogenic operations. However, to address the current concerns of manufacturability, a material's commercial viability should also be discerned to ensure process economics at scale. This presentation will review key product contact material requirements and available data, examine storage and cryogenic process compatibility with respect to functional performance and consider the case study of a material used in storage applications at commercial scale.

Participants

Muhammad Siddiqui - Cold Chain Applications Engineer, Entegris Inc

ROOM 258AB: PolarDry and Biotherapeutic Applications

2:30pm - 3:00pm
Technology Workshop 2

- Formulation, particle engineering and morphology
- Drying in a single step
- Improved temperature control
- Drying peptides and proteins
- Versatile technology
- Compact design and limited footprint
- Potential use for aseptic manufacturing

Participants

Jack Haronian - Sales Engineer, Fluid Air

ROOM 258C: Optimized, Efficient, and Scalable Transient Transfection for High Titer AAV and LV Generation

2:30pm - 3:00pm
Technology Workshop 3

Recombinant adeno-associated virus (AAV) and lentivirus (LV) are essential components of many gene and cell therapies designed to treat and potentially cure a vast array of acquired and heritable diseases. Thus, the need for large-scale manufacture of safe and effective viral vectors for development of biotherapeutics has never been greater. Here, we present optimization strategies for achieving higher AAV and LV titers via transient transfection in both adherent and suspension HEK 293 cells. We will discuss how the TransIT-VirusGENÂ® Transfection Reagent, an innovative blend of lipids and polymers with highly defined architectures, enables significantly higher functional titers than PEI-derived polymers or liposomes alone. Attendees will learn critical parameters for maximizing viral vector production within their process, as well as how VirusGENÂ® GMP AAV and LV products support gene and cell therapy researchers from R&D through commercial manufacturing.

Participants

Leisha Kopp - Applications Scientist, Mirus Bio LLC

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

Room 253C -- A single intensified and continuous platform for a scalable adherence and suspension viral production

2:30pm - 3:00pm
Technology Workshop 4

The continuously growing viral vector demand and expanding number of possible applications exposes an urgent need for flexible and scalable manufacturing solutions. Traditionally process development strategies are strongly coupled with available manufacturing technologies to reach commercial scale. The highly variable gene therapy capacity demand with dose sizes reaching up to 1E20 vgs often result in process scale-out and high production footprint when considering conventional technologies. But what if a dual platform could accommodate both adherent and suspension processes while intensifying and enabling seamless process scale-up?

Participants

Effie Huang - Senior application specialist, Univercells Technologies

David Moccia - Business Development, Univercells Technologies

ROOM 210A: Human Liver-Chips: Qualifying a Preclinical Model System for AAV Vector Development

2:30pm - 2:45pm
Cell Therapy

Participants

S. Jordan Kerns, PhD - Director of Applied Biosciences, Emulate, Inc., USA

ROOM 210B: FectoVIR®-AAV: the next-generation transfection reagent for large-scale AAV manufacturing

2:30pm - 2:45pm
Gene Edited Ex Vivo Cell Therapy

With the rapid growth of the gene therapy market, many manufacturing challenges still need to be addressed in order to efficiently produce large volumes of recombinant AAVs. Transient transfection of suspension cells is the most commonly used production platform for AAV manufacturing. Twenty years of transfection expertise has led Polyplus to the development of the next generation transfection reagent, FectoVIRÂ®-AAV. In our presentation, we will discuss how FectoVIRÂ®-AAV addresses the current AAV manufacturing limitations with i) increased AAV titers, ii) improved industrial transfection protocols, and iii) high quality and GMP compliance.

Participants

Ashlee Sun - Field Application Specialist, Polyplus-transfection, USA

ROOM 210C: Leveraging lessons from the COVID-19 pandemic to accelerate the development and production of adeno-associated virus (AAV)-based gene therapies

2:30pm - 3:00pm
In Vivo Gene Therapy

While there are currently over 1400 clinical cell and gene therapy programs, trial recruitment, raw material supply chains, and low-yield processes are just some of the multiple challenges facing the industry. The recent pandemic revealed that with the proper framework, a drug product can be developed, clinically tested, and produced for hundreds of millions of patients in less than a year. What lessons can we apply from this effort for AAV development and production? How can we rethink regulatory filing strategy? And why does the cell and gene therapy arena so urgently need these learnings?

Participants

Yasser Kehail - Single Use & Enterprise Business Development Leader, Cytiva, USA

ROOM 210B: BioCentriq Cell and Gene Therapy Development and Clinical Manufacturing Center

2:45pm - 3:00pm
Gene Edited Ex Vivo Cell Therapy

Participants

Chathuranga De Silva, PhD - Director, Business Development, BioCentriq, USA

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
Cell Culture and Upstream Processing

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
Recovery & Purification

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
Manufacturing Strategy & Bioprocessing 4.0

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
Analytical & Quality

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
Cell Therapy

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
Gene Edited Ex Vivo Cell Therapy

Networking Refreshment Break in the Exhibit Hall

3:00pm - 4:00pm
In Vivo Gene Therapy

Lessons Learned: Building and Booking a State-of-the-Art Biologics Manufacturing Facility in 18 months amidst Covid and Global Materials Shortages

3:00pm - 3:10pm
Exhibition Hall Content/ Theater Showcase

As Chairman and CEO of Bionova Scientific (a Fremont, California biologics CDMO) Darren Head presided over the planning, design, construction, and commissioning of a fully single-use, commercial-ready biologics manufacturing facility amidst once-in-a-lifetime headwinds. Mr. Head will share experiences and lessons learned about how Bionova completed the facility on-time (18 months) and on-budget despite the challenges of COVID-19 and a frozen global raw materials supply chain. Mr. Head will also share how Bionova was able to book several clinical production slots for the facility well ahead of its planned completion.

Participants

Darren Head - Chief Executive Officer, Bionova Scientific

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

Step into your Cell Culture Media with the REBEL Analyzer

3:10pm - 3:20pm
Exhibition Hall Content/ Theater Showcase

Targeted rapid analysis of cell culture media at the point of need in process development opens the door to expedite data-driven decisions. If you are looking for higher titers and better protein quality, come learn why you should care about media analysis and how to easily bring this into your routine. Amino acids are key to achieving high productivity and desired CQAs. With the power of fresh and spent media analysis at your fingertips, learn how you can complement your workflow with frequent media analysis. The at line REBEL analyzer provides visibility into 30+ exogenous nutrients and metabolites in <10 minutes. Sample preparation is consists of filter and dilute without the need for derivatization. The low sample volume (10 microliters) allows for cell media optimization to occur earlier in the process development stage where total bioreactor volumes are small, and the value of daily assays is high. This talk will highlight examples of the potential benefits of positioning the REBEL at the point-of-need including reduced reliance on the "centralized laboratory" model, more rapid (near real-time) analytics feedback, and improved product quality and titer.

Participants

Kerin Gregory - REBEL Product Manager, 908 Devices

Networking Break

3:20pm - 3:45pm
Exhibition Hall Content/ Theater Showcase

Emerging and Innovative Technology Session

3:45pm - 4:15pm
Exhibition Hall Content/ Theater Showcase

In this Emerging and Innovative Technology session, innovative technologies will be presented before the BioInnovation Panel. The BioInnovation panel's role will be to probe the technology companies along with encouraging audience participation. All are welcome to participate.

3:30- 4:00 Lynne Frick; Cheryl Huie: Intro of BioInnovation group mission, BIG panelists and technology companies

Bioinnovation Panel Members:

Carrie Mason

Michael Mietzner

David Fritsch

Brandon Christensen

Jean Bender

Participants

Lynne Frick - Co-Head, Biologics Franchise, Resilience and Co-Executive Director, The BioInnovation Group

Cheryl Huie - Co-Executive Director, BioInnovation Group

Carrie Mason - Senior Research Development Manager, Lonza

Michael Mietzner - Vice President of Engineering, bioX LLC

David Fritsch - Head of Technology and PMO, Resilience

Brandon Christensen - Director, Visterra Inc.

Jean Bender - Vice President, Pharmaceutical Sciences and Technology Visterra, Inc., Visterra

ROOM 253AB: Comparing Dielectric and Raman spectroscopy for online cell growth monitoring of biotherapeutics manufacturing

4:00pm - 4:30pm
Cell Culture and Upstream Processing

Cell growth is routinely monitored during production of monoclonal antibodies. We will present development approaches, including both Raman and Dielectric spectroscopies, for demonstrating a successful continuous monitoring of cell growth. Advanced multivariate modeling was employed for method performance evaluation in terms of accuracy, precision, and robustness. Certain industrial applications such as probe unifying will also be discussed in this work.

Participants

Feng Xu, Remote - Live with Q & A - Senior Scientist, Merck

ROOM 258AB: BioPhorum's Manifesto of digital capabilities for the Quality Control Lab of the Future

4:00pm - 4:30pm
Recovery & Purification

Participants

Steve M. Muller - Senior Manager, IT for GPS – Global Quality, Bristol Myers Squibb

ROOM 258AB: BioPhorum's Manifesto of digital capabilities for the Quality Control Lab of the Future

4:00pm - 4:30pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Steve M. Muller - Senior Manager, IT for GPS – Global Quality, Bristol Myers Squibb

ROOM 210A: Manufacturing Tissues at Scale - A Platform that Enables Precise Control Over iPS Cell Fate in their Natural Environment

4:00pm - 4:30pm
Analytical & Quality

Participants

Marinna Madrid - Co-Founder, Cellino

ROOM 210A: Manufacturing Tissues at Scale - A Platform that Enables Precise Control Over iPS Cell Fate in their Natural Environment

4:00pm - 4:30pm
Cell Therapy

Participants

Marinna Madrid - Co-Founder, Cellino

Please move to another track

4:00pm - 4:30pm
Gene Edited Ex Vivo Cell Therapy

ROOM 210C: Rational Design & Development of Vector Genome Assay by ddPCR

4:00pm - 4:30pm
In Vivo Gene Therapy

Participants

Santoshkumar Khatwani, Remote - Live with Q&A - Associate Director, Analytical Development, Sangamo Therapeutics

Pak Biosolutions, Joanna Rucker Pezzini, President & Founder

4:15pm - 4:25pm
Exhibition Hall Content/ Theater Showcase

PAK BioSolutions provides solutions for end-to-end continuous manufacture of biopharmaceuticals with increased productivity, lower capital costs and a smaller footprint. The company offers the first and only GMP equipment solution that provides full flexibility and countless user configurations to automate intensified or continuous processing.

Participants

Joanna Rucker Pezzini - President and Founder, PAK Biosolutions

Q & A/Panel Discussion

4:25pm - 4:35pm
Exhibition Hall Content/ Theater Showcase

Discussion between panelists with Joanna Rucker Pezzini, President & Founder, Pak Biosolutions

Participants

Joanna Rucker Pezzini - President and Founder, PAK Biosolutions

Carrie Mason - Senior Research Development Manager, Lonza

Michael Mietzner - Vice President of Engineering, bioX LLC

David Fritsch - Head of Technology and PMO, Resilience

Brandon Christensen - Director, Visterra Inc.

Jean Bender - Vice President, Pharmaceutical Sciences and Technology Visterra, Inc., Visterra

ROOM 253AB: Benchmarking of mAb Solution Behavior

4:30pm - 5:00pm
Cell Culture and Upstream Processing

Poor solution behavior, which manifests as high solution viscosity or opalescence, profoundly affects the developability of mAb-drugs. Our work on a diverse dataset of 59 mAbs and an array of molecular descriptors will be presented. We found that poor solution behavior is prevalent (>30%) in mAbs and is singularly predicted (>90%) by the diffusion interaction parameter (kD). This information was used to set quantitative thresholds for selecting well-behaved therapeutic mAbs during drug-discovery.

Participants

Sarah Auclair - Scientist, Sanofi

ROOM 258AB: Implementation of Tech for Digitalization Transformation – Successes, Lessons Learned, and Impact on Project Workflows

4:30pm - 5:00pm
Recovery & Purification

Participants

Gang Wang, Remote - Live with Q & A - Scientist, Late Stage Process Development, Boehringer Ingelheim

ROOM 258AB: Implementation of Tech for Digitalization Transformation – Successes, Lessons Learned, and Impact on Project Workflows

4:30pm - 5:00pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Gang Wang, Remote - Live with Q & A - Scientist, Late Stage Process Development, Boehringer Ingelheim

ROOM 210A: Autologous iPS Cell Therapy for Macular Degeneration: From Bench-to-Bedside

4:30pm - 5:00pm
Analytical & Quality

Participants

Kapil Bharti - Senior Investigator, National Eye Institute, National Institutes of Health

ROOM 210A: Autologous iPS Cell Therapy for Macular Degeneration: From Bench-to-Bedside

4:30pm - 5:00pm
Cell Therapy

Participants

Kapil Bharti - Senior Investigator, National Eye Institute, National Institutes of Health

ROOM 210B: Unlocking the Bottlenecks in The Supply Chain of Autologous Therapies: A Patient-Centric Approach

4:30pm - 5:00pm
Gene Edited Ex Vivo Cell Therapy

Participants

Gabrielle Humphrey, Remote - Live with Q&A - CMC Consultant, VECTAPLUS (formerly Adaptimmune)

ROOM 210C: New Bioprocess Tools and Designs towards the Continuous Purification of Viral Vectors for Gene Therapy

4:30pm - 5:00pm
In Vivo Gene Therapy

The purification of viral vectors for gene therapy is currently performed with chromatographic adsorbents that provide high product purity but operate in batch mode, which is inefficient, and utilize harsh conditions that damage the product. Key Concept: Introducing purification adsorbents that enable continuous removal of impurities and isolation of gene-loaded vectors under gentle, flow-through conditions will reduce process footprint, cost, and time, and increase the therapeutic efficacy and safety of the products. Technical Approach: We have developed single-use adsorbents that (i) capture all the impurities and enable therapeutic vectors to flow-through unbound, and (ii) fractionate the product stream via mixed-mode interactions to isolate the active vectors loaded with the therapeutic transgene. We used a panel of bioassays to select purification parameters to meet FDA-mandated efficacy and safety requirements. Outcomes: Developed scalable and affordable purification adsorbents and protocols for continuous, robust purification of GTPs.

Participants

Stefano Menegatti - Associate Professor, North Carolina State University, USA

AthemBio, Sunil Mehta, CEO

4:35pm - 4:45pm
Exhibition Hall Content/ Theater Showcase

Athembio invents breakthrough technologies and transforms them into solutions to solve major bioprocessing challenges. CORIg is the first single-use centrifugation technology to offer “true continuous discharge” of both cells/solids and supernatant by deploying a novel geometry that combines multiple forces to perform diverse operations including perfusion, harvest clarification, cell harvest, washing/ buffer exchange, cell concentration and separation of different cells/particles.

Participants

Sunil Mehta - Chief Executive Officer, AthemBio

SESSIONS

CONFERENCE DAY 2 - 22/09/2021

Q & A/ Panel Discussion

4:45pm - 4:55pm
Exhibition Hall Content/ Theater Showcase

Discussion between panelists with Sunil Mehta, CEO, AthemBio

Participants

Sunil Mehta - Chief Executive Officer, AthemBio

Carrie Mason - Senior Research Development Manager, Lonza

Michael Mietzner - Vice President of Engineering, bioX LLC

David Fritsch - Head of Technology and PMO, Resilience

Brandon Christensen - Director, Visterra Inc.

Jean Bender - Vice President, Pharmaceutical Sciences and Technology Visterra, Inc., Visterra

Agile GXP Technologies, John Spohn, CEO

4:55pm - 5:05pm
Exhibition Hall Content/ Theater Showcase

Provide transformative technology to cGMP manufacturing facilities for fast compliant process changes or expansions to help accelerate the delivery of new therapies to patients.

Participants

John Spohn - CEO, Agile GXP

ROOM 210B: AAV Full Capsid Enrichment for Serotypes 5, 8 & 9

5:00pm - 5:30pm
Cell Therapy

Participants

Mark Schofield - Senior Manager, Research and Development, Pall Corporation

ROOM 210B: AAV Full Capsid Enrichment for Serotypes 5, 8 & 9

5:00pm - 5:30pm
Gene Edited Ex Vivo Cell Therapy

Participants

Mark Schofield - Senior Manager, Research and Development, Pall Corporation

ROOM 210B: AAV Full Capsid Enrichment for Serotypes 5, 8 & 9

5:00pm - 5:30pm
In Vivo Gene Therapy

Participants

Mark Schofield - Senior Manager, Research and Development, Pall Corporation

Q & A/ Panel Discussion

5:05pm - 5:15pm
Exhibition Hall Content/ Theater Showcase

Discussion and panelists with John Spohn, CEO, Agile GXP Technologies

Participants

John Spohn - CEO, Agile GXP

Carrie Mason - Senior Research Development Manager, Lonza

Michael Mietzner - Vice President of Engineering, bioX LLC

David Fritsch - Head of Technology and PMO, Resilience

Brandon Christensen - Director, Visterra Inc.

Jean Bender - Vice President, Pharmaceutical Sciences and Technology Visterra, Inc., Visterra

BWB Party

5:30pm - 8:00pm
Cell Culture and Upstream Processing

BWB Party

5:30pm - 8:00pm
Recovery & Purification

BWB Party

5:30pm - 8:00pm
Manufacturing Strategy & Bioprocessing 4.0

BWB Party

5:30pm - 8:00pm
Analytical & Quality

BWB Lawn on D Party

5:30pm - 8:00pm
Cell Therapy

BWB Lawn on D Party

5:30pm - 8:00pm
Gene Edited Ex Vivo Cell Therapy

BWB Lawn on D Party

5:30pm - 8:00pm
In Vivo Gene Therapy

BWB Lawn on D Party

5:45pm - 8:15pm
Exhibition Hall Content/ Theater Showcase

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
7:00AM										**7:30am** - Coffee and Registration							

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
8:00AM		**8:00am** - ROOM 210BC: Coffee and Registration **8:20am** - ROOM 210BC: Chairperson's Opening remarks **8:30am** - ROOM 210BC: Azzur Cleanrooms on Demand – Addressing the								**8:00am** - Chairperson's Opening Remarks **8:10am** - ROOM Ballroom West: Keynote Address - Impact of the Global Pandemic on Biopharmaceutical Manufacturing: Resilience, Regula-							

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
		Buy vs Build Conundrum for Cell and Gene Therapy Manufacturing								tion, and Rubber Bands **8:50am** - ROOM Ballroom West: Keynote Address - How Platform Technologies Tested by Ebola Enabled the Development of COVID-19 Neutralizing							

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
										Antibody Cocktail at Pandemic Speed							

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
9:00AM	**9:30am** - Networking Refreshment Break in the Exhibit Hall	**9:00am** - ROOM 210BC: Charting a new path. Reimagining Automation in Cell Therapy Manufacturing.	**9:30am** - Networking Refreshment Break in the Exhibit Hall		**9:30am** - Networking Refreshment Break and Opening of the Exhibit Hall	**9:35am** - Big Solutions Come in Small Packages: Expanding Sterile Connection Technology to Small-Format Product or Process Fluid Volume Transfer Applications **9:45am** -		**9:30am** - Networking Refreshment Break and Opening of the Exhibit Hall	**9:30am** - Networking Refreshment Break in the Exhibit Hall		**9:30am** - Networking Refreshment Break in the Exhibit Hall	**9:30am** - Networking Refreshment Break in the Exhibit Hall	**9:30am** - Networking Refreshment Break in the Exhibit Hall				

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
						Improved process performance of selected salts **9:55am** - Towards a better understanding of plant hydrolysates in cell culture applications											

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
10:00AM	**10:25am** - ROOM 210BC: Chairperson's Opening Remarks **10:30am** - ROOM 210BC: Building an Analytical Toolbox for Potency Testing for Next Generation CARs **10:50am** - ROOM		**10:25am** - ROOM 253AB: Chairperson's Remarks **10:30am** - ROOM 253AB: How PAT is Enabling Continuous Bioprocessing		**10:25am** - ROOM 210BC: Chairperson's Opening Remarks **10:30am** - ROOM 210BC: Building an Analytical Toolbox for Potency Testing for Next Generation CARs **10:50am** - ROOM	**10:15am** - Driving next-generation biopharmaceutical production from concept to market: Rentschler Biopharma your trusted CDMO partner		**10:25am** - ROOM 210A: Chairperson's Opening Remarks **10:30am** - ROOM 210A: Measuring the DNA cargo of Adeno-Associated Viruses using nanofluidic resonators	**10:25am** - ROOM 253AB: Chairperson's Remarks **10:30am** - ROOM 253AB: How PAT is Enabling Continuous Bioprocessing		**10:25am** - ROOM 258AB: Chairperson's Remarks **10:30am** - ROOM 258AB: A Town Hall Forum: BioProcess and Single-Use Standardization: What are the Next Steps for the Industry?	**10:25am** - ROOM 258C: Chairperson's Remarks **10:30am** - ROOM 258C: Purification of polyclonal Immunoglobulin G from human serum using LigaGuardTM and Liga-	**10:25am** - ROOM 253C: Chairperson's Remarks **10:30am** - ROOM 253C: The Accelerated Development of Rylaze™(asparaginase erwinia chrysanthemi (recombinant)-rywn): A				

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
	210BC: An Introduction to Cell and Gene Therapy Validation Challenges				210BC: An Introduction to Cell and Gene Therapy Validation Challenges							TrapTM adsorbents	Case Study in Leveraging Early Investment in Process Development for Late-Stage Success				

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
11:00AM	**11:10am** - ROOM 210BC: Potency Assay Development for Commercialization **11:30am** - ROOM 210BC: High Throughput Characterization of Antibody, AAV and Cell Therapy		**11:00am** - ROOM 253AB: N-1 Intensification to Improve Fed-batch Production Processes **11:30am** - ROOM 253AB: Commercial Scale Insect Cell Culture: Opportunity and Chal-		**11:10am** - ROOM 210BC: Potency Assay Development for Commercialization **11:30am** - ROOM 210BC: High Throughput Characterization of Antibody, AAV and Cell Therapy			**11:00am** - ROOM 210A: Developing a Fed-Batch process to increase productivity of the Bac/Sf9 Platform **11:30am** - ROOM 210A: Platform Manufacturing Approach for Ade-	**11:00am** - ROOM 253AB: N-1 Intensification to Improve Fed-batch Production Processes **11:30am** - ROOM 253AB: Commercial Scale Insect Cell Culture: Opportunity and Chal-		**11:30am** - ROOM 258AB: Flexible approaches to addressing mRNA vaccine demand	**11:00am** - ROOM 258C: NIIMBL-BioPhorum Buffer Stock Blending System Vision, Collaboration, Design and Outcome **11:30am** - ROOM 258C: A new Protein A resin allowing elution	**11:00am** - ROOM 253C: Streamlined am-br250 Product Characterization Using HTP Purification and Automated Data Structuring				

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
	Aggregates and Particulate Impurities Using the Aura		lenges in a CHO centric world		Aggregates and Particulate Impurities Using the Aura			no Associated Virus: Accelerated Time and Cost Saving	lenges in a CHO centric world			of monoclonal antibodies at pH 5.0					
12:00PM	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall	**12:00pm** - Networking Luncheon in the Exhibit & Poster Hall

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
1:00PM	**1:25pm** - ROOM 210A: Chairperson's Opening Remarks **1:30pm** - Please move to another track		**1:25pm** - Chairperson's Remarks **1:30pm** - ROOM 253AB: Overcoming the challenges in antibody manufacture using mechanistic modelling and machine learning	**1:25pm** - ROOM 210A: Chairperson's Opening Remarks **1:30pm** - Please move to another track			**1:25pm** - ROOM 210B: Chairperson's Opening Remarks **1:30pm** - ROOM 210B: Is Gene Editing a Gene Therapy or Cell Therapy or both? Where does it fit?	**1:25pm** - ROOM 210C: Chairperson's Opening Remarks **1:30pm** - ROOM 210C: Challenges for Potency Assay Development for Gene Therapies & the Matrix Approach			**1:25pm** - Chairperson's Remarks **1:30pm** - ROOM 258AB: Justification of Small-Scale Models: An Industry Perspective	**1:25pm** - Chairperson's Remarks **1:30pm** - ROOM 258AB: Justification of Small-Scale Models: An Industry Perspective					

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
2:00PM	**2:00pm** - ROOM 210A: Process Analytical Technologies for Cell Therapies		**2:00pm** - ROOM 253AB: Implementing PAT at USP - From Lab to Manufacturing	**2:00pm** - ROOM 210A: Process Analytical Technologies for Cell Therapies **2:30pm** - ROOM 210A: Human Liver-Chips: Qualifying a Preclinical Model System for AAV Vector			**2:00pm** - ROOM 210B: Novel Modalities to Address CAR-T Challenges - NK Cell Case Study **2:30pm** - ROOM 210B: FectoVIR®-AAV: the next-generation transfection	**2:00pm** - ROOM 210C: Developing Functional Potency Assay for Gene Therapy Products **2:30pm** - ROOM 210C: Leveraging lessons from the COVID-19 pandemic to acceler-			**2:00pm** - ROOM 258AB: Visualizing Manufacturing Data in Real Time and How the Data Relates to Models for the Process	**2:00pm** - ROOM 258AB: Visualizing Manufacturing Data in Real Time and How the Data Relates to Models for the Process		**2:30pm** - ROOM 253AB: Single-Use Material Selection for Critical Storage Operations in Gene Therapy Development and Scale-up	**2:30pm** - ROOM 258AB: PolarDry and Biotherapeutic Applications	**2:30pm** - ROOM 258C: Optimized, Efficient, and Scalable Transient Transfection for High Titer AAV and LV Generation	**2:30pm** - Room 253C -- A single intensified and continuous platform for a scalable adherence and suspension viral production

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
				Development			reagent for large-scale AAV manufacturing **2:45pm** - ROOM 210B: BioCentriq Cell and Gene Therapy Development and Clinical Manufacturing Center	ate the development and production of adeno-associated virus (AAV)-based gene therapies									

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
3:00PM	**3:00pm** - Networking Refreshment Break in the Exhibit Hall		**3:00pm** - Networking Refreshment Break in the Exhibit Hall	**3:00pm** - Networking Refreshment Break in the Exhibit Hall		**3:00pm** - Lessons Learned: Building and Booking a State-of-the-Art Biologics Manufacturing Facility in 18 months amidst Covid and Global Materials Shortages **3:10pm** -	**3:00pm** - Networking Refreshment Break in the Exhibit Hall	**3:00pm** - Networking Refreshment Break in the Exhibit Hall			**3:00pm** - Networking Refreshment Break in the Exhibit Hall	**3:00pm** - Networking Refreshment Break in the Exhibit Hall					

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CONFERENCE DAY 2 - 22/09/2021

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						Step into your Cell Culture Media with the REBEL Analyzer **3:20pm** - Networking Break **3:45pm** - Emerging and Innovative Technology Session												

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
4:00PM	**4:00pm** - ROOM 210A: Manufacturing Tissues at Scale - A Platform that Enables Precise Control Over iPS Cell Fate in their Natural Environment **4:30pm** - ROOM 210A: Autologous iPS		**4:00pm** - ROOM 253AB: Comparing Dielectric and Raman spectroscopy for online cell growth monitoring of biotherapeutics manufacturing **4:30pm** - ROOM 253AB: Benchmarking	**4:00pm** - ROOM 210A: Manufacturing Tissues at Scale - A Platform that Enables Precise Control Over iPS Cell Fate in their Natural Environment **4:30pm** - ROOM 210A: Autologous iPS		**4:15pm** - Pak Biosolutions, Joanna Rucker Pezzini, President & Founder **4:25pm** - Q & A/ Panel Discussion **4:35pm** - AthemBio, Sunil Mehta, CEO **4:45pm** - Q & A/	**4:00pm** - Please move to another track **4:30pm** - ROOM 210B: Unlocking the Bottlenecks in The Supply Chain of Autologous Therapies: A Patient-Centric Approach	**4:00pm** - ROOM 210C: Rational Design & Development of Vector Genome Assay by ddPCR **4:30pm** - ROOM 210C: New Bioprocess Tools and Designs towards the Continuous Purification of				**4:00pm** - ROOM 258AB: BioPhorum's Manifesto of digital capabilities for the Quality Control Lab of the Future **4:30pm** - ROOM 258AB: Implementation of Tech for Digitalization	**4:00pm** - ROOM 258AB: BioPhorum's Manifesto of digital capabilities for the Quality Control Lab of the Future **4:30pm** - ROOM 258AB: Implementation of Tech for Digitalization					

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
	Cell Therapy for Macular Degeneration: From Bench-to-Bedside		of mAb Solution Behavior	Cell Therapy for Macular Degeneration: From Bench-to-Bedside		Panel Discussion **4:55pm** - Agile GXP Technologies, John Spohn, CEO		Viral Vectors for Gene Therapy			Transformation – Successes, Lessons Learned, and Impact on Project Workflows	Transformation – Successes, Lessons Learned, and Impact on Project Workflows					

SCHEDULE

CONFERENCE DAY 2 - 22/09/2021

TIME	ANALYTICAL & QUALITY	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION	CELL CULTURE AND UPSTREAM PROCESSING	CELL THERAPY	CELL THERAPY/ GENE EDITED EX VIVO CELL THERAPY	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	GENE EDITED EX VIVO CELL THERAPY	IN VIVO GENE THERAPY	INTENSIFIED AND CONTINUOUS PROCESSING	KEYNOTE SESSION	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	SPEED FROM GENE TO MARKET	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	TECHNOLOGY WORKSHOP 3	TECHNOLOGY WORKSHOP 4
5:00PM	**5:30pm** - BWB Party		**5:30pm** - BWB Party	**5:00pm** - ROOM 210B: AAV Full Capsid Enrichment for Serotypes 5, 8 & 9 **5:30pm** - BWB Lawn on D Party		**5:05pm** - Q & A/ Panel Discussion **5:45pm** - BWB Lawn on D Party	**5:00pm** - ROOM 210B: AAV Full Capsid Enrichment for Serotypes 5, 8 & 9 **5:30pm** - BWB Lawn on D Party	**5:00pm** - ROOM 210B: AAV Full Capsid Enrichment for Serotypes 5, 8 & 9 **5:30pm** - BWB Lawn on D Party			**5:30pm** - BWB Party	**5:30pm** - BWB Party					

SESSIONS

CONFERENCE DAY 3 - 23/09/2021

ROOM 253A: Chairperson's Opening Remarks

8:25am - 8:30am
Cell Culture and Upstream Processing

Participants

Kyle McHugh - Scientist, Bristol-Myers Squibb

ROOM 258AB: Chairperson's Opening remarks

8:25am - 8:30am
Recovery & Purification

Participants

David Kahn, Ph.D. - Vice President of Biopharmaceutical Development, Macrogenics

ROOM 258C: Chairperson's Opening remarks

8:25am - 8:30am
Manufacturing Strategy & Bioprocessing 4.0

Participants

Ricardo Suarez-Heredia - Applications Engineer Bioprocessing R&D, MilliporeSigma

ROOM 210A: Chairperson's Opening Remarks

8:25am - 8:30am
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

ROOM 253A: Cell culture media solution preparation: in-process characterization and tech transfer to CMO

8:30am - 9:00am
Cell Culture and Upstream Processing

In-line monitoring platform was employed to evaluate the media dissolution process at development scale. The key factors, i.e., pH, temp, particle size, etc., were real-time monitored to better understand the potential impact that would affect hydration and/or lead the precipitation.

Case study will be shared regarding incomplete dissolution of media solutions during technology transfer to CMO. It will show the importance of using scale down model for screening factors that could impact the media solution preparation process.

Participants

Yue Hu, Ph.D., - Scientist, Material Sciences, Janssen

ROOM 258AB: Host Cell Protein Challenges in the Downstream Process Development of Non-Antibody Processes

8:30am - 9:00am
Recovery & Purification

Participants

Naveenkumar Singh, Ph.D. - Scientist II, Process Development – Downstream, Ambrx

ROOM 258C: Developability Assessment of a Biologic Using an Instrument Developed at AbbVie called the iBEACON that Enables Screening Candidates at Higher Throughput

8:30am - 9:00am
Manufacturing Strategy & Bioprocessing 4.0

Participants

Ramesh Iyer, Ph.D., Remote - Live with Q & A - Principal Research Scientist II, Global Protein Sciences, AbbVie Inc.

ROOM 210A: State of the Industry

8:30am - 9:00am
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

Participants

Janet Lambert - Chief Executive Officer, Alliance for Regenerative Medicine

ROOM 253A: Novel approach for developing a robust scale-down model in ambr® 250

9:00am - 9:30am
Cell Culture and Upstream Processing

High-throughput (HT) automated mini-bioreactor systems, such as ambr® 250, are extensively used for cell culture process development in biopharmaceutical industry. We developed a scale- down model in ambr250 to facilitate process characterization of a monoclonal antibody project. Our focus was on mimicking the pCO2 profiles of manufacturing scale by adjusting the agitation and gas flow rates in ambr® 250. Subsequently we optimized pH control loop settings, including PID gains and maximal CO2 sparging flow rates, to improve pH control in ambr® 250. The result was an ambr® 250 process with cell growth, viability, productivity and product quality consistent with those of manufacturing scale. This case study demonstrates the feasibility of this approach to develop a robust scale-down model using a high-throughput system.

Participants

Amlan Das, Remote - Live with Q & A - CMC Biologics, Teva Pharmaceuticals

ROOM 258AB: Accelerated Depth Filter Screening to Improve Process Impurity Clearance

9:00am - 9:30am
Recovery & Purification

Participants

Geok-Yong Yow - Scientist I, KBI Biopharma

ROOM 258C: Paving the Way for Real time Product Quality Attribute Analysis in Bioprocess Development

9:00am - 9:30am
Manufacturing Strategy & Bioprocessing 4.0

There have been significant attentions and interests developed recently towards advancing analytical paradigms with unprecedented capabilities of real time monitoring of critical process parameters and critical product quality attributes (CQA) in bioprocess development space. The core requirement for real time analytics involves Process Analytical Technology (PAT), a system for designing, analyzing, and controlling manufacturing through real time monitoring of critical quality and performance attributes with the ultimate goal of ensuring final product quality. Regulatory agencies including U.S. Food and Drug Administration endorse the utility of PAT, and embrace the integration of novel analytical technologies for process monitoring. Our PAT landscape during biologics development features broad spectrum of technologies including chromatography, spectroscopy & chemometrics, sensors and mass spectrometry for inline and online analysis by integrating into upstream and downstream unit operations through automated aseptic sample preparation or proprietary flow cell sensors for real time acquisition of analytical data. The roadmap for successful implementation of PAT tools entails strategic identification of critical quality attributes, critical control points and critical process parameters during bioprocess development with deliberate alignment of analytical technologies under the consideration of associated capabilities and limitations. Our vision includes the integration of automated-data processing, visualization, and feedback control capabilities for seamless process control. Mechanistic modeling, machine learning and deep learning techniques are built to allow prescriptive and predictive control of the bioprocess manufacturing. Accurate process understanding and control will enhance our quality by design (QbD) approaches in bioprocess development for more sustainable manufacturing of biopharmaceuticals.

Participants

Julia Ding, PhD, Remote - Live with Q & A - Head, Global Process Analytics, Bristol Myers Squibb

ROOM 210A: Panel: Investment view on Innovation in Cell & Gene Therapy

9:00am - 9:30am
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

- Providing the investor view – how can academia & biotech think about and present their projects to make them more attractive?
- Building personal relationships and the importance of a pitch
- What are the key challenges facing the CGT community, how do investors see these? What are they looking to support?
- Investing in new & novel technologies, balancing our investment against risk – what assurances do we expect?
- How has COVID-19 impacted investment in the CGT space?

Participants

Shaan Gandhi - Director, Northpond Ventures

Walter Kowtonuik - Venture Partner, Third Rock

Anna French - Partner, Qiming Venture Partners USA

Claire Leurent, Ph.D., MBA - Principal, Venture Investments, J&J

Anthony Davies, Ph.D. - Founder & CEO, Dark Horse Consulting

ROOM 210B: Opening remarks and Manufacturing the Future of Biofabrication with ARM

9:00am - 9:30am
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

Participants

Thomas Bollenbach - Chief Technology Officer, Advanced Regenerative Manufacturing Institute

SBR-1 Manufacturing: A Learning Laboratory

9:00am - 9:30am
WORKSHOP - SBR-1 Manufacturing: A Learning Laboratory (Limited to 30 Participants)

Course Objective: It has been well posited that adults learn best through memorable experiences. Effective blended learning programs provide relevant experiences in low risk environments and can be used to anticipate and frame learning needs rather than scavenging learning opportunities from unplanned events. This course is intended as an example of using interactive simulation gaming as a tool for blended learning, specifically introducing participants to the routine and unanticipated elements of operating a biopharmaceutical manufacturing facility. In this session we will touch on elements of capacity and throughput management, statistical process control, quality culture, assignment of roles and responsibilities, and examples of the cost vs value conundrum confronted by manufacturing site governance. Attendees will be participating in a Learning Laboratory experience that is not compatible with coming and going during the session, doing email on your phone, or bailing out when an in control and capable process with fully gaussian outputs, little if any special cause variability, and a very accommodating and flexible management team suddenly goes awry!

Course Outline:

• "Why play games? "and provision of meaningful learning experiences.

• Attendees will all participate in the running of a biopharm manufacturing facility and responding to routine and unexpected events. This will include managing process variability, cost of goods, continuous improvement, and responsibility and accountability in the workplace.

• We will discuss whether using data to support or criticize management decisions is the same thing as data driven management.

• We will further discuss unintended consequences of metrics driven Management by Objective and whether there is a tension between MBO and building a Quality Culture.

• All models are wrong but many are useful. We will have a discussion on how SBR-1 is and is not a realistic representation of actual manufacturing challenges and the relevance of experiences

in the game to experiences in the work place.

• This course is not intended to provide answers to the challenges of biopharmaceutical manufacturing but to challenge the lenses through which such operations are often seen and evaluated. The key deliverable of this course is a new panel of questions participants can take with them to explore in order to identify different solutions to old and recurring problems.

Primary Audience:

• Operational and managerial decision makers at all levels within biopharmaceutical manufacturing with an emphasis on API and final dosage form manufacturing trains.

• Individuals wishing to explore the role of simulation gaming in mentoring, career skills development, and in providing a low risk setting for discussion of difficult topics.

Participants

Jeffrey C. Baker, Ph.D - Former Deputy Director, Office of Biotechnology Products, CDER, FDA

ROOM 253A: Changing the Drug Development Paradigm: From Concept to Clinic in Record Time Using the FastPharming System

9:30am - 10:00am
Technology Workshop 1

Drug development has historically been a time, labor, and money-intensive endeavor where ultimate success is the exception, rather than the rule. This is acutely apparent in the biologics space where the time it takes to manufacture a lead molecule to support first-in-human clinical trials using traditional cell culture expression systems is often measured in years rather than months, with product costs for Phase 1 trials averaging $5MM or more. This presentation will describe the FastPharming system developed by iBio and its inherent benefits in terms of speed, cost, scalability, and sustainability. Using data associated with the current FastPharming platform and considering the opportunities associated with the newly designed FastPharming NextGen platform, a compelling case will be made for why the time is right for FastPharming to take its place as the platform of choice for the next generation of protein therapeutics.

Participants

Randy Maddux - Chief Operating Officer, iBio, Inc.

ROOM 258AB: In-process control for pDNA production

9:30am - 10:00am
Technology Workshop 2

Global demand for pDNA production is at an all time high, due to increased need from Gene Therapy ramp-up. pDNA, as an enabling product, is critical in production of mRNA, AAV and other therapeutic vectors. Increasing yield and purity in the production of pDNA is a vital step in meeting such demand. Supporting reliable in-process control during pDNA purification, PATfix pDNA analytical platform is enabling rapid process development and optimization while providing a reliable analytical platform for production runs.

ROOM 210A: Panel: Investment view on Innovation in Cell & Gene Therapy (Cont.)

9:30am - 9:45am
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

- Providing the investor view – how can academia & biotech think about and present their projects to make them more attractive?
- Building personal relationships and the importance of a pitch
- What are the key challenges facing the CGT community, how do investors see these? What are they looking to support?
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Participants

Shaan Gandhi - Director, Northpond Ventures

Walter Kowtonuik - Venture Partner, Third Rock

Shinichiro (Shin) Fuse, Ph.D. - Managing Director, MPM Capital

Claire Leurent, Ph.D., MBA - Principal, Venture Investments, J&J

Anthony Davies, Ph.D. - Founder & CEO, Dark Horse Consulting

ROOM 210B: Tools and Technologies for Generating High Quality Cellular Starting Material

9:30am - 10:00am
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

Generating high quality and well defined cell banks – what tools, techniques, assays, and measurement technologies can be leveraged to achieve that goal? What do you make that QC process scalable?

Participants

Carter Cliff - Founder & CEO, Vascugen Inc., USA

Room 257A: SBR-1 Manufacturing: A Learning Laboratory

9:30am - 10:00am
WORKSHOP - SBR-1 Manufacturing: A Learning Laboratory (Limited to 30 Participants)

Course Objective: It has been well posited that adults learn best through memorable experiences. Effective blended learning programs provide relevant experiences in low risk environments and can be used to anticipate and frame learning needs rather than scavenging learning opportunities from unplanned events. This course is intended as an example of using interactive simulation gaming as a tool for blended learning, specifically introducing participants to the routine and unanticipated elements of operating a biopharmaceutical manufacturing facility. In this session we will touch on elements of capacity and throughput management, statistical process control, quality culture, assignment of roles and responsibilities, and examples of the cost vs value conundrum confronted by manufacturing site governance. Attendees will be participating in a Learning Laboratory experience that is not compatible with coming and going during the session, doing email on your phone, or bailing out when an in control and capable process with fully gaussian outputs, little if any special cause variability, and a very accommodating and flexible management team suddenly goes awry!

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Participants

Jeffrey C. Baker, Ph.D - Former Deputy Director, Office of Biotechnology Products, CDER, FDA

Networking Refreshment Break

10:00am - 11:00am
Cell Culture & Upstream Processing

Networking Refreshment Break

10:00am - 11:00am
Recovery & Purification

Networking Break

10:00am - 11:00am
Manufacturing Strategy & Bioprocessing 4.0

Networking Break

10:00am - 10:55am
Analytical & Quality

Networking Break

10:00am - 10:55am
Impact of COVID-19 on Bioprocessing

Networking Refreshment Break

10:00am - 10:45am
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

Networking Refreshment Break

10:00am - 10:45am
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

SBR-1 Manufacturing: A Learning Laboratory

10:00am - 12:00pm
WORKSHOP - SBR-1 Manufacturing: A Learning Laboratory (Limited to 30 Participants)

Course Objective: It has been well posited that adults learn best through memorable experiences. Effective blended learning programs provide relevant experiences in low risk environments and can be used to anticipate and frame learning needs rather than scavenging learning opportunities from unplanned events. This course is intended as an example of using interactive simulation gaming as a tool for blended learning, specifically introducing participants to the routine and unanticipated elements of operating a biopharmaceutical manufacturing facility. In this session we will touch on elements of capacity and throughput management, statistical process control, quality culture, assignment of roles and responsibilities, and examples of the cost vs value conundrum confronted by manufacturing site governance. Attendees will be participating in a Learning Laboratory experience that is not compatible with coming and going during the session, doing email on your phone, or bailing out when an in control and capable process with fully gaussian outputs, little if any special cause variability, and a very accommodating and flexible management team suddenly goes awry!

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Participants

Jeffrey C. Baker, Ph.D - Former Deputy Director, Office of Biotechnology Products, CDER, FDA

Accelerating Molecules to Medicines

10:05am - 10:25am
Theatre Showcase

The biopharmaceutical industry has made great strides in delivering cost-effective therapies to the market in the shortest timelines within regulatory manufacturing guidelines. However, these advances are challenged by increasingly complex biologics formats and the subsequent additional analytical work. In todayâ€™s highly competitive landscape, it is necessary for biotech and pharmaceutical companies to focus on core capabilities while relying on a network of collaborators, vendors and regulatory experts to fill gaps. Key to biopharmaceutical R&D is selecting Contract Research Organizations (CROs) that share a companyâ€™s goals of safety, quality, speed and low-cost. This talk will elaborate on strategies to shorten timelines while minimizing safety and regulatory risks.

Participants

Steven Lang, PhD - Vice President, Biologics, Aragen Bioscience

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Panel Discussion: Exploring the Massachusetts Biotech Ecosystem; Fostering Innovation, Spinning out, & Maximising Growth Potential

10:30am - 11:15am
Exhibition Hall Content/ Theater Showcase

- Reviewing the Incubator model and advantages of going down this path.
- Best practices for spinning out from academia
- Considering manufacturing capacity early to secure investment and maximise growth potential.
- Working with corporate partners to move towards commercialization

Participants

Shashi Murthy, PhD - Founder & CTO, Flaskworks

Brian Goodman, PhD - Principal, MPM

Vinit Nijhawan - Managing Director, MassVentures, Lecturer, Boston University, USA

Peter Strack - Scientific VP, Integrative Sciences, Bristol Myers Squibb, USA

ROOM 210A: Dual Dialogue – Anatomy of an Acquisition: Bayer and AskBio

10:45am - 11:45am
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

- Overview of the structure of the acquisition, goals, outcomes
- How the deal came about and COVID-19’s impact on the transaction
- Bayer’s unique operating model to ensure to successful partnerships within its Cell and Gene Therapy Platform
- Advancing AAV manufacturing post-acquisition

Participants

Sheila Mikhail, Remote - Live with Q&A - CEO & Co-Founder, AskBio

Marianne De Backer, MBA, PhD, Remote - Live with Q&A - EVP, Head of Strategy, BD&L, Bayer AG

ROOM 210B: Streamlining Production of Defined Cell Lines

10:45am - 11:15am
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- What tools do we have for directed differentiation that will be both efficient, cost-effective and consistent?
- What is best approach for generating differentiated cell types that meet pre-defined cell phenotypes?
- What role does genetic manipulation play in cell and tissue engineering?

Participants

Paratsoo Khoshakhlagh, Ph.D. - Chief Executive Officer & Co-Founder, GC Therapeutics, USA

Chairperson's Opening Remarks

10:55am - 11:00am
Analytical & Quality

Chairperson's Opening Remarks

10:55am - 11:00am
Impact of COVID-19 on Bioprocessing

SESSIONS

CONFERENCE DAY 3 - 23/09/2021

ROOM 253A: Developing a Chemically Defined Cell Culture Medium for the Production of Adeno-Associated Virus Vectors Using Suspension HEK293 Cells

11:00am - 11:30am
Cell Culture & Upstream Processing

Developing a highly efficient AAV production medium requires in-depth understanding of medium components, the nutrient requirement of the production cell line for cell proliferation and maintenance, and more importantly, the specific nutrient requirement for AAV capsid synthesis and replication of the recombinant viral payload.

In this work, a chemically defined protein-free medium formulation was developed using a combination of medium design approaches, including custom media mixture design, Design of Experiment (DOE) and One Factor At a Time (OFAT) studies. Concentrations of key media components were optimized for cell growth and viral titer. In addition, key components affecting transfection complex formation and subsequent viral production were identified. The resulting medium formulation supports fast cell growth of HEK293 derived cell line with an averaged doubling time of 24 hours and supports AAV production with titers comparing favorably to several commercial AAV production media.

Participants

Zhe (Jill) Zhang - Staff Engineer, Viral Production Core, Preclinical Manufacturing & Process Development, Regeneron Pharmaceutical, Inc.

ROOM 258AB: Phospholipase B-like 2 is Not Responsible for Polysorbate Degradation in Monoclonal Antibody Drug Products

11:00am - 11:30am
Recovery & Purification

- PLBD2 cannot degrade polysorbate in drug products despite it is a lipase that often presents in drug product in high abundance
- 3 experiments had been performed to draw the conclusion, including PLBD2 knockout experiment, PLBD2 depletion experiment and correlation of PS20 degradation with PLBD2 concentration
- Lessons learnt from this study is that spike-in experiment cannot be used as evidence to draw conclusive conclusion of the biological activity of host cell proteins since impurities in recombinant proteins may interfere the spike-in results

Participants

Sisi Zhang, Msc. - Lead Research Specialist, Analytical Chemistry, Regeneron

ROOM 258C: BioPhorum Technology Roadmapping Strategy Vision 2.0

11:00am - 11:30am
Manufacturing Strategy & Bioprocessing 4.0

Participants

Guido Kremer-van der Kamp - Senior Consultant, Global BioPharm Center of Excellence, Merck KGaA

Andrew Whytock - Head of Digitalization and Innovation, Business Segment Pharma, Siemens

Charles Heise, Ph.D. - Senior Staff Scientist, FUJIFILM Diosynth Biotechnologies

ROOM 253C: Leveraging Prior Knowledge for Faster Analytical Method Validation and Transfer

11:00am - 11:30am
Analytical & Quality

Biopharmaceutical industry is in a period of accelerated growth, with increasing number of new products entering development and seeking regulatory approval. We will provide examples in product characterization and quality control of monoclonal antibody therapeutics to illustrate the use of platform methods and prior knowledge to support analytical development of new products for accelerated entry into humans (EIH) studies.

Participants

Christopher Yu, Ph.D., Remote - Live with Q & A - Director, Protein Analytical Chemistry Quality Control, Genentech

ROOM 253B: Rapid Analytical Development of Monoclonal Antibodies for COVID Emergency Use Authorization

11:00am - 11:30am
Impact of COVID-19 on Bioprocessing

Responding to the unmet medical need for an efficacious COVID treatment, Lilly responded rapidly in 2020 with the development of anti-SARS-Cov2 monoclonal antibodies. Typical monoclonal antibody projects leave ample room for analytical development while processes are being developed and clinical trials are ongoing. However, for the COVID antibody projects, the rapid nature of the development exercise left analytical method development on or near the critical path. Through leveraging of platform methods, platform historical knowledge, and smart risk taking, we were able to achieve First Human Dose in record time. This paved the way for a rapid Emergency Use Authorization—just 8 months after initiation of any project work.

Participants

Adam Washburn, Remote - Live with Q & A - Senior Research Scientist, Eli Lilly

ROOM 210B: Label-free Cell Selection and Purification

11:15am - 11:45am
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- Purifying the desired cell population from a heterogenous tissue or cell population

Participants

Travis Block - Chief Technology Officer, Cell X Technologies, USA

Panel: Talent Acquisition, Development and Retention in Novel Therapeutics

11:15am - 12:00pm
Exhibition Hall Content/ Theater Showcase

- Addressing key challenges in TA in novel therapeutics
- How can companies best work with personnel to develop talent into their next roles; ready now/ ready later talent.
- In a competitive area such as Boston, how should we strike a balance between working to retain talent and embracing and supporting personnel moving around.

Participants

Moderator: Andrew Rigoglioso - Associate Director, TA, Cell Therapy Development & Ops, BMS

Juliette Hilliard, Remote - Live with Q&A - Director, TA, Novartis GT

Stacey Veysey - Director, Talent Acquisition, Vertex Pharmaceuticals, USA

ROOM 253A: Identification of hydroxyproline as a novel co-translational modification during cell culture development

11:30am - 12:00pm
Cell Culture & Upstream Processing

Participants

Shanta Boddapati, Remote - Live with Q & A - Senior Scientist, Seagen

ROOM 258AB: Polysorbate, The Good, The Bad and the Ugly

11:30am - 12:00pm
Recovery & Purification

Participants

Linda Yi, Remote - Live with Q & A - Senior Scientist, Analytical Development, Biogen

SESSIONS

CONFERENCE DAY 3 - 23/09/2021

ROOM 258C: CMO Quality Oversight Challenges and FDA's Perspective

11:30am - 12:00pm
Manufacturing Strategy & Bioprocessing 4.0

Participants

Wenyan Liao - ASQ Certified Quality Auditor, Sr. QA Disposition, External Biologics (Global Quality), Takeda Pharmaceutical Company Limited

ROOM 253C: Analytical Life Cycle Management and Challenges for Biologic Products

11:30am - 12:00pm
Analytical & Quality

Participants

Udayanath Aich, Ph.D. - Associate Director, Bristol Myers Squibb

ROOM 253B: Panel Discussion - Benefits Gained from Accelerated Programs on Future of Development Timelines

11:30am - 12:00pm
Impact of COVID-19 on Bioprocessing

Discussion topics include:

- Utilizing new state of the art approaches to development and production
- What was accelerated to get to clinical trials and commercialization? How to you balance speed and safety in a pandemic?
- What speed to IND means post-COVID? Business risks compared to pre-COVID? Will those changes be long lasting?
- How have companies accelerated process development and validation with new analytical approaches
- Accelerated process validation strategies – What truly accelerated process validation looks like

Participants

Denny Kraichely, Ph.D - Department Head, Analytical Project Leadership, Vaccines Research & Development, Merck, Merck

Hanne Bak, Ph.D. - Senior Vice President, Pre-clinical Manufacturing & Process Development, Regeneron Pharmaceutical, Inc.

Adam Washburn, Remote - Live with Q & A - Senior Research Scientist, Eli Lilly

Howard Levine, PhD - National Leader, BioProcess Technology Group

ROOM 210A: Panel: Manufacturing and Distribution Strategies for Commercialising Cell & Gene Therapies

11:45am - 12:30pm
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

- Reviewing the disruption to the CGT industry from the pandemic
- Looking into the cost of manufacturing; how to reduce and keep cost of products down
- Assessing the role of automation & AI
- Macro decisions in manufacturing strategy; in house/outsourcing, domestic/international and the distribution implications of this
- Scaling of manufacturing as industry moves towards chronic diseases and higher populations

Participants

David Peritt - Founder and CSO, Lupagen, USA

Kareem Reda - CBO, Elevate Bio

Maria Cho - VP Business Development & Corporate Strategy, Dendreon, USA

Chathuranga De Silva, PhD - Director, Business Development, BioCentriq, USA

Beth Webb - Chief Commercial Officer, Aldevron, USA

ROOM 210B: Smart and Connected Bioreactor with Wireless Flexible Sensors and Electronics

11:45am - 12:15pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- Real-time and online sensors for cell and tissue attributes during culture, expansion, and maturation
- Sensing for gases, proteins, lipids, chemical substrates, and metabolites. How can some of these platforms be used for proteins and specified to different process needs for sensing?

Participants

W. Hong Yeo - Associate Professor of George W. Woodruff School of Mechanical Engineering, Director of the IEN Center for Human-Centric Interfaces and Engineering, Georgia Institute of Technology, USA

ROOM 253A: Appreciating the Importance of Osmolality in Upstream Processes and it's Impact on AAV Workflows

12:00pm - 12:30pm
Cell Culture & Upstream Processing

Those working with AAVs have the potential to improve the quality and yield of their products during manufacturing. Osmolality acceptance as a critical process parameter in the production of biologics, including those in the Cell and Gene Therapy area continues to grow. This has stimulated new interest in researching its utility. Today's presentation will focus on how osmolality is used in upstream processes, with a spotlight on recent data from a collaboration with the Cell and Gene Therapy Catapult Manufacturing Innovation Centre.

Participants

Mark Rothenberg, PhD - Associate Director Scientific Applications, Advanced Instruments LLC

ROOM 258AB: Supporting Manufacturing Process Optimization by Leveraging Consistent Virus Removal Filter Performance Across Process Scales

12:00pm - 12:30pm
Recovery & Purification

Virus filtration processes are developed, optimized and validated using constant pressure filtration at small scale, and it is critical that this data is predictive and representative of filter performance both at larger scales and under different operation strategies. While using constant pressure at small scale is convenient and common, manufacturing suites typically use pump-driven systems with single-use bags to leverage footprint and workflow advantages. In this study, we extend the previously demonstrated scalability of the Planova 20N virus removal filter to pump-driven control at all sizes. PP7 bacteriophage logarithmic reduction (PP7 LRV) evaluated under constant flow operation across filter sizes 0.001 to 4.0 m2 showed consistent and robust PP7 LRV of 4.3 or greater for all runs, as was observed in previous constant pressure experiments. Filterability performance was also shown to be consistent irrespective of filter operation method. Because different filter operation strategies may be employed at different scales, conditions different from those of the initial process may be factors at other sizes of the scale up. The impacts of pressure fluctuation and extended pump ramp up time on viral clearance were additionally investigated in PPV-spiked filtrations. Robust and consistent PPV clearance was observed with a PPV LRV of 4.4 or greater for these runs. Based on demonstration of consistent filter performance across filter scales and operation methods, we can evaluate the impact of various manufacturing-scale conditions at smaller scales and confidently consider the results to be representative of the filter size of interest.

Participants

Brian Buesing - Associate Scientist, Asahi Kasei Bioprocess America, Inc

ROOM 258C: Application of Raman Spectroscopy for Real-time Monitoring and Control in Mammalian Cell Cultures: A case study on automated glucose control for CHO cell fed batch cultures

12:00pm - 12:30pm
Manufacturing Strategy & Bioprocessing 4.0

Mammalian cell cultures are widely used as the workhorse platform in the production of biological products including antibodies, other therapeutic proteins, and growth factors. Deviations of critical process parameters (CPP) in upstream unit operations can directly lead to physicochemical and biological heterogeneities in the biological expression system and associated critical quality attributes (CQA) in therapeutic product. Hence, Process Analytical Technologies (PAT) have represented an enabler to the Quality by Design (QbD) paradigm to generate adaptive processes that can maintain productivity and reduce product quality deviation through the implementation of sensor technology for process monitoring and control.

Raman spectroscopy has become attractive for PAT applications given its inherent properties such as non-contact, non-destructive, high molecular specificity, and weak water bands for good quality analysis in aqueous solutions. Given the increasing interest for robust process design, optimization and control in established (fed-batch) and emerging (intensified and continuous) upstream platforms, Raman spectroscopy provides a great potential for real-time and in-situ measurement of relevant cell culture process parameters and product quality attributes. Herein, we present a case study on the implementation of a Raman spectroscopy analyzer for real time monitoring and subsequent control of glucose through the implementation of a feedback control loop in a CHO cell fed-batch culture process.

Firstly, a preliminary set of fed-batch cultures (n=4) was conducted for spectral data acquisition and multivariate model development. A parental CHO cell line was cultivated in bench scale stirred tank bioreactors in a chemically defined basal and feed media environment. Raman spectra measurements were acquired using an in-line Raman Analyzer (ProCellicsTM, MilliporeSigma, USA). Off-line analysis, for variable association, included key process parameters such as cell density (VCD and TCD), key nutrient (glucose and glutamine) and by-product metabolites (lactate and ammonia). Spectral data was pre-processed (standard normal variate transformation, Savitzky-Golay derivatives and spectral truncation) and analyzed via Principal Component Analysis (PCA) (Bio4CTM PAT Raman Software, MilliporeSigma, USA). Regression via Partial Least Squares (PLS) was conducted for correlating Raman spectra acquisitions and off-line key process parameters across cultivation time and culture batches (Bio4CTM PAT Raman Software, MilliporeSigma, USA). PLS model predictions were evaluated (RMSEE, RMSECV) and validated (RMSEP) based on root mean squared error (<Â±10%) using independent calibration and test data sets.

Secondly, the Raman analyzer and associated models were used for real time monitoring of key process variables and the implementation of a feedback control loop for maintenance of a glucose concentration setpoint. The feedback control loop consisted of a direct OPC Unified Architecture (UA) communication between the Raman analyzer and the bioreactor control system. Glucose provision through chemically defined feed media was performed fully automated based on soft sensor-pump cascading actions and leading to steady state glucose concentration (5 g L-1) during late exponential and stationary culture phases. The Raman based controlled culture was benchmarked against a standard fed-batch culture based on bolus feeding strategy, demonstrating no change of cell growth profile but a reduced lactate production profile (35% decrease).

Overall, this investigation demonstrated the successful application of an experimental and multivariate modelling approach for the adoption of Raman spectroscopy for in-line monitoring and control in mammalian cell cultures. The increasing implementation of combined advanced sensor technology and process data analytics tools can enable process monitoring, and subsequent control, to improve not only process yields but also to meet product quality requirements in the next generation of upstream platforms.

Participants

Ricardo Suarez-Heredia - Applications Engineer Bioprocessing R&D, MilliporeSigma

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ROOM 253C: On the Importance of Monitoring Both Transfection and Transduction Efficiencies in Cell Therapy Development

12:00pm - 12:30pm
Analytical & Quality

Participants

Derek Lenz, Ph.D., Remote - Live with Q & A - Field Marketing Manager, Beckman Coulter

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ROOM 253B: Scientific Track Presentation

12:00pm - 12:30pm
Impact of COVID-19 on Bioprocessing

Lunch Presentation and Networking Break

12:30pm - 1:25pm
Cell Culture and Upstream Processing

Lunch Presentation and Networking Break

12:30pm - 1:25pm
Recovery & Purification

Lunch Presentation and Networking Break

12:30pm - 1:25pm
COVID-19 Development & Production

Lunch Presentation and Networking Break

12:30pm - 1:30pm
Cell & Gene Therapy Manufacturing and Commercialization – Partnering Track

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Lunch Presentation and Networking Break

12:30pm - 1:30pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

ROOM 253A: Chairperson's Remarks

1:25pm - 1:30pm
Cell Culture and Upstream Processing

Participants

Kyle McHugh - Scientist, Bristol-Myers Squibb

ROOM 253A: Chairperson's Remarks

1:25pm - 1:30pm
Recovery & Purification

Participants

Kyle McHugh - Scientist, Bristol-Myers Squibb

ROOM 253B: Chairperson's Remarks

1:25pm - 1:30pm
COVID-19 Development & Production

Participants

Lynne Frick - Co-Head, Biologics Franchise, Resilience and Co-Executive Director, The BioInnovation Group

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ROOM 253A: Challenges of Harvest Depth Filtration for Bispecific Molecules – A Case Study

1:30pm - 2:00pm
Cell Culture and Upstream Processing

- Depth filtration can potentially provide clearance of product-related species. However, undesired adsorption of target molecule onto the depth filter may also occur
- Depth filters show adsorptive characteristics, the extent and mechanism of which depend on the filter media composition
- Electrostatic and hydrophobic interactions are the main mechanisms of adsorption onto the depth filter media
- Knowledge of structural properties of the target molecule and its related species as well as better understanding of adsorptive characteristics of the depth filters help designing the robust and efficient depth filtration processes

Participants

Ehsan Borujeni - Principal Scientist, Global BioProcess Development, Downstream, Bristol-Myers Squibb

SESSIONS

CONFERENCE DAY 3 - 23/09/2021

ROOM 253A: Challenges of Harvest Depth Filtration for Bispecific Molecules – A Case Study

1:30pm - 2:00pm
Recovery & Purification

- Depth filtration can potentially provide clearance of product-related species. However, undesired adsorption of target molecule onto the depth filter may also occur
- Depth filters show adsorptive characteristics, the extent and mechanism of which depend on the filter media composition
- Electrostatic and hydrophobic interactions are the main mechanisms of adsorption onto the depth filter media
- Knowledge of structural properties of the target molecule and its related species as well as better understanding of adsorptive characteristics of the depth filters help designing the robust and efficient depth filtration processes

Participants

Ehsan Borujeni - Principal Scientist, Global BioProcess Development, Downstream, Bristol-Myers Squibb

ROOM 253B: Portals for Collaboration Between FDA Laboratories and the Scientific Community

1:30pm - 2:00pm
COVID-19 Development & Production

Participants

Jeffrey C. Baker, Ph.D - Former Deputy Director, Office of Biotechnology Products, CDER, FDA

ROOM 210B: Scaling the Production of Tissues Using 3D Printing

1:30pm - 2:00pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- How to speed up production for tissue fabrication using 3D printing?
- How do we address scale for Biofabrication?
- What are the considerations for consistency and reproducibility?
- What does high throughput Biofabrication mean to you?

Participants

Mike Graffeo - CEO & Co-Founder, FluidForm, USA

ROOM 253A: Mitigating Filter Fouling in Continuous ATF Pichia Cultures

2:00pm - 2:30pm
Cell Culture and Upstream Processing

Participants

Chris Kwiatkowski, Remote - Live with Q & A - Engineer, Biopharmaceutical Development, Biogen Idec

ROOM 253A: Mitigating Filter Fouling in Continuous ATF Pichia Cultures

2:00pm - 2:30pm
Recovery & Purification

Participants

Chris Kwiatkowski, Remote - Live with Q & A - Engineer, Biopharmaceutical Development, Biogen Idec

ROOM 253B: Data Integrity for Process and Analytical CMC Studies

2:00pm - 2:30pm
COVID-19 Development & Production

Participants

Nadine Ritter - President and Analytical Advisor, Global Biotech Experts, LLC.

ROOM 210B: Generating Complex Scaffolds and Harnessing Native Material Architecture

2:00pm - 2:30pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- Fabrication of complex scaffold matrixes at high throughput
- Supplying chain considerations when using a natural material source, how to ensure batch to batch consistency?

Participants

Aleks Katane - Liver Program Manager, Miromatrix, USA

ROOM 210B: Developing a scalable process for manufacturing stem cell-derived β cells

2:30pm - 3:00pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- Cutting edge processes and tools for creating an innovative and exciting TEMP product. Where have they had to innovate to develop solutions that will scale with them as they progress toward commercialization?
- How has their equipment and process changed as the product progressed from R&D to clinical?

Participants

Nathaniel Hogrebe - Postdoctoral Research Fellow, Jeffrey Millman Laboratory, Washington University School of Medicine, USA

Networking Refreshment Break

3:00pm - 3:30pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

ROOM 210B: Maturation Techniques and Bioreactor Culture for Tissue Generation

3:30pm - 4:00pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- Cutting edge processes and tools for creating an innovative and exciting TEMP product. Where have they had to innovate to develop solutions that will scale with them as they progress toward commercialization?
- How has their equipment and process changed as the product progressed from R&D to clinical?

Participants

Jane Lebkowski, Remote - Live with Q&A - President, Regenerative Patch Technologies Inc.

ROOM 210B: Trends for the Future of Biomanufacturing

4:00pm - 4:30pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

- High level strategy for developing cell and tissue products; minimizing risk, quality by design, systems integration, data management & analysis, etc.

Participants

Trent Carrier, Remote - Live with Q&A - Chief Operating Officer, L7 Informatics, Inc., USA

SESSIONS

CONFERENCE DAY 3 - 23/09/2021

End of Day

4:30pm - 4:35pm
Bio fabrication – The Path to Commercialization: In collaboration with ARMI

Close of BPI 2021

4:35pm - 4:40pm

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
8:00AM				**8:25am** - ROOM 210A: Chairperson's Opening Remarks **8:30am** - ROOM 210A: State of the Industry		**8:25am** - ROOM 253A: Chairperson's Opening Remarks **8:30am** - ROOM 253A: Cell culture media solution preparation: in-process characterization and tech transfer to CMO			**8:25am** - ROOM 258C: Chairperson's Opening remarks **8:30am** - ROOM 258C: Developability Assessment of a Biologic Using an Instrument Developed at AbbVie called the iBEACON that Enables Screening	**8:25am** - ROOM 258AB: Chairperson's Opening remarks **8:30am** - ROOM 258AB: Host Cell Protein Challenges in the Downstream Process Development of Non-Antibody Processes				

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
									Candidates at Higher Throughput					

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
9:00AM		**9:00am** - ROOM 210B: Opening remarks and Manufacturing the Future of Biofabrication with ARM **9:30am** - ROOM 210B: Tools and Technologies for Generating High Quality Cellular Starting Material		**9:00am** - ROOM 210A: Panel: Investment view on Innovation in Cell & Gene Therapy **9:30am** - ROOM 210A: Panel: Investment view on Innovation in Cell & Gene Therapy (Cont.)		**9:00am** - ROOM 253A: Novel approach for developing a robust scale-down model in ambr® 250			**9:00am** - ROOM 258C: Paving the Way for Real time Product Quality Attribute Analysis in Bioprocess Development	**9:00am** - ROOM 258AB: Accelerated Depth Filter Screening to Improve Process Impurity Clearance	**9:30am** - ROOM 253A: Changing the Drug Development Paradigm: From Concept to Clinic in Record Time Using the Fast-Pharming System	**9:30am** - ROOM 258AB: In-process control for pDNA production		**9:00am** - SBR-1 Manufacturing: A Learning Laboratory **9:30am** - Room 257A: SBR-1 Manufacturing: A Learning Laboratory

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
10:00AM	**10:00am** - Networking Break **10:55am** - Chairperson's Opening Remarks	**10:00am** - Networking Refreshment Break **10:45am** - ROOM 210B: Streamlining Production of Defined Cell Lines		**10:00am** - Networking Refreshment Break **10:45am** - ROOM 210A: Dual Dialogue – Anatomy of an Acquisition: Bayer and AskBio	**10:00am** - Networking Refreshment Break		**10:30am** - Panel Discussion: Exploring the Massachusetts Biotech Ecosystem; Fostering Innovation, Spinning out, & Maximising Growth Potential	**10:00am** - Networking Break **10:55am** - Chairperson's Opening Remarks	**10:00am** - Networking Break	**10:00am** - Networking Refreshment Break			**10:05am** - Accelerating Molecules to Medicines	**10:00am** - SBR-1 Manufacturing: A Learning Laboratory

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
11:00AM	**11:00am** - ROOM 253C: Leveraging Prior Knowledge for Faster Analytical Method Validation and Transfer **11:30am** - ROOM 253C: Analytical Life Cycle Management and Challenges for Biologic Products	**11:15am** - ROOM 210B: Label-free Cell Selection and Purification **11:45am** - ROOM 210B: Smart and Connected Bioreactor with Wireless Flexible Sensors and Electronics		**11:45am** - ROOM 210A: Panel: Manufacturing and Distribution Strategies for Commercialising Cell & Gene Therapies	**11:00am** - ROOM 253A: Developing a Chemically Defined Cell Culture Medium for the Production of Adeno-Associated Virus Vectors Using Suspension HEK293 Cells **11:30am** - ROOM 253A: Identification of hydrox-		**11:15am** - Panel: Talent Acquisition, Development and Retention in Novel Therapeutics	**11:00am** - ROOM 253B: Rapid Analytical Development of Monoclonal Antibodies for COVID Emergency Use Authorization **11:30am** - ROOM 253B: Panel Discussion - Benefits Gained from Accelerated Programs on	**11:00am** - ROOM 258C: BioPhorum Technology Roadmapping Strategy Vision 2.0 **11:30am** - ROOM 258C: CMO Quality Oversight Challenges and FDA's Perspective	**11:00am** - ROOM 258AB: Phospholipase B-like 2 is Not Responsible for Polysorbate Degradation in Monoclonal Antibody Drug Products **11:30am** - ROOM 258AB: Polysorbate, The Good, The Bad and the Ugly				

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
					yproline as a novel co-translational modification during cell culture development			Future of Development Timelines						

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
12:00PM	**12:00pm** - ROOM 253C: On the Importance of Monitoring Both Transfection and Transduction Efficiencies in Cell Therapy Development	**12:30pm** - Lunch Presentation and Networking Break	**12:30pm** - Lunch Presentation and Networking Break	**12:30pm** - Lunch Presentation and Networking Break	**12:00pm** - ROOM 253A: Appreciating the Importance of Osmolality in Upstream Processes and it's Impact on AAV Workflows	**12:30pm** - Lunch Presentation and Networking Break		**12:00pm** - ROOM 253B: Scientific Track Presentation	**12:00pm** - ROOM 258C: Application of Raman Spectroscopy for Real-time Monitoring and Control in Mammalian Cell Cultures: A case study on automated glucose control for CHO cell fed batch cultures	**12:00pm** - ROOM 258AB: Supporting Manufacturing Process Optimization by Leveraging Consistent Virus Removal Filter Performance Across Process Scales **12:30pm** - Lunch Presentation and Networking				

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
										Break				
1:00PM		**1:30pm** - ROOM 210B: Scaling the Production of Tissues Using 3D Printing	**1:25pm** - ROOM 253B: Chairperson's Remarks **1:30pm** - ROOM 253B: Portals for Collaboration Between FDA Laboratories and the Scientific Community			**1:25pm** - ROOM 253A: Chairperson's Remarks **1:30pm** - ROOM 253A: Challenges of Harvest Depth Filtration for Bispecific Molecules – A Case Study				**1:25pm** - ROOM 253A: Chairperson's Remarks **1:30pm** - ROOM 253A: Challenges of Harvest Depth Filtration for Bispecific Molecules – A Case Study				

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
2:00PM		**2:00pm** - ROOM 210B: Generating Complex Scaffolds and Harnessing Native Material Architecture **2:30pm** - ROOM 210B: Developing a scalable process for manufacturing stem cell-derived β cells	**2:00pm** - ROOM 253B: Data Integrity for Process and Analytical CMC Studies			**2:00pm** - ROOM 253A: Mitigating Filter Fouling in Continuous ATF Pichia Cultures				**2:00pm** - ROOM 253A: Mitigating Filter Fouling in Continuous ATF Pichia Cultures				

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
3:00PM		**3:00pm** - Networking Refreshment Break **3:30pm** - ROOM 210B: Maturation Techniques and Bioreactor Culture for Tissue Generation												

SCHEDULE

CONFERENCE DAY 3 - 23/09/2021

TIME	ANALYTICAL & QUALITY	BIO FABRICATION – THE PATH TO COMMERCIALIZATION: IN COLLABORATION WITH ARMI	COVID-19 DEVELOPMENT & PRODUCTION	CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION – PARTNERING TRACK	CELL CULTURE & UPSTREAM PROCESSING	CELL CULTURE AND UPSTREAM PROCESSING	EXHIBITION HALL CONTENT/ THEATER SHOWCASE	IMPACT OF COVID-19 ON BIOPROCESSING	MANUFACTURING STRATEGY & BIOPROCESSING 4.0	RECOVERY & PURIFICATION	TECHNOLOGY WORKSHOP 1	TECHNOLOGY WORKSHOP 2	THEATRE SHOWCASE	WORKSHOP - SBR-1 MANUFACTURING: A LEARNING LABORATORY (LIMITED TO 30 PARTICIPANTS)
4:00PM	**4:35pm** - Close of BPI 2021	**4:00pm** - ROOM 210B: Trends for the Future of Biomanufacturing **4:30pm** - End of Day **4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021	**4:35pm** - Close of BPI 2021

SESSIONS

DIGITAL - SEPT 28 - 28/09/2021

Opening Remarks (LIVE)

11:00am - 11:05am

KEYNOTE: Biomanufacturing Challenges and Opportunities in Cell Therapies for Immuno-oncology

11:05am - 11:35am

While immuno-oncology cell therapies such a CAR T-cells and natural killer cells hold tremendous potential to treat a wide range of cancers, particularly those that have been refractory to other treatments, the manufacturing science for these therapies lags behind the clinical results. This presentation will provide an overview of current and future immuno-oncology therapies and discuss current and potential approaches for manufacturing including novel bioreactors and manufacturing systems.

Participants

Susan Sharfstein - Professor of Nanobioscience, Suny Polytechnic Institute

KEYNOTE: A Collaborative Ecosystem To Accelerate the Commercial Manufacturing of Novel Vaccines and Other Therapeutics

11:40am - 12:10pm

Participants

Nandu Deorkar - Vice President, Avantor

Networking Break

12:10pm - 12:30pm

Multi-Omics and Bioinformatics in Cell Culture Media Design

12:30pm - 1:00pm
Bioprocess International

Because current biopharmaceutical process development requires the use of living cell lines with highly specific nutritional and environmental needs, a number of complex challenges must be overcome. Among these is determining the optimal cell culture media formulation.

Successful media optimization depends on understanding data, specifically how each media component influences the cells. Traditionally, these data have been collected using a technique known as spent media analysis. However, the level of detail that can be obtained using spent media analysis is fundamentally restricted. This is true for both understanding the components themselves, as the technique only permits analysis of major metabolites such as glucose and amino acids, and how they are being used. This latter issue arises as the technique can only identify a limited number of the molecules which are taken up or secreted by the cells, rather than the global molecular changes including signaling and metabolic intracellular pathways the components are involved in.

The only way to accelerate the development of next-generation biopharmaceuticals is to leverage next-generation analytical solutions.

This presentation will illustrate the considerable impact of applying a multi-omics analysis--utilizing proteomics and metabolomics--in obtaining a level of detail that is unparalleled in comparison to a spent media analysis approach. In particular, we will highlight how the extra level of granular intracellular detail can enable developers to either gain actionable results in less experimental iterations or, if not less iterations, gain better results from each iteration that they undertake with the ultimate goal of making development and manufacturing more efficient and cost-effective.

Participants

Paul Gulde, PhD - Staff Scientist, Thermo Fisher Scientific

Midstream Unit Operations: Unsung Heroes in AAV Process Development

12:30pm - 1:00pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Ratish Krishnan - Associate Director - Cell & Gene Therapy BioProcessing, MilliporeSigma

Volume and Agitation Speed Influences the Performance of Recombinant CHO Cells in Spin Tube Bioreactors

1:05pm - 1:35pm
Bioprocess International

Participants

Alan Dickson, Ph.D. - Professor of Biotechnology, Director, Centre of Excellence in Biopharmaceuticals, University of Manchester

Analytics Linked to Process and Critical Quality Attributes for Gene Therapies

1:05pm - 1:35pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Lyndi Rice - Head of QC Viral Vector Analytical, BioMarin

Presentation by PRECISION NANOSYSTEMS

1:40pm - 2:10pm
Bioprocess International

Acceleration of AAV manufacturing process development by using fast USP and DSP HPLC analytics

1:40pm - 2:10pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Ales Strancar, PhD - Managing Director, BIA Separations

BPI Panel Discussion: Workflows & Technologies to Accelerate Early Stage Development

2:15pm - 2:45pm
Bioprocess International

Participants

Zachary Houle - Senior Development Specialist, Upstream Process Development, Takeda

Speaker Q&A (LIVE)

2:15pm - 2:45pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Ratish Krishnan - Associate Director - Cell & Gene Therapy BioProcessing, MilliporeSigma

Lyndi Rice - Head of QC Viral Vector Analytical, BioMarin

Ales Strancar, PhD - Managing Director, BIA Separations

SCHEDULE

DIGITAL - SEPT 28 - 28/09/2021

Delivered as a Hybrid Event from September 20-30, 2021
Live In-Person Experience Delivered September 20-23
Boston Convention and Exhibition Center

TIME	BIOPROCESS INTERNATIONAL	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION
11:00AM	**11:00am** - Opening Remarks (LIVE) **11:05am** - KEYNOTE: Biomanufacturing Challenges and Opportunities in Cell Therapies for Immuno-oncology **11:40am** - KEYNOTE: A Collaborative Ecosystem To Accelerate the Commercial Manufacturing of Novel Vaccines and Other Therapeutics	**11:00am** - Opening Remarks (LIVE) **11:05am** - KEYNOTE: Biomanufacturing Challenges and Opportunities in Cell Therapies for Immuno-oncology **11:40am** - KEYNOTE: A Collaborative Ecosystem To Accelerate the Commercial Manufacturing of Novel Vaccines and Other Therapeutics
12:00PM	**12:10pm** - Networking Break **12:30pm** - Multi-Omics and Bioinformatics in Cell Culture Media Design	**12:10pm** - Networking Break **12:30pm** - Midstream Unit Operations: Unsung Heroes in AAV Process Development
1:00PM	**1:05pm** - Volume and Agitation Speed Influences the Performance of Recombinant CHO Cells in Spin Tube Bioreactors **1:40pm** - Presentation by PRECISION NANOSYSTEMS	**1:05pm** - Analytics Linked to Process and Critical Quality Attributes for Gene Therapies **1:40pm** - Acceleration of AAV manufacturing process development by using fast USP and DSP HPLC analytics
2:00PM	**2:15pm** - BPI Panel Discussion: Workflows & Technologies to Accelerate Early Stage Development	**2:15pm** - Speaker Q&A (LIVE)

SESSIONS

DIGITAL - SEPT 29 - 29/09/2021

Opening Remarks (LIVE)

11:00am - 11:05am

KEYNOTE: Advances in Gene Therapy Intensification and Manufacturing Economics Optimization

11:05am - 11:35am

Participants

René Gantier - Senior Director R&D, Advanced Bioprocess Applications, Repligen

Panel Discussion: Overcoming Downstream Challenges for Emerging Modalities

11:40am - 12:10pm

Participants

Pranav Vengsarkar - Sr. Research Scientist, Avantor

Networking Break

12:10pm - 12:30pm

Process Intensification and Customized CMC Strategy for Recombinant Protein

12:30pm - 1:00pm
Bioprocess International

Drug development has historically been a time, labor, and money-intensive endeavor where ultimate success is the exception, rather than the rule. This is acutely apparent in the biologics space where the time it takes to manufacture a lead molecule to support first-in-human clinical trials using traditional cell culture expression systems is often measured in years rather than months, with product costs for Phase 1 trials averaging $5MM or more. This presentation will describe the FastPharming system developed by iBio and its inherent benefits in terms of speed, cost, scalability, and sustainability. Using data associated with the current FastPharming platform and considering the opportunities associated with the newly designed FastPharming NextGen platform, a compelling case will be made for why the time is right for FastPharming to take its place as the platform of choice for the next generation of protein therapeutics.

Participants

Leon Song - Senior BD Director, GenScript ProBio

AAV manufacturing with stable producer cells for industrial scale vector production

12:30pm - 1:00pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Silke Wissing - CSO, CEVEC

Evaluation of a Next Gen Downstream Approach to Improve Overall Manufacturing Process Intensity

1:05pm - 1:35pm
Bioprocess International

Participants

Aaron Almeida - Manager, Manufacturing Process Optimization, Catalent Biologics

Raw Materials: BOMs, Risks & Securing Supply

1:05pm - 1:35pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Tom Walls - Global Planning and Logistics Lead, Spark Therapeutics

Understanding Monoclonal Antibody Aggregate Behaviour Impacting Chromatographic Process Efficiency

1:40pm - 2:10pm
Bioprocess International

Participants

Courtney O'Dell, MS - Senior Scientist, Avantor

Suman McLinden - Senior Scientist, Avantor

Approaches for Allo CART

1:40pm - 2:10pm
Cell & Gene Therapy Manufacturing & Commercialization

Participants

Sarah Snykers - Cell Therapy Manufacturing Director, Celyad

TBD

2:15pm - 2:45pm
Bioprocess International

Speaker Q&A (LIVE)

2:15pm - 2:45pm
Cell & Gene Therapy Manufacturing & Commercialization

SCHEDULE

DIGITAL - SEPT 29 - 29/09/2021

Delivered as a Hybrid Event from September 20-30, 2021
Live In-Person Experience Delivered September 20-23
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TIME	BIOPROCESS INTERNATIONAL	CELL & GENE THERAPY MANUFACTURING & COMMERCIALIZATION
11:00AM	**11:00am** - Opening Remarks (LIVE) **11:05am** - KEYNOTE: Advances in Gene Therapy Intensification and Manufacturing Economics Optimization **11:40am** - Panel Discussion: Overcoming Downstream Challenges for Emerging Modalities	**11:00am** - Opening Remarks (LIVE) **11:05am** - KEYNOTE: Advances in Gene Therapy Intensification and Manufacturing Economics Optimization **11:40am** - Panel Discussion: Overcoming Downstream Challenges for Emerging Modalities
12:00PM	**12:10pm** - Networking Break **12:30pm** - Process Intensification and Customized CMC Strategy for Recombinant Protein	**12:10pm** - Networking Break **12:30pm** - AAV manufacturing with stable producer cells for industrial scale vector production
1:00PM	**1:05pm** - Evaluation of a Next Gen Downstream Approach to Improve Overall Manufacturing Process Intensity **1:40pm** - Understanding Monoclonal Antibody Aggregate Behaviour Impacting Chromatographic Process Efficiency	**1:05pm** - Raw Materials: BOMs, Risks & Securing Supply **1:40pm** - Approaches for Allo CART
2:00PM	**2:15pm** - TBD	**2:15pm** - Speaker Q&A (LIVE)

SESSIONS

DIGITAL - SEPT 30 - 30/09/2021

Opening Remarks (LIVE)

11:00am - 11:05am

KEYNOTE by Miguel Forte, CEO, Bone Therapeutics, Belgium

11:05am - 11:35am

Participants

Miguel Forte - Chief Executive Officer, Bone Therapeutics

KEYNOTE

11:40am - 12:10pm

Networking Break

12:10pm - 12:30pm

Entering first-in-human clinical trials: considerations for a robust regulatory CMC package

12:30pm - 1:00pm
Bioprocess International

When you enter the clinical trial stage of your molecule's development, you must prepare a dossier to support conducting the clinical research. A critical component of this dossier is the package of documentation that supports the chemistry, manufacturing, and controls (CMC) of your molecule. A robust CMC package provides health authorities with the information to assess the quality of material entering clinical trials. Inadequate CMC supportive evidence or insufficient detail can delay the go-ahead to enter the clinic. At the same time, unnecessary granularity can impact the lifecycle management of the dossier.

Join us to learn how to develop a robust first-in-human (FIH) regulatory CMC package for recombinant biological molecules by integrating the following activities into your project plan.

- Progressively developing knowledge of the molecule's critical quality attributes to justify the manufacturing and control strategy
- Planning for continuing development
- Identifying opportunities to enhance with scientific advice

Participants

Daniela Decina - Senior Director, Regulatory Affairs, Thermo Fisher Scientific

Michele Duggan - Senior Manager, North America Regulatory Affairs, Thermo Fisher Scientific

State of the Industry Webcast

12:30pm - 1:25pm
Cell & Gene Therapy

Our BioProcess Insider editorial team sits down with Joshua Speidel, PhD, Partner, Latham Biopharm Group, Patrick Lucy, President and CEO, Lykan Biosciences, and Amélie Boulais, Head of Market Entry Strategy, Virus Based Therapeutics at Sartorius, to reflect on how the quarterly movements of the wider pharma industry are affecting the biomanufacturing space. Through the analysis of global events, recent deal making, and regulatory and technological advancements, we look to determine the factors driving or squeezing production and pre-empt upcoming trends and concerns facing our sector.

Building a high throughput 2D-HPLC method to support early-stage AAV process development

1:05pm - 1:35pm
Bioprocess International

Development of a robust process for AAV manufacturing is critical for gene therapy product quality and patient safety. Optimizing process performance often requires extensive purification and analytical supports to understand process yield and critical product quality attributes, which can limit the early-stage process development due to required sample volumes and insufficient assay throughput. We developed a two-dimensional HPLC (2D-HPLC) method that leverages the beer-lambert law and extinction coefficients to measure AAV genome titer and full/empty capsid ratios of process intermediates. This 2D-HPLC method enables process monitoring both for upstream and downstream process via a rapid, at-line measurement without exhausting purification and analytical support resources.

Participants

Xiaotong Fu, PhD, Remote - Live with Q & A - Sr. Engineer, Biogen

Presentation by Benchling

1:40pm - 2:10pm
Bioprocess International

Participants

Kate Quigley - Product Marketing Lead, Benchling

Quality by Design Approach (QbD) to Fill-Finish Process Development Studies to Support Scale-Up and Tech Transfer for GMP Manufacturing

2:15pm - 2:45pm
Bioprocess International

Here, we take a QdB approach at designing a comprehensive set of studies for risk assessment and defining process parameters of critical fill-finish unit operations in preparation for GMP manufacturing of an internal mAb drug product. Careful end-to-end mapping of DS to DP manufacturing processes enabled de-risking of freeze-thaw, contact material compatibility, mixing, peristaltic pumping robustness, and filtration. The results from our studies show that there is a low risk of physico-chemical instability or negative impact on product quality after processing at the selected manufacturing site.

Participants

Kelvin Rembert - Scientist, Sanofi

SCHEDULE

DIGITAL - SEPT 30 - 30/09/2021

TIME	BIOPROCESS INTERNATIONAL	CELL & GENE THERAPY
11:00AM	**11:00am** - Opening Remarks (LIVE) **11:05am** - KEYNOTE by Miguel Forte, CEO, Bone Therapeutics, Belgium **11:40am** - KEYNOTE	**11:00am** - Opening Remarks (LIVE) **11:05am** - KEYNOTE by Miguel Forte, CEO, Bone Therapeutics, Belgium **11:40am** - KEYNOTE
12:00PM	**12:10pm** - Networking Break **12:30pm** - Entering first-in-human clinical trials: considerations for a robust regulatory CMC package	**12:10pm** - Networking Break **12:30pm** - State of the Industry Webcast
1:00PM	**1:05pm** - Building a high throughput 2D-HPLC method to support early-stage AAV process development **1:40pm** - Presentation by Benchling	
2:00PM	**2:15pm** - Quality by Design Approach (QbD) to Fill-Finish Process Development Studies to Support Scale-Up and Tech Transfer for GMP Manufacturing	