

Bioprocess International US West

March 11-14, 2019
Santa Clara Convention Center
Santa Clara, CA

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



Bioprocess Experts Share Strategies for Accelerating Biologics Development



Jerry Murry
Vice President
Amgen



Rahul Singhvi
COO
Takeda Vaccines, Inc



Jens Vogel, PhD
President & CEO
BI Fremont Inc.

KNect365
Life Sciences

Register by November 2 and Save \$800

www.BioProcessWest.com

BIOPROCESS INTERNATIONAL US WEST IS YOUR ONE-STOP SHOP TO GAIN THE SCIENCE, TECHNOLOGY AND CONTACTS YOU NEED TO ACCELERATE YOUR BIOLOGICS TOWARDS COMMERCIAL SUCCESS



SCIENCE Access 100+ innovative case studies and new data presentations across 5 focused tracks designed to improve the speed, cost and quality of your process development and manufacturing efforts.



TECHNOLOGY Meet 80+ exhibitors comprised of global CMOs, CROs, suppliers and technology leaders who can help accelerate your product to market.



NETWORKING Solve your current challenges by collaborating with 900+ global end-users and decision makers working across the entire bioprocessing spectrum.



New for 2019!

- ▶ New **Viral Safety track** to drive virus detection, removal and regulatory know-how
- ▶ New **BioProcessing 4.0 sessions** to accelerate your smart manufacturing strategy
- ▶ Four full-day **pre-conference symposia** covering cell & gene therapies, microbial production, continuous bioprocessing and process analytical technologies
- ▶ **Focused sessions** on continuous processing, process intensification, smart facilities, process modelling and more
- ▶ **Industry-led panel discussions** focused in early stage process development, late stage process development, commercial manufacturing and flexible/single-use facilities

First Time Attending BPI US West? Take a virtual tour by watching our 2018 event highlight video at www.BioProcessWest.com

BREAK DOWN SILOS ACROSS DEPARTMENTS AND STAGES OF DEVELOPMENT

The BPI US West 2019 agenda is comprised of five phase-based tracks, designed to bring scientists 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/safety of biologics development.

NEW FOR 2019! VIRAL SAFETY

Ensure regulatory success for your biologics and understand how industry leaders are implementing successful virus detection and viral removal programs.

EARLY STAGE PROCESS DEVELOPMENT

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 downstream processing.

LATE STAGE PROCESS DEVELOPMENT

Increase speed to market while ensuring your product is ready for launch by applying global best practices to develop continuous and intensified processes, achieve process robustness and simplification, streamline process validation and characterization, and alleviate bottlenecks in tech transfers during scale up.

COMMERCIAL MANUFACTURING

Create a sustainable commercial manufacturing program by applying innovating strategies for capacity and continuous improvements, successful launch and lifecycle management, optimizing operational efficiencies, and achieving real-time control strategies.

SINGLE-USE / FLEXIBLE & SMART FACILITIES

Accelerate development for multi-product pipelines, global markets and capacity optimization by meeting requirements for validation, supply chain, design and operational considerations.

Agenda At-A-Glance

Monday, March 11, 2019 • Pre-Conference Symposia				
8:50-5:00	SYMPOSIUM 1: Microbial Production	SYMPOSIUM 2: Continuous and Intensified Bioprocessing	SYMPOSIUM 3: PAT and Advanced Process Control	SYMPOSIUM 4: Cell & Gene Therapy Bioprocessing
4:30-5:00	<i>Keynote Presentation</i>			
Tuesday, March 12, 2019 • Main Conference <i>Exhibit Hall & Poster Viewing Hours: 9:15 am – 6:30 pm</i>				
8:00 - 9:15	PLENARY SESSION			
9:55 - 12:00	TRACK 1: Flexible & Smart Facilities	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
12:00-12:30	Technology Workshops			
12:30-1:55	<i>Networking Luncheon</i>			
1:40 - 2:50	TRACK 1: Flexible & Smart Facilities	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
2:50 - 3:20	Scientific Track Presentations			
4:00 - 5:30	TRACK 1: Flexible & Smart Facilities	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
	<i>Networking Reception in the Poster and Exhibit Hall</i>			
Wednesday, March 13, 2019 • Main Conference <i>Exhibit Hall & Poster Viewing Hours: : 9:15 am - 4:00 pm</i>				
7:30 - 8:00	Technology Workshops with Light Continental Breakfast			
8:00 - 9:15	PLENARY SESSION			
9:55 - 11:30	TRACK 1: Bioprocessing 4.0	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
11:30 - 12:00	Technology Workshops			
12:00 - 1:40	<i>Networking Luncheon</i>			
1:10 - 2:45	TRACK 1: Bioprocessing 4.0	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
2:45 - 3:30	Sponsored Presentations			
4:00 - 5:30	TRACK 1: Bioprocessing 4.0	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
5:30	<i>Offsite Networking Reception (location to be announced)</i>			
Thursday, March 14, 2019 • Main Conference				
7:15 - 8:00	Technology Workshops with Light Continental Breakfast			
8:00-9:30	PLENARY SESSION			
9:20 - 9:50	Technology Workshops			
9:50 - 12:30	TRACK 1: Single-Use Applications	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
12:35-1:25	<i>Networking Luncheon</i>			
1:25-3:00	TRACK 1: Single-Use Applications	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
3:00	<i>Close of Conference – see you in 2020!</i>			


SYMPOSIUM 1: Microbial Production	SYMPOSIUM 2: Continuous and Intensified Bioprocessing	SYMPOSIUM 3: PAT and Advanced Process Control	SYMPOSIUM 4: Cell & Gene Therapy Bioprocessing
<p>This multi speaker symposium will focus on the latest developments and application of microbial based production (yeast and E. coli). Some of the topics to be addressed through case study examples include:</p> <ul style="list-style-type: none"> • New Technologies for Primary Recovery and Cell Harvesting • Downstream Processing in Microbial Production • Automation, Robotics and High Throughput Process Development • Developing a Roadmap to Perform Effective Scale Up in Microbial Manufacturing • Developing and Validating Process Monitoring and Control Technologies for Robust Monitoring of Microbial Production • Upstream Processing - Optimising Yield, Expression and Strain Development • Adapting New Technologies and Equipment for Large Scale Microbial Production 	<p>Improving Process Efficiency using Process Intensification & Continuous Processing Tony D'Amore, Vice President, Product Research and Development, <i>Sanofi Pasteur, Canada</i></p> <p>Prevention & Removal of Contamination in an Open Environment during Continuous Processing Raquel Orozco, Senior Bioprocess Engineer, <i>Boehringer Ingelheim, USA</i></p> <p>Improving Fed-Batch using Process Intensification Ruchika Bandekar, Associate Scientist II, <i>MedImmune, UK</i></p> <p>CASE STUDY: USP Intensified Perfusion & DSP Purification Application: Round Table: TABLE 1: Intensified Perfusion: Improving the Basics, A Case Study Daisie Ogawa, Engineer II, Bioprocess Engineering, <i>Boehringer Ingelheim, USA</i></p> <p>TABLE 2: Robust Units, Constant Product Mass Flow and How Alternative Purification Methods Can Achieve Both for Antibody Production Peter Satzer, PhD, Department of Biotechnology, <i>University of Natural Resources and Life Science, Vienna</i></p> <p>Introduction to Novel Modalities & Continuous Bioprocessing: A Look at Antibody Drug Conjugates Daniel Milano, Scientist I, <i>Immunogen, USA</i></p> <p>Design of a Custom Continuous Process for Vaccine Formulations Kirsten Strahlendorf, Senior Scientist, BioProcess Research and Development/Formulation and Stability, <i>Sanofi Pasteur, Canada</i></p> <p>Hybrid Approach versus Fully Continuous Michael Sokolov, COO, <i>DataHow, ETH, Zurich</i></p> <p>PAT & The Roadmap to IPC & RTRT for Continuous Biomanufacturing Richard Wu, Principal Scientist, Process Analytics, <i>Amgen, USA</i></p> <p>Upgrading Small Scale to Commercial Manufacturing Aleksandar Cvetkovic, Head of Continuous Manufacturing Skill Center, <i>Sanofi, USA</i></p>	<p>Landscape of PAT Technologies A Representative, <i>Boehringer Ingelheim, USA</i></p> <p>Requirements of Automation in Analytics: A Big Biopharma Perspective A Representative, <i>Regeneron, USA</i></p> <p>ROUND TABLE: The Chemometrics of PAT & Avoiding Excel Hell TABLE 1: Update on Computer Software Techniques & Data Handling Elliott Schmitt, Scientist II, Analytical Development, <i>Biogen, USA</i></p> <p>TABLE 2: Streamlining Analytics in a Time Saving Manner Betty Tso, Cell Culture & Upstream Engineer, <i>Bayer, USA</i></p> <p>Process Control Strategies and Describing the Critical Parameters for Product Quality When Making mAbs Udayanath Aich, Principal Scientist, <i>Sanofi, USA</i></p> <p>PAT & The Roadmap to IPC & RTRT for Continuous Biomanufacturing Richard Wu, Principal Scientist, Process Analytics, <i>Amgen, USA</i></p> <p>Unconfirmed Michael Sokolov, COO, <i>DataHow, ETH, Zurich</i></p>	<p>Challenges in the Manufacture, Release, and Distribution of Cell Therapy Products Prentice Curry, Senior Vice President, Quality and Compliance, <i>Kite Pharma, USA</i></p> <p>New Platforms for T cell Bioprocessing Shashi Murthy, Professor, Chemical Engineering, <i>Northeastern University, USA</i></p> <p>Strategies to Increase Cell Culture Productivity: Scaling Up hMSC Bioreactor Culture Katrina Adlerz, Scientist, Process Development, <i>RoosterBio, Inc., USA</i></p> <p>Adopting Various Manufacturing Closed Systems to Gene Modified T Cell Therapies Ali Mohamed, VP, CMC, <i>Immatic, USA</i></p> <p>Closed Systems/Automation Ohad Karnieli, CEO & CO-Founder, <i>ATVIO Biotech Ltd., Israel</i></p> <p>Session Wrap Up & End of Day Q&A</p>











4:30 **KEYNOTE ADDRESS: Fully Integrated Continuous Manufacturing v2.0 – Leveraging Lessons Learned and Technologies to Meet Evolving Biopharma Needs**

Jens Vogel, Ph.D., President & CEO, *Boehringer Ingelheim Fremont, Inc.*







MAIN CONFERENCE • Tuesday, March 12, 2019

7:00	<i>Registration & Coffee</i>					
Plenary Session						
8:00	Chairperson's Remarks					
8:05	Knowledge and Technology Management to Launch and Lifecycle Management Jerry Murry, Ph.D., Vice President, Amgen Operationalizing the Biotech Industry – Driving Us to the Future AbbVie					
9:15	<i>Networking Refreshment Break and Grand Opening of Poster & Exhibit Hall</i>					
	TRACK 1: Flexible & Smart Facilities	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond	TRACK 5: Viral Safety	TRACK 6: Novel Technologies
9:55	Chairperson's Remarks	Chairperson's Remarks		Chairperson's Remarks	Chairperson's Remarks	<i>Sponsored by:</i> 
10:00	Next Generation Biomanufacturing and Facility Implementation: Technical Advances in Manufacturing Technologies to Improve Process Productivity Parrish Galliher, Chief Technology Officer, Upstream, Founder, Xcellerex Inc., a GE Healthcare Life Sciences Company	KEYNOTE ADDRESS: Technology and Innovation for Commercial Manufacturing: Living at the Interface of Development and Manufacturing Paul Wu, Head of Upstream Development, Pharmaceuticals, Bayer		Next Generation Biomanufacturing and Facility Implementation: Technical Advances in Manufacturing Technologies to Improve Process Productivity Parrish Galliher, Chief Technology Officer, Upstream, Founder, Xcellerex Inc., a GE Healthcare Life Sciences Company	A Novel Dual Orthogonal Virus Inactivation in a Single Unit Operation In Antibody Production June Zou, Process Scientist, Pathogen Safety, Bayer Healthcare LLC, USA	
10:30	Improvements in Facility Design and Readiness for Diversity of Products Ken Hamilton, Director of Process Engineering, Genentech	Early Stage Process Development And Interfacing With Late Stage Aaron Chen, Principal Scientist, Seattle Genetics, USA		Improvements in Facility Design and Readiness for Diversity of Products Ken Hamilton, Director of Process Engineering, Genentech	Effective Inactivation of a Wide Range of Viruses by Pasteurisation Michael Burdick, Senior Director, Global Pathogen Safety Support, CSL Behring, USA	
11:00	Transformation of CAR-T Manufacturing Through Use of Closed-Processing, Process Automation and Strategic Raw Material Configuration Randy Schweickart, MS, Director of Engineering, Juno Therapeutics, Inc.	Developing Phase 1 Process with Line of Sight to Commercial Sigma Mostafa, Ph.D., Vice President, Process Development, KBI Biopharma		Transformation of CAR-T Manufacturing Through Use of Closed-Processing, Process Automation and Strategic Raw Material Configuration Randy Schweickart, MS, Director of Engineering, Juno Therapeutics, Inc.	Virus Barrier Filtration – Eli Lilly Case Study Sean O'Donnell, Principal Research Scientist, Eli Lilly & Company, USA	
11:30	THOUGHT LEADERS DISCUSSION: Multiproduct Facilities Review – Evaluating Costs of Goods and Practicalities of Implementation Panelist: Adam Goldstein, Principal Scientist, Global Manufacturing Sciences, Roche	PANEL DISCUSSION: Can We Achieve Single-Phase Process Development? What Will it Take? Moderator: Nikki Nogal, Ph.D., Senior Biologics Development Consultant, Latham Biopharm Group		THOUGHT LEADERS DISCUSSION: Multiproduct Facilities Review – Evaluating Costs of Goods and Practicalities of Implementation Panelist: Adam Goldstein, Principal Scientist, Global Manufacturing Sciences, Roche	The Use of Detergents in Viral Inactivation – Case Study on a Patented ECO Alternative Alexis Henry, Senior Associate Scientist, Biogen, USA	





MAIN CONFERENCE • Tuesday, March 12, 2019

12:00	Concurrent Technology Workshop <i>Sponsored by:</i> 				
12:30	Lunch n Learn Presentations <i>(limited seating available)</i> <i>Sponsored by:</i>  				
12:30	Networking Lunch in the Poster & Exhibit Hall				
	TRACK 1: Flexible & Smart Facilities	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond	TRACK 5: Viral Safety
1:40	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks
1:45	Modular Platform Delivery Considerations for Today's New Drug Production Facilities: Case Studies from Recent Design Competitions Peter Cramer , Vice President Life Science Facility Design, Exyte U.S., Inc	CASE STUDY: Developing Early Stage Platforms to Accelerate Speed to Market Qinghai Zhao , VP of Technical Development and Manufacturing, FortySeven Inc.	Registration Enabling Campaign for Accelerated Development Jessica Wu , Ph.D. Senior Engineer, Late Stage Cell Culture, Genentech	How to Shorten Launch Timelines for New Products Jody Logan , Associate Director of Tech Transfer, Genentech	Hepatitis A/E Case study Barry Gooch , Associate Director of Pathogen Safety NC, Bioscience Industrial Group R&D, Grifols, USA
2:15	Plug and Play Automation for Single Use Equipment Eugene Tung , Executive Director of Manufacturing IT, Merck MSD	PANEL DISCUSSION: Strategies to Increase Speed from DNA to IND	High Speed Late Stage Development to Support Accelerated Launch of Products Presenter to be Determined	Managing Lifecycle of a Break Through Therapy Designated Product Gargi Maheshwari , Ph.D., Executive Director, Biologics Process Development & Commercialization, Merck & Co.	Pathogen Safety Considerations During ATMP Product Development Mark Plavsic , Chief Technology Officer and Head of Nonclinical Safety, LYSOGENE, USA <i>(pending final confirmation)</i>
2:50	Scientific Track Presentation <i>Sponsored by:</i> 	Scientific Track Presentation <i>Sponsored by:</i> 	Scientific Track Presentation <i>Sponsored by:</i> 	Scientific Track Presentation <i>Sponsored by:</i> 	Scientific Track Presentation <i>Sponsored by:</i> 
3:20	Networking Refreshment Break in the Poster and Exhibit Hall				
4:00	Implementation of PAT and Digital Tools for Real-Time Process Monitoring and Quality Control Gary Li , Pr. Scientist in Core Technology, Amgen, USA	Early Development Assessment Strategies to Predict Successful Molecules: A Case Study on Developability Assessment of Bispecific Molecules Duc M. Nguyen , Group Head, Novartis Institute for Biomedical Research, USA	Title TBC Dharmesh Kanani , Sr Scientist, Downstream Development & Operation, TEVA Pharm, USA	Life After Launch – Factors to Consider when Navigating Post-Approval Process Optimization Nathan McKnight , Ph.D., Associate Director, Genentech	Title TBC Dharmesh Kanani , Sr Scientist, Downstream Development & Operation, TEVA Pharm, USA
4:30	Data at Your Fingertips: The Benefits of an Integrated Informatics System Carly Cox , Process Informatics Manager, Global Engineering, Pfizer	Early Stage Molecule and Candidate Selection Strategies	Viral Clearance Validation Across Continuous Capture Chromatography Srinivas Chollangi , Manager, Bristol-Myers Squibb, USA	Data at Your Fingertips: The Benefits of an Integrated Informatics System Carly Cox , Process Informatics Manager, Global Engineering, Pfizer	Viral Clearance Validation Across Continuous Capture Chromatography Srinivas Chollangi , Manager, Bristol-Myers Squibb, USA
5:00	Update on BPOG Technology Roadmap Workstream on Knowledge Management Bert Frohlich , Ph.D., Principal and Owner, Biopharm Designs, LLC	Manufacturing Assessment Strategies and Integration at the Interface of R&D and Early Stage Process Development	Demonstrating Viral Clearance for a Novel Approach to Continuous Viral Filtration Tarl Vetter , Senior Scientist, Sanofi, USA	Update on BPOG Technology Roadmap Workstream on Knowledge Management Bert Frohlich , Ph.D., Principal and Owner, Biopharm Designs, LLC	Viral Clearance for a Novel Approach to Continuous Viral Filtration Tarl Vetter , Senior Scientist, Sanofi, USA
5:30	Networking Reception in the Poster and Exhibit Hall				

MAIN CONFERENCE · Wednesday, March 13, 2019

7:15	Technology Workshop with Light Continental Breakfast Sponsored by:  REPLIGEN INSPIRING ADVANCES IN BIOPROCESSING				
Plenary Session					
8:00	Chairperson's Remarks				
8:05	Digitalization Rahul Singhvi, Ph.D., Chief Operating Officer, Takeda Vaccines, Inc.				
9:15	<i>Networking Refreshment Break in the Poster & Exhibit Hall</i>				
	TRACK 1: BioProcessing 4.0	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond	TRACK 5: Viral Safety
9:55	Chairperson's Remarks	Chairperson's Remarks		Chairperson's Remarks	Chairperson's Remarks
10:00	Featured Presentation: Digital Transformation to Advance Next-Generation Biomanufacturing through Data Integration and Analytics Tom Mistretta, Director, Data Science, Amgen	Early Stage Perfusion Process Development Of A mAb Using GS-CHO Cell Line Rajesh Beri, Technical Director Biomanufacturing, Research and Technology, Lonza Biologics, USA		Featured Presentation: Digital Transformation to Advance Next-Generation Biomanufacturing through Data Integration and Analytics Tom Mistretta, Director, Data Science, Amgen	Ask the Regulators – Regulatory Breakfast Briefing Arifa Khan, Supervisory Microbiologist, CBER, U.S. Food and Drug Administration, USA (pending final confirmation)
10:30	Case Studies from the Pathway to Industry 4.0 Paul Hanson, Director, Technical Operations, Takeda Pharmaceuticals, USA	Integrated Bioprocess from Harvest to Purified Bulk in 6 Hours Ping Y. Huang, Head of Drug Substance Bioprocess, AbbVie		Case Studies from the Pathway to Industry 4.0 Paul Hanson, Director, Technical Operations, Takeda Pharmaceuticals, USA	
11:00	Industry 4.0 and Continuous Biopharmaceutical Manufacturing Samet Yildirim, MS, PSM, Manager, Technology & Innovation, Global Technology Management, Boehringer Ingelheim Fremont, Inc	Featured Presentation - Development of an Automated, on Demand Buffer Preparation System – A Technology Journey from Inception to Implementation to Widespread Adoption Natraj Ram, Ph.D., Associate Director, Purification, Manufacturing Sciences, AbbVie		Industry 4.0 and Continuous Biopharmaceutical Manufacturing Samet Yildirim, MS, PSM, Manager, Technology & Innovation, Global Technology Management, Boehringer Ingelheim Fremont, Inc	
11:30	Concurrent Technology Workshops Sponsored by:  BD   IrvineScientific  DYADIC II				
12:00	Lunch n Learn Presentation (limited seating available) Sponsored by: 				
12:00	<i>Networking Lunch in the Poster & Exhibit Hall</i>				

MAIN CONFERENCE · Wednesday, March 13, 2019

	TRACK 1: BioProcessing 4.0	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond	TRACK 5: Viral Safety
1:10	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks
1:15	Online Cell Culture Titer/Capture Load Density Monitoring and Control Joe Sexton, Senior Technical Specialist, Genentech, USA	Managing Process Characterization and Validation on a Breakthrough Therapy Program Michael Glacken, Ph.D., Senior Consultant, BPTC Joan Connolly, Senior Vice President, Technical Operations, Stemline Therapeutics	Online Cell Culture Titer/Capture Load Density Monitoring and Control Joe Sexton, Senior Technical Specialist, Genentech, USA	Case Study: Next Generations Sequencing and Adventitious Virus Detection Cassandra Braxton, Senior Manager, Global Quality Control Virology, Biogen, USA	
1:45	Real-Time Monitoring for Process Trending Kostantinos Spetsieris, Ph.D., Process Analysis and Optimization Group Head, Bayer	Translating Scale Down Models to Scale Up Success: Designing Predictive Scale Down Models Parviz Shamlou, Professor, Director of Amgen Bioprocessing Center, Keck Graduate Institute	How Timeline Compression for Breakthrough Therapies Impact Characterization and Validation Niket Bubna, Upstream Group Leader, KBI	Real-Time Monitoring for Process Trending Kostantinos Spetsieris, Ph.D., Process Analysis and Optimization Group Head, Bayer	2nd Generation Reference Materials for Adventitious Virus Detection by Deep Sequencing Edward Mee, Senior Scientist, Live Viral Vaccines Group, National Institute for Biological Standards and Control, UK
2:15	Real Time Process Analytics Implementation and Establishing Process Monitoring Programmes Richard Wu, Principal Scientist / Process Analytics, Amgen, USA	Automation and Digitalization in Upstream Process Development: Embedding Advanced Microscale Bioreactors (ambr) In An Efficient Sample And Data Workflow Timo Frensing, Senior Scientist, Large Molecule Research, Roche Pharma Research and Early Development, Roche Diagnostics GmbH, Germany	Approach to Determining CQAs Zhimei Du, Ph.D., Director, Bioprocess Development, Merck	Real Time Process Analytics Implementation and Establishing Process Monitoring Programmes Richard Wu, Principal Scientist / Process Analytics, Amgen, USA	Plant-derived Raw Material Control for adventitious virus in cell banking and biologics production Serge Monpoeho, Senior Director & Chief Virologist, Regeneron, USA
2:45	Scientific Track Presentation Sponsored by:  PALL Biotech	Scientific Track Presentation Sponsored by: 	Scientific Track Presentation Sponsored by:  ThermoFisher Scientific	Scientific Track Presentation Sponsored by:  Millipore Sigma	Scientific Track Presentation Opportunity Available
3:15	<i>Networking Refreshment Break in the Poster & Exhibit Hall</i>				
4:00	DIY Digital Transformation, Design and Development Thibault Dutronc, Associate Scientist, Merck Serono SA, Switzerland	Novel Cell Line Screening and Clone Selection Technologies for Faster, More Predictive Identification of High Quality Producers Yang Ou, Postdoctoral Fellow, Merck, USA	A First-Principles Approach to Cleaning Validation: Rational Acceptance Limits for Biopharmaceutical Process Residues Rizwan Shamez, B. Tech., M.S., Ph.D., Scientific Director, Process Development, Amgen Inc.	DIY Digital Transformation, Design and Development Thibault Dutronc, Associate Scientist, Merck Serono SA, Switzerland	
4:30	Big Data to Smart Data – Feedback from the BioPhorum Automated Facility Workstream Bob Lenich, Life Sciences Business Director, Emerson Automation Solutions / BioPhorum Automated Facility Workstream, USA	Assuring and Proving Monoclonality	How to Achieve Tech Transfer Goals? What are the Timelines? How to Overcome the Bottlenecks? Padmadhar Madupu, Technical Manager, Pfizer	Big Data to Smart Data – Feedback from the BioPhorum Automated Facility Workstream Bob Lenich, Life Sciences Business Director, Emerson Automation Solutions / BioPhorum Automated Facility Workstream, USA	
5:00	THOUGHT LEADERS DISCUSSION: Strategies for Aligning Industry 4.0 and a Smart Manufacturing Vision with Biopharma	New Tools and Technologies to Enhance Cell Line Development: A Case Study from Pfizer A Representative from Pfizer	Lessons from Back-to-Back Technology Transfers from an Established DS Manufacturing Production Site to a Non-Licensed Facility Lisa Day, Engineer, Process Engineering, Genentech	THOUGHT LEADERS DISCUSSION: Strategies for Aligning Industry 4.0 and a Smart Manufacturing Vision with Biopharma	

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	TRACK 1: Single-Use Applications	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
7:15	Technology Workshops with Light Continental Breakfast			
8:00	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks
8:15	Evaluation, Implementation, and Process Scale-up to a 2000 L Single Use Bioreactor System Jesse Knaub, Process Scientist, Upstream Operations, Biopharmaceutical Development, Pharmaceutical Science and Technology, Eisai Inc.	Utilising Process Modelling and Advanced Analytics in Early Process Development	Development Perspectives – Implementation of New Techniques/Technologies Katherine Chaloupka, Amgen	
8:45	Addressing Sustainability and Environmental Impacts of Single Use Systems	Implementation of Advanced Analytical Methods in Early Stage Process Development	Cell Culture Manufacturing Continuous Process Improvement: Enhancing the Control Capability of Product Quality Attributes for Marketed Biopharmaceutical Product Lifecycle Ting-Kuo Huang, Ph.D., Senior Engineer, Manufacturing Science and Technology, Genentech	
9:20	Concurrent Technology Workshops			
9:50	<i>Networking Refreshment Break in the Poster and Exhibit Hall</i>			
10:25	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks
10:30	Design and Implementation of Robust, Reliable, Real Time Sensor Technologies for Disposable Manufacturing	Cell Culture Media Development and Feed Optimisation to Enhance Product Quality and Productivity	How These Improvements Impacted Quality and Comparability Amanda Ashcraft, Manager, Process Engineering Development, Manufacturing Technical Support, Sanofi	
11:00	Quality Control of Single Use Systems to Ensure Supply Chain Security	A User Requirement Specification for new Harvest Clarification technology for High Density Cell Cultures A Representative, BPOG Technology Roadmapping Harvest Clarification Workstream	Panel Discussion: Interdisciplinary Perspectives on Maximizing the Interplay Between Late Stage and Commercial Manufacturing <i>Moderator:</i> Natraj Ram, Ph.D., Associate Director, Purification, Manufacturing Sciences, AbbVie	
11:35	Sponsored Scientific Track Presentations			
12:05	<i>Networking Luncheon in the Exhibit & Poster Hall</i>			

MAIN CONFERENCE • Thursday, March 14, 2019

	TRACK 1: Single-Use Applications	TRACK 2: Early Stage Process Development	TRACK 3: Late Stage Process Development	TRACK 4: Commercial Manufacturing & Beyond
1:25	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks	Chairperson's Remarks
1:30	Internal Alignment of Standards and Best Practices Enabling Rapid Low-Cost Deployment of Single Use Jeffrey Johnson, New Technology Lead and Director, Global Engineering Solutions, Merck & Co., Inc.	Upstream Strategies to Address Process & Quality Challenges Associated with Molecules of New Modality Ravindra Pangule, Associate Principal Scientist, Merck & Co., Inc., USA	Achieving Next Level Technologies – Leveraging Community and Collaborative Efforts Between End Users and Technology Providers to Develop Them This session will contain a series of presentations and discussions highlighting the latest approaches to develop and implement disruptive technologies within the bioprocessing industry.	Internal Alignment of Standards and Best Practices Enabling Rapid Low-Cost Deployment of Single Use Jeffrey Johnson, New Technology Lead and Director, Global Engineering Solutions, Merck & Co., Inc.
2:00	Alternative Materials and Construction to Compete with Existing Stainless Steel Technologies – What's Out There? What are the Challenges? What's the ROI for Each? Adam Goldstein, Principal Scientist, Global Manufacturing Sciences, Roche	Overcoming the Issues Observed With Early Stage Production Of Glycoproteins Troy Mcsherry, Senior Research Scientist, Abbott Laboratories, USA		Alternative Materials and Construction to Compete with Existing Stainless Steel Technologies – What's Out There? What are the Challenges? What's the ROI for Each? Adam Goldstein, Principal Scientist, Global Manufacturing Sciences, Roche
2:30	Single Use Systems Integration in Existing Commercial Manufacturing Facilities Presenter to be determined	Developing A Robust Downstream Process For Early Phase ADC Manufacturing Under Tight Timelines Chi Zhang, Scientist, Ambrx, USA		Single Use Systems Integration in Existing Commercial Manufacturing Facilities Presenter to be determined
3:00	<i>Conference Recap, Closing Remarks and Look Ahead to BPI West 2020</i>			

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Presentation Sponsors: **AsahiKASEI**
BIOPROCESS



Exhibitors (as of October 19, 2018)

Aber Instruments Ltd	Levitronix
ABL	LEWA Nikkiso America
AGC Biologics	Lonza
ANGUS Life Sciences	MabPlex
Aragen Bioscience	MaxCyte, Inc.
Asahi Kasei Bioprocess	Meissner Filtration Products
Avid Bioservices	Millipore Sigma
BASF	NOVA Biomedical
BD Bioscience	Novo Nordisk Pharmatech
Beckman Coulter Life Sciences	O3 Sterilization Systems
Bionova Scientific	Pall Life Sciences
Bio-Rad Laboratories	Parker Domnick Hunter Process Filtration
BioTech Logic	PendoTech
Boehringer Ingelheim	PerkinElmer
Broadley James Corp	Pneumatic Scale Angelus
Canopy Biosciences	Premas Biotech
Charles River	ProMetic BioSciences
CPC	Qosina
Cygnus Technologies, LLC	Rentschler Biopharma SE
Cytovance	Repligen
Distek, Inc.	Roche Diagnostics
DPL-US	Saint-Gobain
Eppendorf	Sartorius Stedim Biotech
Farrar Scientific	Shimadzu Scientific Instruments
ForteBio	Spectrum Chemical
FrieslandCampina Ingredients	Texcell
Fujifilm Diosynth Biotechnologies	Thermo Fisher Scientific
Gyros Protein Technologies	Tosoh Bioscience
Hamilton	Vanrx Pharmsystems
Irvine Scientific	VR Analytical
JNC Cellufine	Watson-Marlow Fluid Technology Group
JSR Life Sciences	YSI
Kaneka	
KBI Biopharma	
Kühner Shaker	

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