BioProcess International West

March 19-22, 2018
Hilton San Francisco Union Square
San Francisco, CA

THE LEADING PHASE-BASED BIOPROCESSING EVENT FOR ADVANCING PROMISING BIOLOGICS TOWARDS COMMERCIAL SUCCESS

KNect365
Life Sciences

Pharma Experts Help You Break Down Silos Across Departments

Post Approval Changes in Biotechnology Products: Navigate through Regulatory Requirements
Arulvathani Arudchandran, Ph.D., Product Quality Reviewer
FDA-CDER

Process Development and Manufacturing of Autologous Cell Therapy Products
Vijay Chiruvolu, Ph.D., Vice President, Process Sciences and Engineering
KITE PHARMA, INC.

Accelerating Development and Innovation: Advances and Challenges in Vaccine Development
Tony D'Amore, Ph.D., MBA, Vice President, Product Research and Development
SANOFI PASTEUR

A Look at the Trends and Influences Driving the Life Sciences Industry in California for 2018 and Beyond
Sara Radcliffe, President and CEO
CALIFORNIA LIFE SCIENCES ASSOCIATION (CLSA)

Application of Frontier Science – Lessons from Implementation of Next Generation Manufacturing at Amgen's Singapore Facility
Christopher Crowell, Ph.D., Executive Director, Global Operations
AMGEN INC.

Redefining Competition – Thinking about our Industry in a Revolutionary Way
Kimball Hall, Senior Vice President and Head of Drug Manufacturing, Pharma Technical Operations
GENENTECH, INC.

Achieving Efficiency through a Comprehensive Approach to Facility, Organization and Process
Jason Bock, Ph.D., Vice President, Biologics CMC
TEVA PHARMACEUTICALS

Register by March 2 and Save $200
www.BioProcessWest.com

WHAT'S ON DECK FOR BPI WEST 2018?

850+ Global BioProcessing Scientists and Executives

100+ Thought-Leading Speaker Presentations

80+ Exhibitors

40+ Scientific Posters

Polish Your Skillset with New Half-Day Symposia

Before you take a deep-dive into the main conference sessions, freshen up your skillset by attending one of our three expert-led symposia:

• Cost-Modeling • Cell & Gene Therapies • Continuous Processing

Let's Face It: Coordinating Efforts Across Multiple Departments Is a Pain

That's where we come in. Our unique phase-based agenda allows you to discuss trends, challenges and solutions with global scientists and engineers across multiple departments that work in your stage of development.

The One-Stop Shop to Find Your Next Supplier, CMO or CRO

Grab a cup of coffee (or glass of wine!) and walk through our world-class exhibition that features 80+ global technology leaders who can propel your biologic towards commercial success.

Build Up Your Rolodex and Connect with Old Friends

Our 2018 meeting offers 8+ hours of dedicated networking, providing the perfect forum for you to establish partnerships and talk shop with like-minded scientists from 25+ countries. Plus, you'll be able to view the attendee list and arrange meetings before you arrive in San Francisco with our conference app included in your main conference registration.

Back in the Heart of San Francisco

After a short 20-minute ride from the airport, you'll arrive at the Hilton San Francisco Union Square. You are just footsteps away from the finest restaurants, shopping and views that San Francisco has to offer. Be sure to book your hotel room using our attendee discount to save even more (see pricing page for details).

BREAK DOWN SILOS ACROSS DEPARTMENTS

The BPI West 2018 agenda is comprised of four phase-based tracks, designed to bring attendees working across multiple departments together to collectively share challenges and discuss the solutions needed to improve the speed, lower the cost and increase the quality of biologics development.

SINGLE-USE/ FLEXIBLE FACILITY TRACK

Accelerate development for multi-product pipelines, global markets and capacity optimization by meeting today's requirements for disposable manufacturing, facility design, cost-modeling and validation.

EARLY STAGE PROCESS DEVELOPMENT TRACK

Advance promising biologics from early stage process development to IND by learning how industry leaders reduce timelines, lower costs, develop robust cell lines, and utilize new technologies in upstream processing.

LATE STAGE PROCESS DEVELOPMENT TRACK

Achieve clinical and commercial success by applying best practices from recent case studies explaining how to streamline process characterization, control raw material variability, scale-up manufacturing efforts, and lower cost of goods.

COMMERCIAL MANUFACTURING TRACK

Create a sustainable commercial manufacturing program by applying innovating strategies for capacity improvements, supply chain continuity, lifecycle management and operational efficiencies.

"BioProcess International West brings together leading researchers in biopharma along the entire lifecycle of products. It is an important venue for sharing of key information and moving the field forward."

sGargi Maheshwari, Ph.D., Associate Vice President, Merck

AGENDA AT-A-GLANCE

Monday, March 19, 2018 • Pre-Conference Symposia

1:00-5:00	*Symposium #1:* Continuous Processing: Early and Late Stage Process Development	*Symposium #2:* Innovations Leading to Simplification, Cost Reduction, and Cost-Modeling	*Symposium #3:* Introduction and Innovations in Cell & Gene Therapies	(9:00am - 4:00pm) *Workshop and Site Tour:* **DOE using Mixed Mode Chromatography Resins** *Sponsored by* **Bio-Rad Laboratories** *(Free-to-attend; conference registration is not required)*
5:05 - 5:30	**Process Development and Manufacturing of Autologous Cell Therapy Products** Vijay Chiruvolu, Ph.D., VP Process Science and Engineering, Kite Pharmaceuticals			
5:45 - 6:45	*Speed Networking Event – Sponsored by* **BD Biosciences**			

Tuesday, March 20, 2018 • Main Conference

Exhibit Hall & Poster Viewing Hours: 9:45 am-6:30 pm

	Flexible & Smart Facilities	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
8:40-9:15	**Accelerating Development and Innovation: Advances & Challenges in Vaccine Development** Tony D'Amore, Ph.D., Vice President, Sanofi **Application of Frontier Science: Lessons from Implementation of Next Generation Manufacturing at Amgen's Singapore Facility** Christopher Crowell, PhD, Executive Director, Global Operations, Amgen Inc.			
9:15-9:55	*Networking Refreshment Break in the Poster and Exhibit Hall*			
9:55-11:30	Flexible and Smart Facilities	Molecule Selection and Manufacturability	Optimizing Timelines	Continuous Production
11:30-12:30	Flexible and Smart Facilities	Speed to IND	Process Characterization Case Studies (Upstream and Downstream)	Overcoming Challenges of High Concentration Formulations
12:30-1:40	*Luncheon Presentation* ***Sponsored by Sartorius***			
1:40-2:45	Flexible and Smart Facilities	Case Studies in Cell Line Development	Process Characterization Case Studies (Upstream and Downstream)	Process Validation
2:50-3:20	*Technology Workshops Sponsored by* **Cytovance, GE Healthcare, Pall ForteBio, Patheon**, *and* **Riffyn**			
3:20-4:00	*Networking Refreshment Break in Poster & Exhibit Hall*			
4:00-5:30	Facility Design and Challenges	Technology and Innovation	Technology and Innovation	Process Validation
5:45-6:45	*Networking Reception in the Poster and Exhibit Hall co-sponsored by* **GE Healthcare**			

Wednesday, March 21, 2018 • Main Conference

Exhibit Hall & Poster Viewing Hours: March 21: 9:45 am-4:00 pm

	Analytics and Models for Bioprocessing: Insights from R&D to Manufacturing	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
8:05-9:15	**Redefining Competition – Thinking About Our Industry in a Revolutionary Way** Kimball Hall, Senior Vice President and Head of Drug Substance Manufacturing, Pharma Technical Operations, Genentech, Inc. **Post Approval Changes in Biotechnology Products: Navigate through Regulatory Requirements** Arulvathani Arudchandran, Ph.D., Microbiologist, FDA-CDE			
9:15-9:55	*Networking Refreshment Break in Poster & Exhibit Hall*			
9:55-12:00	Analytics and Models for Bioprocessing	Cell Culture and Media	Tech Transfer and Commercial Launch Prep	**Track Presentations** *Sponsored by* Sartorius Stedim Biotech
12:00-1:15	*Networking Luncheon in the Poster & Exhibit Hall*			
	Analytics and Models for Bioprocessing: Insights from R&D to Manufacturing	**Early Stage Process Development**	**Late Stage Process Development**	**Commercial Manufacturing**
1:15-2:20	Process Monitoring	Cell Culture and Media	Viral Filtration	Case Studies: Scale-Up
2:25-2:55	*Technology Workshops Sponsored by* **Asahi Kasei Bioprocess, GE Healthcare, Irvine Scientific,** *and* **Repligen**			
2:55-3:45	*Final Networking Refreshment Break in the Poster and Exhibit Hall*			
3:45-5:15	Analytics and Models for Bioprocessing	Non-Platform Molecules	Raw Materials	Platform
5:30-6:30	*Networking Reception at CityScape – Hilton 46th Floor*			

Thursday, March 22, 2018 • Main Conference

	Single-Use	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
8:40-9:10	**Achieving Efficiency through a Comprehensive Approach to Facility Organization and Process Design** Jason Bock, PhD, Vice President, Biologics CMC, Teva Pharmaceuticals **California Life Sciences State of the Industry 2018: A Look at the Trends and Influences Driving the Life Sciences Industry In California for 2018 And Beyond** Sara Radcliffe, President and CEO, California Life Sciences Association (CLSA)			
9:15-9:40	*Networking Refreshment Break in Poster & Exhibit Hall*			
9:40-12:15	Case Studies and Innovations	Process Intensification	Recovery and Purification	Quality Assurance
		High Throughput Development and Monitoring	Young Scientists Presentations and Award *Sponsored by* **3M**	Cost Modeling
12:15-1:25	*Networking Luncheon*			
1:25-2:30	Case Studies and Innovations	Interface between Early Stage and Late Stage		Beyond the Plant
2:30	*Close of Conference – see you in 2019!*			

PRE-CONFERENCE SYMPOSIA • Monday, March 19, 2018 • 1:00 pm – 5:00 pm

Symposium #1:

Continuous Processing: Early and Late Stage Process Development

1:00 **Introduction and Chairperson's Remarks**

1:30 **Feasibility of Continuous Processing**

2:00 **Combining Siloed Unit Operations into a Fully Continuous Process**
Kenneth Lee, Ph.D., Scientist II, MedImmune and Lindsay Arnold, Ph.D., Scientist, MedImmune

3:00 *Refreshment Break*

3:30 **How Can Continuous Bioprocessing Deliver the Flexibility and Cost Gains Promised by its Champions?** CASE STUDY
John Bonham-Carter, Director, Commercial, Repligen

4:00 **iSKID: Next Gen Continous and Integrated Manufacturing**
Raquel Orozco, Ph.D., Senior Bioprocess Engineer, Boehringer-Ingelheim

4:30 **High Cell Density Cryopreservation for Upstream Process Intensification Using Frozen Seed Train Intermediates**
Mona Bausch, Scientist, Perfusion Systems Laboratory, MilliporeSigma

5:00 *Close of Symposium*

Symposium #2:

Innovations Leading to Simplification, Cost Reduction, and Cost-Modeling

Reducing cost of goods is the goal for all drug product manufacturers. This workshop is designed to help you: assess costs, calculate ROI, and present project requests to management (illustrating the value of the project).

You will discuss the following:

- Reducing cost of goods (COGs) and how to calculate them
- How does continuous manufacturing affect your budget?
- What are the right questions to ask and steps to take when tasked with determining ROI?
- How does single-use affect your manufacturing budget?

Presenters:

Tiffany Rau, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc

Rick Stock, Ph.D., Consultant, BioProcess Technology Consultants, Inc.

5:00 *Close of Symposium*

Symposium #3:

Introduction and Innovations in Cell & Gene Therapies

1:00 **Introduction and Chairperson's Opening Remarks**
Sohel Talib, Ph.D., Associate Director, Therapeutics, California Institute for Regenerative Medicine

1:30 **Cell and Gene Therapies: A Breaking Wave of Innovation**
Nick Timmins, Ph.D., Vice President, Process Science, Bluerock Therapeutics

2:00 **Unique Considerations for Cell and Gene Therapy Manufacturing**
Khandan Baradaran, Ph.D., Vice President and Head of Quality, Ultragenyx

2:30 **Case Study: Engineering Exosomes for Targeted Delivery of Therapeutic MicroRNAs** CASE STUDY
Kerstin Otte, Ph.D., Professor, University of Applied Sciences Biberach

3:00 *Refreshment Break*

3:30 **Delivering Automated Platforms for CAR-T Cell Manufacturing: A Case Study** CASE STUDY
Rodney Rietze, Ph.D., Senior Research Investigator, Novartis Cell & Gene Therapy Unit

4:00 **Manufacturing Processes and Strategies for Cell and Gene Therapy Products**
Qasim Rafiq, Senior Lecturer, Bioprocessing of Regenerative, Cellular and Gene Therapies, University College London

4:30 **Chemically-Defined Culture Media for Advancing Cell Therapy Technology**
Jessie Ni, Ph.D., Chief Scientific Officer, R&D, Irvine Scientific

5:00 *Close of Symposium*

Workshop and Site Tour – DOE using Mixed-Mode Chromatography Resins

9:00 am-4:00 pm

BIO-RAD

Workshop Overview

Bio-Rad Laboratories invites you to participate in this hands-on workshop that will provide best practices and guidelines for design of experiments (DOE) using mixed-mode chromatography resins. This DOE workshop will provide an intuitive approach to method development and process optimization. It will guide process scientists to develop optimum purification conditions offered by the large design space of mixed-mode resins.

This workshop will be held at Bio-Rad Laboratories in Hercules, California. A bus will transport attendees from BPI West Conference at the Hilton San Francisco Union Square to Bio-Rad and return to the hotel by 4:00 PM.

Topics to be covered:

- Overview of mixed-mode chemistries
- Introduction to DOE
- Hands-on experience designing experiments
- Analysis of purification results
- Scale-up using NGC™ Chromatography System

Register at **info.bio-rad.com/DOEworkshop** for a complimentary pass to the workshop only. Seating is limited.

This is a free workshop. Registration includes round-trip transportation, morning reception and networking lunch.*

If registering for a BPI West Conference pass, please check the box to attend this free workshop during the check out process.

Inquiries about the workshop, please email process@bio-rad.com

***Bio-Rad Offsite Workshop is free-to-attend and a conference registration is not required to participate.**

KEYNOTE PRESENTATION

Monday, March 19, 2018 • 5:10 pm

5:05 **Chairperson's Remarks**

5:10 **Process Development and Manufacturing of Autologous Cell Therapy Products**
Vijay Chiruvolu, Ph.D., VP, Process Science and Engineering, **Kite Pharmaceuticals**

5:45 – 6:45 **Join your industry peers for the BPI West Speed Networking Event.**
More details to come...

Sponsored by: BD

MAIN CONFERENCE • Tuesday, March 20, 2018

	Flexible & Smart Facilities	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
7:00	*Registration & Coffee*			
8:00	**Chairperson's Remarks**			
8:05	**Accelerating Development and Innovation: Advances & Challenges in Vaccine Development** Tony D'Amore, Ph.D., Vice President, Sanofi			
8:40	**Application of Frontier Science – Lessons from Implementation of Next Generation Manufacturing at Amgen's Singapore Facility** Christopher Crowell, PhD, Executive Director, Global Operations, Amgen Inc.			
9:15	*Networking Refreshment Break and Grand Opening of Poster & Exhibit Hall*			
9:55	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks**
	Flexible and Smart Facilities	**Molecule Selection and Manufacturability**	**Optimizing Timelines**	**Continuous Production**
10:00	**Keynote Address: Future Facility Design Considerations with Single Use Based on Prior Experience** Ken Green, Ph.D., Head of Manufacturing Science and Technology, Shire	**Improve Manufacturability: Evaluating and Mitigating Manufacturing Issues** Sujeewa Wijesuriya, Ph.D., formerly Associate Director, XOMA	**The Evolution of the Global Technology Roadmap: Latest developments from BPOG** Reed Harris, Senior Staff Scientist, Technical Development, Genentech, a member of the Roche group	**Throughput Optimization of Continuous Biopharmaceutical Manufacturing Facilities** Fernando Garcia, Ph.D., Process Engineer/Data Scientist, Just Biotherapeutics Inc.
10:30	**Innovation in Bio-Manufacturing: Disposables, Ballroom Plants and Continuous Processing** Berthold Boedeker, Ph.D., Chief Scientist, Bayer AG	**Structure vs. Function: In-Vivo and In-Vitro Modification of N'Linked Glycosylation on Monoclonal Antibody Bases Therapeutics** NEW DATA Yekaterina Lin, Ph.D., Senior Scientist II, Abbvie	**From Here to There: Technology Transfer and Improving Timelines** NEW DATA Javier Femenia, Ph.D., Principal Scientist, Cell Culture Process Development, BioMarin Pharmaceutical, Inc.	**Commercialization of an Integrated Continuous Biomanufacturing Process** Franqui Jimenez, Ph.D., Senior Director of Manufacturing Science and Technology, Sanofi Genzyme
	Scientific Sponsored Track Presentations			
11:00	**Producing More With Less – A Look at Total Cost of Ownership Using a Standardized Approach to Single-Use Technology Implementation** Sara Bell, Senior Marketing Manager, Single-Use Technologies, MilliporeSigma	**Presentation Title Coming Soon** MaxCyte	**Expertise in Vaccine Process Development Leads to Successful Clinical Trials** David E. Clements, MD, Director of Vaccine Research, Hawaii Biotech	**Presentation Title Coming Soon**
	Flexible and Smart Facilities	**Speed to IND**	**Process Characterization Case Studies (Upstream and Downstream)**	**Overcoming Challenges of High Concentration Formulations**
11:30	**Next Generation Biomanufacturing** CASE STUDY NEW DATA Chris Miles, Process Engineer, CRB and Matthew Kennedy, Bioprocess Engineer, CRB	**Gene to GMP in 9 Months Through Use of High Throughput Technologies** Sigma Mostafa, Ph.D., Vice President, KBI Biopharma Inc.	**At-Line In-Process Titer Determination Using Variable Pathlength Spectrophotometry to Eliminate HPLC Hold Step** NEW DATA Joe Sexton, Senior Technical Specialist, Genentech	**Evaluation of the Technology Landscape for Development of a High Concentrated mAb Formulation** Radhakrishna (RK) Maroju, Senior Scientist, Teva Pharmaceuticals
12:00	**Evolving Role of the Process Architect: Case Studies Using a Modular Delivery Approach** CASE STUDY NEW DATA Peter Cramer, Vice President, Life Sciences Facility Design, M+W Group	**Development of a Scalable Platform for Protease Triggered Immuno-oncologic Activators** Ulrich Ernst, Ph.D., COO, Senior Vice President, Amunix	**Mechanisms of Monoclonal Antibody Low Molecular Weight (LWM) Formation and Strategies of Mitigation in Bioprocessing** CASE STUDY NEW DATA Yuanli Song, Ph.D., Scientist II, Bristol-Myers Squibb	**Challenges in Development of a High Concentration Liquid Formulation for mAb process** CASE STUDY Daniel Chen, Scientist, Protein Science, Boehringer Ingelheim
12:30	**LUNCHEON PRESENTATION AND PANEL DISCUSSION: Implementation Process Intensification in Commercial Manufacturing: Drivers & Challenges** *(seating is limited)* *sponsored by* sartorius stedim biotech Detlef Eisenkraetzer, Director, Fermentation Development Pharma, Roche Diagnostics GmbH Miriam Monge, Director of Marketing Integrated Solutions, Sartorius Stedim FMT SAS Raquel Orozco, Ph.D., Senior Bioprocess Engineer, Boehringer-Ingelheim Gerben Zijlstra, Continuous Processing Platform Manager, Sartorius Mandar Dixit, Director of Marketing, Filtration Technologies, Sartorius Stedium Biotech Fritjof Linz, VP Purification, Sartorius Stedium Biotech Anna Persson, Senior Principal Data Scientist, Sartorius Stedium Biotech			
12:30	*Networking Lunch in the Poster & Exhibit Hall*			

MAIN CONFERENCE • Tuesday, March 20, 2018

	Flexible & Smart Facilities	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
1:40	**Chairperson's Remarks**	**Chairperson's Remarks** Camilla Oxley, PhD, Janssen	**Chairperson's Remarks**	**Chairperson's Remarks**
	Facility Design and Challenges	**Case Studies in Cell Line Development**	**Process Characterization Case Studies (Upstream and Downstream)**	**Process Validation**
1:45	**Evolution of a Flexible Development Facility to Accommodate the Increasingly Fast-Paced Pharmaceutical Landscape** Paul Ko, Ph.D., Senior Scientist, Cell Technologies, API Large Molecule, Janssen R&D	**Industry Perspectives and Case Studies towards Demonstration of Monoclonality for Biologics Manufacture Development** CASE STUDY Amie Lundquist, Senior Development Specialist II, Shire & BPOG	**In-Process Pool Mixing: Impact on Product Quality and Process Performance** CASE STUDY NEW DATA Jim Keba, Engineer II, Genentech	**Relevance of a Risk-Based Approach in the Successful Commercialization of a Monoclonal Antibody** Marlene Castro-Melchor, Ph.D., Senior Engineer, Genentech
2:15	**The Art of the Possible: How You Convert a Human Process into a Machine Process**	**Methods to Verify a Clonal Cell Origin** Amritha Menon, Associate Scientist, Gilead Sciences	**Case Study: Determine CQAs for a Late Stage Complex Fusion Protein** Johnson Varghese, Ph.D., Celgene	**Analytical Approach for Implementation of Visual Inspection** NEW DATA Mariann Neverovitch, MS Pharmacy, Research Scientist, Bristol-Myers Squibb
	Concurrent Technology Workshops			
2:50	**Process Characterization – A Road Map to EnhanceProcess Understanding** CASE STUDY NEW DATA Cytovance Biologics Eliza Yeung, PhD. Strategic Projects Manager & PC Study Directory, R&D, Cytovance Biologics **Start with the End in Mind: New Solutions for High Capacity mAb Capture and Efficient Transition to GMP Environment** GE Avril Vermunt, Bioprocess Hardware Specialist, GE Healthcare		**Process Development: The Key to a Successful Biomanufacturing Strategy** Patheon A HEALTHIER WORLD. DELIVERED. Brad Johnson, Ph.D, Manager, Purification Development, Patheon **Laboratory Data to Machine Learning in 30 Seconds** Riffyn Tim Gardner, PhD, Founder and CEO, Riffyn **High Throughput BLI Potency Assay for Screening of Product Degradation by Industrial Cleaning Solutions** PALL ForteBio Jonathan Crane, PhD, Senior Development Scientist, AGC Biologics	
3:20	*Networking Refreshment Break in the Poster and Exhibit Hall*			
	Facility Design and Challenges	**Technology and Innovation**	**Technology and Innovation**	**Process Validation**
4:00	**Modular Doesn't Necessarily Mean Flexible** Dennise Powers, Director of Sales Engineering, G-CON Manufacturing	**Integration of Automation Technologies for Efficient Stable Cell Line Generations from Transfection to GMP Clone for Viral Antigens** CASE STUDY NEW DATA Naga Chalamalasetty, Scientist, NIAID, NIH, Vaccine Research Center	**Manufacturing Incytes: Leveraging Online Biomass Probes for Robust Seed Train Performance** CASE STUDY NEW DATA C. Eric Hodgman, Ph.D., Engineer II, Bristol-Myers Squibb	**Challenges in Developing a Representative Scale-Down Model** CASE STUDY NEW DATA Shyamsundar Subramanian, Ph.D., MS, MSc, Director, Teva Pharmaceuticals
4:30	**A Suite-Focused Flexible Facility Design for Biologics Production** Sue Behrens, Ph.D., Sr. Director, Process Design, IPS-Integrated Project Solutions	**Technology Toolboxes and Modeling Approaches to Expedite Process Development** Natraj Ram, Ph.D., Associate Director, Purification, Manufacturing Sciences, AbbVie	**Hydrogen Deuterium Exchange Mass Spectrometry (HDX-MS) for Formulation and Process Optimization of Lyophilized Protein Formulations** CASE STUDY NEW DATA Lokesh Kumar, Ph.D., Associate Scientist, Genentech	**Pharma Quality System and Validation Best Practices** Hamid Mollah, Ph.D., Principal Engineer, Genentech
5:00	**Lessons Learned From a Retrofit Manufacturing Facility**	**Developing a Better Understanding of the Interactions Between New ADC Payloads and Antibody Post Conjugation** Scott Hilderband, Ph.D., Senior Scientist, ImmunoGen, Inc.	**Progress Towards Continuous Upstream Process Monitoring Using Raman Spectroscopy** Nobel Vale, Research Scientist II, Bristol-Myers Squibb	**Process Validation and Regulatory Approval Strategies Required for Drugs That Have Been Designated Fast-Track** CASE STUDY Tracy TreDenick, Head of Regulatory and Quality Assurance and Founding Partner, BioTech Logic
5:30	*Networking Reception in Poster & Exhibit Hall*			

MAIN CONFERENCE · Wednesday, March 21, 2018

	Plenary Session				
7:00	*Registration & Coffee*				
8:00	**Chairperson's Opening Remarks**				
8:05	**Redefining Competition – Thinking about our Industry in a Revolutionary Way** Kimball Hall, Senior Vice President and Head of Drug Substance Manufacturing, Pharma Technical Operations, Genentech, Inc.				
8:40	**Post Approval Changes in Biotechnology Products: Navigate through Regulatory Requirements** Arulvathani Arudchandran, Ph.D., Microbiologist, FDA-CDER				
9:15	*Networking Refreshment Break in the Poster and Exhibit Hall*				
	Analytics and Models for Bioprocessing: Insights from R&D to Manufacturing	**Early Stage Process Development**	**Late Stage Process Development**	**Commercial Manufacturing**	**Track Presentations** *Sponsored by* sartorius stedim biotech
9:55	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks** David Brindley, DPhil, Meng, FRSA, Managing Partner, Biolacuna & Senior Research Fellow, Nuf eld, Department of Paediatrica, University of Oxford	**Chairperson's Opening Remarks**		**Chairperson's Opening Remarks**
	Analytics and Models for Bioprocessing	**Cell Culture and Media**	**Tech Transfer and Commercial Launch Prep**		
10:00	**System Integration for a New Large-scale Manufacturing Facility** CASE STUDY Jordan Croteau, MBA, Sr. Engineer, Global Executive Systems, Biogen	**Comparison Between Fed-bath and Perfusion Cell Culture System** CASE STUDY NEW DATA Daryl Powers, Ph.D., Associate Director, Sanofi	**Points to Consider in QC Method Validation and Transfer for Biological Products** Weijun Li, Ph.D., Senior Manager, Analytical Transfers & Special Projects, Bayer		**Development of 'ambr 250 perfusion' – A Novel Automated Single-Use Perfusion Mini-Bioreactor** Melisa Carpio, Field Marketing Manager, Fermentation Technologies, Sartorius Stedim North America Inc.
10:30	**De-risk Clinical Candidates Using Protein Sequence Variant Analysis**	**Integrated Media Blending Increases Efficiency of Clone Selection** CASE STUDY NEW DATA David Bruehlmann, Ph.D., Manager, EMD Serono	**Tech Transfer from Late Stage to Commercial Lauch** Padmadhar Madupu, MS, Technical Manager, Pfizer		**Gain Manufacturability Information for Downstream Processing Already During Your Candidate Selection** Marc Jenke, Senior Product Manager Crossflow Systems, Sartorius Stedim Biotech GmbH
11:00	**Process Analytics to Control Variability**	**Cell Culture Media: an API or Ancillary Material?** David Brindley, DPhil, Meng, FRSA, Managing Partner, Biolacuna & Senior Research Fellow, Nuf eld, Department of Paediatrics, University of Oxford	**Tech Transfer Simplified with Model-Based Process Fit and Process Control** Steven Rose, MS, Director, BioProcess Engineering, MedImmune		**Application of Model Predictive Control Methods for Forecasting and Optimization Of Biological Processes** Anna Persson, Senior Principle Data Scientist, Sartorius Stedim Data Analytics AB
	Scientific Sponsored Track Presentations				
11:30	**On-demand Nutrient Feed During Automated Cell Culture Process: Integrating Eppendorf's Bioprocess System with Flownamics Segflow and Roche's Cedex Bio HT Systems** Robert Berish, Scientist, Zoetis	**A Molecule's Journey – Breaking Down Roadblocks to Commercial Success** Guillaume Plane, Global Development and Marketing Manager, MilliporeSigma	**Saturn™ and FlexFactory: Transforming an Existing Facility to Multi-Product Ballroom** Thomas Page, Ph.D., Vice President, Engineering and Asset Development, FUJIFILM Diosynth Biotechnologies		
12:00	*Networking Luncheon in the Poster and Exhibit Hall*				

	Analytics, Models and Insights' to Analytics and Models for Bioprocessing: Insights from Process Development to Manufacturing	Early Stage Process Development & Clinical Manufacturing	Late Stage Process Development & Commercial Launch Preparation	Commercial Manufacturing & Beyond
1:15	**Chairperson's Remarks** Eric Langer, Managing Partner, BioPlan Associates, Inc.	**Chairperson's Remarks** Ashley Hesslein, Ph.D., Associate Director, Bayer Healthcare LLC	**Chairperson's Remarks**	**Chairperson's Remarks**
	Process Monitoring	**Cell Culture and Media**	**Viral Filtration**	**Case Studies: Scale-Up**
1:20	**Next Generation Process Science, Beyond Proteins** Nick Timmins, Ph.D., Vice President, Process Sciences, Bluerock Therapeutics	**Cell-Controlled Hybrid Perfusion/ Fed-Batch Effectively Circumvents the Inherent Limitations of Fed-Batch** Ana Maria Ovalle, Senior Associate Scientist, Pfizer	**Two Decades of Exploration in Viral Filtration** Shawn Liu, Ph.D., Principal Scientist, Head of Dept., Bayer	**Case Study: Alleviating Downstream Bottlenecks to Accommodate Increased Titers of a Commercial mAb Process** CASE STUDY Kimberly Fuller, Scientist, Bristol-Myers Squibb
1:50	**Monitoring and Controlling Viable Biomass in Bioprocesses Using Dielectric Spectroscopy for PAT Applications** CASE STUDY Aditya Bhat, Ph.D., Director of Technology, Aber Instruments Inc.	**Overcome Challenges to Successful Development of Chemically-Defined Media through Manipulation of the TCA Cycle in CHO Cells** CASE STUDY NEW DATA Le You, Ph.D., Scientist, Ambrx	**Viral Contamination of Media Using Upstream Barrier Method** NEW DATA Kathryn Remington, Ph.D., Principal Scientist, BioReliance	**Process Validation Evaluation Criteria**
	Concurrent Technology Workshops			
2:25	**OPUS® 80R cm column** Fletcher Malcolm, Director, Product Manager, Repligen **A New Media Panel that Unlocks Your Cells' Potential** Jenny Bang, Manager, Research and Development, Irvine Scientific	REPLIGEN INSPIRING ADVANCES IN BIOPROCESSING IrvineScientific	**Planova™ Virus Filtration as a Highly Effective Robust Step in Viral Clearance** Esha Vyas, Field Applications Manager, Asahi Kasei Bioprocess America **Pinpoint your Key Parameters for a Successful Perfusion Process** Helena Ohrvik, Ph.D., Scientist, R&D Bioprocess, GE Healthcare	AsahiKASEI BIOPROCESS
2:55	*Final Networking Refreshment Break in the Poster and Exhibit Hall*			
	Analytics, Models and Insights' to Analytics and Models for Bioprocessing: Insights from Process Development to Manufacturing	**Non-Platform Molecules**	**Recovery and Purification**	**Selecting and Working with CMOs**
3:45	**Data and Trends for Future SUS Bioprocessing: Is Single-Use Cost Effective** Eric Langer, Managing Partner, BioPlan Associates, Inc.	**Selectivity Analysis Cation-Exchange Chromatography on Protein Impurity Separation** CASE STUDY NEW DATA Keith Selvitelli, Senior Associate Scientist, Process Biochemistry, Biogen	**Assessment of Clarification Options for High Density Cell Cultures** CASE STUDY NEW DATA Kirk McLean, Senior Development Scientist, Bayer	**How to Select the "Right" CMO at Early Stage CMC Development** Qinghai Zhao, Ph.D., Vice President, FortySeven Inc.
4:15	**Analytical Data Trends Used in Making Process Decisions** Frank Agbogbo, PhD, Cytovance Biologics	**Challenges and Strategies of Downstream Processing for a Complex Bispecific Antibody** Ji Zheng, Ph.D., Associate Director, Celgene	**Challenges to Making a Ready to Fill Antisense Oligonucleotide (ASO) Formulation for Intrathecal Delivery** NEW DATA Hien Nguyen, Associate Scientist III, Biogen	**Featured Panel Discussion: Cultivating a Better Working Relationship with Contract Manufacturing Organizations (CMOs)** *Moderator:* S. Anne Montgomery, Editor in Chief, BioProcess International; *Panelists:* Yuyi Shen, Ph.D., Principal Scientist, Grifols; Xiao-Ping Dai, Ph.D., Sr. Director, Head of Biologics DS Development, Celgene; Tad Thomas, Ph.D., Director and Global Lead, Biologics Process Transfer and Launch Global Biological Development, Bayer Healthcare LLC; and Ruby Casareno, Ph.D., Vice President, CMC, Allakos, Inc.
4:45	**Utilizing Simulation and Optimization Techniques to Evaluate Different CAR-T Cell Therapy Manufacturing Paradigms** Jon Gunther, Ph.D., Associate Director, Juno Therapeutics	**Non-platform Biologics Process Development and Technical Transfer for Early Clinical Phase API Production** CASE STUDY Christopher Rode, Scientific Director, API-Large Molecule/Pharmasceutical Development Manufacturing Sciences, Janssen R&D	**Crystallization as a Tool for Scalable, Efficient Purification Techniques in Process Step for Purifying Recombinant Proteins** CASE STUDY Partha Hazra, Ph.D,, General Manager RND, Biocon Research Limited	
5:30	*Networking Reception at CityScape – Hilton 46th Floor*			

MAIN CONFERENCE • Thursday, March 22, 2018

	Single-Use	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
7:30	*Registration & Coffee*			
8:00	**Chairperson's Remarks**			
8:05	**California Life Sciences State of the Industry 2018: A Look at the Trends and Influences Driving the Life Sciences Industry In California for 2018 And Beyond** Sara Radcliffe, President and CEO, California Life Sciences Association (CLSA)			
8:40	**Achieving Efficiency through a Comprehensive Approach to Facility, Organization and Process Design** Jason Bock, Ph.D., Vice President, Biologics CMC, Teva Pharmaceuticals			
9:15	*Networking Refreshment Break*			
9:40	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks**
	Case Studies and Innovations	**Process Intensification**	**Raw Materials**	**Quality Assurance**
9:45	**Large Scale Single Use Bulk Drug Substance Freeze and Thaw Platform** Jeffrey Johnson, Director and New Technology Lead, Global Engineering solutions, Merck & Co., Inc.	**Process Development To Minimize A Light-Chain Mispaired Variant In A Bispecific Antibody** CASE STUDY NEW DATA Ambrose Williams, Ph.D., Scientist, Genentech	**Assessment of Clarification Improved Characterization of Animal Serum for Use in Cell Culture** NEW DATA Rosemary Versteegen, Ph.D., CEO, International Serum Industry Association, ISIA	**Contamination Control and Prevention Program at an Aging Facility** CASE STUDY NEW DATA Yuval Shimoni, Ph.D., Principal Engineer, Bayer Healthcares
10:15	**Presentation Title Coming Soon** Genentech	**Lessons Learned: Progressing a CHO Expression System Fed-Batch Process from the Incubator to Bench-Scale Bioreactors** CASE STUDY NEW DATA Robert Voyer, MASc, Team Leader-Process Intensification, National Research Council of Canada	**Elemental Impurities in Chemically Defined Media Powders: Impact to Upstream Cell Culture Processes** Nicole Migliore, Scientist, Janssen R&D	**Global Particle Library for Drug Product Inspection** Adrian Bennis, Principal Engineer, Amgen
	Scientific Sponsored Track Presentations			
10:45	**Presentation Title Coming Soon**	**Utilizing the ambr 15 and ambr 250 Perfusion as Tools for Small-Scale Process Intensification and Continuous Processing** Sartorius	**Presentation Title Coming Soon**	**Presentation Title Coming Soon**
	Case Studies and Innovations	**High Throughput Development and Monitoring**	**Young Scientists Presentations and Award** *Sponsored by* 3M	**Cost Modeling**
11:15	**Feedback on Single-Use Manufacturing And A New Approach for Scale Transfer** CASE STUDY Christophe Martin, USP Production Manager, MilliporeSigma	**Coupling of the Ambr 250 with Robocolumns for Upstream/Downstream Screening** Ashley Hesslein, Ph.D., Associate Director, Bayer Healthcare LLC	11:15 **Chairperson's Opening Remarks** Andrew Tustian, Associate Director, Regeneron Pharmaceuticals 11:30 **Young Scientist Presentation #1 Roche/Genentech** Presenter to be determined 11.45 **Young Scientist Presentation #2 Just Biotherapeutics** Presenter to be determined 12:00 **Young Scientist Presentation #3 Bayer** Presenter to be determined 12:15 **Young Scientist Presentation #4 Amgen** Presenter to be determined 12:30 **Young Scientist Presentation #5 Gilead** Presenter to be determined 12:45 **Award committee deliberates on the session and nominates a winner** 12:55 **Presentation of Young Scientist Award Winners** Andrew Tustian, Associate Director, Regeneron Pharmaceuticals & 3M Representative 1:00 *Close of Session*	**Leveraging Process Simulation Models at Different Phases of Development and Commercialization** Rick Stock, Ph.D., Consultant and Modeling Manager, BioProcess Technology Consultants
11:45	**Technology Transfer and Scale-Up of a Late Clinical Stage Biotherapeutic to a Nearly Completely Single-Use Manufacturing Facility** Kishan Rao, MS, Associate Director Clinical Technical Services, Alexion	**High Throughput TFF for Formulation Robustness** NEW DATA Anthony Portolesi, Technical Development Research Associate, Genentech		**Will the Cost of Manufacturing be the Death of Your New Therapy** Jennifer Chain, Ph.D., Science Officer, Oklahoma Blood Institute
12:15	**Luncheon Technology Workshops available for Sponsorship**	**Luncheon Technology Workshops available for Sponsorship**		**Luncheon Technology Workshops available for Sponsorship**

MAIN CONFERENCE • Thursday, March 22, 2018

	Single-Use	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
1:25	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks**
	Case Studies and Innovations	**Interface between Early Stage and Late Stage**		**Beyond the Plant**
1:30	**In Process Monitoring in Single Use Manufacturing of Dendritic Cells** CASE STUDY NEW DATA Shashi Murthy, Ph.D., Professor of Chemical Engineering & Sherman Center Director, Northeastern University	**Interface between Discovery, Early Stage and Late Stage - Innovations and Case Studies** CASE STUDY Duc Nguyen, Ph.D., Lab Head Novartis		**Key Highlights of the Biologics Competition & Innovation Act - an Attorney-Scientist's Perspective** Verne Luckow, Ph.D., JD, Managing Member, The IP Law Office of Verne A. Luckow, LLC
2:00	**Comparison of USP <665> and BPOG Protocols for Extractables Studies of SUS Components - Raymond Colton, BPOG** Raymond Colton, MBA, Founder, VR Analytical	**Best Practices: Transferring Processes from Pre-clinical, to Clinical, to Commercial Launch Prep.**		Feel free to attend one of the other 2:00 presentations
2:30	*Close of Conference - See you in 2019!*			




Sponsor and Exhibit Opportunities

Secure your exhibit booth or sponsorship today and highlight your company's expertise to a global audience of 850+ bioprocessing scientists and decision makers across USA, Europe and Asia.

Sponsors *(as of February 6, 2018)*

Event Partner

Platinum Sponsor

Gold Sponsor

Silver Sponsors

Bronze Sponsor

Technology Workshop Sponsors

Presentation Sponsors

Speed Networking Sponsors

Exhibitors *(as of February 6, 2018)*

3M
Abzena
AllCells
ANGUS Life Sciences
Aragen Bioscience
Asahi Kasei Bioprocess
Avid Bioservices
BASF
BD Bioscience
Beckman Coulter Life Sciences
Berkeley Lights
Bio-Rad Laboratories
BioNova
BioTech Logic
BioVectra
Boehringer Ingelheim
Broadley James Corp
Canopy Biosciences
Capsugel
Catalent
Charles River
ChemoMetec
CMC Biologics
CPC
Cygnus Technologies
Cytovance
Distek, Inc.
Ensinger
Eppendorf
Farrar Scientific
Fluxa
FrieslandCampina Ingredients
Fujifilm Diosynth Biotechnologies
GE Healthcare
GenCure
Gyros Protein Technologies
Hamilton
ILC Dover
Irvine Scientific
JNC
JSR Life Sciences
Kaneka
KBI Biopharma
Kuhner Shaker
Levitronix
LEWA
MabPlex
Malvern Panalytical
Maxcyte
Meissner Filtration Products
MilliporeSigma
Namocell
NOVA Biomedical
Novasep
O3 Sterilization Systems
Optimum Processing Inc.
Pall Life Sciences
Parker Domnick Hunter Process Filtration
Patheon
PendoTech
PerkinElmer
Pneumatic Scale
Premas Biotech
ProMetic BioSeparations
Purolite Life Sciences
Qosina
Rentschler Biopharma SE
Repligen
Revise Fujifilm Diosynth Biotechnologies
Revise MilliporeSigma with no space
Revise Parker Domnick Hunter Process Filtration on one line
Roche Diagnostics
Saint-Gobain
Sartorius Stedim Biotech
SpectrumLabs.com
Steri-Tek
Texcell
Thermo Fisher Scientific
Tosoh Bioscience
Vanrx Pharmasystems
VR Analytical
Watson-Marlow Fluid Technology Group
WuXi AppTec
YSI

Contact Our Team Today for Pricing & Package Details:

Jennifer Wickett (Companies A-L): P. +1 (857) 504-6694 • E: jennifer.wickett@knect365.com

Patrick Shaughnessy (Companies M-Z): P. +1 (857) 262-5325 • E: patrick.shaughnessy@knect365.com

MEET THE GLOBAL CMOS, CROS, SUPPLIERS AND TECHNOLOGY LEADERS WHO CAN ACCELERATE YOUR PRODUCT TO MARKET

Register for an exhibit hall only pass to gain entrance to the exhibition, luncheons, and networking functions at BPI West 2018. Exhibit hall passes start at $75/day and provide you direct access to:

- Face-to-face time with 850+ bioprocessing scientists, engineers and decision makers
- Live technology demonstrations from 80+ exhibitors
- Scientific poster hall containing peer-submitted unpublished data
- Innovation Live mini theater containing product demos and panel discussions
- Networking luncheon and refreshment breaks with fellow attendees and speakers

The exhibition is open on
Tuesday, March 20
9:45am-6:30pm
Wednesday, March 21
9:45am-4:00pm

Register for an exhibit hall only pass at www.BioProcessWest.com

Please note: In order to access the scientific sessions, you will need to register for a 3-day main conference pass.