

# 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  
**SANOPI 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](http://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	<i>Symposium #1: Continuous Processing: Early and Late Stage Process Development</i>	<i>Symposium #2: Innovations Leading to Simplification, Cost Reduction, and Cost-Modeling</i>	<i>Symposium #3: Introduction and Innovations in Cell &amp; Gene Therapies</i>	(9:00am - 4:00pm) <i>Workshop and Site Tour: DOE using Mixed Mode Chromatography Resins Sponsored by Bio-Rad Laboratories (Free-to-attend; conference registration is not required)</i>
5:05 - 5:30	<b>Process Development and Manufacturing of Autologous Cell Therapy Products</b> Vijay Chiruvolu, Ph.D., VP Process Science and Engineering, Kite Pharmaceuticals			
5:45 - 7:00	<i>Speed Networking Event – Sponsored by BD Biosciences</i>			

## 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	<b>Accelerating Development and Innovation: Advances &amp; Challenges in Vaccine Development</b> Tony D'Amore, Ph.D., Vice President, Sanofi <b>Application of Frontier Science: Lessons from Implementation of Next Generation Manufacturing at Amgen's Singapore Facility</b> Christopher Crowell, PhD, Executive Director, Global Operations, Amgen Inc.			
9:15-9:55	<i>Networking Refreshment Break in the Poster and Exhibit Hall</i>			
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	<i>Luncheon Presentation Sponsored by Sartorius</i>			
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	<i>Technology Workshops Sponsored by Cytovance, GE Healthcare, Pall ForteBio, Patheon, and Riffyn</i>			
3:20-4:00	<i>Networking Refreshment Break in Poster &amp; Exhibit Hall</i>			
4:00-5:30	Facility Design and Challenges	Technology and Innovation	Technology and Innovation	Process Validation
5:30-6:45	<i>Networking Reception in the Poster and Exhibit Hall co-sponsored by GE Healthcare</i>			

## 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	<b>Redefining Competition – Thinking About Our Industry in a Revolutionary Way</b> Kimball Hall, Senior Vice President and Head of Drug Substance Manufacturing, Pharma Technical Operations, Genentech, Inc. <b>Post Approval Changes in Biotechnology Products: Navigate through Regulatory Requirements</b> Arulvathani Arudchandran, Ph.D., Product Quality Reviewer, Microbiologist, FDA-CDE			
9:15-9:55	<i>Networking Refreshment Break in Poster &amp; Exhibit Hall</i>			
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	<i>Networking Luncheon in the Poster &amp; Exhibit Hall</i>			
	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	<i>Technology Workshops Sponsored by Asahi Kasei Bioprocess, GE Healthcare, Irvine Scientific, and Repligen</i>			
2:55-3:45	<i>Final Networking Refreshment Break in the Poster and Exhibit Hall</i>			
3:45-5:15	Analytics and Models for Bioprocessing	Non-Platform Molecules	Raw Materials	Platform
5:30-6:30	<i>Networking Reception at CityScape – Hilton 46th Floor</i>			

## Thursday, March 22, 2018 • Main Conference

	Single-Use	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
8:40-9:10	<b>Achieving Efficiency through a Comprehensive Approach to Facility Organization and Process Design</b> Jason Bock, PhD, Vice President, Biologics CMC, Teva Pharmaceuticals <b>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</b> Sara Radcliffe, President and CEO, California Life Sciences Association (CLSA)			
9:15-9:40	<i>Networking Refreshment Break in Poster &amp; Exhibit Hall</i>			
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	<i>Networking Luncheon</i>			
1:25-2:30	Case Studies and Innovations	Interface between Early Stage and Late Stage		Beyond the Plant
2:30	<i>Close of Conference – see you in 2019!</i>			

Register by March 2 and Save \$200 off the standard rate! [www.BioProcessWest.com](http://www.BioProcessWest.com)

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 Continuous 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:** 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, Ph.D., Associate Professor, 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



**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](http://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](mailto: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...










# MAIN CONFERENCE • Tuesday, March 20, 2018

	Flexible & Smart Facilities	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
7:00	<i>Registration &amp; Coffee</i>			
8:00	<b>Chairperson's Remarks</b>			
8:05	<b>Accelerating Development and Innovation: Advances &amp; Challenges in Vaccine Development</b> Tony D'Amore, Ph.D., Vice President, Sanofi			
8:40	<b>Application of Frontier Science – Lessons from Implementation of Next Generation Manufacturing at Amgen's Singapore Facility</b> Christopher Crowell, PhD, Executive Director, Global Operations, Amgen Inc.			
9:15	<i>Networking Refreshment Break and Grand Opening of Poster &amp; Exhibit Hall</i>			
9:55	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b>
	<b>Flexible and Smart Facilities</b>	<b>Molecule Selection and Manufacturability</b>	<b>Optimizing Timelines</b>	<b>Continuous Production</b>
10:00	<b>Keynote Address: Future Facility Design Considerations with Single Use Based on Prior Experience</b> Ken Green, Ph.D., Head of Manufacturing Science and Technology, Shire	<b>Improve Manufacturability: Evaluating and Mitigating Manufacturing Issues</b> Sujeewa Wijesuriya, Ph.D., formerly Associate Director, XOMA	<b>The Evolution of the Global Technology Roadmap: Latest developments from BPOG</b> Reed Harris, Senior Staff Scientist, Technical Development, Genentech, a member of the Roche group	<b>Commercial Capacity Planning and Forecasting for Low-cost bnAb Manufacturing for Sub-Saharan Africa Using Flexible Facilities</b> Fernando Garcia, Ph.D., Process Engineer/Data Scientist, Just Biotherapeutics Inc.
10:30	<b>Innovation in Bio-Manufacturing: Disposables, Ballroom Plants and Continuous Processing</b> Berthold Boedeker, Ph.D., Chief Scientist, Bayer AG	<b>Structure vs. Function: In-Vivo and In-Vitro Modification of N-Linked Glycosylation on Monoclonal Antibody Based Therapeutics</b> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Yekaterina Lin, Ph.D., Senior Scientist II, Abbvie	<b>From Here to There: Technology Transfer and Improving Timelines</b> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Javier Femenia, Ph.D., Principal Scientist, Cell Culture Process Development, BioMarin Pharmaceutical, Inc.	<b>Commercialization of an Integrated Continuous Biomanufacturing Process</b> Franqui Jimenez, Ph.D., Senior Director of Manufacturing Science and Technology, Sanofi Genzyme
<b>Scientific Sponsored Track Presentations</b>				
11:00	<b>Producing More With Less – A Look at Total Cost of Ownership Using a Standardized Approach to Single-Use Technology Implementation</b> Sara Bell, Senior Marketing Manager, Single-Use Technologies, MilliporeSigma	<b>Presentation Title Coming Soon</b> MaxCyte	<b>Expertise in Vaccine Process Development Leads to Successful Clinical Trials</b> David E. Clements, MD, Director of Vaccine Research, Hawaii Biotech	<b>Presentation Title Coming Soon</b>
	<b>Flexible and Smart Facilities</b>	<b>Speed to IND</b>	<b>Process Characterization Case Studies (Upstream and Downstream)</b>	<b>Overcoming Challenges of High Concentration Formulations</b>
11:30	<b>Next Generation Biomanufacturing</b> <span style="background-color: #000080; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Derek Ung, Senior Process Engineer, CRB Peter Walters, Process Engineer, CRB	<b>Gene to GMP in 9 Months Through Use of High Throughput Technologies</b> Sigma Mostafa, Ph.D., Vice President, KBI Biopharma Inc.	<b>At-Line In-Process Titer Determination Using Variable Pathlength Spectrophotometry to Eliminate HPLC Hold Step</b> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Joe Sexton, Senior Technical Specialist, Genentech	<b>Evaluation of the Technology Landscape for Development of a High Concentrated mAb Formulation</b> Radhakrishna (RK) Maraju, Senior Scientist, Teva Pharmaceuticals
12:00	<b>Evolving Role of the Process Architect: Case Studies Using a Modular Delivery Approach</b> <span style="background-color: #000080; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Peter Cramer, Vice President, Life Sciences Facility Design, M+W Group	<b>Development of a Scalable Platform for Protease Triggered Immuno-oncologic Activators</b> Ulrich Ernst, Ph.D., COO, Senior Vice President, Amunix	<b>Mechanisms of Monoclonal Antibody Low Molecular Weight (LWM) Formation and Strategies of Mitigation in Bioprocessing</b> <span style="background-color: #000080; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Yuanli Song, Ph.D., Scientist II, Bristol-Myers Squibb	<b>Challenges in Development of a High Concentration Liquid Formulation for mAb process</b> <span style="background-color: #000080; color: white; padding: 2px;">CASE STUDY</span> Daniel Chen, Scientist, Protein Science, Boehringer Ingelheim
12:30	<b>LUNCHEON PRESENTATION AND PANEL DISCUSSION: Implementation Process Intensification in Commercial Manufacturing: Drivers &amp; Challenges</b> <i>(seating is limited)</i> sponsored by 	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 Stedim Biotech Fritjof Linz, VP Purification, Sartorius Stedim Biotech Anna Persson, Senior Principal Data Scientist, Sartorius Stedim Biotech	
12:30	<i>Networking Lunch in the Poster &amp; Exhibit Hall</i>			







# MAIN CONFERENCE • Tuesday, March 20, 2018

	Flexible & Smart Facilities	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
1:40	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b> Camilla Oxley, Ph.D., Scientist, Process Development and Manufacturing Sciences, API-LM, Janssen	<b>Chairperson's Remarks</b> Shawn Liu, Ph.D., Chief Scientist & Department Head, Bayer Healthcare LLC	<b>Chairperson's Remarks</b>
	Facility Design and Challenges	Case Studies in Cell Line Development	Process Characterization Case Studies (Upstream and Downstream)	Process Validation
1:45	<b>Evolution of a Flexible Development Facility to Accommodate the Increasingly Fast-Paced Pharmaceutical Landscape</b> Paul Ko, Ph.D., Senior Scientist, Cell Technologies, API Large Molecule, Janssen R&D	<b>Industry Perspectives and Case Studies towards Demonstration of Monoclonality for Biologics Manufacture Development</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> Amie Lundquist, Senior Development Specialist II, Shire & BPOG	<b>In-Process Pool Mixing: Impact on Product Quality and Process Performance</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Jim Keba, Engineer II, Genentech	<b>Relevance of a Risk-Based Approach in the Successful Commercialization of a Monoclonal Antibody</b> Marlene Castro-Melchor, Ph.D., Senior Engineer, Genentech
2:15	<b>The Art of the Possible: How You Convert a Human Process into a Machine Process</b>	<b>Methods to Verify a Clonal Cell Origin</b> Amritha Menon, Associate Scientist, Gilead Sciences	<b>Case Study: Determine CQAs for a Late Stage Complex Fusion Protein</b> Johnson Varghese, Ph.D., Celgene	<b>Analytical Approach for Implementation of Visual Inspection</b> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Mariann Neverovitch, MS Pharmacy, Research Scientist, Bristol-Myers Squibb
<b>Concurrent Technology Workshops</b>				
2:50	<b>Process Characterization – A Road Map to Enhance Process Understanding</b> Eliza Yeung, PhD, Strategic Projects Manager & PC Study Directory, R&D, Cytovance Biologics  <b>Start with the End in Mind: New Solutions for High Capacity mAb Capture and Efficient Transition to GMP Environment</b> Avril Vermunt, Bioprocess Hardware Specialist, GE Healthcare	<span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span>  	<b>Process Development: The Key to a Successful Biomanufacturing Strategy</b> Brad Johnson, Ph.D, Manager, Purification Development, Patheon  <b>Laboratory Data to Machine Learning in 30 Seconds</b> Tim Gardner, PhD, Founder and CEO, Riffyn  <b>High Throughput BLI Potency Assay for Screening of Product Degradation by Industrial Cleaning Solutions</b> Jonathan Crane, PhD, Senior Development Scientist, AGC Biologics	  
3:20	<i>Networking Refreshment Break in the Poster and Exhibit Hall</i>			
	Facility Design and Challenges	Technology and Innovation	Technology and Innovation	Process Validation
4:00	<b>Modular Doesn't Necessarily Mean Flexible</b> Dennise Powers, Director of Sales Engineering, G-CON Manufacturing	<b>Integration of Automation Technologies for Efficient Stable Cell Line Generations from Transfection to GMP Clone for Viral Antigens</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Naga Chalamalasetty, Scientist, NIAID, NIH, Vaccine Research Center	<b>Manufacturing Incytes: Leveraging Online Biomass Probes for Robust Seed Train Performance</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> C. Eric Hodgman, Ph.D., Engineer II, Bristol-Myers Squibb	<b>Challenges in Developing a Representative Scale-Down Model</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Shyamsundar Subramanian, Ph.D., MS, MSc, Director, Teva Pharmaceuticals
4:30	<b>A Suite-Focused Flexible Facility Design for Biologics Production</b> Sue Behrens, Ph.D., Sr. Director, Process Design, IPS-Integrated Project Solutions	<b>Technology Toolboxes and Modeling Approaches to Expedite Process Development</b> Natraj Ram, Ph.D., Associate Director, Purification, Manufacturing Sciences, AbbVie	<b>Hydrogen Deuterium Exchange Mass Spectrometry (HDX-MS) for Formulation and Process Optimization of Lyophilized Protein Formulations</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Lokesh Kumar, Ph.D., Associate Scientist, Genentech	<b>Pharma Quality System and Validation Best Practices</b> Hamid Mollah, Ph.D., Principal Engineer, Genentech
5:00	<b>Lessons Learned From a Retrofit Manufacturing Facility</b>	<b>Developing a Better Understanding of the Interactions Between New ADC Payloads and Antibody Post Conjugation</b> Scott Hilderband, Ph.D., Senior Scientist, ImmunoGen, Inc.	<b>Progress Towards Continuous Upstream Process Monitoring Using Raman Spectroscopy</b> Nobel Vale, Research Scientist II, Bristol-Myers Squibb	<b>Process Validation and Regulatory Approval Strategies Required for Drugs That Have Been Designated Fast-Track</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> Tracy TreDenick, Head of Regulatory and Quality Assurance and Founding Partner, BioTech Logic
5:30	<i>Networking Reception in Poster &amp; Exhibit Hall</i>			

# MAIN CONFERENCE · Wednesday, March 21, 2018





## Plenary Session

7:30	Registration & Coffee			
8:00	Chairperson's Opening Remarks			
8:05	<b>Redefining Competition – Thinking about our Industry in a Revolutionary Way</b> Kimball Hall, Senior Vice President and Head of Drug Substance Manufacturing, Pharma Technical Operations, Genentech, Inc.			
8:40	<b>Post Approval Changes in Biotechnology Products: Navigate through Regulatory Requirements</b> Arulvathani Arudchandran, Ph.D., Product Quality Reviewer, 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 <small>Sponsored by</small>  sartorius stedim biotech
9:55	Chairperson's Opening Remarks	<b>Chairperson's Opening Remarks</b> David Brindley, DPhil, Meng, FRSA, Managing Partner, Biolacuna & Senior Research Fellow, Nuf eld, Department of Paediatrics, University of Oxford	<b>Chairperson's Opening Remarks</b> Shawn Liu, Ph.D., Chief Scientist & Department Head, Bayer Healthcare LLC	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	<b>System Integration for a New Large-scale Manufacturing Facility</b>  Jordan Croteau, Sr. Engineer, Global Execution Systems, Biogen	<b>Comparison Between Fed-batch and Perfusion Cell Culture System</b>   Daryl Powers, Ph.D., Associate Director, Upstream Process Development, Sanofi	<b>Points to Consider in QC Method Validation and Transfer for Biological Products</b> Weijun Li, Ph.D., Senior Manager, Analytical Transfers & Special Projects, Bayer	<b>Development of 'ambr 250 perfusion' – A Novel Automated Single-Use Perfusion Mini-Bioreactor</b> Melisa Carpio, Field Marketing Manager, Fermentation Technologies, Sartorius Stedim North America Inc.	
10:30	<b>Using Protein Sequence Variant Analysis to De-risk Clinical Candidates at the Cell Line Selection Stage</b> Heather Oakes, Mass Spectrometry Lead Scientist, Lonza Pharma & Biotech	<b>Integrated Media Blending Increases Efficiency of Clone Selection</b>   David Bruehlmann, Ph.D., Manager, EMD Serono	<b>Tech Transfer from Late Stage to Commercial Launch</b> Padmadhar Madupu, MS, Technical Manager, Pfizer	<b>Gain Manufacturability Information for Downstream Processing Already During Your Candidate Selection</b> Marc Jenke, Senior Product Manager Crossflow Systems, Sartorius Stedim Biotech GmbH	
11:00	<b>Process Analytics to Control Variability</b>	<b>Cell Culture Media: an API or Ancillary Material?</b> David Brindley, DPhil, Meng, FRSA, Managing Partner, Biolacuna & Senior Research Fellow, Nuf eld, Department of Paediatrics, University of Oxford	<b>Tech Transfer Simplified with Model-Based Process Fit and Process Control</b> Steven Rose, MS, Director, BioProcess Engineering, MedImmune	<b>Development of a Process Monitoring System 0-60 in 9 Months</b> Jeffrey Simeone, Associate Director, Technical Services, Shire	
	<b>Scientific Sponsored Track Presentations</b>				
11:30	<b>On-demand Nutrient Feed During Automated Cell Culture Process: Integrating Eppendorf's Bioprocess System with Flownamics Segflow and Roche's Cedex Bio HT Systems</b> Robert Berish, Scientist, Zoetis	<b>A Molecule's Journey – Breaking Down Roadblocks to Commercial Success</b> Guillaume Plane, Global Development and Marketing Manager, MilliporeSigma	<b>Saturn™ and FlexFactory: Transforming an Existing Facility to Multi-Product Ballroom</b> Thomas Page, Ph.D., Vice President, Engineering and Asset Development, FUJIFILM Diosynth Biotechnologies		
12:00	Networking Luncheon in the Poster and Exhibit Hall				



# MAIN CONFERENCE · Wednesday, March 21, 2018

	Analytics and Models for Bioprocessing: Insights from Manufacturing	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
1:15	<b>Chairperson's Remarks</b> Eric Langer, Managing Partner, BioPlan Associates, Inc.	<b>Chairperson's Remarks</b> Ashley Hesslein, Ph.D., Associate Director, Bayer Healthcare LLC	<b>Chairperson's Remarks</b> Matthew Luther, Development Associate II, Late Stage Purification Development, Alexion	<b>Chairperson's Remarks</b> Tiffany Rau, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc.
	Process Monitoring	Cell Culture and Media	Viral Filtration	Case Studies: Scale-Up
1:20	<b>Next Generation Process Science, Beyond Proteins</b> Nick Timmins, Ph.D., Vice President, Process Sciences, BlueRock Therapeutics	<b>Cell-Controlled Hybrid Perfusion/ Fed-Batch Effectively Circumvents the Inherent Limitations of Fed-Batch</b> Ana Maria Ovalle, Senior Associate Scientist, Pfizer	<b>Two Decades of Exploration in Viral Filtration</b> Shawn Liu, Ph.D., Principal Scientist, Head of Dept., Bayer	<b>Case Study: Alleviating Downstream Bottlenecks to Accommodate Increased Titters of a Commercial mAb Process</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> Kimberly Fuller, Scientist, Bristol-Myers Squibb
1:50	<b>Monitoring and Controlling Viable Biomass in Bioprocesses Using Dielectric Spectroscopy for PAT Applications</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> Aditya Bhat, Ph.D., Director of Technology, Aber Instruments Inc.	<b>Overcome Challenges to Successful Development of Chemically-Defined Media through Manipulation of the TCA Cycle in CHO Cells</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #0000ff; color: white; padding: 2px;">NEW DATA</span> Le You, Ph.D., Scientist, Ambrx	<b>Mitigation of Risk of Viral Contamination of Media Using Upstream Barrier Method</b> <span style="background-color: #0000ff; color: white; padding: 2px;">NEW DATA</span> Kathryn Remington, Ph.D., Principal Scientist, BioReliance	<b>Process Validation Evaluation Criteria</b>
<b>Concurrent Technology Workshops</b>				
2:25	<b>OPUS® 80R cm column</b> Fletcher Malcolm, Director, Product Manager, Repligen  <b>A New Media Panel that Unlocks Your Cells' Potential</b> Jenny Bang, Manager, Research and Development, Irvine Scientific	 	<b>Planova™ Virus Filtration as a Highly Effective Robust Step in Viral Clearance</b> Esha Vyas, Field Applications Manager, Asahi Kasei Bioprocess America  <b>Pinpoint your Key Parameters for a Successful Perfusion Process</b> Helena Ohrvik, Ph.D., Scientist, R&D Bioprocess, GE Healthcare	 
2:55	<i>Final Networking Refreshment Break in the Poster and Exhibit Hall</i>			
	Analytics and Models for Bioprocessing: Insights from Process Development to Manufacturing	Non-Platform Molecules	Recovery and Purification	Selecting and Working with CMOs
3:45	<b>Data and Trends for Future SUS Bioprocessing: Is Single-Use Cost Effective</b> Eric Langer, Managing Partner, BioPlan Associates, Inc.	<b>Selectivity Analysis Cation-Exchange Chromatography on Protein Impurity Separation</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #0000ff; color: white; padding: 2px;">NEW DATA</span> Keith Selvitelli, Senior Associate Scientist, Process Biochemistry, Biogen	<b>Assessment of Clarification Options for High Density Cell Cultures</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #0000ff; color: white; padding: 2px;">NEW DATA</span> Kirk McLean, Senior Development Scientist, Bayer	<b>How to Select the "Right" CMO at Early Stage CMC Development</b> Qinghai Zhao, Ph.D., Vice President, FortySeven Inc.
4:15	<b>Analytical Data Trends Used in Making Process Decisions</b> Frank Agbogbo, PhD, Cytovance Biologics	<b>Challenges and Strategies of Downstream Processing for a Complex Bispecific Antibody</b> Ji Zheng, Ph.D., Associate Director, Celgene	<b>Challenges to Making a Ready to Fill Antisense Oligonucleotide (ASO) Formulation for Intrathecal Delivery</b> <span style="background-color: #0000ff; color: white; padding: 2px;">NEW DATA</span> Hien Nguyen, Associate Scientist III, Biogen	<b>Featured Panel Discussion: Cultivating a Better Working Relationship with Contract Manufacturing Organizations (CMOs)</b> 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	<b>Utilizing Simulation and Optimization Techniques to Evaluate Different CAR-T Cell Therapy Manufacturing Paradigms</b> Jon Gunther, Ph.D., Associate Director, Juno Therapeutics	<b>Non-platform Biologics Process Development and Technical Transfer for Early Clinical Phase API Production</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> Christopher Rode, Scientific Director, API-Large Molecule/Pharmaceutical Development Manufacturing Sciences, Janssen R&D	<b>Crystallization as a Tool for Scalable, Efficient Purification Techniques in Process Step for Purifying Recombinant Proteins</b> <span style="background-color: #ff0000; color: white; padding: 2px;">CASE STUDY</span> Partha Hazra, Ph.D., General Manager RND, Biocou Research Limited	
5:30	<i>Networking Reception at CityScape – Hilton 46th Floor</i>			

# MAIN CONFERENCE • Thursday, March 22, 2018

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

# MAIN CONFERENCE • Thursday, March 22, 2018

	Single-Use	Early Stage Process Development	Late Stage Process Development	Commercial Manufacturing
1:25	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b>	<b>Chairperson's Remarks</b> Tiffany Rau, Ph.D., Senior Consultant, BioProcess Technology Consultants, Inc.
	<b>Case Studies and Innovations</b>	<b>Interface between Early Stage and Late Stage</b>		<b>Beyond the Plant</b>
1:30	<b>In Process Monitoring in Single Use Manufacturing of Dendritic Cells</b> <span style="background-color: #800000; color: white; padding: 2px;">CASE STUDY</span> <span style="background-color: #000080; color: white; padding: 2px;">NEW DATA</span> Shashi Murthy, Ph.D., Professor of Chemical Engineering & Sherman Center Director, Northeastern University	<b>Interface between Discovery, Early Stage and Late Stage - Innovations and Case Studies</b> Duc Nguyen, Ph.D., Lab Head Novartis		<b>Unresolved Ambiguities in the Biologics Price Competition and Innovation Act (BPCIA) of 2010 Continue to Challenge Drug Product Sponsors</b> Verne Luckow, Ph.D., JD, Managing Member, The IP Law Office of Verne A. Luckow, LLC
2:00	<b>Comparison of USP &lt;665&gt; and BPOG Protocols for Extractables Studies of SUS Components - Raymond Colton, BPOG</b> Raymond Colton, MBA, Founder, VR Analytical	<b>Best Practices: Transferring Processes from Pre-clinical, to Clinical, to Commercial Launch Prep.</b>		Feel free to attend one of the other 2:00 presentations
2:30	<i>Close of Conference - See you in 2019!</i>			



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