COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Eighth Annual

THE BIOPROCESSING SUMMIT

Practical Solutions for Today's Bioprocess Challenges

August 15-19, 2016 | Westin Boston Waterfront , Boston, MA

Cambridge Healthtech Institute

Premier Sponsors PALL Life Sciences UNCHAINED LABS

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EVENT AT A GLANCE

	Monday - Tuesday August 15 - 16	Wednesday - Thursday AM August 17 - 18	Thursday PM - Friday August 18 - 19
STREAM #1 **Upstream Processing**	Optimizing Cell Culture Technology	Bioproduction: Scale, Bioreactors & Disposables	Optimizing Cell Line Development
STREAM #2 **Downstream Processing**	Continuous Processing in Biopharm Manufacturing	Advances in Purification Technologies	Virus & Pathogen Clearance & Safety in Biologics
STREAM #3 **Analytical & Quality**	Host Cell Proteins: Detection, Analysis & Removal	Early Analytical Development for Biotherapeutics	Process Characterization, Qualification & Control
STREAM #4 **Formulation & Stability**	Rapid Methods to Assess Quality & Stability of Biologics	Overcoming Formulation Challenges	High-Concentration Protein Formulations
STREAM #5 **Cell & Gene Therapy Production**	Cell Therapy CMC, Quality & Analytics	Cell Therapy Bioproduction, Operations & Logistics	Gene Therapy Bioproduction
	Manufacturing & CMC Strategies for Biologics		
Cambridge Healthtech Training SEMINARS	Introduction to Bioprocessing Introduction to Extractables & Leachables & Packaging Identifying & Managing Risk during Development, Scale-Up, & Validation of Biological Processes	Current & Emerging Global Regulatory Expectations for Analytical Elements of Biotechnology/Biosimilar Products Introduction to Cell Culture	Introduction to Analytical Method Development & Validation for Therapeutic Proteins Introduction to Downstream Processing
	SHORT COURSES **Monday, August 15**	**DINNER SHORT COURSES** **Tuesday, August 16**	**DINNER SHORT COURSES** **Thursday, August 18**

ABOUT THE SUMMIT

The Bioprocessing Summit convenes more than 1,000 international bioprocess professionals to share practical solutions for today's bioprocess challenges. Now in its eighth year, the event features 16 distinct meetings ranging from cell line development and ensuring quality, to formulation, analytical development, continuous processing, purification, viral clearance and safety, and bioproduction. New programming in 2016 will continue to expand the scope of the event and includes weeklong programming on cell and gene therapy production, and a meeting on manufacturing and CMC strategies for biologics. Along with the impressive array of conferences, the Summit also includes Short Courses and Training Seminars that provide in-depth coverage of critical bioprocess topics.

Give yourself a Bioprocess Holiday this summer! Stimulate and enrich yourself at the 8th Annual The Bioprocessing Summit—the leading bioprocess event!

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- Optimizing Cell Line Development

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PLENARY KEYNOTE SESSION Wednesday, August 17

Preparing for Next-Generation Products: Emerging Technologies & Innovative Strategies

4:45 Chairperson's Remarks

John Sterling, Editor-in-Chief, Genetic Engineering & Biotechnology News (GEN)

4:50 Challenges Associated With Biomanufacturing of Evolving Portfolios

Morrey Atkinson, Ph.D., Vice President, Process Sciences, Bristol-Myers Squibb

The accelerating pace of biological product development and high rate of technology advancement is causing shifts in biomanufacturing. As an industry, we are being compelled to match this change with increased flexibility. From clinical supplies to late life-cycle commercial production, demand for innovation and creativity has never been greater, particularly to reliably supply transformational medicines such as the new immuno-oncology products.

E. Morrey Atkinson, Ph.D., is currently the Vice President of Biologics Development at Bristol-Myers Squibb Company. Morrey is responsible for leading a team of scientists and engineers across five sites that is responsible for process development, analytical sciences, and manufacturing support for the company's biologics portfolio, directing the development of innovative manufacturing platforms and process improvements for clinical and commercial projects. Morrey holds a B.S. from Indiana University and a Ph.D. from Stanford University. Prior to BMS, Morrey's career has included various management roles at Eli Lilly and Company, Cook Pharmica and Targeted Genetics Corporation.

5:25 Next-Generation Processes, Technologies and Operations

Craig Beasley, Vice President, Next Generation Manufacturing, Biogen

A critical step in meeting the demand of biologic production worldwide involves implementing disruptive manufacturing technologies, processes and capabilities. This talk will evaluate Biogen's new manufacturing site in Switzerland, due to go online in 2019, including the new processes, operational models and technologies being adopted to drive value through innovation and deliver new medicines in areas such as Alzheimer's.

6:00 Networking Reception in the Exhibit Hall with Poster Viewing

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Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference materials, your abstract must be submitted, approved and your registration paid in full by July 15, 2016.

- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes
- Your poster abstract will be published in the conference materials
- Receive $50 off your registration fee

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EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

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- Host Cell Proteins: Detection, Analysis & Removal
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- Process Characterization, Qualification & Control

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

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SHORT COURSES

MONDAY, AUGUST 15
MORNING COURSES | 9:00 – 11:30 AM

SC1: Optimizing Media for Culturing Cells

This course will provide helpful strategies for improving process robustness, extending culture viability, and increasing productivity. The course will cover essential ingredients needed to culture cells, as well as new ways to replace traditional elements with chemically-defined components, and provide optimal culture conditions. Reducing process variability and influencing key product quality attributes will also be addressed.

Instructors:

Sara Gall, MS, Senior Engineer, Process Development, Drug Substance Technology & Engineering, Amgen, Inc.

Kamal A. Rashid, Ph.D., Director, Biomanufacturing Education & Training Center, Worcester Polytechnic Institute

Andrew Salazar, M.Sc., Ph.D. Student, Biomaterial and Technology Development, Merck Lifescience

Catherine Lynes, MSc., MEng., Associate Scientist II, Technical Development, Biogen

SC2: Accelerated Stability Testing of Biologics

This short course will aim to guide the researcher in designing studies for accelerated stability testing of biologics. The course will begin with basic underlying concepts governing protein drug product stability, and focus on design principles for measuring stress and accelerated stability testing of not only the protein of interest, but also of excipients and primary packaging components. Strategies to handle complexities arising from their interactions will also be discussed.

Instructor:

Jan Jezek, Ph.D., CSO, Development, Arecor Ltd.

Sanket Patke, Ph.D., Research Investigator, Drug Product Science and Technology, Pharmaceutical Development, Bristol-Myers Squibb

SC3: New USP Initiatives and Standards for Biologics

- Latest updates on USP Chapters and Monographs
- Feedback and comments from industry
- USP approaches to biologics

Instructor:

Maura Kibbey, Ph.D., Director, Science and Standards, Global Biologics, USP

SC4: Advanced Process Control Strategies in Bioprocessing

This course is focused on critical issues during implementation of advanced process control strategies in bioprocesses. We will summarize specific aspects from data acquisition, data processing to advanced control strategies. We will also discuss software requirements for data management and process control within and along different process scales. The topic is strongly related to PAT/QbD implementation in bioprocesses.

Instructor:

Gerald Striedner, Ph.D., Assistant Professor, Department of Biotechnology, University of Natural Resources and Life Sciences, Vienna, Austria, Head of Working Group Fermentation Technology, Co-Founder of enGenes Biotech GmbH

TUESDAY, AUGUST 16
DINNER COURSES | 6:00 – 8:30 PM

SC5: Analytical Strategies for Comparability in Bioprocess Development

Bioprocess changes can impact quality attributes of biologics and may affect efficacy and safety of the product. During development and throughout the product lifecycle, when process improvements are implemented, it is essential to gather sufficient data to support the conclusion that product safety and efficacy has not been adversely affected. This demonstration exercise requires careful planning of the comparability studies and is based on the background knowledge of protein structure, biological function, and clinical attribute profiles of the product accumulated during development.

In this short course, we will discuss the key concepts of establishing product quality profiles, defining control strategies, the common analytical characterization technologies used, and the hierarchical assessment approach to demonstrating comparability of the product in support of process changes.

Instructor:

Christine P. Chan, Ph.D., Principal Scientist/Technical Lead, Global Manufacturing Science & Technology, Specialty Care Operations, Sanofi

SC7: Protein Aggregation: Mechanism, Characterization and Consequences

Protein aggregation is recognized by regulatory agencies and the biopharmaceutical industry as a key quality attribute of biotherapeutics. Various aggregates hold the potential for adversely impacting production and patients in a variety of ways. This in-depth workshop reviews the origins and consequences of aggregation in biotherapeutics, and then examines strategies for predicting and quantifying aggregation in biopharmaceuticals. It benefits scientists engaged in development, production, analytical characterization and approval of biotherapeutics and who require a good working knowledge of protein aggregation.

Instructor:

Thomas Laue, Ph.D., Professor, Biochemistry and Molecular Biology; Director, Biomolecular Interaction Technologies Center (BITC), University of New Hampshire

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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SHORT COURSES

TUESDAY, AUGUST 16
DINNER COURSES | 6:00 - 8:30 PM CONTINUED

SC8: Purification of Advanced Medicine Therapy Products

Advanced Therapy Medicinal Products (ATMPs), as stem cell-based products, virus and virus-like particles have a unique complexity that challenges the design of robust and effective biomanufacturing processes. Already established downstream processing steps should be rethought and redesigned to cope with the specific demands for these types of therapeutic products, maintaining their final quality attributes in terms of identity, potency, purity and safety.

In this short course we will provide a comprehensive and detailed outline of hands-on issues for ATMPs´ purification and an overview of the main challenges that these type of products pose and how we can tailor current processes to fit their particular requirements.

Instructors:

Ricardo Silva, Ph.D., Researcher, Downstream Processing Lab, Animal Cell Technology, iBET – Instituto de Biologia Experimental e Tecnologica

Barbara Cunha, MSc, Animal Cell Technology, iBET – Instituto de Biologia Experimental e Tecnologica

THURSDAY, AUGUST 18
DINNER COURSES | 6:00 – 8:30 PM

SC10: Transient Protein Production in Mammalian Cells

This short course introduces both the fundamental concepts and technologies needed to establish transient protein production in mammalian cells. This allows for the rapid generation, purification and characterization of milligram-to-gram quantities of secreted or intracellular recombinant proteins for therapeutic, functional and structural studies. The course combines instruction and case studies in an interactive environment.

Instructors:

Richard Altman, MS, Scientist, Protein Technologies, Amgen, Inc.

Henry C. Chiou, Ph.D., Associate Director, Cell Biology, Life Science Solutions, Thermo Fisher Scientific

Dominic Esposito, Ph.D., Director, Protein Expression Laboratory and Ras Reference Reagents Program, Frederick National Laboratory for Cancer Research (FNLCR)

SC11: Regulatory and Scientific Base of Monoclonality for Generating Protein Expression Cell Banks

- Understand the current regulatory requirements for the monoclonality of the Master Cell Bank
- Ensure the monoclonality during the cell line development and establishment of the cell banks
- Provide interactive case studies to understand the control of the monoclonality with different cell line development, cloning and screening technologies

Instructor:

Audrey Jia, Ph.D., Consultant to the Biotech Industry

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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MONDAY, AUGUST 15 - TUESDAY, AUGUST 16
DAY 1 1:00-5:00 PM • DAY 2 8:00 AM-5:15 PM

(TS1) Introduction to Bioprocessing

The Introduction to Bioprocessing training seminar offers a comprehensive survey of the steps needed to produce today's complex biopharmaceuticals, from early development through commercial. We begin with a brief introduction to biologic drugs and the aspects of protein science that drive the intricate progression of analytical and process steps that follows. We then step through the stages of bioprocessing, beginning with the development of cell lines and ending at scaling up for commercial production. The seminar also explores emerging process technologies, facility design considerations and regulatory and quality standards.

- Introduction to biopharmaceuticals and bioprocessing
- Analytical methods for characterization and release
- Quality systems
- The science and technologies of bioprocess unit operations
- Drug product development

Instructors:

Sheila G. Magil, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc.

Frank J. Riske, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc.

(TS2) Introduction to Extractables and Leachables and Packaging

Chemical substances can be leached into biologics from various components used in the manufacture, storage or delivery of a therapeutic product leading to a negative impact on the product and potential for an undesirable effect on the patient. This training seminar will provide a background on regulatory expectations for materials and components in contact with biologics and the unique applications to biologic delivery systems.

- Regulatory expectations for container closure and delivery systems
- Overview of materials used to manufacture, store and deliver biologics
- Designing studies to qualify materials for intended use
- Controlled extractables testing (CES)
- Leachables studies

Instructors:
Diane Paskiet, MS, Senior Director, Global Scientific Affairs, West Pharmaceuticals

Fran Degrazio, Vice President, Global Scientific Affairs And Technical Services, West Pharmaceuticals

(TS3) Identifying and Managing Risk during Development, Scale-Up, and Validation of Biological Processes

This seminar will look at the common, and some less common tools for risk assessment and risk management and will provide guidance on how these tools can be applied to the management of risk in pharmaceutical development, process scale-up and process validation of biological processes. The seminar will consist of presentations, break out workshops and discussions of examples of successful risk management programs.

- Historical and regulatory background of risk management; mitigating and managing risk
- Identification of risks in process development, scale-up and process manufacturing
- Tools for risk assessment in pharmaceutical development and manufacturing
- Examples of the application of risk assessment tools in development, scale-up and process validation
- New approaches to validation of bioprocesses

Instructor:
Trevor Deeks, Ph.D., QA and QC Consultant, Teva Biopharmaceuticals USA, Inc.

WEDNESDAY, AUGUST 17 - THURSDAY, AUGUST 18
DAY 1 8:00 AM-3:50 PM • DAY 2 8:30 AM-12:15 PM

(TS4) Current and Emerging Global Regulatory Expectations for Analytical Elements of Biotechnology/Biosimilar Products

This class will present the driving concepts that distinguish the regulatory approach to the production and testing of biologically derived from chemical, small molecule pharmaceutical products. It provides a comprehensive overview of how analytical elements come together in global regulatory dossiers, which can be used to drive the nature and timing of key CMC studies. It also provides an overview of how regulatory dossier CMC sections in marketing authorizations (BLA/MAA) are linked to analytical expectations in regulatory pre-approval inspections.

- Regulatory differences for biologics vs. traditional chemical products
- Worldwide regulations covering CMC analytical requirements for biotechnology products
- Staging of CMC analytical studies during the product development lifecycle
- Commonly used analytical methods for various types of biotechnology products
- Method validation and qualification

Instructor:
Nadine M Ritter, Ph.D., President & Senior Analytical Advisor, Global Biotech Experts LLC

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EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

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- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

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- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
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REGISTRATION INFORMATION
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WEDNESDAY, AUGUST 17 - THURSDAY, AUGUST 18
DAY 1 8:00 AM-3:50 PM • DAY 2 8:30 AM-12:15 PM

(TS5) Introduction to Cell Culture

This 1.5-day Intro to Cell Culture training seminar is a lecture based course intended for the beginner who is thinking about culturing animal cells for the first time or for intermediate cell culturists wanting to know more about how animal cell culture works and how to improve their process. Attendees will learn about most of the critical aspects of cell culture from equipment maintenance and media selection to cell growth and cryopreservation. Participants will have ample time to ask specific questions and get worthwhile answers.

- Equipment use and decontamination
- Contamination prevention and types of contamination
- Cell culture media
- Clonal isolation of animal cells
- Primary culture and animal cell attachment and signaling; growth curves, strategies for growing animal cells in culture

Instructor:
Timothy Fawcett, Ph.D., Scientific Director, BioTechnical Institute of Maryland,Inc. and Founder, BioSciConcepts

THURSDAY, AUGUST 18 - FRIDAY, AUGUST 19
DAY 1 2:00-5:15 PM • DAY 2 8:30 AM-3:15 PM

(TS6) Introduction to Analytical Method Development and Validation for Therapeutic Proteins

This course is a panoramic review of analytical method development and validation for therapeutic proteins, including antibodies and enzymes. It is intended for scientists working on therapeutic proteins in Analytical Development, Quality Control, Product Development or related functional areas. The course emphasizes practical applications, real-world examples and useful tips.

- Manufacturing of protein drugs, regulatory affairs, protein chemistry
- Commonly used analytical methods for proteins
- Method validation and method transfer
- Regulatory compliance at different stages of product development
- Application of DOE and QbD

Instructor:
Jichao (Jay) Kang, Ph.D., RAC, Director, Analytical and Formulation Development,Patheon Biologics

(TS7) Introduction to Downstream Processing

This activity-packed course focuses on the science, technologies and strategies needed to understand and implement an effective downstream process for biological development and production. The course begins with an in-depth look at DSP design and development – from recovery to purification to formulation - before moving onto pertinent issues surrounding HTPD, single-use systems, continuous processing, PAT, CPPs, viral clearance, platform development and process validation. The course concludes with real-world examples for both traditional and emerging modalities.

- Intro and principles of downstream processing
- Recovery and Purification
- Future considerations and challenges
- Process design & economics; process validation; continuous processing
- Quality by Design and critical process parameters; analytics and PAT solutions

Instructor:
Professor Jean-Francois Hamel, Academic Researcher and Instructor, Chemical Engineering Department, Massachusetts Institute of Technology

Each CHI Training Seminar offers 1.5 Days of instruction with start and stop times for each day shown above and on the Event-at-a-Glance published in the onsite Program & Event Guide. Training Seminars will include morning and afternoon refreshment breaks, as applicable, and lunch will be provided to all registered attendees on the full day of the class.

Each person registered specifically for the training seminar will be provided with a hard copy handbook for the seminar in which they are registered. A limited number of additional handbooks will be available for other delegates who wish to attend the seminar, but after these have been distributed no additional books will be available.

Though CHI encourages track hopping between conference programs, we ask that Training Seminars not be disturbed once they have begun. In the interest of maintaining the highest quality learning environment for Training Seminar attendees, and because Seminars are conducted differently than conference programming, we ask that attendees commit to attending the entire program, and NOT engaging in track hopping, as to not disturb the hands-on style instruction being offered to the other participants.

To view Training Seminar Agendas in full and Instructor Biographies, visit:
BioprocessingSummit.com/BPD/Training-Seminars

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EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

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- Rapid Methods to Assess Quality & Stability of Biologics
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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
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STREAM #1
Upstream Processing

The weeklong Upstream Processing stream spans cell line selection and developability through the creation of scale-down models and scaling up production. Along the way, developing a greater understanding of cells, particularly CHO, will be examined, as well as tools and technologies that support analyzing quality to more rapidly achieve productivity and mitigate risk. Bioreactors and disposable / single-use systems will also be explored in this weeklong investigation of the 'nuts and bolts' of bioprocessing.

AUGUST 15-16
Optimizing Cell Culture Technology

AUGUST 17-18
Bioproduction: Scale, Bioreactors & Disposables

AUGUST 18-19
Optimizing Cell Line Development

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

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- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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12th Annual

Optimizing Cell Culture Technology

Enhancing Knowledge for Growing Cells

MONDAY, AUGUST 15

8:00 am Short Course Registration

9:00 – 11:30 Recommended Morning Short Course*
Optimizing Media
** Separate registration required, see page 5 for details.*

11:30 Main Conference Registration Opens

QUALITY & PRODUCTIVITY

1:00 pm Chairperson's Opening Remarks
Jeffrey Chalmers, Ph.D., Professor, Chemical and Biomolecular Engineering, The Ohio State University

1:10 OPENING KEYNOTE PRESENTATION:
Trends and Aspects of Improving Cell Culture Process Productivities
Thomas Ryll, Ph.D., Vice President, Process and Analytical Development, ImmunoGen, Inc.
A number of driving forces have resulted in enormous improvements to cell culture production processes over the last 25 years. Based on the author's experience, titers of antibody fed-batch production have doubled about every 6-7 years. This presentation will review some of the driving forces and accomplishments, and will give a personal opinion on what we can expect in terms of productivity and process robustness in the years to come.

1:45 FEATURED PRESENTATION:
Analytical and Device Technologies for Bioprocess Engineering
James Piret, Sc.D., Professor, Michael Smith Laboratories, University of British Columbia
This presentation is focused on research to improve the understanding and performance of mammalian cell based processes. We have developed single-cell Raman spectroscopy methods for cell analysis to detect the types of Chinese Hamster Ovary cell death and to detect the early stages of apoptosis based on macromolecular changes in the cell composition. Also, we are addressing the increasing need for high cell concentration perfusion technology, including in scale-down bioreactors.

2:15 Early Development Strategies for Innovative Therapeutic Molecules
Nicola Beaucamp, Ph.D., Head, Process Research, Large Molecule Research, Pharma Research and Early Development, Roche Innovation Center Penzberg
A number of novel antibody formats have been advanced into clinics by Roche pRED. In order to discover and develop differentiated monoclonal antibodies Roche's strategy is based on engineering technologies which bear several challenges for technical development. Examples on innovative therapeutic molecules for multi-pathway-inhibition and specific tumor-targeting will be given.

2:45 Refreshment Break

QUALITY & PRODUCTIVITY

3:15 Strategies for Optimizing the Productivity of a Cell Culture Platform without Impacting Product Quality
Nattu Vijayasankaran, Ph.D., Senior Engineer, Late Stage Cell Culture, Genentech Inc. – A Member of the Roche Group
Cell culture processes are generally simplified when needed as a robust platform technology. But both culture medium and process parameters are customized for specific cell lines when there is a need to achieve high titer. A case study will be used to demonstrate that changes made to the platform process to maximize productivity could alter the product quality profile. Strategies to minimize these product quality changes will be discussed.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 Using High-Seeding Density to Improve Cell Culture Process Efficiency and Increase Manufacturing Facility Capacity
Ning Liu, Ph.D., Associate Senior Consultant Engineer, Bioproduct Research and Development, Eli Lilly and Company
A high-seeding density fed-batch process with N-1 perfusion culture was developed at Lilly that has significantly increased volumetric productivity. A case study will be presented to demonstrate that the new process could shorten the production time from 14 days to 7 days and achieve the same titer with comparable product qualities, or increase the titer by 50%. Considerations for implementation at manufacturing sites will also be discussed.

4:30 Breakout Discussions

5:30 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

TUESDAY, AUGUST 16

7:30 am Registration Opens and Morning Coffee

CULTURING CHO CELLS

7:55 Chairperson's Remarks
Jonathan Bones, Ph.D., Principal Investigator, National Institute for Bioprocessing Research & Training (NIBRT), University College Dublin

8:00 Using Quantitative Proteomics to Link Critical Quality Attributes to Critical Process Parameters
Jonathan Bones, Ph.D., Principal Investigator, National Institute for Bioprocessing Research & Training (NIBRT), University College Dublin
Quantitative proteomics is a powerful tool to understand cellular behavior at the molecular level. Quantitative proteomics of an IgG1 mAb producing CHO cell line was performed following systematic alteration of bioprocess conditions using a limited Plackett-Burman design of experiments approach. In

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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12th Annual

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addition to investigating changes in cellular behavior, complete characterization of the expressed mAb was also performed to investigate the link between product critical quality attributes and alterations in critical process parameters.

8:30 Harmonizing Transient and Stable CHO Expression Platforms for Early-Phase Drug Discovery

Yashas Rajendra, Ph.D., Research Scientist, Bio-TDR Cell Culture, Eli Lilly and Company

We describe the development of transient CHO system capable of rapidly (7 days) generating high titers, scalable up to 6L. Additionally, we describe the use of stable CHO pools (instead of master wells or clones) for generation of gram quantities of therapeutic protein. Using the same CHO cell line and media package for both platforms streamlines expression during early phase biologic drug discovery.

9:00 An 'Omics' Approach to Understanding Performance of a CHO-Fc Fusion Process at 5000-L Scale

Amanda M. Lewis, Ph.D., Scientist II, Biologics Development, Bristol-Myers Squibb

A CHO bioprocess, where the product is a sialylated Fc-fusion protein, showed significant variation of sialylation at large scale. Lower sialylation correlated with elevated mannose, a shift in glucose metabolism, and increased oxidative stress. This information was used to optimize a 5-L scale-down model able to reproduce the large-scale phenotypic profiles. Targeted transcriptomics and metabolomics were used to develop a proposed biological mechanism linking large-scale operation, oxidative stress, and sialylation.

9:30 Automated Sampling to Drive Decision Making for Bioprocess Control *Sponsored By* FLOWNAMICS

Speaker to be Announced

Employment of the Seg-Flow® automated reactor sampling system to deliver samples to a bioprocess analyzer will be described. This PAT solution enables real-time analysis of cell culture process parameters and automated feedback control. Decision making logic is programmed into the Seg-Flow to ensure the validity of the results received from the analyzer prior to feed, initiating re-sample of the bioreactor if invalid results received, and to control the amount of feed added.

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

EMERGING CELL CULTURE TECHNOLOGIES

10:30 Next-Generation Cellular Models for Drug Discovery

T. Oliver Chao, Ph.D., Head, Emerging Biomedical Sciences, Strategy & Innovation, Sanofi

How to improve cell culture technology for a more relevant and more translational models for drug discovery? From stem cells to artificial cells, from single cell platforms to organs-on-chips, from cultures derived from humanized animals to 3D cultures built by human cells. We will discuss several emerging approaches that hopefully would help us to achieve this goal.

11:00 Mammalian Cell Fluid Mechanics and Scale-Up Considerations for Cell Therapy

Jeffrey Chalmers, Ph.D., Professor, Chemical and Biomolecular Engineering, The Ohio State University

The perception of "shear sensitivity" has historically put an arbitrary upper limit on agitation and aeration in bioreactor operation; however, as cell densities and productivities continue to increase, mass transfer requirements can exceed those imposed by these arbitrary low limits. This presentation will mainly focus on some recent experimental data on microcarrier cultures regarding the effect of hydrodynamic forces on industrially relevant animal cells, and on scale-up.

11:30 Genome-Scale RNA Interference Screen Identifies Key Pathways and Genes for Improving Recombinant Protein Production in Mammalian Cells

Joseph Shiloach, Ph.D., Director, Biotechnology Core Laboratory, Intramural Research, NIDDK/NIH

A high-throughput RNA interference screen was conducted using HEK293 cells expressing firefly luciferase. The gene encoding the ornithine decarboxylase antizyme1 was selected for detailed investigation, and our study shows that this gene is a novel target for improving expression of recombinant proteins. The genome-scale screening demonstrated in this work can establish the foundation for targeted design of an efficient mammalian cell platform for different biotechnological applications.

12:00 pm Use of a Scalable, Continuous Processing Platform to Solve Production Challenges in Mammalian Cell Cultures *Sponsored By* C3 CELL CULTURE COMPANY

Scott Waginer, Vice President, Bioservices, Cell Culture Company

Traditionally difficult-to-express proteins perform well in a continuous processing bioreactor system as it provides long-term sustainable homeostatic pH conditions, metabolite and waste levels, as well as continuous collection of the protein of interest for 3-9 months. This stable, *in vivo* like environment enables increased cell viability and a higher yield compared to typical fed-batch systems. This presentation will highlight the steady-state production of a monoclonal antibody and the scalability of an automated single-use, perfusion bioreactor.

12:30 ExpiCHO: Latest Developments in High-Titer Transient CHO Expression *Sponsored By* ThermoFisher SCIENTIFIC

Jonathan Zmuda, Ph.D., Director, Cell Biology, Thermo Fisher Scientific

The Gibco Expi293 and ExpiCHO Expression Systems have become premier tools for protein expression in many pharma, biotech and academic laboratories, enabling high-titer recombinant protein production for a broad range of research applications. Here, we present the latest updates on the ExpiCHO Expression System with regard to optimizing protein expression, purification and characterization from 96 well plates up to 10L bioreactors.

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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12th Annual

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IMPROVING & INNOVATING PROCESSES

1:55 Chairperson's Remarks

James Piret, Ph.D., Professor, Michael Smith Laboratories, University of British Columbia

2:00 Strategies to Improve Process Robustness for Monoclonal Antibody Production: A Case Study

Jeffrey Ly, MS, Senior Scientist, Process Development and Commercialization, Merck & Co., Inc.

During the manufacture of a monoclonal antibody, consistent product quality was maintained, but large variations in bioreactor harvest titer (>2X) were observed between lots. Investigations into this titer variation led us to identify correlations between cellular metabolism, feeding strategy and harvest titer. As a result, process modifications have successfully been developed to obtain a more robust production bioreactor process while maintaining product quality.

2:30 Challenges in Cell-Line, Process and Analytical Development of a Single-Chain Antibody and Solutions

Hanuman Mallubhotla, Ph.D., Research Director, Biopharmaceutical Development, Syngene International, Ltd.

Single chain antibodies are more difficult to express well than full-length antibodies, and have additional issues with their purification. Two clone systems have been developed. Using semi-empirical and DOE strategies, methods and processes were developed for both systems with quality and productivity targets. A titer of > 3 g/L was obtained for the single-chain antibody.

3:00 Production of Recombinant Biotherapeutic Proteins in *Spodoptera frugiperda* (Sf9) Insect Cells for Vaccine Development

Rajiv Gangurde, Ph.D., Associate Director, Protein Production, Genocea Biosciences

Therapeutic proteins used for the prevention or treatment of human diseases have been manufactured in a variety of different expression systems, with baculovirus-infected insect cells providing a solid platform for the production of glycosylated proteins. One of our lead programs, GEN-003, is a therapeutic HSV-2 vaccine containing two proteins expressed independently in insect cells. Here we discuss strategies, challenges and advantages of employing this system for the production of GEN-003.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

OPTIMIZING CELL CULTURE CONDITIONS

4:15 Case Study: Evaluation of High Temperature-Short Time Treatment of Basal and Feed Media for Production of a Monoclonal Antibody

Amanda L. Carpenter, MS, Associate Scientist II, Drug Substance Manufacturing Sciences and Technology (Upstream), Bristol-Myers Squibb

In the biopharmaceutical industry, high temperature-short time (HTST) treatment of cell culture media and solutions is being implemented to mitigate the risk of potential viral or other contamination of the cell culture. As a proof-of-concept, the impact of HTST-treated basal and feed media was evaluated for a monoclonal antibody in scale-down production bioreactors. The results demonstrate that implementing HTST-treatment of basal and feed media into manufacturing for this monoclonal antibody is feasible.

4:45 Optimization, Simplification and Intensification of Cell Culture Processes

Jochen B. Sieck, Ph.D., Lab Head, Cell Culture Media R&D, Process Solutions R&D, Merck KGaA

Fed-batch processes are the standard cultivation method for the manufacturing of biopharmaceuticals with CHO cells today. Besides the production organism, cell culture media and feeds have a great impact on process productivity optimization. Our recent introduction of chemically modified amino acids for cell culture media allow for a significant simplification of CHO fed-batch processes by eliminating the second, typically caustic feed. Furthermore, increases in productivity were observed, resulting in more productive fed-batch as well as highly intensified perfusion processes.

5:15 End of Conference

5:15 Registration for Dinner Short Courses

6:00 – 8:30
Recommended Dinner Short Course*
Analytical Strategies for Comparability in Bioprocess Development
** Separate registration required, see page 5 for details.*

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy Bioproduction, Operations & Logistics
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- Manufacturing & CMC Strategies for Biologics

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6th Annual

Bioproduction: Scale, Bioreactors & Disposables

Making it Work

WEDNESDAY, AUGUST 17

7:00 am Registration Opens and Morning Coffee

KEEPING UP WITH PRODUCTION DEMAND

8:05 Chairperson's Opening Remarks
Stefan Junne, Ph.D., Group Leader and Chair, Bioprocess Engineering, Biotechnology, Technische Universität Berlin

8:15 KEYNOTE PRESENTATION: Innovation in Bioprocessing and Manufacturing Facility Design – Current Trends
Berthold Bödeker, Ph.D., Chief Scientist, Global Drug Discovery - Global Biologics, Biotech Development, Bayer AG
Disposables, closed system operation, and continuous processing, as well as less segregated simplified plant design, have made significant advances in the past years. This talk will summarize several aspects of these innovative elements on modern bioprocessing and plant design as well as some risks associated with these technologies particularly in the area of continuous processing and ball room concept plant design.

9:00 FEATURED PRESENTATION: Developing and Adapting Manufacturing Processes for More Complex Products
Lada Laenen-Horvat, Ph.D., Senior Director & Head, Allston Manufacturing Science & Technology, Genzyme Corp., A Sanofi Company

9:30 Multivariate Data Analysis for Glycoprotein Manufacturing Process Improvement: A Case Study of Raw Material Control Impact on Process Performance and Product Quality
Siguang Sui, Ph.D., Development Scientist II, Late Stage Upstream Development, Alexion Pharmaceuticals, Inc.
A glycoprotein manufacturing process exhibited out-of-trend lower sialylation in the bulk drug substance. Multivariate statistical analysis revealed sialylation was correlated to many process parameters and attributes, among which the daily viabilities from N-1 and production bioreactor, though only differed by a few percent, had the strongest correlation observed. Small-scale experiments were conducted to evaluate the correlation of Pluronic lot on the process performance and product quality.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

INTEGRATING DISPOSABLES

10:45 Single-Use Versus Stainless Steel Bioreactors: Quality Factors for Consideration when Selecting a Suitable System
Trevor Deeks, Ph.D., QA and QC Consultant, Teva Biopharmaceuticals USA, Inc.
The relative merits of single-use as compared to stainless steel bioreactors has been widely covered in the literature and in conference presentations. Relative cost, convenience and capabilities have been the main areas for discussion, but there has been relatively little debate about Quality considerations. Quality considerations are not often part of the decision-making process to determine the type of system to select. This presentation discusses these Quality factors and the relevance to the process, and how these factors might influence the decision to use single-use or stainless steel systems.

11:15 The Decision Process for the Utilization of Disposables in Bioprocessing
Stefan Schmidt, Ph.D., MBA, Vice President, Process Science and Production, Rentschler Biotechnology
The competition between stainless steel and single-use equipment has increased over the last decade. We have systematically assessed the rationale when it makes sense to implement disposable equipment and where a conventional approach is favorable. Here we discuss the main decision points regarding cost, scale and safety and illustrate our reasoning by a number of case studies and examples.

11:45 Expansion of Human Stem Cells in BioBLU® Single-Use Vessels from Eppendorf
Sponsored By eppendorf
Stacey Willard, Ph.D., Senior Technical Applications Specialist, Bioprocess, Eppendorf
Experimentation involving human stem cells (HSCs) is one of the fastest growing fields in research and development due, in large part, to its potential for revolutionizing human disease treatment. There are multiple HSC platforms being investigated, including human mesenchymal stem cells (hMSCs) and human induced pluripotent stem cells (hiPSCs).

12:00 pm Sponsored Presentation
(Opportunity Available)

12:15 Luncheon Presentation: Optimize Continuous Processing with Smarter Tools
Sponsored By Finesse
Barbara Paldus, Ph.D., CEO, Finesse Solutions
The current biopharma development and manufacturing models create challenges for the enterprise to meet their goals for high success rates, lower cost and faster time to market. With the paradigm shifting from titer to process optimization and analytics, the biopharma business model can be improved using continuous processing to manage complexity. Smart technology exists today which can increase flexibility, decrease cost, and improve production.

1:00 Session Break

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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6th Annual

Bioproduction: Scale, Bioreactors & Disposables

Making it Work

SCALING UP & DOWN

1:45 Chairperson's Remarks
Trevor Deeks, Ph.D., QA and QC Consultant, Teva Biopharmaceuticals USA, Inc.

1:50 Bioreactor Concepts and Soft Sensor Tools for Scale-Up and Down
Stefan Junne, Ph.D., Group Leader and Chair, Bioprocess Engineering, Biotechnology, Technische Universität Berlin
For scale-down experiments, several designs of multi- and single-use bioreactors are applied. Scalability is of basic importance to mimic industrial scale conditions properly. Aside from stirred reactors, rocking and orbitally shaken single-use bioreactors exhibit a very good scalability. Application of process analytical technologies support the identification of suitable scale down conditions: whenever lack of knowledge restrict a classical engineering approach, physiological and morphological features of cells should be considered.

2:20 Scaling-Down Local Mixing Effects for Biotechnology Applications
Suzanne M. Kresta, Ph.D., Professor, Chemical & Materials Engineering, University of Alberta, Edmonton
One of the most critical steps for a process scale-down or scale-up is to have a fully turbulent flow regime in the bench scale mixing vessel. We compare scale-down methods for the conventional stirred tank, the confined impeller stirred tank (CIST), and shaker flasks. These results have implications both for scale-up and for many industrial applications. Consideration of meso-mixing effects and local concentration and turbulence effects are important considerations.

2:50 Establishing a Single-Use Benchtop Bioreator Model to Support Flexible Manufacturing Strategies
Seth Kitchener, Associate Director, Upstream Process Development, ImmunoGen, Inc.
Representative bioreactor scale-down models are essential for successful development, transfer, and scale-up of cell culture processes. These needs are coupled with increasing demand for speed and flexibility as programs and manufacturing strategies evolve. This case study will describe the implementation of a new single-use benchtop bioreactor scale-down model to support late-phase process characterization studies and future, flexible manufacturing strategies. Collaboration with CMO and comparability of process performance and product quality relative to existing models is discussed.

3:20 Development and Process Verification of Novel Scale-Down Tools for Periplasmic Fab Extraction
Asma Ahmad, Eng.D., Researcher, Biochemical Engineering, University College London
A 20ml miniature vessel was designed and used as a scale-down model to successfully mimic the periplasmic Fab extraction process 10,000 fold from the 200L scale, using constant power per unit volume (P/V). The process has been scaled down a further 10 fold into disposable 24 micro-well plates and recent data comparing 20L and 2L extractions to 2ml is promising and indicates feasibility of using plates to increase throughput.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Plenary Keynote Session (see page 3 for details)

6:00 Networking Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

THURSDAY, AUGUST 18

8:00 am Registration Opens and Morning Coffee

INCREASING PRODUCTIVITY

8:25 Chairperson's Remarks
Stefan Schmidt, Ph.D., MBA, Vice President, Process Science and Production, Rentschler Biotechnology

8:30 Expression Tuning for Enhanced Recombinant Protein Production in *E.coli*
David J. Wurm, Project Assistant, Biochemical Engineering, Vienna University of Technology
Strong induction of recombinant protein production in *E. coli* can lead to agglomeration of inactive product. We developed a feeding strategy to tune recombinant protein expression on a cellular level which leads to higher yields of soluble and active product. We successfully applied this system to the production of 1) GFP, 2) a pharmaceutically highly relevant enzyme and 3) an antibody fragment.

9:00 Increasing Protein Production with Novel Cell Ess Supplement
Adam Elhofy, Ph.D., CSO, Essential Pharmaceuticals
Enhancing protein production is a common goal in the biomanufacturing industry. At a concentration of 1% Cell Ess supplement resulted in a 37% increase in productivity. When using the supplement as a feed it resulted in in a 25% increase in yield and an extension of peak protein production. Functional protein increase and desired glycosylation achieved. Our results suggest that an increase in protein production may not necessarily require a change in the metabolic state of the cells.

9:30 Presentation to be Announced

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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6th Annual

Bioproduction: Scale, Bioreactors & Disposables

Making it Work

OPTIMIZING PRODUCTON STRATEGIES

10:45 Overcoming the Quality Challenges in Transferring a CHO Fed-Batch Process for Large-Scale Manufacturing

Yun Jiang, Ph.D., Principal Scientist, Project Team Leader Upstream, Drug Design & Development, Swedish Orphan Biovitrum AB

A CHO fed-batch process has been transferred to two CMO facilities. The comparability study showed that drug substance produced at the two manufacturing sites had different patterns in the second product main peak in the RP-HPLC chromatography. It was found that the difference was due to an increased level of product variants at the second site. A risk assessment of the product variants was performed and a process change was implemented to secure a robust production process over the time.

11:15 Harnessing Exosome Biology to Develop the Biotherapeutics of the Future

Kathryn Golden, M.Eng., Associate Director, Upstream Development and Manufacturing, Codiak Biosciences

Codiak Biosciences is currently developing exosomes, natural vesicles that mediate inter-cellular communication, as both a powerful therapeutic modality and an advanced diagnostic system. An introduction to the biology and therapeutic benefits of exosome technology will be discussed. The philosophy and methodology of transforming a traditionally academic production approach into an optimized full-scale manufacturing process will also be outlined, including updating historically nonscalable upstream and downstream methods, improving limited analytical capability, and working with CMOs.

11:45 Case Study on Microbially-Based Bioproduction Strategies

Mayo Pujols, MS, Vice President, Manufacturing, Advaxis, Inc.

12:15 Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

1:55 End of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Optimizing Cell Line Development

Enhancing Expression

THURSDAY, AUGUST 18

11:30 am Registration Opens

12:15 pm Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

INNOVATING CELL LINE DEVELOPMENT PROCESSES

1:55 Chairperson's Opening Remarks
Nathan E. Lewis, Ph.D., Assistant Professor, Department of Pediatrics, University of California, San Diego

2:00 KEYNOTE PRESENTATION: Tilting at Windmills: Cell Line Development Impacts on Quality, Time and Costs
Steven Lang, Ph.D., M.B.A., Director, Early Stage Cell Culture, Genentech, Inc., a member of the Roche Group
Advances in technology and processes have made significant improvements in cell line development efficiency. However, the continued pressure to reduce timelines and costs while delivering on quality has created imaginary giants. This talk will discuss cell line development challenges and how focusing on real issues can improve the value of clinical programs.

2:45 Technology Toolbox for Cell Line Development – Next-Generation Cell Line Development Technologies
Holger Laux, Ph.D., Fellow, Novartis
A novel toolbox of vector elements and novel engineered CHO cell lines were developed which results in significant increase of titer and improved product quality. We have evaluated novel vector elements with a variety of antibody projects resulting in an increase of titer. Especially the combination of the recently published CHO genome in combination with screening methods and cell line engineering tools has enabled the development of a superior CHO cell.

3:15 What is Your Cell Line Really Translating? Enhancing Protein Production with Ribosomal Profiling and Systems Biology Analysis
Nathan E. Lewis, Ph.D., Assistant Professor, Department of Pediatrics, University of California, San Diego
Mammalian cells channel their resources to produce recombinant protein drugs, but it is unclear how recombinant genes impact global translation and if they are translated as efficiently as host genes. To answer these questions, we gained a global view of mRNA translation in IgG-producing CHO cells using ribosomal profiling. We demonstrate how these data can be harnessed to guide cell line development for protein production.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 Refreshment Break

CELL LINE SCREENING

4:15 A Novel Platform for High Throughput Cell Line Screening & Development
Christoph Freiberg, Ph.D., Senior Scientific Consultant, Biologics, Genedata
Co-developed with leading biopharmaceutical companies, we have implemented a dedicated cell line development platform for fully automating the clone line selection and assessment process to increase process efficiency and quality. It supports the entire cell line development workflow including seeding, selection, incubation, passaging, analyzing, and cryo-conservation and tracks the full history of all clones along with product quality and analytics data. It directly integrates with instruments, such as pipetting robots, colony pickers, and bioanalyzers.

4:45 Alleviate the Downstream Burden of Harvest Filterability through Upstream Process Optimization and Cell Line Screening
Sheng (Sam) Zhang, Ph.D., Senior Scientist, Process Sciences, AbbVie
In this study, instead of looking into alternate harvest clarification approaches, we are exploring other options in upstream processing. These approaches are designed to enhance the harvest filterability by significantly reducing the cell mass, debris and/or other impurities while boosting productivity. To move a step further, we are implementing the same upstream condition(s) in the early stage of cell line screening to preferentially select line(s)/clone(s) that may not encumber the platform downstream process.

5:15 End of Day

5:15 Registration for Dinner Short Courses

6:00 – 8:30 Recommended Dinner Short Course*
Regulatory and Scientific Base of Monoclonality for Generating Protein Expression Cell Banks
** Separate registration required, see page 5 for details.*

FRIDAY, AUGUST 19

8:00 am Registration Opens and Morning Coffee

CHO CELL LINE DEVELOPMENT

8:25 Chairperson's Remarks
Susan Sharfstein, Ph.D., Associate Professor, Nanobioscience, Nanoscale Science and Engineering, SUNY Polytechnic Institute

8:30 Accelerated Genome Engineering of CHO Cell Factories for Improved Protein Production
Helene Faustrup Kildegaard, Ph.D., Senior Researcher and Co-Principal Investigator, Novo Nordisk Foundation Center for Biosustainability, Technical University of Denmark
Chinese hamster ovary (CHO) cells are widely used in the biopharmaceutical industry as a host for the production of complex pharmaceutical proteins. Thus, accelerated genome engineering of CHO cell factories to improve product yield and quality is of great interest. Here, our recent efforts in generating desirable CHO cell factories with predicted performance using genome engineering, systems biology data and high-throughput screening, will be presented.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Optimizing Cell Line Development

Enhancing Expression

9:00 Cell Line Development: Glycoengineering of Chinese Hamster Ovary Cells for Improving Biotherapeutics' Efficacies

Andrew Chengyu Chung, MSE, Researcher, Chemical and Biomolecular Engineering, Johns Hopkins University

Many biotherapeutics include post-translational modifications such as glycosylation. The chemical composition of these glycans can influence drug effectiveness. Sialylation is one of the most important glycan modifications due to its negative charge and terminal location. In this study, we applied genetic engineering strategies to modulate the level of sialylation content on various potential biotherapeutics.

9:30 Epigenetic Effects on Antibody Production in CHO Cells

Susan Sharfstein, Ph.D., Associate Professor, Nanobioscience, Nanoscale Science and Engineering, SUNY Polytechnic Institute

Identifying characteristics of high productivity cell clones is critical for rapid cell line development. We evaluated epigenetic differences between parental clones and DHFR-amplified progeny including transcription factor activation and DNA methylation. These studies suggest that transcription factor binding is altered in different families of parental cell lines and progeny, providing possible strategies for cell line engineering.

10:00 Networking Coffee Break

CELL LINE AUTHENTICATION

10:30 Know Thy Cells: Improving Biomedical Research Reproducibility

Leonard P. Freedman, Ph.D., President, Global Biological Standards Institute

Sources of irreproducibility are often magnified by the explosion of high-throughput technologies, genomics, and other data-intensive disciplines. This presentation will use examples of biological materials and reagents, specifically cell lines and antibodies, on the impact of irreproducibility in basic/preclinical research and development, and how the implementation of consensus-based standards to authenticate and certify these reagents will lead to both increased rates of reproducibility and dramatic returns on research funding investments.

11:00 Cell Line and Biospecimen Authentication: Challenges and Solutions for Biomedical Science

Richard M. Neve, Ph.D., Senior Research Scientist I, Gilead Sciences, Inc.

The use of cell lines and biosamples are widespread in biomedical research. Contamination of stocks and confusion of cell line/sample origin frequently occur, resulting in wasted research funds and delaying development of important medicines for patients. This presentation outlines solutions for these issues by defining a framework of quality controls and best practices to prevent and detect the most common forms of cross-contamination.

11:30 Authentication of Mouse, CHO, and Rat Cell Lines

Jamie Almeida, Microbiologist, Biochemical Science Division, Bioassay Methods Group, NIST

Cell line authentication has never been more necessary in the current environment. Currently, there are no standards for cell line authentication for nonhuman cell lines. We have developed rapid, sensitive, and specific multiplex PCR assays targeting short tandem repeat markers for mouse and Chinese hamster cell lines, and we have identified STR markers specific to rat. Use of these assays provide assurance in cell line identity for the validation of downstream products.

12:00 pm Sponsored Presentations *(Opportunities Available)*

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Session Break

EMERGING TECHNOLOGIES

1:25 Chairperson's Remarks

Christoph Freiberg, Ph.D., Senior Scientific Consultant, Biologics, Genedata

1:30 Greater Predictability in Establishing Optimal Biologic Production Systems Using Integrated Synthetic Biology Approaches

Ian Fotheringham, Ph.D., Managing Director, Ingenza, Ltd.

In this talk, I will describe how Ingenza develops and applies various synthetic biology tools to enable us to more predictably achieve efficient, soluble and stable expression of active biologics using both mammalian cell lines and microbial strains. I will describe scaled commercial examples that solved customer problems and illustrate the utility of our approach.

2:00 Switchable Membrane Reporter (SwiMR) Technology for Facile Cell Line Development

Bo Yu, Ph.D., Co-Founder & CSO, Larix Bioscience

Switchable Membrane Reporter (SwiMR) technology is the most efficient technology available today for the isolation of production cell lines. It utilizes a unique switchable reporter system to facilitate FACS-based enrichment and isolation of high producing cells. This eliminates the requirement for gene amplification and reduces cell line screening time from 4-8 months to 2-3 months. The SwiMR technology has been used to generate production CHO cells for multiple antibodies.

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SHORT COURSES
TRAINING SEMINARS
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CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Optimizing Cell Line Development

Enhancing Expression

CLONE STRATEGIES

2:30 Towards a Novel Site-Specific Integration System for Cell Line Development

Mara C. Inniss, Ph.D., PostDoc Fellow, Cell Line Development, Pfizer, Inc

The growth of the biopharmaceutical market in recent years has prompted dramatic improvements in recombinant protein production. Pfizer's site-specific integration (SSI) platform, based on the Flp/FRT recombinase-mediated cassette exchange (RMCE), promises unparalleled ease and consistency in generating CHO cell lines. To further advance our mammalian expression technology, we are developing a novel site-specific integration system which is comparable and orthogonal to the Flp/FRT system, offering flexibility and user-defined capability in generating recombinant cell lines for biopharmaceutical production..

3:00 Towards One Round of Cloning in Cell Line Development

Nathalie Veith, Ph.D., Senior Scientist, Upstream Development, Synthon Biopharmaceuticals

Regulatory guidelines state that production cell lines need to be derived from one cell progenitor. In order to guarantee this with a high probability, biopharmaceutical industries use two rounds of limiting dilution, FACS-based procedures and/or imaging techniques to ensure clonality of a cell line. Since time lines play an important role for CMC projects, many efforts are undertaken to decrease the effort and time to prove clonality of a cell line. Synthon Biopharmaceuticals want to present their approach using two different devices to support their strategy ensuring clonality of a cell line.

3:30 Close of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
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- Optimizing Cell Line Development

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- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

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- Host Cell Proteins: Detection, Analysis & Removal
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- Process Characterization, Qualification & Control

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- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
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STREAM #2
Downstream Processing

Process integration and *process intensification* are the current buzz words among biopharm scientists and executives today. This is especially prevalent and true in the downstream processing field, where economics and efficiencies are driving companies to look into innovative technologies in downstream processing to meet the demands of higher upstream titers, giving rise to new trends like continuous processing; advanced strategies for purification of bispecifics, vaccines and recombinant proteins, and improved techniques for virus and pathogen clearance and better risk management strategies. The weeklong Downstream Processing stream highlights exciting developments in downstream today.

AUGUST 15-16
Continuous Processing in Biopharm Manufacturing

AUGUST 17-18
Advances in Purification Technologies

AUGUST 18-19
Virus & Pathogen Clearance & Safety in Biologics

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- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

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2nd Annual

Continuous Processing in Biopharm Manufacturing

Reinventing Process Architecture with Integration, Intensification and Automation

MONDAY, AUGUST 15

8:00 am Short Course Registration

9:00 – 11:30 Recommended Morning Short Course*
Advanced Process Control Strategies in Bioprocessing
** Separate registration required, see page 5 for details.*

11:30 Main Conference Registration Opens

CONTINUOUS UPSTREAM PROCESSING

1:00 pm Chairperson's Opening Remarks
Andrew Sinclair, MBA, President and Founder, Biopharm Services

1:10 KEYNOTE PRESENTATION: Upstream and Downstream Approaches to Continuous Biopharmaceutical Manufacturing: A Journey Not a Destination
John Knighton, MBA, Head, API Large Molecule, Pharmaceutical Development and Manufacturing Sciences, Janssen R&D
The topic will explore broadly the biopharmaceutical industry's different viewpoints of continuous manufacturing, specifically providing some Janssen continuous manufacturing examples. For some, it is more holistic view from vial thaw to filled drug product in one facility. For others like Janssen, continuous manufacturing is comprised of continuous aspects of upstream and downstream as the technology develops and as the need for more plant efficiency increases.

1:45 Medium Development for Next-Generation Perfusion Processes
Jochen B. Sieck, Ph.D., Lab Head, Cell Culture Media R&D, Process Solutions R&D, Merck KGaA
Perfusion processes have fundamentally different requirements for cell culture media, compared to fed-batch processes. Desirable characteristics also depend on the type of perfusion process that is targeted. In this talk we will present how different manifestations of perfusion impact these requirements and present data on how they can be addressed in medium development.

2:15 Scalability of Growth Characteristics and Product Quality: Efficient Downscale Perfusion Bioprocess Development Using DOE Studies
Steffen Kreye, MSc, Scientist, USP Development, Glycotope GmbH
The sedimentation based down-scale perfusion system SAM (10mL reactor volume) has been developed to characterize the upstream process parameters and their influence on product quality. Using DoE studies we gain a highly efficient method for media development as well as process optimization to achieve higher cell densities and higher productivities. Scalability and reproducibility of perfusions bioreactors (10mL – 1000L) will be highlighted with data of the fully human, high yield production and glycooptimization platform GlycoExpress (GEX).

2:45 Refreshment Break

3:15 Perfusion Process Applicability
Jacob Jensen, Ph.D., Senior Manager, Manufacturing Sciences, Biogen
Perfusion processes extends the time in the manufacturing bioreactor and may not be directly applicable to conventional fed-batch processing. This talk will focus on how the benefits of perfusion can be integrated in a fed-batch process to increase product output.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 A Membrane-Less Cell Retention Device Based on Inertial Sorting for Perfusion Cultures
Taehong Kwon, MSc, Research Assistant, Electrical Engineering and Computer Science, MIT
Membrane-based cell retention technologies (e.g., hollow fiber membranes) are currently used in perfusion cultures despite the limitations of membrane fouling and clogging. We developed a membrane-less clog-free retention device based on inertial sorting, and used it for IgG-producing perfusion CHO cultures. This talk will introduce the novel cell retention device and discuss its challenges and promises for continuous processing in biopharmaceutical manufacturing.

4:30 Breakout Discussions

5:30 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

TUESDAY, AUGUST 16

7:30 am Registration Opens and Morning Coffee

CONTINUOUS DOWNSTREAM PROCESSING

7:55 Chairperson's Remarks
Robert Dream, PE, CPIP, Managing Director, HDR Company, LLC

8:00 KEYNOTE PRESENTATION: Continuous Precipitation-Based Processes for Protein Purification
Todd Przybycien, Ph.D., Professor, Chemical Engineering and Biomedical Engineering, Carnegie Mellon University

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

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Continuous Processing in Biopharm Manufacturing

Reinventing Process Architecture with Integration, Intensification and Automation

8:30 Continuous Manufacturing, Hybrid Options Transitioning from Batch to Continuous: Economics and Operational Implications

Andrew Sinclair, MBA, President and Founder, Biopharm Services

This presentation will assess the reality of transitioning to the hybrid option by providing insights on where this makes practical and economic sense within a process. This allows us to identify those factors that require optimization/ development in terms of the potential now and for the future. Here the focus is on describing the approaches to hybrid downstream processing in terms of the mode of operation, integrating batch processing into continuous operations and looking at the impact on buffer supply to the process.

9:00 Continuous Chromatography for Purification of Virus and Virus-Like Particles Targeting Vaccine and Gene Therapy Applications

Ricardo Silva, Ph.D., Researcher, Downstream Processing Lab, Animal Cell Technology Unit, iBET – Instituto de Biologia Experimental e Tecnologica

Novel biopharmaceutical products are a challenging task for downstream processing. Alternative purification strategies that can improve the purification yield, such as continuous chromatography, are regarded nowadays as enabling technologies to overcome the capacity bottleneck in biomanufacturing. The current talk will focus on the development of multi-column chromatographic systems aimed at the purification of gene therapy vectors and enveloped virus-like particles produced using insect cell-based expression system for vaccine applications.

9:30 Sponsored Presentation *(Opportunity Available)*

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

MONITORING, CONTROL & VALIDATION OF CONTINUOUS PROCESSES

10:30 Implementation of Model Predictive Fermentation Process Control Strategies - Experienced Challenges and Strategies on How to Solve These Problems

Gerald Striedner, Ph.D., Assistant Professor, Biotechnology, University of Natural Resources and Life Sciences

We established data driven models for real time prediction of relevant process variables as basis for an advanced process control strategy. We used the predicted biomass in the process to calculate the inducer feed profile that allowed for setting a constant inducer to biomass ratio and thereby indirect control of the product formation rate. During implementation and evaluation of this advanced process control strategy we experienced various challenges and we also identified strategies on how to further advance this concept.

11:00 Continuous Bioprocessing – PAT Strategies in Support of Process Monitoring and Control to Enable Rapid Product Release

Jeffrey Doyle, Manager, PAT Projects, Pfizer, Inc.

11:30 Validation, Continuous Verification and Compliance of Continuous Manufacturing Operations

Michelle Bailey, Ph.D., Head, Validation of Continuous Manufacturing and Process Automation, Vertex Pharmaceuticals

The pharmaceutical industry is adopting continuous manufacturing models to drive efficiency and higher quality. These new technologies require effective approaches for validation. This presentation discusses challenges encountered and approaches taken to validate continuous manufacturing for multiproduct solid dosage product and preparing for a successful regulatory inspection.

Sponsored By

PALL Life Sciences

12:00 pm A High Performance Integrated and Disposable Clarification Solution for Continuous Bioprocessing

Mike Collins, Principal Research Engineer, Pall Life Sciences

There is a growing interest within the biopharmaceutical industry in adopting continuous processing in place of current batch processing for biological molecules and primarily monoclonal antibodies (mAbs). Expectations from this transition are multiple including reduced product cost of goods, capital expenses and facility foot print while process productivity and flexibility is increased. But the adoption of continuous bioprocessing requires first to achieve a smooth transition for each process step from batch to continuous. The clarification is a key early step within the process which poses the challenge of reducing the cost and foot print of filtration in the context of a continuous mAb purification process.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

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Continuous Processing in Biopharm Manufacturing

Reinventing Process Architecture with Integration, Intensification and Automation

INTEGRATED UP- AND DOWN-STREAM CONTINUOUS BIOMANUFACTURING

1:55 Chairperson's Remarks

Todd Przybycien, Ph.D., Professor, Chemical Engineering and Biomedical Engineering, Carnegie Mellon University

2:00 Manufacturing Technologies to Enable Process Intensification

Sponsored By MilliporeSigma

Jim Neville, Director, Technology Management-Americas', MilliporeSigma

The biopharmaceutical industry is adopting a more strategic view toward manufacturing, seeking solutions that offer increased productivity and improved economics without sacrificing process robustness. The industry addresses these challenges through process intensification efforts including unit operation optimization, linked and continuous processing. This presentation provides insight into upstream and downstream intensification approaches to improve processes. Examples include high producing and stable cell lines, column size reduction, product purity improvement and enabling a continuous process.

2:30 Building an Integrated Continuous Manufacturing Platform

Jonathan Souquet, Ph.D., Head, Biotech Process Sciences Technology & Innovation, Biopharma Global Manufacturing & Supply, Merck Serono

The objective of this presentation will be to provide invaluable insight into the design and development of a fully integrated platform manufacturing process operated in continuous mode. Challenges of integrating discrete unit operations to create a compact continuous processing drug substance manufacturing solution will be reviewed. Process design considerations and enabling technologies required to monitor, control and optimize the process will be discussed.

3:00 Integration of Single-Use Technologies and Continuous Processing for the Manufacturing of Therapeutic Proteins

Jorgen Magnus, Ph.D., Project Manager, R&D, Bayer Technology Services

Bayer is developing a novel production concept for monoclonal antibodies within the Mobidik project. All surfaces in contact with the product are in single-use technology and the downstream processing is run as a truly continuous process without intermediate storage. A process control system and on-line / at-line PAT are developed to give a high level of automation. GMP related issues are addressed at an early stage.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Challenges in the Development of Continuous Processes for Vaccines

Daniel C. Vellom, Ph.D., Senior Director, Global Technology Innovation, Sanofi Pasteur Biologics

Vaccine developers pursuing continuous manufacturing need to consider the nature of the batch production process and the economics supporting the transition to a new mode of manufacturing. Will the "new" product be comparable to the existing vaccine, or be considered a next-generation product in the eyes of the regulatory agencies? This presentation will outline these challenges and propose a general approach to development of a continuous vaccine production process, and new tools that can enable such development.

4:45 Closing Presentation Integrated Continuous Biomanufacturing Enables More Efficient Cost-Effective Drug Manufacturing and Improved Process Safety

Robert Dream, PE, CPIP, Managing Director, HDR Company, LLC

The importance and value of continuous bioprocessing has economic and sustainability advantages and due to the modular nature of continuous bioprocesses it means that the industry is able to adapt more rapidly to changing market demands. Continuous manufacturing is as productive and with a much smaller footprint of the manufacturing plant, avoiding multiple non-value added unit operations. In essence, the investment for a continuous plant is much smaller compared to a batch-operated one.

5:15 End of Conference

5:15 Registration for Dinner Short Course

6:00 – 8:30 Recommended Dinner Short Course*

Purification of Advanced Medicine Therapy Products

** Separate registration required, see page 5 for details.*

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
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- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Advances in Purification Technologies

Economics and Efficiencies for Next-Generation Biomanufacturing

TUESDAY, AUGUST 16

6:00 – 8:30 Recommended Dinner Short Course*
Purification of Advanced Medicine Therapy Products
** Separate registration required, see page 5 for details.*

WEDNESDAY, AUGUST 17

7:00 am Registration Opens and Morning Coffee

8:05 Chairperson's Opening Remarks
Christoph Brandenbusch, Ph.D., Group Leader, Department of Biochemical and Chemical Engineering, Laboratory of Thermodynamics, TU Dortmund University

KEYNOTE SESSION

8:15 From Purification to Vaccine Development: A Challenging but Rewarding Journey
Yan-Ping Yang, Ph.D., Head, Bioprocess R&D North America, Sanofi Pasteur
The vaccine industry has high risk, long cycle time, and requires approximately 12 years bringing a product from pre-clinical to licensure at a cost of ~$1 billion. Purification of vaccine candidates to achieve consistent product purity and quality in a timely manner is an integral part of vaccine product development process. This presentation focuses on the applications of cutting edge purification technologies to facilitate vaccine process development and move faster to clinical evaluations.

9:00 Positioning Downstream Processing to Successfully Conquer Future Challenges
John Pieracci, Ph.D., Director, Purification Development, Biogen
The talk would include challenges the biotech industry is facing in the future (new modalities, price pressures, nimbly supplying small and large markets, etc.), building platform downstream processes for new modalities (antisense oligonucleotides, gene therapy, bi-specific mAbs, etc.), and the criticality to drive down CoGs to meet the pressures of large indications/markets and governmental forces by leveraging new technologies or driving up the productivity of existing processes.

DEFINING DESIGN SPACE

9:30 Defining Process Design Space for a Multimodal Chromatography Purification Step by Custom Design
Jie Chen, Ph.D., Senior Scientist, Process Development, Bristol-Myers Squibb
A process characterization study was performed to gain understanding of the multimodal chromatography (MMC) purification process and to map the design space. Seven factors out of thirty-eight process parameters were identified to be important. Custom design was employed to study multi-dimensional combination of operational variables for mapping of the process design space. A robust operating window was identified for this multimodal chromatography process that enabled sufficient impurity removal while ensuring acceptable process yield.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

CONTINUOUS AQUEOUS TWO-PHASE EXTRACTION

10:45 Continuous Aqueous Two-Phase Extraction of Proteins Part I – Estimating Process Windows and Industrial Applicability
Christoph Brandenbusch, Ph.D., Group Leader, Department of Biochemical and Chemical Engineering, Laboratory of Thermodynamics, TU Dortmund University
Increasing product titers in pharmaceutical protein production lead to a demand for novel workup strategies (eg: protein extraction by Aqueous 2-Phase System). However the effort and costs required in selecting appropriate ATPS and the determination of process windows hinders the industrial applicability. To enable estimations on the applicability of this workup strategy, hybrid ShortCut models to calculate partition coefficients have to be available.

11:15 Continuous Aqueous Two-Phase Extraction of Proteins Part II – Separation Principle and Novel Techniques
Gerhard Schembecker, Ph.D., Professor, Biochemical and Chemical Engineering, TU Dortmund University
Aqueous Two Phase Extraction (ATPE) offers a gentle and biocompatible environment to separate industrially interesting enzymes from complex mixtures. The presentation will introduce the separation principle and existing and novel techniques will be discussed particularly in the light of continuous operation. Besides single and multi-stage mixer settler setups innovative processes immobilizing one of the two aqueous phases either in the pores of particles or by use of a centrifugal force fields will be investigated.

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PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
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- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

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- Host Cell Proteins: Detection, Analysis & Removal
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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

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Advances in Purification Technologies

Economics and Efficiencies for Next-Generation Biomanufacturing

Sponsored By
JSR Life Sciences

11:45 Amsphere A3: Considerations of Bead and Pore structure, Surface Chemistries, and Ligand Design for Affinity Resins

Masayoshi Nagaya, Business Strategy Manager, Bioprocess, JSR Life Sciences

Industry needs, patent expirations of ligand design and market dynamics have accelerated the development and availability of many protein affinity resins. Technology providers must consider a range of design parameters such as resin backbone, bead size, pore size, surface chemistry, ligand construct and how they relate to performance criteria such as DBC, life time, caustic stability, and column packing among others. The balance between resin design and performance will be illustrated through a case study.

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:00 Session Break

IMPROVEMENTS IN CHROMATOGRAPHY & ANALYTICAL TECHNIQUES FOR PURIFICATION

1:45 Chairperson's Remarks

Yan-Ping Yang, Ph.D., Head, Bioprocess R&D North America, Sanofi Pasteur

1:50 Creating an Efficient Biopharmaceutical Factory: Protein Purification Using a Self-Cleaving Split Intein

Merideth Cooper, MSc, Chemical and Biomolecular Engineering, Ohio State University

Although affinity tags are commonly used in laboratory settings, tagged proteins cannot be used as therapeutics because of the potential immunogenicity of the tag. In this work, we describe a novel self-cleaving tag technology, based on a highly modified split-intein cleaving element. This approach is convenient and effective for the purification of traceless target glycoproteins from mammalian cell culture, and is currently being applied in a BioMOD platform device for on-demand biologics production.

2:20 The PA Tag Toolbox Offers a System for Easy Affinity Isolation, Robust Detection, and Recyclable Immobilization of High-Value Target Proteins

Junichi Takagi, Ph.D., Professor, Institute for Protein Research, Osaka University

We recently developed a novel and versatile epitope tag system dubbed "PA tag". It is a dodecapeptide tag recognized by an antibody NZ-1, with a characteristic slow dissociation kinetics. PA tag enables purification, detection, and stable and reversible capturing of high value target proteins produced in mammalian cells. We also find that the PA tag can be "inserted" into a protein domain, which adds unique advantage over the existing tagging systems.

2:50 Application of Negative Mode Expanded Bed Chromatography to Improve Filtration-Based Washing Strategies of Human Mesenchymal Stem Cells

Barbara Cunha, MSc, Animal Cell Technology, iBET – Instituto de Biologia Experimental e Tecnologica

The use of human mesenchymal stem cells (hMSC) in autologous and allogeneic therapies has been increasing over the last decade. To be applied in a clinical setting, hMSC need to comply with specific requirements in terms of identity, potency and purity. This talk will focus on the improvement of established tangential flow filtration-based washing strategies, by increasing hMSC purity, using negative mode expanded bed adsorption (EBA) chromatography with a new multimodal prototype matrix based on core-shell bead technology.

3:20 Accelerating Bispecific Drug Discovery Using Enhanced Purification and Analytical Techniques

Daniel Yoo, Scientist, Biologics, Amgen

Isolating high quality proteins from other undesired byproducts of expression, including aggregates, half antibodies, homodimer molecules, and mispaired species, poses significant purification challenges due to the similarities in physical properties of these molecules. Here, I present strategies we have explored to accelerate bispecific drug discovery using a combination of higher throughput screening, automated sample handling, and enhanced purification and analytical techniques to identify higher quality therapeutic candidates.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Plenary Keynote Session (see page 3 for details)

6:00 Networking Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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3rd Annual

Advances in Purification Technologies

Economics and Efficiencies for Next-Generation Biomanufacturing

THURSDAY, AUGUST 18

8:00 am Registration Opens and Morning Coffee

PURIFICATION OF EMERGING BIOMOLECULES

8:25 Chairperson's Remarks

Guy de Roo, Ph.D., Project Leader, Downstream Processing, Synthon BV

8:30 KEYNOTE PRESENTAITON: Development and Manufacturing of MCLA-128 and MCLA-117 Biclonics® Common Light Chain Bispecific Antibodies

Lex Bakker, Ph.D., Senior Vice President & CDO, Merus Biopharmaceuticals

MCLA-128 is an ADCC-enhanced bispecific IgG1 antibody targeting HER2 and HER3. MCLA-117 is a T cell engaging bispecific antibody targeting CD3 and CLEC12A, a novel AML-associated antigen. MCLA-128 and MCLA-117 are produced using Merus' proprietary CH3 heterodimerization technology. Both Biclonics® product leads are manufactured using IgG1 platform approaches.

9:00 Purification of Viral Particles

Yingxia Wen, Ph.D., Head, Protein Biochemistry, Seqirus

9:30 Inline Protein Concentration for Downstream Processing

Sponsored By C Technologies, Inc.

Ramsey Shanbaky, Product Manager, Sales, C Technologies, Inc

Accurate concentration measurement is critical during downstream processes. Providing real-time concentration during protein purification processes expedites process development and reduces risk in manufacturing processes. The FlowVPE is a new tool to provide real-time concentration during downstream processes. This talk will discuss applications in chromatography and UF/DF.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Process Development of the Antibody-Drug Conjugate (ADC) SYD985 - A Case Study

Guy de Roo, Ph.D., Project Leader, Downstream Processing, Synthon BV

SYD985 is an antibody-drug conjugate (ADC) based on trastuzumab and a cleavable linker-duocarmycin payload. A case study will be presented in which a hydrophobic interaction chromatography (HIC) purification process was developed allowing removal of the undesired antibody species together with unbound linker-drug. It was possible to elute the product (SYD985) using mild conditions without requirement for any organic solvent. The HIC purification step was scaled up, demonstrating consistency and robustness.

11:15 Preparative Separation of VLP and Extra Cellular Particles (Exosomes)

Alois Jungbauer, Ph.D., Professor, Laboratory of Protein Technology and Downstream Processing, Austrian Center of Biotechnology, Department of Biotechnology, University of Natural Resources and Life Sciences

Enveloped VLPs are interesting candidates for vaccines and cancer immunotherapy. They have a size of about 100 -200 nm which is similar to exosomes and other extra cellular particles. The surface properties are very similar because VLPs and extra cellular particles are budded from the host cell. A strategy is shown who solve this extremely challenging purification task using HIV-gag VLP expressed in CHO cells as model.

11:45 Navigating the Downstream Processing Challenges for Novel Monoclonal and Bispecific Antibodies

Chen Wang, Ph.D., Principal Scientist, Process Sciences, Abbvie Bioresearch Center

As we expand our biotherapeutic product portfolio, significant processing limitations have arisen with the existing platform for some of the novel monoclonal and bi-specific antibodies such as dual variable domain immunoglobulins (DVD-IgsTM). Through exploring unconventional chromatographic methods, adopting state-of-the-art purification technologies and understanding protein-protein interaction mechanism, we were able to develop effective strategy and toolbox to overcome processing challenges for molecules with platform fit concern.

12:15 Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

1:55 End of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
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2nd Annual

Virus and Pathogen Clearance and Safety in Biologics

Adventitious Agent Contamination, Risk Mitigation, New Technologies and Case Studies

THURSDAY, AUGUST 18

11:30 am Registration Opens

12:15 pm Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

VIRAL SAFETY, RISK ASSESSMENT & MANAGEMENT

1:55 Chairperson's Opening Remarks
Mark Plavsic, Ph.D., Senior Director, Product Biosafety, Industrial Operations, Sanofi

2:00 KEYNOTE PRESENTATION: Title to be Announced
Arifa Khan, Ph.D., Supvy Microbiologist, Viral Products, FDA CBER

2:45 Design, Evaluation, and Characterization of Viral Clearance Procedures: USP Chapter <1050.1>
Mark Plavsic, Ph.D., Senior Director, Product Biosafety, Industrial Operations, Sanofi

The new USP Chapter <1050.1> on viral clearance will be published in 2016. It is meant to supplement USP Chapter <1050> and the ICH guidance Q5A. The purpose of this talk is to provide an overview of key features of this new publication and make the audience aware of the value it brings to those practicing the art of viral clearance.

3:15 Protein A: The Untold Story
Pete Gagnon. Vice President, Process Sciences, Avid Bioservices, Inc.

This presentation will review recent discoveries about the way protein A really works: how it affects IgG, why it is generally unable to reduce host contaminants below 500 ppm, and how to enable it to reduce them below 10 ppm. New data will be shown from case studies conducted with prospective biosimilar Humira, Herceptin, and other antibodies. Examples will demonstrate consistently better purification with 2 chromatography steps than can be achieved by the traditional 3-step platform.

3:45 Genetic Engineering of CHO Cells for Viral Resistance to Minute Virus of Mice (MVM) *Sponsored By* MilliporeSigma
Joaquina Mascarenhas, Ph.D., Senior Research & Development Scientist, MilliporeSigma

4:00 Refreshment Break

4:15 Improvements and Selection of Downstream Viral Clearance Technology
Jon Gingrich, Avid Bioservices

This panel will discuss technology advancements available to biological drug manufacturers to meet viral clearance standards. Protein react to these methods will be explored and discussed.

- Nanofiltration technology advancements resulting in the removal of large virus/pathogens
- Inactivation and removal- chromatography / anion exchange
- Single-use pathogen removal

5:15 End of Day

5:15 Registration for Dinner Short Course

FRIDAY, AUGUST 19

8:00 am Registration Opens and Morning Coffee

VIRAL SAFETY: CHARACTERIZATION & INACTIVATION

8:25 Chairperson's Remarks
Donald Jarvis, Ph.D., Professor, Molecular Biology, University of Wyoming & President, GlycoBac LLC

8:30 Redevelopment of a Viral Filtration Step for a Large and Complex Monoclonal Antibody Based Fusion Protein
George Enriquez, Ph.D., Senior Process Development Specialist, Bio Process Department, Shire

A quality by design (QbD) based, late stage purification process development approach was used for a 300kD, complex monoclonal antibody (Mab) based fusion protein. A manufacturability risk assessment identified viral filter fouling as a high risk to a robust, cost effective manufacturing operation. Through systematic filter scouting and optimization development work, the combination of a pre-filter and a viral filter was found to deliver high throughput, high recovery & short processing time.

9:00 Characterization of an Sf-rhabdovirus Negative Insect Cell Line
Donald Jarvis, Ph.D., Professor, Molecular Biology, University of Wyoming & President, GlycoBac LLC

The recent discovery that insect cell lines derived from *Spodoptera frugiperda* (Sf) are contaminated with a rhabdovirus raised questions about their biosafety as a commercial recombinant protein production substrate. To address this problem, we created Sf-rhabdovirus-negative (Sf-RVN) cells, which have no detectable trace of this adventitious agent. In this presentation, we will describe the features of Sf-RVN cells as an alternative host for use in the baculovirus-insect cell system.

9:30 Downstream Process Development Studies
David Cetlin, Founder & CEO, MockV Solutions LLC

Viral clearance studies are accomplished by challenging scaled-down versions of purification steps with live viral "spikes". These studies are typically conducted in BSL-2 facilities and are costly. A non-infectious viral surrogate would be useful for scientists developing or characterizing downstream purification process steps. Discussed here is an attempt to use a Virus Like Particle to determine the Mouse Minute Virus removal efficacy of a chromatography column step.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
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2nd Annual

Virus and Pathogen Clearance and Safety in Biologics

Adventitious Agent Contamination, Risk Mitigation, New Technologies and Case Studies

10:00 Networking Coffee Break

CLEARANCE SELECTION METHODS

10:30 Retrospective Evaluation of Low pH Viral Inactivation and Viral Filtration Data from Multiple Company Collaboration

Xinfang Li, Principal Scientist, Process Science and Engineering, ImmunoGen, Inc.

Considerable resources are spent within the biopharmaceutical industry to perform viral clearance studies which are conducted for widely used unit operations that are known to have robust and effective retrovirus clearance capability. The collaborative analysis from the members of BioPhorum Development Group Viral Clearance Working Team considers two common virus reduction steps in biopharmaceutical processes: low pH viral inactivation and viral filtration.

11:00 Viral Clearance for Commercial-Scale Norovirus Virus-Like Particle Manufacturing Processes

Ross Taylor, Ph.D., Director, Process Development, Takeda Pharmaceuticals Inc.

12:00 pm Presentation to be Announced

Sponsored By PALL Life Sciences

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Session Break

FUTURE OF VIRAL CLEARANCE & BIOLOGIC SAFETY

1:25 Chairperson's Remarks

David Cetlin, Founder & CEO, MockV Solutions LLC

1:30 Future of Viral Clearance

Speaker to be Announced

With an increasing number of biological drug producers outsourcing their viral clearance studies, exploring the relationship between CRO and biologic manufacturers is crucial to the success of viral clearance.

- The role of biologics companies in downstream clearance studies
- Establish clear target clearance goals

2:30 Breakout Discussions

3:30 Close of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Gene Therapy Bioproduction

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STREAM #3
Analytical & Quality

The weeklong Analytical & Quality stream offers in-depth updates on critical steps in biopharmaceutical development that impact product quality, safety and regulatory compliance. Separate meetings will focus on the detection, analysis and removal of host cell proteins, early stage analytical development and the implementation of process qualification and control strategies. Over fifty in-depth presentations will give attendees insight into the best practices being applied across the industry.

AUGUST 15-16
Host Cell Proteins: Detection, Analysis & Removal

AUGUST 17-18
Early Analytical Development for Biotherapeutics

AUGUST 18-19
Process Characterization, Qualification & Control

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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Inaugural

Host Cell Proteins

Detecting, Analyzing and Controlling HCPs for Improved Quality and Safety

MONDAY, AUGUST 15

8:00 am Short Course Registration

9:00 – 11:30 Recommended Morning Short Course*
New USP Initiatives and Standards for Biologics
** Separate registration required, see page 5 for details.*

11:30 Main Conference Registration Opens

CURRENT HCP CHALLENGES, RISK ASSESSMENT & CONTROL STRATEGIES

1:00 pm Chairperson's Opening Remarks
Judy Shimoni, Ph.D., Senior Scientist and Group Leader, PTDU, Protein Analytical Chemistry, Genentech

1:10 KEYNOTE PRESENTATION: Best Practices for Host Cell Protein Measurement: USP Chapter <1132>
Maura Kibbey, Ph.D., Director, Science and Standards, Global Biologics, USP
USP's official chapter <1132> provides expert guidance on (1) HCP immunogen and standard preparation and characterization; (2) immunization; (3) purification and characterization of antibodies; (4) immunoassay development and validation; (5) lifecycle management; and (6) orthogonal tools to supplement the primary immunoassay technology. Due to these complex, multi-antigen HCP immunoassays, emphasis is placed on unique challenges (e.g., sample dilution linearity, validation, and reporting of results).

1:45 HCP Testing, Control Strategy and Risk Assessment
Judy Shimoni, Ph.D., Senior Scientist and Group Leader, PTDU, Protein Analytical Chemistry, Genentech
The presentation is intended to share some current thinking and to use case studies to demonstrate the application of orthogonal methods complementing HCP workhorse testing method and supporting process development and control strategy; also to illustrate the use of risk assessment for HCP identification and control with consideration of clinical information.

2:15 Immunogenicity Risk Assessment of Host Cell Protein in Therapeutic Monoclonal Antibodies
Qingchun Zhang, Ph.D., Senior Scientist, Amgen
In this study, we investigated the HCP profiles for partially purified in-process samples and highly purified DS-like samples for four therapeutic mAbs. The results indicated in-process samples with up to 4000 ppm HCP content (levels >200 times greater than the drug substance) did not pose a higher immunogenicity risk than highly-purified DS samples. Furthermore, sequence associated immunogenicity risk of over 20 common HCPs was evaluated using *in silico* algorithms.

2:45 Refreshment Break

HCP RISK ASSESSMENT, CONTROL STRATEGIES & DESIGN SPACE

3:15 HCP Assays as In-Process Tests
Carl Co, Ph.D., Senior Scientist, Biogen Idec
HCPs must be removed to ensure product efficacy and safety. ICH specifications guidance, Q6B, states that for certain impurities, testing of drug substance may not be included in specifications if control or removal to acceptable levels is demonstrated. Case studies will be presented which highlight the challenges of our strategy of performing HCP assays for in-process and not for release.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 Platform Reagents. The Design-Space of Generating Platform Reagents for HCP Monitoring by Assessing the Impact of Upstream Process Condition Variations on HCP Expression Profile
Fengqiang Wang, Ph.D., Associate Principal Scientist, Merck Research Laboratories, Merck & Co. Inc.
Mock host cell proteins produced from a null cell line without the product-encoding gene are commonly used as the calibration standards for HCP ELISA. The generation of mock HCPs often follows similar or identical upstream manufacturing process as the production cell culture. We explored the upstream process range or design space where a platform assay can remain to be relevant and suitable for monitoring HCP clearance.

4:30 Breakout Discussions

5:30 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

TUESDAY, AUGUST 16

7:30 am Registration Opens and Morning Coffee

HCP CHARACTERISATION & MASS SPECTROMETRY STRATEGIES

7:55 Chairperson's Remarks
Phoebe Baldus, Ph.D., Principal Scientist and Group Leader, Pfizer

8:00 Adding MS to a Host Cell Protein Workflow
Phoebe Baldus, Ph.D., Principal Scientist and Group Leader, Pfizer

8:30 Analysis of Host Cell Proteins throughout Biopharmaceutical Purification
Martha Stapels, Ph.D., Senior Scientist, Biopharmaceuticals Development, Sanofi Genzyme Corporation
Methods have been developed to identify and quantify HCPs by mass spectrometry, but these typically involve 2D chromatography. We have developed a high throughput method to analyze HCPs where peptide identification occurs where the HCP is most abundant, followed by quantitation in samples across the purification process. Statistical analysis is then used to evaluate purification steps and optimize the process.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Inaugural

Host Cell Proteins

Detecting, Analyzing and Controlling HCPs for Improved Quality and Safety

9:00 Utilization of Mass Spectrometry for HCP Analysis during Process Development

Gang Xiao, Ph.D., Scientist, Process Development, Amgen

It is critical to measure individual HCP by mass spectrometry in order to troubleshoot or optimize the bioprocess. In this presentation, we will demonstrate how mass spectrometry can be utilized for HCP analysis during the bioprocess from upstream cell production, through downstream purification, to final product releasing.

9:30 HCP Identification and Absolute Quantification with a Multifaceted Mass Spectrometry Platform

Sponsored By CAPRION

Daniel Chelsky, Ph.D., CSO, Research & Development, CAPRION

A highly sensitive discovery platform has been developed, employing fractionation, deglycosylation, custom databases, and multiple search engines, to enable the identification and relative quantification of low ppm HCP from any host cell (CHO, human, yeast, bacteria), without the need to remove the drug substance. Targeted MRM mass spectrometry is then used for absolute quantification down to 1 ppm. These assays enable process improvement, clearance monitoring, determination of reproducibility, impact of scale-up and other monitoring needs for antibodies, blood products or peptide manufacture.

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

HCP TESTING STRATEGIES FOR BIOSIMILARS

10:30 Quantitative MS/MS in the Determination of HCP Levels

Nesredin A Mussa, Ph.D., Head, Process Analytics and Method Development, Biologics Development, Global Manufacturing and Supply, Bristol-Myers Squibb

11:00 Host Cell Protein Analysis by Mass Spectrometry and Its Application in a Comparability Exercise

Michael Gattner, Ph.D., Associate Scientist, Physico-Chemical Characterization, Sandoz Biopharmaceuticals/ Hexal AG

Host cell proteins (HCPs) are process-related impurities present in biopharmaceuticals and are generally considered to be critical quality attributes. Here we discuss the usage of ELISA and mass spectrometry to monitor HCP populations in the context of comparability and similarity excercises. A case study employing mass spectrometry-based HCP analysis following a manufacturing change is provided.

11:30 Host Cell Proteins: The Hidden Side of Biosimilarity Assessment

Roxana Butoi, Ph.D., Manager, Analytical Development, R&D Platform Technology and Science, GlaxoSmithKline

Results illustrate the efforts to assess "biosimilarity" for a specific group of process-related impurities, the host cell proteins (HCP). Extensive characterization of HCP in the drug substance of a biosimilar candidate guided process development to improve HCP clearance. The data presented illustrate the challenge of matching the reference product on either quantitative or qualitative aspects of HCP impurities.

12:00 pm Integration of Data from Orthogonal Methods to Provide a Comprehensive Analysis of HCPs in Final Drug Substance

Sponsored By CYGNUS TECHNOLOGIES

Kenneth Hoffman, Ph.D., President, Cygnus Technologies

Because of certain limitations of ELISA, orthogonal methods of analysis are required. This talk discusses how data from 2D HPLC, Antibody Affinity Extraction (AAE), 2D PAGE, and LCMS/MS when integrated with ELISA data can be used to give a comprehensive analysis of individual HCPs that persist through a purification process.

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

ASSAY DEVELOPMENT – PLATFORMS, VALIDATION, COVERAGE, CRITICAL REAGENTS

1:55 Chairperson's Remarks

Fengqiang Wang, Ph.D., Associate Principal Scientist, Merck Research Laboratories, Merck & Co. Inc.

2:00 Platform Host Cell Protein Assays: How to Demonstrate Fitness for Use

Oliver Anderka, Ph.D., Fellow, Functional Lead Bioanalytics, Novartis Pharma AG

"Platform" host cell protein assays are used by biomanufacturers to test a variety of products made from the same type of host organism. An outline is given of how to demonstrate a platform assay's fitness for use. This includes reagent characterization/qualification, reagent replacement, assay validation, as well as criteria for application of a platform assay to a new product or process.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Inaugural

Host Cell Proteins

Detecting, Analyzing and Controlling HCPs for Improved Quality and Safety

2:30 HCP Analysis for a Spectrum of Products Generated from Multiple CHO Cell Lines Including a Comparison of the Performance of a Panel of Different HCP Commercial Kits

Heather Boux, Ph.D., Group Leader, Quality Group, Bristol-Myers Squibb

3:00 Cover Your Assay: Approaches to Evaluate HCP ELISA Reagent Coverage

Denise Krawitz, Ph.D., Senior Manager Analytical Operations, Genentech

In order to use ELISAs, we must demonstrate that the antibodies used in the assay recognize a majority of the proteins produced by the host cell. While 2D SDS-PAGE and Western blots techniques are valuable for a qualitative assessment of antibody coverage, they have limited value as a quantitative tool. Additionally, platform HCP ELISAs are used to monitor HCPs in multiple products. Proteomics studies of different cell lines grown under different culture conditions suggest that the vast majority of proteins expressed are the same between cell lines.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

HCP DETECTION IN BIOPROCESSING

4:15 Finding Needles in a Haystack – Strategies and Tools for HCP Identification In Biopharmaceuticals

Xiaohui Lu, Ph.D., Senior Scientist, BioPharma Development, Biogen

Identification of host cell proteins (HCPs) in biopharmaceuticals drug is hampered by the presence of overwhelming amount of the products. This case study compared different strategies to remove product and enrich HCPs. Applying these enrichment technologies will greatly improve MS-based HCP identification, and provide much needed HCP information for purification process development and risk assessments.

4:45 High Throughput HCP Assays for Bioprocess Development

Christopher Larkin, Ph.D., Scientist II, MedImmune a Member of the AstraZeneca Group

Purification processes without an affinity capture step often require extensive process development, potentially generating many thousands of samples for HCP testing. Analytical approaches to meet the required throughput, whilst producing high quality data, are desirable. Here, we describe the use of a high throughput platform for HCP testing to enable rapid process development and optimization. Case studies will be presented where we have employed this approach to successfully reduce and control HCP levels.

5:15 End of Conference

5:15 Registration for Dinner Short Course

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Gene Therapy Bioproduction

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4th Annual

Early Analytical Development for Biotherapeutics

Optimizing the Selection and Performance of Preclinical Analytical Studies

WEDNESDAY, AUGUST 17

7:00 am Registration Opens and Morning Coffee

8:05 Chairperson's Opening Remarks

Jason Huang, Ph.D., Senior Research Investigator, Bristol-Myers Squibb

8:15 KEYNOTE PRESENTATION: Integrated Microfluidic Capillary Electrophoresis-Electrospray Devices for Analysis of Intact mAbs and ADCs

J. Michael Ramsey, Ph.D., Minnie N. Goldby Distinguished Professor of Chemistry, University of North Carolina

Microfluidic devices that include monolithically integrated nano-electrospray emitters are used to electrophoretically separate charge variants of intact monoclonal antibody (mAbs) biotherapeutics and antibody drug conjugates (ADCs). Specialized channel wall coatings allow the use of electrospray friendly buffer systems while maintaining high performance electrophoretic separative performance. Analyses are typically performed in three minutes with little sample preparation while utilizing mass spectrometers with modest resolving power.

ASSAY DEVELOPMENT

9:00 Characterization of Therapeutic Protein by Two Dimensional-LC (2D-LC) System

Shenjiang Yu, Ph.D., Associate Principal Scientist, Analytical Method Development, Merck

Two-dimensional liquid chromatography (2D-LC) is a powerful tool for analyzing highly complex samples such as therapeutic proteins. Both dimensions have orthogonal separation selectivity, thereby increasing the potential peak capacity to the product of the individual peak capacities. With this advanced technology, 2D-LC provides the possibility to combine two orthogonal methods and discover the correlation of the data. This correlation provides critical information for total characterization of therapeutic proteins.

9:30 Best Practices for Early Stage Bioassay Development

Kari Sweeney Efferen, Ph.D, Principal Scientist, Pfizer

Incorporation of bioassays is crucial in bioprocess and formulation development since it is often difficult to assess the relevant structure or critical epitopes linked to a particular biological activity using traditional biochemical or biophysical techniques during early development. It is necessary to ensure that the assay answers the question being asked, such as stability of a critical epitope or relevant structure that can be linked to particular biological activity of that material.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Intact Mass Analysis of Monoclonal Antibodies by Capillary Electrophoresis (CE) – Mass Spectrometry (MS)

Mei Han, Scientist, Pharmacokinetics & Drug Metabolism, Amgen, Inc.

Intact mass protein characterization provides important sequence integrity and post-translational modification information. While LC-MS is widely used in the biopharmaceutical industry, CE-MS is an attractive alternative for its high separation efficiency, sensitivity, and minimal sample carryover. However, the intrinsic technical difficulty has hindered the application of this technique. Here, we report the implementation of a recently developed CE-MS interface for proteins from predose and postdose pharmacokinetic samples characterization.

11:15 Ion-Pairing Effect on the Behavior of Synthetic Peptides in Reversed-Phase Liquid Chromatography

Jason Z. Huang, Ph.D., Senior Research Investigator, Bristol-Myers Squibb

We have conducted a systematic study of ion pairing reagents for the reversed-phase HPLC analysis of therapeutic peptides with the goal of improving impurity separations. We studied the influence of ion pairing reagents TFA, NaClO4 and KPF6 on retention and peak shape of peptides on RPLC. As a model system several cyclic and linear peptides with a wide range of molecular weight, polarity and charge were studied.

11:45 Sponsored Presentations *(Opportunities Available)*

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:00 Session Break

HIGH THROUGHPUT ANALYTICAL DEVELOPMENT

1:45 Chairperson's Remarks

Udayanath Aich, Principal Scientist, Process Analytics, Biopharmaceutical Development, Sanofi-Genzyme

1:50 Application of DoE to Optimize Product and Process Parameters

Steve LaBrenz, Ph.D., Scientific Director, Janssen R&D LLC

The adoption of Quality by Design during drug product development as a regulatory requirement may necessitate the use of DoE in the laboratory to satisfy development activities. Multivariate analysis can be accomplished in many different experimental designs (Taguchi, traditional, definitive), as well as modeling approaches (PLS, PCA). To gain the full benefit of a DoE, consideration needs to be given to the normalized form of data from which means and limits can be derived.

2:20 Recent Advances in Process Analytics for High-throughput Analysis of N-Glycans from Therapeutic Recombinant Proteins

Udayanath Aich, Principal Scientist, Process Analytics, Biopharmaceutical Development, Sanofi-Genzyme

With the increase of regulatory expectations, the evolution of PAT and emerging manufacturing processes create a demand for robust, sensitive, accurate profiling of protein glycosylation. Potential shortcomings in protein glycosylation profiling include the high hands-on time required for sample preparation and several hours for data acquisition and analysis. This presentation will focus on the state-of-art process analytics for the high throughput sample preparation and analysis of N-glyans from therapeutic proteins.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
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Early Analytical Development for Biotherapeutics

Optimizing the Selection and Performance of Preclinical Analytical Studies

2:50 High Throughput Assays for Evaluation of Post-Translational Modifications

Andras Guttman, Ph.D., Senior Manager, SCIEX; MTA-PE Lendulet Professor of Translational Glycomics, Horváth Csaba Laboratory of Bioseparation Sciences, University of Debrecen, Hungary

With the sharp increase in the number of approved protein therapeutics, comprehensive characterization of these new generation drugs is crucial for the biopharmaceutical industry and regulatory agencies. Biotherapeutics possess various post-translational modifications (PTMs) and prone to potential degradation hotspots during the manufacturing process that may affect their efficacy and immunogenicity. This presentation will cover the state of the art of high throughput separation methods for structural elucidation of protein modifications.

3:20 Application of HT Electrophoresis in Early Biosimilar Development

Urška Kristan, Ph.D., Researcher and Analyst, Analytical Development, Sandoz Biopharmaceuticals, Slovenia

Current initiatives in biosimilar development require thorough understanding of the relationship between product quality and process parameters. In order to achieve this it is necessary to analyze many samples in a short time, therefore HT analytics is often applied in early development. Microchip capillary electrophoresis is one of the HT techniques with many advantages but also some disadvantages, which will be presented in this talk.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Plenary Keynote Session (see page 3 for details)

6:00 Networking Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

THURSDAY, AUGUST 18

8:00 am Registration Opens and Morning Coffee

ANALYTICAL DEVELOPMENT FOR NOVEL BIOTHERAPEUTICS

8:25 Chairperson's Remarks

Joel Bard, Ph.D., Principal Research Scientist, Pfizer

8:30 Analytics by Design: Early Stage Method Development Guided by Molecular Features

Felix Schumacher, Ph.D., Senior Scientist, Large Molecule Research, Roche Diagnostics GmbH, Germany

"Analytics by Design" is a novel concept for early stage analytical method development. Here, analytical packages are tailored to the critical quality attributes of next-generation biotherapeutics, in contrast to the use of generic platform methods. A streamlined method development is based on theoretical considerations and data collected during developability assessment. Such an approach yields valuable insights into multiple aspects of early stage process development, which may guide CMC considerations of future project stages.

9:00 Mass Spectrometric Analysis of Novel Antibody-Drug Conjugates (ADCs) in a Fast-Paced Environment

Lintao Wang, Ph.D., Principal Scientist and Mass Spectrometry Group Lead, Analytical and Pharmaceutical Science, ImmunoGen, Inc.

Designing a safe and effective ADC involves extensive screening of various antibody, linker and payload combinations, which require efficient analysis of a large number of samples with different physicochemical properties. This presentation will focus on the capabilities of size-exclusion chromatography coupled with electrospray mass spectrometry (SEC-MS), a platform assay that is used for generating important information about quality attributes of both antibodies and ADCs in a fast-paced developmental environment.

9:30 A Combination of Structural and Empirical Analyses Delineates the Key Contacts Mediating Stability and Affinity Increases in an Optimized Biotherapeutic Single-Chain Fv

Joel Bard, Ph.D., Principal Research Scientist, Pfizer

Single-chain Fv proteins are key building blocks of bispecific therapeutic antibodies. The causes of scFv instability problems remain poorly understood. We performed detailed structural and biochemical analyses to understand the mechanisms that confer both tighter binding and improved stability on the result of a phage display optimization campaign. This work demonstrates that, aside from being the critical mediators of target binding, CDRs may also be primary drivers of biotherapeutic developability.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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Early Analytical Development for Biotherapeutics

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10:45 Characterization of Formulation Excipient Using Thermal and Spectroscopic Methods for Robust Drug Product Development

Rushikesh Patel, Associate Research Scientist, Bristol-Myers Squibb

Excipient performance during processing can have a significant impact on critical quality attributes of the product. Therefore, detailed characterization of excipient behavior is critical during early development and process design. Here, we present application of multiple thermal and spectroscopic methods for understanding phase behavior of trehalose, a commonly used stabilizer, during freeze/thaw process. The impact of phase change on product quality of a fusion protein is also highlighted.

11:15 A Novel Approach to Isolate and Characterize Product Variants in a Monoclonal Antibody

Xiaoxiao Li, Ph.D., Senior Scientist, Analytical Development, Abbvie Biotherapeutics

Characterization of binding potency of product variants is required as part of the well-characterized biotherapeutic paradigm. Here we present a novel "divide and conquer" approach to directly isolate variants that differ in binding potency. This approach is applicable to a wide range of biotherapeutics, requires no prior knowledge of the variants, and enables rapid identification and characterization of all variants that differ in binding potency from the main product.

11:45 A Chromatographic Method for Quantifying Individual Monoclonal Antibodies (mAb) in a Co-Formulated Solution

Lin Luo, Research Associate, Formulation Development, Regeneron Pharmaceuticals, Inc.

Developing a method to separate and quantify individual mAb's from a mixture of multiple monoclonal antibodies is challenging because the mAb molecules may have similar molecular weights, protein structures and molecular charges. In this case study, we present our approaches to developing a quantification method for a co-formulation of three different monoclonal antibodies. In addition, the advantages and limitations of the different methods will be discussed.

12:15 Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

1:55 End of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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2nd Annual

Process Characterization, Qualification and Control

A best practices forum for process characterization, control strategies and maintaining quality throughout the product lifecycle

THURSDAY, AUGUST 18

11:30 am Registration Opens

12:15 pm Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

1:55 Chairperson's Opening Remarks

Paul Bigwarfe, Ph.D., Director, Analytical Sciences, Regeneron Pharmaceuticals

2:00 KEYNOTE PRESENTATION: Line of Sight to the Process Control Strategy: A Plan for Commercial Success

Timothy Schofield, Senior Advisor, GlaxoSmithKline

The biopharmaceutical control strategy is a covenant between the manufacturer and the customer. Early consideration of manufacturing conditions and constraints, coupled with process and analytical knowledge, inform process and analytical development. The control strategy represents the translation of development experiences and supporting plans to ensure product quality and supply. This presentation highlights a proactive approach to development of a robust control strategy that meets the requirements of both patients and manufacturers.

PROCESS CHARACTERIZATION AND DESIGN SPACE

2:45 DOE Studies in Support of Early Stage Process Characterization

Paul Bigwarfe, Ph.D., Director, Analytical Sciences, Industrial Operations and Product Supply, Regeneron Pharmaceuticals

A DOE is becoming an essential part of the method development life cycle to better understand the acceptable ranges for the method. However, for methods at preclinical and Phase I stages, resources may not exist to evaluate every parameter. A rational strategy has been designed to analyze the most critical parameters for release assays for each new molecule, saving a more comprehensive robustness study for later in development.

3:15 Efficient High-Throughput Biological Process Characterization

Mitchell Tai, Ph.D., Scientist, Biologics Process Development, Bristol-Myers Squibb

Systems for high-throughput process characterization are poised to greatly improve development timelines. Here we combine the Sartorius ambr250 system with definitive screening design experiments to perform rapid process characterization for a microbial process for recombinant protein production. Main effects screening and process modeling can be generated within a single round of experimentation. The results demonstrate a quality-by-design (QbD) approach for both early-stage process development and late-stage process characterization.

3:45 Presentation to be Announced

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4:00 Refreshment Break

4:15 Multi-Attribute LC/MS Methods for Process Characterization and Design Space Development

Kristin Krukenberg, Ph.D., Analytical Scientist, Process Development, Shire

Complex biologics provide a unique analytical challenge for characterizing and monitoring multiple CQAs. We developed an LC/MS based approach that provides more detailed information than six "standard" analytical methods reducing analytical testing time and allowing for more comprehensive and timely support of process characterization and development.

4:45 Analytical Considerations for QbD and PAT of Biotechnology/Biosimilar Process Development

Nadine M. Ritter, Ph.D., President & Principal Advisor, Global Biotech Experts LLC

The value derived from QbD studies and PAT measurements is only as good as the analytical methods they employ. If analytical data are inaccurate or inconsistent due to method performance capabilities, the observations and conclusions could be erroneous. This presentation will highlight some of the most challenging analytical aspects of process characterization, illustrate examples of common mistakes made, and provide recommendations on how to minimize the analytical risks to process design and process control.

5:15 End of Day

5:15 Registration for Dinner Short Course

FRIDAY, AUGUST 19

8:00 am Registration Opens and Morning Coffee

PROCESS QUALIFICATION AND VALIDATION

8:25 Chairperson's Remarks

Shailendra Singh, Ph.D., Senior Scientist, MedImmune

8:30 Case Study: Upstream Process Parameter Classification, Control Strategy Definition and Process Validation

Shailendra Singh, Ph.D., Senior Scientist, Biopharmaceutical Development, MedImmune Inc.

Examples from upstream process will be presented discussing (1) the quantitative methodology to classify process parameters into critical or key/non-key categories (2) the control strategy definition to identify process and analytical controls at commercial scale and (3) process validation at scale. The upstream cell culture process characterization, data analysis and subsequent control strategy development will be discussed, with antibody fragmentation as a model critical quality attribute and product titer as a model performance attribute.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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Process Characterization, Qualification and Control

A best practices forum for process characterization, control strategies and maintaining quality throughout the product lifecycle

9:00 Extraction Study of a Cartridge Filter Based upon the BioPhorum Operations Group (BPOG) Recommendation

Kurt Moyer, Ph.D., Director, Research, NSF Health Sciences

In this study the extractables from a process filter were evaluated based upon the protocol developed by BPOG. The sample was extracted in six extraction solvents at 40°C with orbital rotation for 7 days. Sample extracts were analyzed for organic and inorganic extractables. For the organic extractables, a total of 9 were observed with 6 being identified. For the inorganic extractables, a total of 7 were observed and identified.

9:30 Whole Molecule LC-MS Analysis for HT Monitoring of Asn-Ser Substitution in an Antibody: Challenges in Method Performance Assessment

Céline Duhot, Assistant Manager, Biotech Process Sciences, Merck KGaA, Germany

Product quality testing along process development and characterization requires HT tools as well as deep method understanding. This presentation discusses the case study of Asn-Ser substitution analysis of an IgG by whole molecule LC-MS. Method performances were evaluated using a genomically designed fully substituted antibody. Talk addresses challenges in assessing semi-quantitative performances of MaxEntropy deconvoluted data for the monitoring of small Dmass, not fully resolved even on a state-of-the-art Q-Tof.

10:00 Networking Coffee Break

CONTROL STRATEGIES AND REAL TIME PROCESS CONTROL

10:30 Technology Update: Process Analytical Technologies for Biologics Manufacturing

Sheila G. Magil, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc.

11:00 Plant-Wide Process Control Model for Biologics Manufacturing

Richard Braatz, Ph.D., Edwin R. Gilliland Professor of Chemical Engineering, Massachusetts Institute of Technology

A case study is presented in which mechanistic models are constructed for all unit operations in an integrated biopharmaceutical manufacturing pilot plant. The individual models are interconnected to form a dynamic operations model of the entire plant. The mechanistic models are used in the design of control systems for individual unit operations, and a strategy is described in which the overall plantwide control strategy is designed to suppress the effects of disturbances and uncertainties on the critical quality attributes.

11:30 Production Process Optimization and the Development of In-Process Controls Utilizing In-Line Spectroscopic Measurements

Terrence Dobrowsky, Ph.D., Senior Engineer, Biogen

Second generation process development offers an opportunity to increase productivity and process robustness by implementing process changes and new control schemes. DOE practices were used to optimize parameters and increase productivity for an IgG producing CHO culture. Additionally, Raman spectroscopy enabled online glucose control to reduce glycated product. This work increased productivity, decreased scale up and raw material risk, and demonstrated the relative ease of implementing advanced process analytics.

12:00 pm Sponsored Presentations
(Opportunities Available)

12:30 Extractables Leachables for Single Use Systems in Bio Manufacturing

Sponsored by

Sandi Schaible, Directo,r Analytical Chemistry, WuXi AppTec

Extractables Leachables for Single Use Systems in Bio Manufacturing : Regulatory, industry and risk considerations for designing a successful extractables leachables program. A review of current regulatory environment, a summary of recognized industry schools of thought and risk to be considered in development of a customized approach that works for your system and product application.

1:15 Session Break

1:25 Chairperson's Remarks

James Rose, Engineer, Biogen

1:30 A Two-Tiered Approach to Process Characterization for Late Stage Monoclonal Antibody Programs

Michael Clark, Ph.D., Senior Scientist, Process Sciences, AbbVie

For efficiency of downstream process characterization, first tier DOE studies utilized Definitive Screening Design (DSD) to identify the process parameters with the highest impact on product quality attributes. This allowed minimalized second tier DOE studies using Response Surface Design (RSD) to thoroughly investigate these high impact parameters. This presentation describes the statistical design and model selection of the studies, and provides a comparative analysis of the DSD and RSD results.

2:00 Vaccine Control Strategy Evolution during Late-Stage Development and Commercialization

Jennifer Dashnau, Ph.D., Director, Global Vaccines and Biologics Commercialization, Merck & Co., Inc.

Modern vaccines are amenable to characterization through a wide range of analytical techniques and robust control strategies may be developed. GARDASIL®9 provides an opportunity to understand

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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2nd Annual

Process Characterization, Qualification and Control

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analytical control strategy evolution for a well-characterized, recombinant vaccine product from late-stage development to commercialization. Examples of the impact of 1) process modifications made during development and 2) increased process and product performance understanding gained during commercialization on control strategy will be provided.

2:30 Application of Monte Carlo Simulations in the Development of Advanced Control Strategies and Manufacturing Facility Fit

James Rose, Engineer, Biogen

Real time control strategies introduce additional complexity to the task of setting process controls on bioprocesses. Stochastic cell growth modeling and Monte Carlo simulation methods were evaluated for use in dealing with the relative complexity of setting appropriate control limits for these types of processes, as well as other common facility fit or scale-up concerns. Use of these new methods allows for controls that ensure process consistency and reliable performance.

3:00 Real-Time Product Attribute Control of N-Linked Glycan Levels

Jeff Underhill, Senior Associate, Pivotal Cell Sciences & Technology, Amgen

The active control of product quality in biologic manufacturing processes is challenging due to measurement lags, system nonlinearities, and a lack of robust control levers. A product attribute control method utilizing nonlinear model predictive control coupled with a rapid PAT system will be presented along with data from a pilot scale bioreactor run where this method successfully maintained a critical product quality attribute, percent high mannose, at a predetermined level.

3:30 Close of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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STREAM #4
Formulation & Stability

The weeklong Formulation & Stability stream brings together researchers in analytical and formulation sciences to share practical insights and case studies on biotherapeutic formulation development, development of high concentration protein formulations, application of high-throughput/high resolution screening tools in early stage development and prediction and manipulation for protein stability and instabilities. The three conferences together will feature cutting edge approaches for understanding and managing protein formulation development, aggregation, high viscosity, and rapid analytical methods to predict and screen formulation stability and quality issues.

AUGUST 15-16
Rapid Methods to Assess Quality & Stability of Biologics

AUGUST 17-18
Overcoming Formulation Challenges

AUGUST 18-19
High-Concentration Protein Formulations

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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4th Annual

Rapid Methods to Assess Quality & Stability of Biologics

Improving Prediction and Screening

MONDAY, AUGUST 15

8:00 am Short Course Registration

9:00 – 11:30 Recommended Morning Short Course*
Accelerated Stability Testing of Biologics
** Separate registration required, see page 5 for details.*

11:30 Main Conference Registration Opens

RAPID TOOLS FOR PREDICTION & ASSESSMENT OF QUALITY & STABILITY

1:00 pm Chairperson's Opening Remarks
Peter Tessier, Ph.D., Department of Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute

1:10 KEYNOTE PRESENTATION: Methods for Selecting and Engineering Monoclonal Antibodies with Improved Biophysical Properties
Peter Tessier, Ph.D., Department of Chemical & Biological Engineering, Center for Biotechnology and Interdisciplinary Studies, Rensselaer Polytechnic Institute
It is critical to optimize the biophysical properties of monoclonal antibodies in addition to their bioactivities due to the increasing demands for processing and formulating antibodies at high concentration. I will discuss our work on developing novel methods for identifying, engineering and characterizing antibodies with reduced propensity to self-associate and increased developability (high solubility, low viscosity, low non-specific interactions).

1:45 A Fast Method for Monitoring Multiple Attributes of Therapeutic Proteins
Wei Xu, Ph.D., Principal Scientist, Analytical Method Development, Merck
Therapeutic proteins such as mAbs have become the top choice in treating many life threatening disease conditions. An increased demand for new therapeutic mAbs and higher regulatory expectations require the biopharmaceutical industry to increase efficacy in the research and manufacturing process. High speed analytical methods are highly desirable to speed up the bioprocess of therapeutic proteins. Discussion will focus on development of a fast peptide mapping method with very short sample preparation and analysis time using design of experiments.

2:15 Thermodynamics of Liquid-Liquid Phase Separation in Monoclonal Antibody (mAb) Solutions
Prasad Sarangapani, Ph.D., Scientist, Renegeron, Inc.

2:45 Refreshment Break

3:15 Rapid Peptide Mapping for Monitoring Multiple mAb Attributes
Nisana Andersen, Ph.D., Associate Scientist, Protein Analytical Chemistry, Genentech, a Member of the Roche Group
Characterization of mAbs and their attributes is an important aspect in identification of critical quality attributes. LC-MS/MS peptide mapping, intended for in-depth analysis of mAb attributes, is employed during characterization. Once attributes have been identified and characterized, fast MS-only methods capable of monitoring these attributes can be more suitable. Here, application of a rapid peptide map method used to monitor relative amounts of previously characterized mAb attributes is discussed.

3:45 Presentation to be Announced

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4:00 Preclinical Tools in Formulation Optimization to Improve Biological Performance of Antibodies
Sabine Eichling, Ph.D. Candidate, NBE Formulation Development, AbbVie
Formulation development for biologics has focused on the refinement of physical and chemical stability during shelf-live. Effects of formulation composition following s.c. injection were usually not considered. The addition of biological read out parameters, such as bioavailability and ultimately efficacy, enables further improvement in the antibody transport to the target tissue. The aim of this work is to develop translatable models to understand the transport of antibodies following s.c. injection and predict the effect of the formulation.

4:30 Breakout Discussions

5:30 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

TUESDAY, AUGUST 16

7:30 am Registration Opens and Morning Coffee

SUBVISIBLE PARTICLES, AGGREGATES & STABILITY

7:55 Chairperson's Remarks
Richard Cavicchi, Ph.D., Physicist, Bioprocess Measurements Group, National Institute of Standards and Technology

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
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- Gene Therapy Bioproduction

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4th Annual

Rapid Methods to Assess Quality & Stability of Biologics

Improving Prediction and Screening

8:00 Current Technologies for Subvisible Particle Analysis for Biologics

Andrea Hawe, Ph.D., CSO, Coriolis Pharma

An overview on analytical methods for sub-micrometer and micrometer particles in biopharmaceutical products will be given, with respect to measurement principle, capabilities for sizing, quantification and identification, typical applications, and limitations. Methods covered include: field flow fractionation, analytical ultracentrifugation, flow cytometry, laser diffraction, dynamic light scattering, nanoparticle tracking analysis, resonant mass measurement, electrical sensing zone analysis, light obscuration, flow imaging and Raman microscopy.

8:30 Dimers and Aggregates – Criticality and Specifications - Are We Barking up the Wrong Tree?

Volker Schnaible, Ph.D., Senior Principal Scientist, Pharma Technical Development Europe (Biologics) Analytics, F. Hoffmann-La Roche AG

Theoretical concerns about the role of aggregates/particles as a contributing factor to immunogenicity events (e.g. ADA) and the lack of a solid database translate into specific requirements from health authorities. We performed extensive biophysical characterization of different dimer species of monoclonal antibodies. The immunogenicity of these species was evaluated in transgenic mice that are tolerant against human IgG1 but immunocompetent. The outcome of these studies is presented.

9:00 Particulate Characterization for Biotherapeutics – Overcoming Technique Challenges and New Learnings

Ankit Patel, Ph.D., Scientist, Genentech

In this presentation, we will discuss the inherent instability of a conjugate type vaccine, various reasons for such instability and appropriate mitigation strategy that can be employed.

9:30 Sponsored Presentation *(Opportunity Available)*

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

10:30 Effect of Particle Density on the Sizing and Counting of Subvisible Protein Aggregates by Orthogonal Methods

Richard Cavicchi, Ph.D., Physicist, Bioprocess Measurements Group, National Institute of Standards and Technology

Measurements of protein aggregates using different techniques often result in discrepancies arising from the differences in measured properties, e.g. flow imaging: area, electrical sensing zone: volume, resonance mass: mass, etc. A key parameter that relates the results reported by orthogonal methods is the particle density. We attempt to estimate this parameter by performing two measurements on individual aggregates, and will discuss how this result can be used to relate measurements by orthogonal methods.

11:00 Visible and Subvisible Particulates in Biologics: Strategy and Control

Nataliya Afonina, Ph.D., President, AN Biologics Consulting LLC

A characterization and control of visible (≥ 100 µm) and subvisible (2 -10 µm) particles in biologics remain a hot topic in the industry. A presence of inherent visible and subvisible particles in biologics may impact Critical Quality Attributes (CQAs) such as purity, stability and quality of drug product. A strategic, risk-based approach for control of visible particles, including specification development and characterization of subvisible particles, will be discussed in light of regulatory and international compendia requirements.

11:30 Detection and Quantitation of Residuals in Vaccine Components Using NMR

Marina Kirkitadze, Ph.D., MBA, Deputy Director, Analytical R&D Biochemistry, Sanofi Pasteur

The focus of the presentation is the NMR method development to determine the limit of quantitation (LOQ) and limit of detection (LOD) of the process-related residuals in the vaccine product candidates. The results demonstrated that NMR method can successfully identify and quantify a residual in protein component of vaccine and in viral vaccine samples.

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12:00 pm Prometheus NT.48: Biologics Stability Screening has Never Been Faster, Easier & More Fun

Dennis Breitspecher, Ph.D., Head, Research & Development, Biochemistry Research & Development, NanoTemper Technologies, GmbH

Prometheus NT.48 allows for rapid and precise high-throughput stability screenings, while providing best-in-class high resolution thermal unfolding data for biologics, independent of buffer or protein concentration. It allows for an exact detection of aggregation onset temperatures and aggregation behavior to find the conditions in which the protein is most stable.

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12:15 Presentation to be Announced

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

HIGH-THROUGHPUT & HIGH RESOLUTION SCREENING

1:55 Chairperson's Remarks

Danny Chou, Ph.D., President and Founder,

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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4th Annual

Rapid Methods to Assess Quality & Stability of Biologics

Improving Prediction and Screening

Compassion BioSolution; Former Senior Research Scientist, Biologics Development, Gilead Sciences

2:00 Automated and Rapid Methods to Assess Quality & Stability of Biologics: Recent Developments and the Keys to Successful Implementation in Formulation and Bioprocess Development

Danny Chou, Ph.D., President and Founder, Compassion BioSolution; Former Senior Research Scientist, Biologics Development, Gilead Sciences

The goal of this presentation is to describe new developments in the field of analytical technologies for protein aggregate testing and characterization. Particular focus will be on techniques that are automated, high throughput, and capable of detecting subvisible particulates. Methods that detect changes in other quality attributes will also be discussed.

2:30 Analytical Methods in Support of High Throughput Conjugation Process Development for ADCs

Michael Fleming, MS, Scientist, Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.

Assays that are suitable of providing rapid results about important ADC related attributes (e.g. size and charge variants, drug loading, residual free small molecules) will be discussed in this presentation.

3:00 Development of High-Throughput Quantitative UPLC-High Resolution Mass Spectrometry Multi-Attribute Methodology for Biologics

Pilsoo Kang, Ph.D., Scientist I, Analytical Science and Technology, Sanofi

Understanding product quality attributes is crucial in Quality by Design approach drug development. To accomplish this, appropriate analytical methodologies are required. Generally, the number of analytical methods used in protein characterization is large. To increase efficiency, we developed a quantitative UPLC-high resolution mass spectrometry-based method which permits monitoring multiple quality attributes of biologics products. This multi-attribute methodology can be applied to other products as a platform approach.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 High Throughput Biophysical and Biochemical Stability Screening for Early Stage Antibody Discovery

Yingda Xu, Ph.D., Director, Protein Analytics, Adimab

Problems in the development of antibodies can often be traced back to their intrinsic poor biophysical and biochemical stabilities. High throughput screening assays are developed or adapted to fit in the scope of early discovery stage to filter out candidates with poor properties.

4:45 Panel Discussion: Challenges in Adopting New Methods in QC Labs

Moderator:
Danny Chou, Ph.D., President and Founder, Compassion BioSolution; Former Senior Research Scientist, Biologics Development, Gilead Sciences
Panelists:
Michael Fleming, MS, Scientist, Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.
Pilsoo Kang, Ph.D., Scientist I, Analytical Science and Technology, Sanofi
Yingda Xu, Ph.D., Director, Protein Analytics, Adimab

5:15 End of Conference

5:15 Registration for Dinner Short Course

6:00 – 8:30 Recommended Dinner Short Course*

Protein Aggregation: Mechanism, Characterization and Consequences

* Separate registration required, see page 5 for details.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
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- Gene Therapy Bioproduction

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4th Annual

Overcoming Formulation Challenges for Biopharmaceutical Development

Formulation and Process Optimization, Analytics, Device Integration and New Biologics

WEDNESDAY, AUGUST 17

7:00 am Registration Opens and Morning Coffee

FORMULATION DEVELOPMENT OF NOVEL BIOLOGICS

8:05 Chairperson's Opening Remarks
Christian Schöneich, Ph.D., Takeru Higuchi Distinguished Professor and Chair, Pharmaceutical Chemistry, University of Kansas

KEYNOTE PRESENTATIONS:

8:15 Considerations about Development of Stable Liquid Formulations for Maytansinoid ADCs
Alex Lazar, Ph.D., Head of Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.
The attachment of the small molecules in ADCs changes the physicochemical properties of the proteins. In order to stabilize the ADCs, we need to study their behavior under different conditions in order to design appropriate formulations.

9:00 Glycoform Diversity and Antibody-Drug Conjugation Control the Chemical Stability of Antibodies
Christian Schöneich, Ph.D., Takeru Higuchi Distinguished Professor and Chair, Pharmaceutical Chemistry, University of Kansas
Antibodies are target for a large variety of chemical degradation reactions during processing and storage. This presentation will provide new examples, where forced degradation studies have led to the characterization of novel degradation products generated during storage. Experimental evidence for the effect of glycoform diversity and antibody-drug conjugation on the chemical degradation of antibodies will be presented.

9:30 Inherent Instability of a Conjugate Type Vaccine- Cause and Mitigation Strategy
Sumit Goswami, Ph.D., Senior Scientist, Pharmaceutical R&D, Biotherapeutics Pharmaceutical Sciences, Pfizer, Inc.
In this presentation, we will discuss the inherent instability of a conjugate type vaccine, various reasons for such instability and appropriate mitigation strategy that can be employed.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

CRITICAL CONSIDERATIONS FOR FORMULATION OPTIMIZATION: NEW EXCIPIENTS, SURFACTANTS & MORE

10:45 Effects of Arginine Counter Ions in Solubility, Protein-Protein Interaction, and Stability of a Monoclonal Antibody
Haripada Maity, Ph.D., Research Advisor, Formulation Development, CMC Development, Eli Lilly and Company
The most commonly used salt of arginine in protein formulation development is arginine hydrochloride. Although anions are considered to be more effective compared to cations, a limited number of studies have been performed at understanding the effects of counter ions of arginine on various solution properties of proteins. This presentation will discuss the effects of different counter ions and will shed some light on understanding the mechanism of arginine-X (X refers to counter ion) interaction with proteins.

11:15 Formulation of High Concentration Monoclonal Antibodies to Minimize Aggregation Caused by Distinctive Protein Isoforms
Julie Yu Wei, Ph.D., Scientist II, Protein Product Development, Biogen

Sponsored By UNCHAINED LABS

11:45 Automated Buffer Exchange: Can an Automated System Provide Comparable Results?
Russell Burge, Ph.D., Applications Scientist, Unchained Labs
Buffer prep, buffer exchange and protein concentration can take 2-4 days of a scientist's time and it's all manual. Not anymore! Now there is a way better process that will give you the same results. The GRUNT totally automates protein formulation prep in a single, easy-to-use system. With just a 20 minute setup, the GRUNT prepares up to 12 protein formulations, at a volume of 0.5–8mL with protein concentrations up to 200 mg/mL. In this presentation, we will provide an overview of the GRUNT and compare the system's novel micro UF/DF process to current techniques.

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:00 Session Break

CRITICAL CONSIDERATIONS FOR FORMULATION OPTIMIZATION: NEW EXCIPIENTS, SURFACTANTS & MORE

1:45 Chairperson's Remarks
Haripada Maity, Ph.D., Research Advisor, Formulation Development, CMC Development, Eli Lilly and Company

1:50 Polysorbate 20 Degradation and Free Fatty Acid Release in a Sulfatase Drug Product: Identification of Residual Host Cell Protein as a Potential Root Cause
Nitin Dixit, Ph.D., Scientist, Drug & Combination Product Development, Shire
This study investigated the root cause behind an observed free fatty acid particle formation and Polysorbate 20 loss in a sulfatase drug product upon long term storage. The current work highlights the importance of early detection of potential impurities in the protein drug substance that may contribute

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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4th Annual

Overcoming Formulation Challenges for Biopharmaceutical Development

Formulation and Process Optimization, Analytics, Device Integration and New Biologics

to polysorbate degradation to make a judicious selection of the surfactant and its optimized concentration for the final drug product.

2:20 Alternative Surfactants: A Search for Substitutes to Polysorbates

Kishore Ravuri, Ph.D., Principal Scientist, Formulation Development, Europe Biologics, F. Hoffmann-La Roche

Surfactants are often indispensable components of biologic, parenteral formulations. Polysorbates have always been the best choice till date. Recent studies have pointed towards certain disadvantages which Polysorbates might pose if not carefully monitored. This could range from surfactant degradation to peroxide induced Drug Product oxidation. With the increasing number of novel protein formats entering the research pipeline, it is worthwhile to look for potential alternatives to polysorbates which can overcome challenges which polysorbates tend to pose. The current talk focuses on our evaluation of alternatives to polysorbates.

2:50 i-Raman Portable Spectrometer to Identify Raw Materials and Active Components of Novel Vaccines

Marina Kirkitadze, Ph.D., MBA, Deputy Director, Analytical R&D Biochemistry, Sanofi Pasteur

The topic of this presentation is Raman Spectroscopy method development to identify biological raw materials for a novel recombinant adjuvanted vaccine, and active components and excipients of novel viral vaccine during the formulation. The advantages of using i-Raman portable spectrometer will be discussed.

3:20 Use of Viscosity Surrogate Solutions to Identify Equipment Operating Conditions in Fill-Finish Process for High Concentration Biologic Drug Product

Zach Zhu, Ph.D., Scientist II, Pharmaceutical Operations & Technology, Biogen

A platform approach was applied to the development of several fill-finish process unit operations for a highly concentrated biologic drug product. The approach utilized viscosity surrogate solutions to identify operational parameters for a scaleable single-use system (SUS), which is applied for mixing, pooling, and filtration steps in the manufacturing operation. Accordingly, at-scale equipment operating conditions were successfully identified, leading to a significant reduction in characterization of the commercial-scale process using active product. A GMP production run of active drug product further confirmed the suitability of process parameters identified from the surrogate solutions.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Plenary Keynote Session (see page 3 for details)

6:00 Networking Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

THURSDAY, AUGUST 18

8:00 am Registration Opens and Morning Coffee

ACCELERATING BIOLOGICS DRUG DEVELOPMENT

8:25 Chairperson's Remarks

Mark L. Brader, Ph.D., Independent Consultant - Protein Drug Product Formulation and Biophysical Characterization

8:30 Bringing Back the Good Stuff: X-Ray Crystallography to Accelerate Biologics Drug Development

Mark L. Brader, Ph.D., Independent Consultant - Protein Drug Product Formulation and Biophysical Characterization

X-ray crystallography enables atomic-level insight into protein structure, function, and mechanistic pathways in biology. It plays a prominent role in structure-based lead discovery yet is largely ignored as a characterization tool during development. This presentation will examine some common myths surrounding protein crystallization and x-ray crystallography, and explore how recent advancements allow this technique to be applied in new and creative ways to aid the development of complex therapeutic biomacromolecules.

9:00 QbD Based Forced Degradation -- The Key of Efficient Drug Product Development

Yu Tang, Ph.D., Principal Scientist, Drug & Combination Product Development, Shire

Forced degradation is widely used through the life cycle of biological product development. Implementation of properly designed forced degradation studies can improve the efficiency of product development. This presentation focuses on application of QbD strategy to assist the design and implementation of forced degradation studies for efficient product development. A case study will be provided to demonstrate the QbD strategy based study design, implementation time, and application of data package.

9:30 Sponsored Presentations *(Opportunities Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Development Challenges for Low Dose Antibody Formulations

Joanna MacKay, Ph.D., Scientist, Drug Product Development, Janssen R&D

11:15 Overcoming Freeze-Thaw Agglomeration of a Meningococcal Vaccine

Christopher Mensch, Scientist, Vaccine Drug Product Development, Merck

The purpose of this work was to investigate the susceptibility of an aluminum adjuvant and an aluminum-adjuvanted native outer membrane vesicle (nOMV) vaccine formulation to freeze/thaw–induced agglomeration using static light scattering and micro-flow Imaging analysis; and to

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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4th Annual

Overcoming Formulation Challenges for Biopharmaceutical Development

Formulation and Process Optimization, Analytics, Device Integration and New Biologics

evaluate the use of propylene glycol as a vaccine formulation excipient by which freeze/thaw–induced agglomeration of a nOMV vaccine formulation could be mitigated. Our results indicate that including 7% v/v propylene glycol in a nOMV containing aluminum adjuvanted vaccine formulation, mitigates freeze/thaw–induced agglomeration.

11:45 Panel Discussion: Special Considerations for Biophysical Analysis in Formulation Development

Moderator:

Mark L. Brader, Ph.D., Independent Consultant - Protein Drug Product Formulation and Biophysical Characterization

Panelists:

Mark L. Brader, Ph.D., Independent Consultant - Protein Drug Product Formulation and Biophysical Characterization

Yu Tang, Ph.D., Principal Scientist, Drug & Combination Product Development, Shire

Joanna MacKay, Ph.D., Scientist, Drug Product Development, Janssen R&D

Christopher Mensch, Scientist, Vaccine Drug Product Development, Merck

12:15 Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

1:55 End of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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High-Concentration Protein Formulations

Formulation, Manufacturing, Analytics, High Viscosity, Aggregation, Devices and Delivery

THURSDAY, AUGUST 18

11:30 am Registration Opens

12:15 pm Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

PROTEIN-PROTEIN INTERACTIONS, VISCOSITY & AGGREGATION

1:55 Chairperson's Opening Remarks

Atul Saluja, Ph.D., Senior Research Investigator II, Drug Product Science & Technology, Bristol-Myers Squibb

KEYNOTE PRESENTATION:

2:00 Correlating Protein-Protein Interactions and Aggregation Rates over Broad Concentration Range: Misconceptions, Challenges and Promising Approaches

Atul Saluja, Ph.D., Senior Research Investigator II, Drug Product Science & Technology, Bristol-Myers Squibb

Protein–protein interactions (PPI) and rates of aggregation (kagg) were quantified systematically for a monoclonal antibody (MAb) across a broad range of concentration in presence and absence of excipients. Hypotheses based on thermodynamic activity and fluctuation theory were inconsistent with experimental kagg and scattering data. However, arguments based on surface contact probabilities were reasonably successful in providing a semi-quantitative correlation. Challenges and opportunities for such an approach are further discussed.

KEYNOTE PRESENTATION:

2:45 Applications of AU-FDS to High-Concentration Antibody Interactions

Thomas Laue, Ph.D., Professor, Biochemistry and Molecular Biology; Director, Biomolecular Interaction Technologies Center (BITC), University of New Hampshire

Will discuss two applications of AU-FDS. First, high-concentration antibody solutions may exhibit excessive viscosity due to weak interactions between proteins. A case will be built that they are a consequence of a balance between attractive electrostatic energies and repulsive desolvation energies. Second, how does a high-concentration protein background influence an IgG-antigen interaction? Here, both the IgG and the antigen are multi-valent, which leads to very large networks being formed in dilute solution. Are these large structures observed in serum?

3:15 Computational Protein Engineering for Guided Formulation Development

Ertan Eryilmaz, Ph.D., Senior Scientist, Immune Modulation and Biologics Discovery, Boehringer Ingelheim Pharmaceuticals, Inc.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 Refreshment Break

4:15 Breakout Discussions

5:15 End of Day

5:15 Registration for Dinner Short Course

FRIDAY, AUGUST 19

8:00 am Registration Opens and Morning Coffee

PROCESS CHALLENGES

8:25 Chairperson's Remarks

Mark Yang, Ph.D., Director, Fill Finish Development, Sanofi Genzyme

8:30 Detection and Management of Protein Aggregates during Downstream Processing

Danny Chou, Ph.D., President and Founder, Compassion BioSolution; Former Senior Research Scientist, Biologics Development, Gilead Sciences

It is known that protein aggregation is a significant bottleneck in the development of efficient and cost-effective biologics purification process. The goal of this presentation is to use a case study to illustrate how one may detect the "seeds" of protein aggregate that occur early in the process in order to reduce the formation of larger particulate in the final drug product and reduce processing cost.

9:00 Case Study: Formulation pH Shift Caused by Protein Concentration Increase

Mark Yang, Ph.D., Director, Fill Finish Development, Sanofi Genzyme

In this new case study, it has been observed that the formulation pH decreases as its protein concentration increases. This pH shift becomes more pronounced in the high concentration formulations or in the diafiltration step where protein gets concentrated. The underlining mechanisms responsible for this pH shift, along with mitigation strategies, will be discussed.

9:30 Impact of Charge Isoforms on Stability of Antibody Formulations Manufactured Using High Titer Bioprocess

Jason Fernandez, M.Sc., Scientist, Protein Pharmaceutical Development, Biogen

This presentation will cover how molecular charge isoforms from upstream drug substance process influence protein stability in the downstream drug

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

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- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
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High-Concentration Protein Formulations

Formulation, Manufacturing, Analytics, High Viscosity, Aggregation, Devices and Delivery

product. Particular post-translational modifications and chemical degradation will be discussed that lead to charge isoform impacting protein aggregation. Further, isoform fractionation approaches and novel stability study designs will be presented that help elucidate the impact of isoform species in high titer and high concentration biopharmaceuticals.

10:00 Networking Coffee Break

FORMULATION & ANALYTICAL STRATEGIES FOR HIGH-CONCENTRATION PROTEIN FORMULATIONS

10:30 Co-Formulation Development of Monoclonal Antibodies and Recombinant Human Hyaluronidase (rHuPH20) – A Case Study

Claudia Mueller, Ph.D., Senior Scientist, Group Leader, Late-Stage Pharmaceutical and Process Development, F. Hoffmann-La Roche Ltd.

Subcutaneous application faces limitations with regards to the drug volume that can be administered. To enable delivery of the necessary doses, increase in the concentration of the drug and/or temporary enlargement of the interstitial space at the injection site, e.g. by using rHuPH20, are potential strategies to face this challenge. This presentation highlights the drug product development of co-formulations consisting of highly concentrated monoclonal antibodies and rHuPH20. The talk will focus on formulation and process development challenges arising from combination of two very different proteins in order to maintain both stable and active within one formulation.

11:00 Formulation Strategies for High-Concentration, Low-Volume Injectables

Charles Wescott, Ph.D., Vice President, Research and Development, Protein Formulation, Arsia Therapeutics

At concentrations exceeding 100 mg/mL, many biologics are highly viscous, and can suffer reduced colloidal stability. Formulation designs targeting the protein-protein interactions mediating these problems can produce highly-concentrated drug products with good stability, syringeability, and injectability characteristics. These advanced high-concentration formulations allow biologics that would otherwise be dosed by i.v. infusion to be administered by s.c. injection, or delivered by low-volume devices.

11:30 Building a Better Bridge: Biophysical Tools to Better Understand the Complexities of High Concentration Biotherapeutics

Mike Marlow, Ph.D., Senior Staff Scientist, Protein Biochemistry, Regeneron Pharmaceuticals, Inc.

The thermodynamic interactions that govern a variety of protein therapeutic and solution properties are distinctly protein concentration dependent. Manufacturing and dosing of therapeutic monoclonal antibodies frequently calls for high protein concentration solutions and the resulting non-ideality complicates reliable estimation of critical properties from measurements under dilute conditions. We illustrate the utility of different biophysical tools in bridging the dilute - high concentration gap by characterizing two antibodies that exhibit contrasting concentration-dependent behavior.

12:00 pm Sponsored Presentations *(Opportunities Available)*

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Session Break

DELIVERY & DEVICES FOR HIGH-CONCENTRATION / HIGH-VOLUME FORMULATIONS

1:25 Chairperson's Remarks

Jan Jezek, Ph.D., CSO, Research & Development, Arecor Ltd.

1:30 Strategies for Overcoming Long Reconstitution Times of Lyophilized Highly Concentrated Protein Formulations

Robin Bogner, Ph.D., Associate Professor, Pharmaceutical Sciences, University of Connecticut

High protein concentration is often accompanied by unacceptably long reconstitution times of 40-60 minutes. Formulation and lyophilization cycles have been found to influence the time to achieve complete reconstitution. In addition, there are an increasing battery of methods to assess the potential for long reconstitution times. Several strategies, some of which may be counterintuitive, can be used to reduce the reconstitution times of challenging formulations.

2:00 Product Differentiation through Formulation and Device

Jan Jezek, Ph.D., CSO, Research & Development, Arecor, Ltd.

In the increasingly competitive biopharmaceutical market, convenience of use has become an essential feature for a product to succeed. Convenience can be achieved by smart devices as well as formulations that enable high protein concentration or use of the product outside the cold chain. This talk will focus on unique formulation strategies for stable concentrated products as well as related device choices that enable development of competitive biopharmaceuticals.

2:30 Mitigation of High Concentration Formulation Issues of a Human IgG1 Monoclonal Antibody via Rational, Structure-Guided Protein Engineering

Reza Esfandiary, Ph.D., Scientist II, Department of Formulation Sciences, MedImmune

3:00 CMC Strategies on Scaling Up and Down for High-Concentration Protein Formulations

Jamie Tsung, Ph.D., Principal Scientist, Momenta Pharmaceuticals, Inc.

Highly concentrated therapeutic proteins are prone to be viscous and aggregate posing developmental and CMC challenges in purification, formulation, analytical development, manufacturing, product stability, syringeability and injectability. This talk provides a review of current strategies and technologies used in product development to overcome these CMC challenges and minimize the impact on product quality.

3:30 Close of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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STREAM #5
Cell & Gene Therapy Production

This week-long Cell and Gene Therapy Production stream focuses on the analysis, process development, scale-up and manufacture of cell and gene-based products, with particular attention on CAR-T and TCR-based therapies. First stop is Cell Therapy CMC, looking at potency assay development, raw materials, comparability, target product profiles and quality control, followed by two days on cell therapy bioproduction – from scale-up to automation and closed systems; operations to logistics. The final part of the week focuses on gene therapy and the challenges in vector design, development and manufacture for AAV and lentiviruses, with supplementary sessions on analytics and CMC.

AUGUST 15-16
Cell Therapy CMC, Quality & Analytics

AUGUST 17-18
Cell Therapy Bioproduction, Operations & Logistics

AUGUST 18-19
Gene Therapy Bioproduction and CMC

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

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- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Cell Therapy CMC, Quality and Analytics

Understanding Your Product and Process for Late-Stage Success

MONDAY, AUGUST 15

8:00 am Short Course Registration

9:00 – 11:30 Recommended Morning Short Course*
Advanced Process Control Strategies in Bioprocessing
** Separate registration required, see page 5 for details.*

11:30 Main Conference Registration Opens

LATEST TRENDS & RAW MATERIALS

1:00 pm Chairperson's Opening Remarks
Christopher Bravery, Ph.D., Consultant Regulatory Scientist, Consulting on Advanced Biologicals Ltd.

1:10 KEYNOTE PRESENTATION: Classification of Cell Therapies and Recent Trends
Alexey Bersenev, Ph.D., Director, Advanced Cell Therapy Lab, Yale University
Cell therapy is administration of living cells in human with therapeutic purpose. In this presentation I will discuss classification and categories of cell therapies in terms of cell types, therapeutic purpose, degree of manipulation and regulatory pathways. I will highlight differences between immunocellular therapies and regenerative medicine and present recent trends in academic and commercial development of advanced cell therapies.

1:45 Defining and Qualifying Raw Materials for Use in Cell Therapies
Fouad Atouf, Ph.D., Director, United States Pharmacopeia
Qualification of raw materials used in the manufacturing of cellular therapies, require the use of risk assessment strategies to categorize the critical components of a manufacturing process. In addition to cell culture supplements, excipients and other formulation's components must meet the required quality to ensure consistency in manufacturing and subsequently the quality and safety of finished cell therapy products. Testing strategies for raw materials may be achieved by the use of established and validated procedures as well as the availability of reference materials.

2:15 Ensuring Quality of Cellular Starting Material
Elizabeth Read, M.D., Senior Vice President, Product Development, Medeor Therapeutics, Inc.
For cell therapy products, the starting material contains living, functional cells that become an integral part of the active drug substance and final product. Quality specifications for the donor, collection process, and shipping/storage/hold steps of starting material should be considered early in CMC development. Donor-to-donor variability, availability of clinically representative starting materials, and starting material stability create unique development challenges.

2:45 Refreshment Break

STARTING MATERIALS & INTERNATIONAL REGULATORY UPDATES

3:15 Developing a Clinical Grade Process Starting from a Research Method: Practical Consideration of Raw Materials for Cell Therapy Production
Benjamin Fryer, Ph.D., Team Leader, Processing/ Manufacturing, Heart Regeneration Program, University of Washington School of Medicine
In order to generate an approved cell therapy an aseptic and well controlled manufacturing process must be developed. This begins with proper raw material sourcing via secure and trust worthy supply chains, and material validation via identity and/or in-process testing. Planning ahead in early stage development should facilitate development of a scalable cold supply chain cell therapy product.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 Panel Discussion: Navigating International Regulations for Cell and Gene Therapies
Panelists: Christopher Bravery, Ph.D., Consultant Regulatory Scientist, Consulting on Advanced Biologicals Ltd.
Scott Burger, M.D., Consultant, Advanced Cell and Gene Therapy
- Global Regulatory Updates and Developments
- Building a Regulatory Strategy
- Common Regulatory Issues

4:30 Breakout Discussions

5:30 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

TUESDAY, AUGUST 16

7:30 am Registration Opens and Morning Coffee

POTENCY ASSAYS, QBD & PRODUCT QUALITY

7:55 Chairperson's Remarks
Bernadette Keane, Ph.D., Consultant, CMC/Quality/ Regulatory Compliance, Specializing in Gene and Cell Therapies

8:00 Overcoming Challenges in Developing Potency Assays for Heterogeneous Cell Products
Therese Choquette, Ph.D., Fellow, TRD Cell & Gene Therapy, Novartis Pharmaceuticals
The ideal potency assay reflects the mechanism of action (MoA), predicts clinical response, is easy to perform and shows low variability. However, for cell and gene therapy products, often containing heterogenic cell populations, this ideal is rarely achievable. Several challenges exists; including unknown MoA, bystander activations, unspecific responses, and patient-to-patient variations. This presentation illustrates some of our experiences of potency assay development for CART cells.

8:30 QbD "Thinking" in the Development of Cell Therapy Products
Chaya Mazouz, Ph.D., Vice President, Quality and Regulatory Affairs, Enlivex Therapeutics
Cell therapies, rely heavily on their manufacturing processes to meet final-product quality attributes. In the development of Allocetra (apoptotic cells), a patient-specific product, QbD approach was introduced at an early stage. Building quality

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Cell Therapy CMC, Quality and Analytics

Understanding Your Product and Process for Late-Stage Success

into this product with an understanding of the manufacturing process while taking into account the end user, the patient, enabled the development of a well-defined reproducible product.

9:00 The Challenge of Maintaining Product Consistency for Autologous Cell Therapies
Bo Kara, Head, Process Development, Cell Gene Therapy, Platform CMC, GSK

9:30 Sponsored Presentation *(Opportunity Available)*

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

TARGET PRODUCT PROFILES & DEFINING QUALITY

10:30 Use of Target Product Profile During Development
Stefano Baila, Ph.D., Manager, Process Development, Celyad
The Target Product Profile serves as the foundation of the product and clinical development plan, with the final product properties and use in mind. This approach takes all aspects into account, including quality, cost of goods, scalability and clinical use and ensures alignment of all stakeholders during the development phases

11:00 A Multiparametric Approach for Defining Product Quality
Damian Marshall, Ph.D., Head, Analytical Department, UK Cell Catapult
The manufacture of cell therapy products can take several weeks or even months and involve a range of complex processing steps. As a result it can be challenging to define what cell characteristics are most appropriate to measure in order to ensure product quality is being maintained. This presentation will demonstrate a novel approach for marker screening and analysis that can be used to develop a framework to track product quality and to define the best approach for in-process control monitoring.

11:30 Early Process Development of CAR-T Therapies
Eileen Higham, Ph.D., Director, Platform and Early Process Development, Juno Therapeutics

12:00 pm Presentation to be Announced
Sponsored By World Courier AmerisourceBergen

12:30 Go Beyond: How to Make Novel Therapies a Reality in Tomorrow's Complex Biopharma Landscape
Sponsored By MilliporeSigma
Julie Murrell, Ph.D., Head, Cell Therapy Bioprocessing, MilliporeSigma
A recent survey conducted by the Economist Intelligence Unit highlights the new products that the biopharma industry identifies as most disruptive to their growth strategies in the next five years. The findings raise a challenge to biopharma to go beyond barriers to bringing new products to market by presenting ways to overcome these hurdles and make novel therapies a reality.

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

RELEASE CRITERIA & COMPARABILITY STUDIES

1:55 Chairperson's Remarks
Bernadette Keane, Ph.D., Consultant, CMC/Quality/Regulatory Compliance, Specializing in Gene and Cell Therapies

2:00 Identifying Stability-Indicating Parameters for Stability Studies and Beyond
Christopher Bravery, Ph.D., Consultant Regulatory Scientist, Consulting on Advanced Biologicals Ltd.
This talk will address the need to identify stability-indicating parameters for the product and discuss how accelerated and/or forced degradation studies can be useful to achieve this. Considerations for the design and execution of a comprehensive stability program and the use of stability data and stability-indicating parameters beyond stability studies will also be discussed.

2:30 Release Testing Considerations for Different Cell Therapy Paradigms
Joseph Sondej, Senior Manager, QC Operations, Celgene Cellular Therapeutics
Using examples this presentation will layout considerations for testing fresh and frozen cell therapy products as part of release testing considerations for different cell therapy paradigms.

3:00 Mitigating Risk of Process Change: Strategies and Tactics for Effective Comparability
Scott Burger, M.D., Consultant, Advanced Cell and Gene Therapy
Manufacturing process changes are inevitable - processes are scaled up, methods and technology are improved, raw materials are changed, operations are transferred to new manufacturing sites. Any change to the manufacturing process, however, risks altering the cell therapy product itself. This session will discuss methods, tactics, and requirements for prospectively managing process changes and demonstrating comparability.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

COMPARABILITY & CMC STRATEGIES FOR CAR-Ts

4:15 CAR-T Manufacturing and CMC Strategies
Nina Kotsopoulou, D.Phil., Director, Process Development, Autolus
Autolus is a biopharmaceutical company focused on delivering CAR-T cell products to patients. This presentation will focus on the challenges of combining efficient and fast delivery of Phase I/II suitable processes and products, with ensuring timely delivery at Phase III (and with minimal comparability risk) of improved, robust processes suitable for commercialisation.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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4:45 Autologous Gene Therapy Manufacturing Comparability: Meeting the Challenge through Process Understanding and Product Characterization

Michael Paglia, Ph.D., Senior Director, Technical Operations, Cellular Process Development and Manufacturing, bluebird bio

Demonstrating comparability of *ex vivo* autologous gene therapy products and processes across multiple facilities in the US and EU may be required to meet capacity requirements. A comparability plan should therefore incorporate elements to support both BLA and MAA as early in the development lifecycle as possible. A summary of comparability approaches for *ex vivo* autologous gene therapy products will be presented.

5:15 End of Conference

5:15 Registration for Dinner Short Course

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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3rd Annual

Cell Therapy Bioproduction, Operations and Logistics

Industrializing Cell Therapy Production for Commercial Manufacture

WEDNESDAY, AUGUST 17

7:00 am Registration Opens and Morning Coffee

PREPARING FOR LATE-STAGE CELL THERAPY MANUFACTURING

8:05 Chairperson's Opening Remarks

Ohad Karnieli, Ph.D., Chair, Process and Product Development committee, (ISCT) and CEO of Karnieli Ltd

8:15 KEYNOTE PRESENTATION: Applying Concepts of mAb and Vaccine Manufacturing to Cellular Immune Therapy

Alain Pralong, Ph.D., Senior Vice President, Manufacturing Operations, CellMedica

Massive evolution in cellular immune therapies for treatment of cancers has taken place over the last decade. A significant number of new companies has been created. Some have gained massive value through promising therapeutic approaches. Manufacturing and GMP compliance has not reached the maturity level of mAb and Vaccine manufacturing. How can proven concept be implemented in cellular immune therapy?

9:00 Preparing for Late-Stage Clinical and Commercial Manufacture of Cell Therapies

Sagi Moran, Ph.D., Vice President, Operations and Manufacturing, Pluristem

9:30 Transitioning from Early Stage Clinical Trial Manufacturing to Phase III Pre-Product Launch Manufacturing

Donna Rill, Ph.D., Chief Development Officer, Opexa Therapeutics

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

SCALE-UP & SCALE-OUT STRATEGIES TO REDUCE COST OF GOODS

10:45 Successful Cell Therapy Manufacturing: Think Big!

Knut Niss, Ph.D., Asset Leader Cell Therapies, Director, PO&T, Biogen

Close logistical coordination is required from obtaining the starting material to delivering the product ("bedside to bedside" or "arm-to-arm"). While these challenges can be managed in early clinical trials through close interaction between the manufacturing organization and the clinical site, commercial needs require a focus on cost effective operations. Thus, to reach a commercially successful cell therapy, logistical challenges in combination with processing technologies need to be evaluated.

11:15 Scale-Up Strategies and Process Optimisation for Cell Therapies

Ravinder Bhatia, Ph.D., Director, Pharmaceutical Development and Manufacturing Sciences, Johnson & Johnson

In this presentation, a case study will be presented on the considerations to select technologies to develop a robust, and scalable process for allogeneic cell therapy products. Also, a control strategy based on QbD principles to consistently meet product quality by controlling the raw materials attributes and process parameters will be discussed.

11:45 Sponsored Presentations *(Opportunities Available)*

12:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:00 Session Break

AUTOMATION, NEW TECHNOLOGIES & WORKING WITHIN CLOSED SYSTEMS

1:45 Chairperson's Remarks

Ohad Karnieli, Ph.D., Chair, Process and Product Development Committee, (ISCT) and CEO of Karnieli Ltd.

1:50 New Technologies Driving A Closed System Manufacturing Process

Ohad Karnieli, Ph.D., Chair, Process and Product Development committee, (ISCT) and CEO of Karnieli Ltd.

As cell therapy matures moving form bed side to clinic, the need for automated closed system manufacturing technologies become critical to insure quality, availability and cost efficiency of the treatments. This need enhances dramatically in cases of autologous therapies. The talk will describe case studies of process development work and present available and new technologies for closed and automated cell culturing systems.

2:20 The Pros and Cons of Using Automated Closed Systems for Cell Therapy Trials

Barbara Seymour, MBA, Senior Director, Manufacturing, Unum Therapeutics

Manufacturing autologous cell therapies in automated closed systems may become industry standard, but many challenges can manifest when adapting a process to a system or vice versa. Labor savings and microbial reduction may be offset by extended time in development to confirm process robustness or the effects of any change. Understanding system limitations, staffing, costs and potential business continuity is essential for good clinical programs.

2:50 Transportating and Tracking Cell Therapies across Sites

Professor Adrian Gee, Ph.D., Center for Cell & Gene Therapy, Baylor College of Medicine

As cellular therapies move towards licensure centralized manufacturing is inevitable. This necessitates development of optimal methods for shipping starting cells and final products. Recent evidence suggests that functionality of some cells is impaired by cryopreservation and that transportation of fresh cultures is preferable. In parallel, systems must be developed for tracking and tracing cells from the time of collection to patient administration.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Cell Therapy Bioproduction, Operations and Logistics

Industrializing Cell Therapy Production for Commercial Manufacture

3:20 Deviation Prevention, Reduction, Training, and Error Prevention to Ensure These Therapies Are Produced Safely and Consistently

Gary du Moulin, Ph.D., MPH, RAC, Associate Professor, Massachusetts College of Pharmacy and Health Sciences University

Errors committed during production steps or during quality control testing continue to be a major concern in this growing industry. This presentation describes how an understanding of human factors and causality of errors can minimize deviations. Improvements in training approaches can lead to a goal of zero defects in cell therapy manufacturing operations. The importance of leadership and inculcating a culture of quality will also be emphasized in building robust quality systems.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:45 Plenary Keynote Session (see page 3 for details)

6:00 Networking Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

THURSDAY, AUGUST 18

8:00 am Registration Opens and Morning Coffee

CAR-T MANUFACTURING STRATEGIES

8:25 Chairperson's Remarks

Ohad Karnieli, Ph.D., Chair, Process and Product Development Committee, (ISCT) and CEO of Karnieli Ltd.

8:30 Commercialization of *ex vivo* Cell and Gene Therapy Products: Establishing Processes, Manufacturing and Supply Chains

Bo Kara, Head, Process Development, Cell Gene Therapy, Platform CMC, GSK

The complexities of the CGT supply chain requires cost sensitivity analysis driven process development for cost efficient delivery of plasmid DNA's, vector manufacturing and cell processing. This presentation will discuss the technology and process development challenges in the delivery of ex-vivo cell gene therapy medicines and describe approaches to scale-up and commercialization.

9:00 Developing a Scalable, Robust and Cost-Effective CAR-T Process

Dawn Maier, Senior Manager, Cellular Process Development and Manufacturing, bluebird bio Inc.

Adoptive transfer of autologous T cells genetically engineered to express chimeric antigen receptors (CARs) has emerged as a promising approach for the treatment of cancer. However, to fully realize the therapeutic potential of these engineered T cells, simple and robust manufacturing processes that decrease time and cost are required. A summary of the data to support bluebird bio's approach and clinical platform will be presented.

9:30 Sponsored Presentations *(Opportunities Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

OFF-THE-SHELF/ OFF-SITE CAR-T MANUFACTURING

10:45 Manufacturing Cellectis' Allogeneic UCART Product Candidates

Sylvain Arnould, Head, Manufacturing, Cellectis

At Cellectis, we are manufacturing allogeneic off-the-shelf UCART-cell product candidates. The specificity of those allogeneic therapies is that T-cells from healthy donors are genetically edited with our proprietary technology TALEN®. This approach could lead to a cost-effective drug, easily distributed across all geographies and available to cancer patients.

11:15 Off-Site Manufacturing Challenges when Dealing with CAR-T Cells

Sean Smith, Ph.D., Cell Processing Specialist, Dana-Farber Cancer Institute

Off site manufacturing is a viable option for some companies producing cell therapies, but like any other process, it has its pros and cons. New start up companies. New ideas. Both are a important parts of an ever changing biotech landscape. But sometimes these new companies are not equipped, or just cannot afford to pursue these ideas. They have great ideas, but need some help. Sometimes a more established institution with a trained staff is needed. This is where off-site manufacturing comes in.

11:45 Cellular immunotherapy: Product, Process and Patents

David Brindley, Ph.D., Cooksey-Botnar-Saïd Fellow, Saïd Business School/Paediatrics, University of Oxford

CAR-T immunotherapy efficacy is building, however certain critical aspects of manufacturing processes remain largely unexplored, notably the impact of leachables and extractables. Combined with a complex patent landscape and a shift away from patenting the therapeutic entity towards patents of processes and components, a number of pertinent challenges for both academia and industry exist.

12:15 Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

1:55 End of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Gene Therapy Bioproduction and CMC

Process Development, Scale-Up and Analysis of Gene Therapies

THURSDAY, AUGUST 18

11:30 am Registration Opens

12:15 pm Lunch Available for Purchase in the Exhibit Hall

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

PROCESS DEVELOPMENT STRATEGIES FOR LENTIVIRUS-BASED PROCESSES

1:55 Chairperson's Opening Remarks

Michael Kelly, Ph.D., Director, Asset Leadership, Gene Therapy, Biogen

2:00 KEYNOTE PRESENTATION: Optimising the Production of Lentiviruses

Steven Howe, Ph.D., Head, Process Research, Cell & Gene Therapy Platform CMC, GSK

This presentation will discuss the progress made in retroviral vectorology in recent years and now that gene therapy is a clinical reality, new challenges and opportunities associated with producing lentiviral viruses on a commercial scale. Understanding and refining these processes will lead to more cost-effective manufacture of vectors to enable wider application of gene therapy.

2:45 Enabling Industrial Scale Production of Lentiviral Vectors for Gene Therapy

Kelly Kral, Ph.D., Senior Manager, Vector Process Development and Manufacturing, bluebird bio

Lentiviral vectors are an ideal platform for indications requiring long-term, stable expression, but the production processes have historically been limited by scale. This presentation will focus on the evaluation of platforms for the next-generation manufacturing process, with the guiding principles of preserving the comparability of the lentiviral product profile.

3:15 Lentiviral Vector Optimization Strategies for Higher LV Production and Safety

Dmitriy Lukashev, Ph.D., Principal Scientist, Novartis Institutes for BioMedical Research

Using case studies, this presentation discusses rationale for changes in lentiviral vector to increase infectious titer and improve safety; Comparison of various titer methods for evaluation of LV titers in process development; Significance of transfer vector cis-elements in production of lentiviral vectors.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 Refreshment Break

MANUFACTURING, COMPARABILITY & TECH TRANSFER

4:15 Lentiviral Vector Manufacturing Strategies to Support Cell and Gene Therapies

Carol Knevelman, Ph.D., Senior Manager, Process R&D Department, Oxford Biomedica Ltd.

Successful development and commercialization of gene and cell-based therapies is highly dependent on establishing robust and efficient cGMP manufacturing processes that meet the key challenges of scale, quality, cost of goods supplied (COGS), and sustainability. This talk will discuss new manufacturing modalities that are being developed for cGMP production of these vectors.

4:45 Demonstrating Comparability during Gene Therapy Tech Transfer

Christopher Bravery, Ph.D., Consultant Regulatory Scientist, Consulting on Advanced Biologicals Ltd.

Changing the manufacturing site (tech transfer) should always include an assessment of comparability, however the ability to demonstrate this varies between early and late development. This talk will discuss common pitfalls and mistakes and highlight key aspects of the comparability exercise.

5:15 End of Day

5:15 Registration for Dinner Short Course

FRIDAY, AUGUST 19

8:00 am Registration Opens and Morning Coffee

CMC, QUALITY & POTENCY ASSAY DEVELOPMENT

8:25 Chairperson's Remarks

Jude Samulski, Ph.D., Scientific Founder and Chairman, Bamboo Therapeutics

8:30 Gene Therapies for All: How to Approach Industrialization of Gene Therapies on a Large Scale

Ben Locwin, Ph.D., MBA, MS, President, Healthcare Science Advisors

While precision medicine, personalized medicine, and gene therapies represent the future of targeted therapies for improved disease management and resolution, there are challenges of scale that must be faced in order to make GT viable for society. In this engaging discussion about the future of GT, best practices will be shown to increase the likelihood that gene therapies can successfully represent the next generation of medicine. Concepts covered will include Quality Risk Management, Quality by Design, CPPs, and CQAs.

9:00 Analytics for AAV Gene Therapy, Strategies for Phase I

Genine Winslow, Ph.D., Director of Research Analytics, Audentes Therapeutics, Inc.

Using case studies this presenation will look at an overview of CMC requirements for phase 1 CTA/IND applications, AAV CMC analytics challenges with emphasis on achieving comparable vector genome titers across sites, and a brief discussion of potency assays. The talk will also look at strategies for successful coordination of AAV analytics with CMOs.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction
- Manufacturing & CMC Strategies for Biologics

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Gene Therapy Bioproduction and CMC

Process Development, Scale-Up and Analysis of Gene Therapies

9:30 Developing a Potency Assay Matrix for an AAV Gene Therapy Product

Barb Thorne, Ph.D., Consultant, Thorne Bio-Consulting LLC, Former Executive Director Process Development, Celladon

A case study will be presented on the potency matrix for a gene therapy product formerly under development, AAV1/SERCA2a. The approach was based on FDA Guidance on Potency Tests for Cellular and Gene Therapy Products, and the matrix included three complementary quantitative assays used for product lot release and stability testing as well as a challenging qualitative enzyme activity assay.

10:00 Networking Coffee Break

PROCESS DEVELOPMENT FOR AAV-BASED PROCESSES

10:30 A Commercially Viable Novel CMC Approach to Bioprocessing AAV for Rare Diseases

Sam Wadsworth, Ph.D., CSO, Dimension Therapeutics

This presentation will look at creating a continuum for both upstream and downstream, viewing large scale manufacture from the very beginning and the main challneges associated with cost and scale-up.

11:00 AAV Journey to Large-Scale Production

Jude Samulski, Ph.D., Scientific Founder and Chairman, Bamboo Therapeutics

With the onslaught of AAV gene therapy programs entering the clinic, there are a number of key production issues that need addressing in a timely manner. This presentation will cover our journey with transition to bioreactors, cost of goods, downstream processing, and where does scale up go from here with respect to Big Pharma?

11:30 From Initial Phase I Supply with CRO to Phase III CMO Supply

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Jean-Philippe Combal, Ph.D., COO, GenSight Biologics, France

Daniel Dubois, Ph.D., Project Manager, Novasep

More rigorous product characterization, process development and regulatory hurdles for phase 3 or even commercial batches require highly skilled and critical transfer. Challenges and anticipation from rights to know-how transfer and regulatory impact requires significant perspectives to ensure large-scale cGMP and regulatory compliance. Viewpoint from both biotech and cGMP will be discussed.

12:00 pm Sponsored Presentations *(Opportunities Available)*

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Session Break

PROCESS DEVELOPMENT & SCALE-UP STRATEGIES

1:25 Chairperson's Remarks

1:30 rAAV Vector Production in the Baculovirus/Sf9 platform and in HEK293 Suspension Cell System

David Dismuke, Director, Vector Production, Voyager Therapetuics

2:00 Strategies to Deliver Scalable and Reliable Lentiviral Vector Biomanufacturing

Jeffrey Bartlett, Ph.D., Senior Vice President, R&D, Calimmune

One important consideration in designing processes for the clinical production of lentiviral vectors is minimizing lot-to-lot variation. With a mind towards developing a scalable, reliable, cGMP-compliant biomanufacturing process for lentiviral vectors we have established the Cytegrity stable cell line system and have defined key regulatory parameters to facilitate cGMP production and regulatory approval using this system.

2:30 Gene and Cell Therapy for Inherited Diseases: Cystic Fibrosis and Sickle Cell Anemia

We have developed protocols for efficiently correcting disease associated mutations in the CF transmembrane conductance regulator (CFTR) and human beta-globin using CRISPR/Cas9 and TALEN to enhance polynucleotide gene editing. We have developed protocols for assessment of efficient clonal isolation of corrected iPS cells and their directed differentiation into airway and hematopoietic progenitor cells to promote efficacious therapeutic transplantation.

3:00 Panel Discussion: Commercializing Gene Therapies

Panelists:

David Dismuke, Director, Vector Production, Voyager Therapetuics

Jeffrey Bartlett, Ph.D., Senior Vice President, R&D, Calimmune

Dieter Gruenert, Ph.D., Professor, Department of Otolaryngology, Head and Neck Surgery, University of California

Topics to be covered include:

- Pricing - from process to reimbursement
- Scaling up - unit operations, platforms, analytics
- Gene therapy supply - from rare disease to larger indications
- Facility design

3:30 Close of Conference

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Manufacturing and CMC Strategies for Biologics

Flexible Manufacturing and CMC Strategies for Emerging and Legacy Products

MONDAY, AUGUST 15

8:00 am Short Course Registration

9:00 – 11:30 Recommended Morning Short Course*
New USP Initiatives and Standards for Biologics
** Separate registration required, see page 5 for details.*

11:30 Main Conference Registration Opens

SINGLE-USE MANUFACTURING & FACILITY DESIGN

1:00 pm Chairperson's Opening Remarks
Jeff Odum, Global Technology Partner, NNE Pharmaplan

1:10 Single Use Technologies and Implementation for Biomanufacturing: The Design Manager's Challenge
Jeff Odum, Global Technology Partner, NNE Pharmaplan
As companies develop both short and long-term manufacturing strategies, operational efficiency and utilization become very critical to optimizing cost-of-goods, manpower planning, and supply chain management. This article will provide insights into the challenges faced by Design Managers implementing new single-use technology platforms and the sometimes unforeseen issues they face. The topics will include defining the process and optimizing time-and motion analysis, equipment definition and platform technology analysis.

1:45 KEYNOTE PRESENTATION: Developing Practical Single-Use Processes for New Vaccine Formulations
Kirsten Strahlendorf, P.Eng, M.Eng, Senior Scientist, Sanofi Pasteur Ltd.
In order to successfully implement a new vaccine formulation process using closed system, single-use technologies, both end-user process and study design require careful thought and execution. This presentation will review some of the aspects of filtration, mixing, formulating and dispensing that can impact homogeneity, adsorption, concentration and other critical product attributes.

2:15 Setting Standards in Single-Use Systems: Update from SUTAP, The Single-Use Technology Assessment Program
Alain Pralong, Ph.D., Senior Vice President, Manufacturing Operations, CellMedica
The shift from traditional to single-use technology is changing the distribution of responsibility and accountability within the drug manufacturing value chain as more components are procured ready-to-use without further modification by the end-user meaning the effective drug manufacturer. This presentation will outline how the creation of SUTAP – the single-use technology assessment program – has progressed, where we stand today and give a comprehensive overview on the next steps.

2:45 Refreshment Break

MANUFACTURING STRATEGIES FOR NOVEL BIOLOGICS

3:15 Analytical Testing Strategy for Kadcyla Cleaning Validation
Lan Dai, Ph.D., Associate QA Scientist, Global Biologics Quality Control, Genentech/Roche
Cleaning Validation is a key step to de-bottleneck during manufacturing site transfer. The complexity is increased for ADC product where the cyctotoxic residuals must be removed to be below a pre-determined Maximum Allowable Carryover level after equipment cleaning. A holistic approach has been used in designing the QC testing/validation strategy, including considerations to link downstream analytical testing to the particular cleaning process and to ensure compliance in accordance to local CMO and company network practice.

3:45 Sponsored Presentation *(Opportunity Available)*

4:00 An Integrated Platform for Mass Production of Immunotherapy Applications
Robert Dream, Ph.D., Consultant
Thus far using gene-modified cells has mainly been carried out by investigators who have developed their manufacturing process for small scale clinical trials by using the devices and infrastructure at hand. Anyone who has embarked on the task of admittedly agree that it is quite an undertaking.

4:30 Breakout Discussions

5:30 Grand Opening Reception in the Exhibit Hall with Poster Viewing

7:00 End of Day

TUESDAY, AUGUST 16

7:30 am Registration Opens and Morning Coffee

PRODUCT LIFECYCLE MANAGEMENT & CONTINUOUS PROCESS IMPROVEMENT

7:55 Chairperson's Remarks
Franqui Jimenez, Ph.D., Senior Director, Head of Manufacturing Science and Technology, Genzyme

8:00 Application of Advanced Manufacturing Process Strategies and Analytical Tools for Increased Process Throughput, Improved Product Understanding, and Efficient Process Control
Valerie Tsang, Ph.D., Senior Engineer III, Technical Development, Biogen
In order to meet the potentially high commercial demand for some biologics programs, manufacturing process changes are often necessary during the late stages of clinical product development. To accommodate the anticipated market needs while maintaining consistently high quality products comparable to those used in early phase clinical studies, Biogen has developed and implemented a series of process technologies and analytical tools to increase productivity and throughput, improve process consistency and product understanding.

8:30 Seizing Opportunities and Overcoming Challenges in Continuous Improvement of Legacy Processes
Franqui Jimenez, Ph.D., Senior Director, Head of Manufacturing Science and Technology, Genzyme

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Manufacturing and CMC Strategies for Biologics

Flexible Manufacturing and CMC Strategies for Emerging and Legacy Products

9:00 Product Lifecycle Management and Continuous Process Improvement

Amanda Ashcraft, Ph.D., Associate Director, Purification and Analytical Operations, Manufacturing Sciences and Technology, Genzyme

Balancing the more pressing needs of a current process with the more strategic needs of a future generation is a daunting task, it can be especially difficult when improving a legacy process. Technical agendas can easily be too narrow, failing to enable necessary design space knowledge or performance enhancements that can be a bridge to the next generation. This is a case study of a plan that attempts to balance the needs of both.

9:30 Sponsored Presentation *(Opportunity Available)*

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

BIOSIMILARS: MANUFACTURING & CMC STRATEGIES

10:30 Biosimilars Manufacturing Strategies: Can New Entities, CMOs and Others Effectively Compete with Big Bio/Pharma?

Eric S. Langer, President and Managing Partner, BioPlan Associates

11:00 Choosing between Patent and Trade Secret to Protect Bioproduction Methods

Paul Calvo, Ph.D., Director, Biotechnoogy Group, Sterne, Kessler, Goldstein & Fox P.L.L.C.

With estimates that approximately $65 billion worth of biologics will be coming off patent by 2020, the choice of trade secrets versus patent protection has taken on renewed importance in the biotechnology sector. This talk will dicuss choosing between patent and trade secret to protect bioproduction methods.

11:30 CMC Challenges in Practice: Comparability vs. Similarity

Beatrix Metzner, Ph.D., Director, Global CMC Strategy & Tech RA, Boehringer Ingelheim Pharma GmbH & Co. KG

The impact of manufacturing changes is well understood by means of comparability exercises. Mostly analytical testing is sufficient. The establishment of biosimilarity requires a comprehensive analytical comparability exercise very sensitive to differences and allows determining if a proposed biosimilar is shown to be "highly similar". Therefore the scientific principle of a biosimilarity exercise is based on the comparability approach.

12:00 pm Sponsored Presentations *(Opportunities Available)*

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

1:15 Dessert Refreshment Break in the Exhibit Hall with Poster Viewing

CMC STRATEGIES TO ACCELERATE TOWARDS IND

1:55 Chairperson's Remarks

2:00 Regulatory CMC for Biosimilars: The Comparability Exercise

Michel Mikhail, Ph.D., Expert in Biosimilars

For the approval of biosimilars, a meaningful "Finger-Print"-like analysis algorithm is needed to demonstrate similarity of the biosimilar product to the Reference Product. This presentations looks at a stepwise approach starting with analytics to prove highly similar physio-chemical attributes, batch-to-batch variability of the quality attributes of the Reference Product and analytical structural characterisation for biosimilar comparability.

2:30 Accelerating Timeline to IND by Using Pool for Tox Strategy

Wendy Hsu, Engineer and Group Leader, Early Stage Cell Culture, Genentech

Speed to IND submission is essential in establishing a competitive advantage for a therapeutic product. CMC activities are often on the critical path to IND-enabling toxicology (Tox) studies. The use of a "Pool for Tox" strategy where a pool of clonally derived cell lines is used instead of a single, clonally derived cell line to generate Tox material, can accelerate timelines by several months. The success of the strategy relies on the ability to generate comparable Phase I material using a single, clonally derived cell line.

3:00 A Client's Perspective- Developing an Accelerated Timeline to File an IND

Deborah Meshulam, Ph.D., Director, Contract Manufacturing, Scholar Rock

Scholar Rock has developed proprietary technology based on new insights into the structural biology and activation mechanisms of protein growth factors. The process of developing and manufacturing antibodies which can modulate these growth factors can be accelerated to file an IND using a GPEx technology cell line. In this presentation, key parameters and potential risks will be identified and discussed.

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

IMPROVING MANUFACTURING, FORMULATION & PRODUCT DESIGN

4:15 Novel Stability and Concentration Enhancing Formulations for Improved Administration of Biotherapeutics

Neil Schauer, Ph.D., Advisor, ReForm Biologics

The current trend in biologic drug delivery is towards development of formulations that enable room temperature stable, high protein concentration drug products in prefilled syringes and auto injectors. This trend requires novel formulation strategies. This presentation addresses product viscosity and stability issues for the improved administration of biotherapeutics.

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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Manufacturing and CMC Strategies for Biologics

Flexible Manufacturing and CMC Strategies for Emerging and Legacy Products

4:45 Facilitating the Design of Recombinant Protein Therapeutics with the Aid of Comprehensive Genomic Codon Usage Data

Chava Kimchi-Sarfaty, Ph.D., Principal Investigator, Hematology, FDA/CBER

Codon usage is an active area of research that plays a major role in the expression and folding of proteins, and is especially important in the creation of recombinant therapeutics. However, genomic codon usage data is outdated, inaccurate, or unavailable in existing databases for many organisms, limiting opportunities for research. We are creating a new database to provide codon usage data for every available organism.

5:15 End of Conference

5:15 Registration for Dinner Short Course

6:00 – 8:30 Recommended Dinner Short Course*

Analytical Strategies for Comparability in Bioprocess Development

** Separate registration required, see page 5 for details.*

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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REGISTRATION INFORMATION
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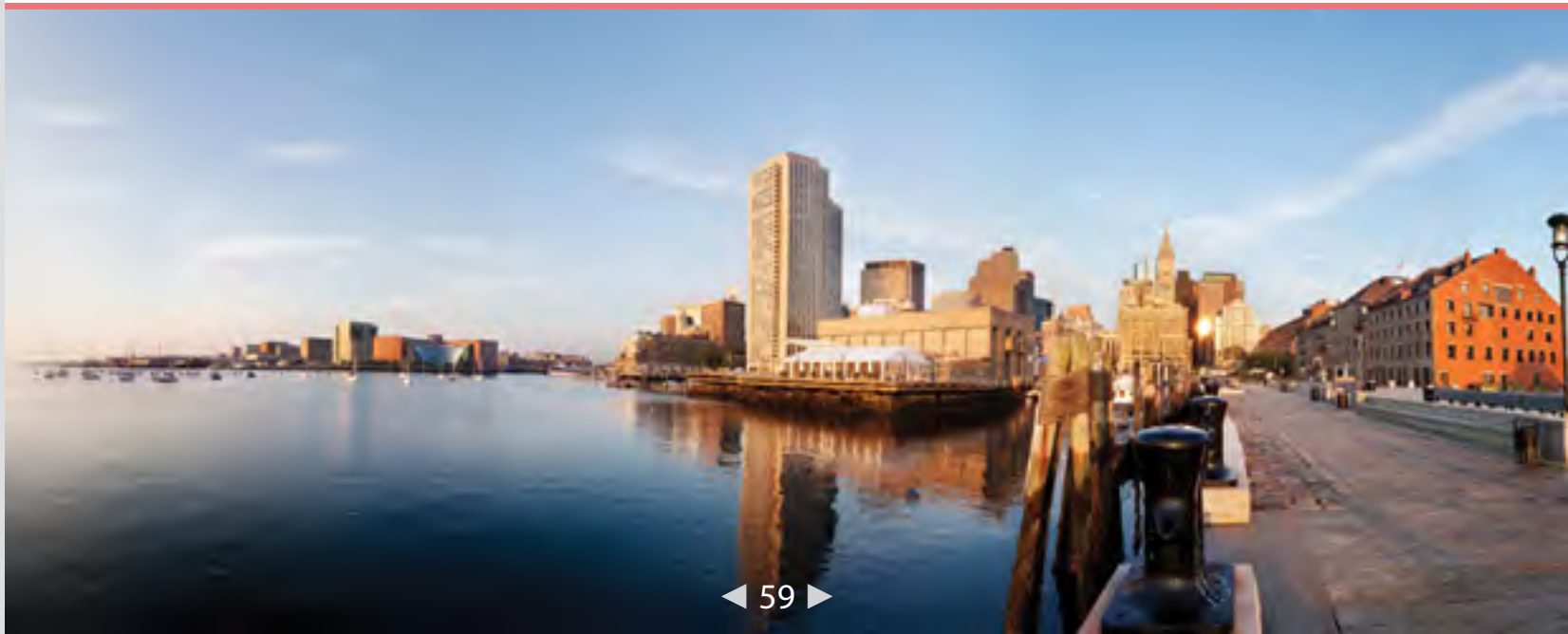

COVER
EVENT AT A GLANCE
PLENARY KEYNOTE SESSION
SHORT COURSES
TRAINING SEMINARS
UPSTREAM PROCESSING
- Optimizing Cell Culture Technology
- Bioproduction: Scale, Bioreactors & Disposables
- Optimizing Cell Line Development

DOWNSTREAM PROCESSING
- Continuous Processing in Biopharm Manufacturing
- Advances in Purification Technologies
- Virus & Pathogen Clearance & Safety in Biologics

ANALYTICAL & QUALITY
- Host Cell Proteins: Detection, Analysis & Removal
- Early Analytical Development for Biotherapeutics
- Process Characterization, Qualification & Control

FORMULATION & STABILITY
- Rapid Methods to Assess Quality & Stability of Biologics
- Overcoming Formulation Challenges
- High-Concentration Protein Formulations

CELL & GENE THERAPY PRODUCTION
- Cell Therapy CMC, Quality & Analytics
- Cell Therapy Bioproduction, Operations & Logistics
- Gene Therapy Bioproduction

- Manufacturing & CMC Strategies for Biologics

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