

# THE WATERSIDE CONFERENCE™

DEVELOPMENT & PRODUCTION OF

**THERAPEUTIC PROTEINS**

**NOVEMBER 12-14, 2018  
NORFOLK, VIRGINIA USA**

**REGISTER NOW!**

## Process Analysis & Automation

Chaired By:

**Barry Rosenblatt, PhD**

SME Biotech Consulting

**Robert R. Boulanger, PhD**

CRB

## Expansion & Expression

Chaired By:

**Swapnil Bhargava, PhD**

Seattle Genetics, Inc.

**Blair McNeill, PhD**

Roivant Sciences, Inc.

## Cell Line Characterization & Banking

Chaired By:

**Fang Tian, PhD**

American Type Culture Collection (ATCC)

**Alissa M. Resch, PhD**

Coriell Institute for Medical Research

## Contaminant Control

Chaired By:

**Jeri Ann Boose, PhD**

Eurofins Lancaster Laboratories, Inc.

**Raymond Nims, PhD**

RMC Pharmaceutical Solutions, Inc.

## Raw Materials Science & Control

Chaired By:

**David Kolwyck**

Biogen

**Henry Lin, PhD**

Merck & Co., Inc.

### SUNDAY • NOVEMBER 11, 2018

4:00 pm – 7:00 pm

**Welcome Reception and Registration** in the Main Ballroom Foyer, Fourth Floor

### MONDAY • NOVEMBER 12, 2018

7:00 am – 8:00 am

**Registration and Breakfast** in the Main Ballroom Foyer, Fourth Floor

8:00 am – 8:30 am

**Meeting Overview** in Salon A, Fourth Floor

#### Process Analysis & Automation

Salon A, Fourth Floor

#### Expansion & Expression

Salon G, Fourth Floor

#### Cell Line Characterization & Banking

Salon F, Fourth Floor

#### Contaminant Control

Paul D. Fraim Center for Excellence, Fourth Floor

#### Raw Materials Science & Control

Salon B, Fourth Floor

8:30 am – 9:15 am

*Process Analysis and Automation*  
**Robert R. Boulanger, PhD**  
CRB

*Comparing Insect Culture and Mammalian Expression Systems*  
**Christopher W. Kemp, PhD**  
Kempbio, Inc.

*Assessing Genomic Stability and Quality in Cell Lines*  
**Alissa M. Resch, PhD**  
Coriell Institute for Medical Research

*Virus Risk Mitigation in Cell Culture Media Using Virus Retentive Membranes*  
**Sherri Dolan**  
Sartorius Stedim Biotech

*Raw Material Control Strategy in a Cell Culture-Based Biologics Manufacturing Process*  
**Indrajit Giri, PhD**  
Immunomedics, Inc.

9:15 am – 10:00 am

*Process Analytical Technology (PAT) for Continuous Bioprocessing*  
**Edita Botonjic-Sehic, PhD**  
Pall Biotech

*Highly Intensified Perfusion Cell Culture: Making More Therapeutic Protein, Faster, in a Smaller Manufacturing Footprint Than Traditional Fed-Batch Processes*  
**Daisie Ogawa**  
Boehringer Ingelheim Corporation

*A Comprehensive View of Cell Authentication and Characterization*  
**Fang Tian, PhD**  
American Type Culture Collection (ATCC)

*Where in the World Did Your FBS Come From? Geographic Testing for Serum Origin*  
**Rosemary J. Versteegen, PhD**  
International Serum Industry Association (ISIA)

*Bioprocessing Raw Material Characterization and Control Strategy*  
**David Kolwyck**  
Biogen

10:00 am – 10:30 am

**Morning Break** in the Exhibit Area

	<b>Process Analysis &amp; Automation</b> Salon A, Fourth Floor	<b>Expansion &amp; Expression</b> Salon G, Fourth Floor	<b>Cell Line Characterization &amp; Banking</b> Salon F, Fourth Floor	<b>Contaminant Control</b> Paul D. Fraim Center for Excellence, Fourth Floor	<b>Raw Materials Science &amp; Control</b> Salon B, Fourth Floor
10:30 am – 11:15 am	<i>Deploying Automated Buffer Production for cGMP Use</i> <b>Ioana Erlandsson</b> GE Healthcare Bio-Sciences AB	<i>The Cumate-Inducible Switch for Stable CHO Pool and Clone Generation</i> <b>Yves Durocher, PhD</b> National Research Council Canada	<i>Strategies and Trends for Improving Sample Quality Following Cryopreservation</i> <b>John M. Baust, PhD</b> CPSI Biotech	<i>Development of an Efficient Hepatitis E Virus Cell Culture Infectivity Assay for Evaluating the Clearance Capacity of Biological Manufacturing Processes</i> <b>Michael Burdick, PhD</b> CSL Behring	<i>Refractive Index Technology to Model Raw Material Dissolution Consistency for Media Hydration Operations</i> <b>Gitanjali Talreja</b> Biogen
11:15 am – 12:00 noon	<i>Accelerated Timelines to IND and from Process Characterization to PPQ Through Implementation of Various HT-Technologies</i> <b>Christian Müller, PhD</b> AGC Biologics	<i>Development of a Targeted Integration System for Therapeutic Protein Expression</i> <b>Sherman Ku, PhD</b> Just Biotherapeutics, Inc.	<i>An Update on CO1 Multiplex PCR and Barcode Sequencing Analysis for Species Identification</i> <b>Balsam Shawky</b> American Type Culture Collection (ATCC)	<i>Phage Contamination in a Fermentation Facility: What Can be Done, Except for Burning it Down, to Stop the Phage?</i> <b>Marcin Łoś, PhD, DSc</b> Phage Consultants	<i>Spectroscopic Online Monitoring Methods to Identify the Impact of Preparation Parameters and Raw Materials on Chemically Defined Cell Culture Media Quality</i> <b>Andreas Unsöld</b> Boehringer Ingelheim GmbH
12:00 noon – 1:30 pm	<b>Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm)</b>				
1:30 pm – 2:15 pm	<i>Established Tools for Cell Line Screening and Early Process Development</i> <b>Marc Mitchell</b> Sartorius Stedim North America Inc.	<i>A Multipronged Approach to Develop an In-House Chemically-Defined Media System for a CHO Fed-Batch Process</i> <b>David Lee</b> Seattle Genetics, Inc.	<i>Assuring Fitness-for-Purpose in Biobanking: Standards Development in ISO/TC276 Biotechnology</i> <b>Clare M. Allocca</b> National Institute of Standards & Technology (NIST)	<i>Low Endotoxin Recovery (LER): the Good, the Bad, and the Ugly</i> <b>Allen L. Burgenson</b> Lonza Walkersville, Inc.	<i>Establishing an Attribute-Focused Approach to Raw Materials</i> <b>Matthew Hammond, PhD</b> Amgen Inc.
2:15 pm – 3:00 pm	<b>Roundtable Discussion</b>	<b>Roundtable Discussion</b>	<b>Roundtable Discussion</b>	<i>Optimization of Neutralizing Antibody Conditions for Adventitious Virus Testing of micro-RNA Attenuated Oncolytic Herpes Simplex Virus</i> <b>Laura Viggiano Salta</b> Oncorus	<i>USP Standards to Support Qualification of Raw Materials and Cell Substrates for Biomanufacturing</i> <b>Maura Kibbey, PhD</b> US Pharmacopeial Convention (USP)
3:00 pm – 3:30 pm	<b>Afternoon Break in the Exhibit Area</b>				
3:30 pm – 4:15 pm	<b>Continuous Processing Session</b> <i>Moderated by</i> <b>Edita Botonjic-Sehic, PhD</b> Pall Biotech	<b>BioSimilar Session</b> <i>To Accelerate Development, the FDA Releases its Biosimilars Action Plan (BAP) Eight Years After Enactment of the Biologics Price Competition and Innovation Act (BPCIA)</i> <b>Verne A. Luckow, PhD, JD</b> The Intellectual Property Law Office of Verne A. Luckow, LLC	<b>Contract Services Session</b>	<i>Virus Filtration in Continuous Bioprocessing: Considerations for Filter Design Space and Validation</i> <b>Daniel Eshete, MD, PhD</b> Pall Biotech	
4:15 pm – 5:00 pm		<b>BioSimilar Session</b> <i>Biosimilars – An Economic Opportunity Provided by a Smarter Development and Commercialization Path or, Keeping up With FDA's Biosimilar Initiatives</i> <b>Mark F. Witche, PhD</b> Semi-Retired Engineer/Executive			
5:00 pm – 7:00 pm	<b>Reception in the Exhibit Area</b>				

**TUESDAY • NOVEMBER 13, 2018**

<b>Breakfast in the Exhibit Area</b>					
7:30 am – 8:30 am					
8:30 am – 9:15 am	<i>Continuous Processing in Biomanufacturing: Case Studies in Biologic Development Scale-Down Models and Manufacturing</i> <b>Emily Schirmer, PhD</b> Catalent Pharma Solutions, Inc.	<i>Bioprocess Strategies to Control Product Glycosylation in Mammalian Cell Culture</i> <b>Michael Butler, PhD</b> National Institute for Bioprocessing Research & Training (NIBRT)	<i>Trehalose as an Alternative to DMSO for Cryopreservation of Cells</i> <b>Kelvin G.M. Brockbank, PhD</b> Tissue Testing Technologies LLC	<i>Faster Test, Faster Results: Degenerate PCR Panel Assay for Biosafety Testing</i> <b>Afshin Sohrabi, PhD</b> MilliporeSigma BioReliance® Services	<i>Towards Eliminating the Impact of Raw Material Variability in Biologics Manufacturing: A Case Study with Poloxamer 188</i> <b>Salim P. Charaniya, PhD</b> Genentech, a Member of the Roche Group
9:15 am – 10:00 am	<i>Process Design and Scaling of Multi-Column Chromatography for Capture of Monoclonal Antibodies</i> <b>Eric Gershenow</b> Pall Biotech	<i>Modulation of Cell Culture Productivity and Product Quality Through Optimization of Production Media</i> <b>Nikki Nogal, PhD</b> Latham BioPharm Group	<i>Current Trends in Storage and Usage of Biological Samples: Supporting the Biologicals Revolution in Life Science</i> <b>Steve Broach</b> LiCONic Instruments	<i>The Wild-Type Ancestor of SF-Rhabdovirus Can Infect Monkey Cells</i> <b>Donald L. Jarvis, PhD</b> GlycoBac LLC	<i>Determination and Quantification of Hydrophobic Impurities Shown to Cause Variable Cell Culture Performance in Poloxamer 188 Using RP-HPLC</i> <b>Francis S. Romanski, PhD</b> BASF Corporation
10:00 am – 10:30 am	<b>Morning Break in the Exhibit Area</b>				

	<b>Process Analysis &amp; Automation</b> Salon A, Fourth Floor	<b>Expansion &amp; Expression</b> Salon G, Fourth Floor	<b>Cell Line Characterization &amp; Banking</b> Salon F, Fourth Floor	<b>Contaminant Control</b> Paul D. Fraim Center for Excellence, Fourth Floor	<b>Raw Materials Science &amp; Control</b> Salon B, Fourth Floor
10:30 am – 11:15 am	<i>Successful Product Development – Yield, Purity, and Comparability: How Many Products Fail Phase III Clinicals Because They Are Not Comparable to the Product Designed and Tested Earlier?</i> <b>Mark F. Witcher, PhD</b> Semi-Retired Engineer/Executive	<i>Next Generation Manufacturing for Biologics: Integration of a Hybrid Model for Continuous Manufacturing Concepts into a Clinical Facility</i> <b>Michael C. Borys, PhD</b> Bristol-Myers Squibb Company	<i>The Importance of Biobanking for Precision Medicine and Public Health</i> <b>Jim Vaught, PhD</b> Biopreservation and Biobanking	<i>Approach to Pre- and Post-Viral Clearance Room Segregation</i> <b>Serge Monpoeho, PhD</b> Regeneron Pharmaceuticals, Inc.	<i>Raw Material Investigations for Managing Variability in Charge Variant Profiles of a Monoclonal Antibody</i> <b>Jonathan Cacciatore, PhD</b> Merck & Co., Inc.
11:15 am – 12:00 noon	<i>Flexible Bioprocess Design for Maximizing Upstream Throughput</i> <b>Eric A. Rudolph</b> ABEC, Inc.	<i>Evaluation of New and Current Process Intensification Scenarios For Predicting the Most Cost-Effective Processes</i> <b>Priyanka Gupta</b> Sartorius Stedim Biotech	<i>Cell Count, Viability, and Cell Health Characterization Using Image Cytometry</i> <b>Jean Qiu, PhD</b> Nexcelom Bioscience LLC	<i>Source Determination Testing of Foreign and Unknown Particulate Matter in Pharmaceutical Products</i> <b>Antonio J. Scatena</b> Gateway Analytical LLC	<i>Bovine Serum Import Policy Overview, Updates, and APHIS' Response When Serum Fails Safety Testing</i> <b>Lisa M. Dixon, DVM</b> USDA APHIS
Free Afternoon with Recommended Group Activities:					
12:00 noon – 6:00 pm	<b>River Cruise on the <a href="#">Victory Rover</a> • Admission to <a href="#">Nauticus and the Battleship Wisconsin</a> • Guided Historical Walking Tour • Glass Blowing Workshop at the <a href="#">Chrysler Glass Studio</a></b>				
6:00 pm – 9:00 pm	<b>Mad Hatter Banquet at the <a href="#">Granby Theater</a></b>				

**WEDNESDAY • NOVEMBER 14, 2018**

	<b>Breakfast in the Exhibit Area</b>				
7:30 am – 8:30 am					
8:30 am – 9:15 am	<i>Development, Automation, and Qualification of Scale-Down Models for Protein Production and Purification</i> <b>Barry Rosenblatt, PhD</b> SME Biotech Consulting	<i>Understanding the Effect of Preparation Methods on Bioavailability of Components in a Cell Culture Feed</i> <b>Mark Berge</b> MedImmune, A member of the AstraZeneca Group	<i>Biobanking Samples and the Need to Raise the Standard: Are Your Samples Fit for Purpose?</i> <b>Nahid Turan, PhD</b> Coriell Institute for Medical Research	<i>Detection of Adventitious Agents in CHO Cell Cultures Using Ultra-High Multiplex PCR and Next-Generation Sequencing</i> <b>Michael Brewer</b> Thermo Fisher Scientific	<i>Enabling Rapid Raw Material Identification and Release by Raman Spectroscopy and X-Ray Fluorescence</i> <b>Thomas Matthews, PhD</b> Biogen
9:15 am – 10:00 am	<i>Small-Scale Model Development That Mimics the Manufacturing Scale CO<sub>2</sub> Profile</i> <b>Naveenganesh Muralidharan</b> Patheon, part of Thermo Fisher Scientific	<b>Joint Session in Expansion &amp; Expression Room</b> <i>Efficient Expression of Complex Proteins in Mammalian Cells</i> <b>Gregory T. Bleck, PhD</b> Catalent Pharma Solutions, Inc.		<i>Pitfalls of Viral Clearance Studies</i> <b>Stephen Stoltzfus</b> Eurofins Lancaster Laboratories, Inc.	<i>Impact of Elemental Impurities on Complex Chemically Defined Media</i> <b>Balasubramanian Ramanathan, PhD</b> Janssen Pharmaceuticals, Inc.
10:00 am – 10:30 am	<b>Morning Break in the Exhibit Area</b>				
10:30 am – 11:15 am	<i>Reduced Scale Model Qualification Using Multivariate Visualization &amp; Bayesian Inferential Methods</i> <b>Christopher Canova</b> Janssen Research & Development, LLC	<b>Joint Session in Expansion &amp; Expression Room</b> <i>Limitations of Subcloning as a Tool to Characterize Homogeneity of a Cell Population</i> <b>Kristi Daris</b> Amgen Inc.		<i>Next-Generation Sequencing Versus Traditional Methods: A New Frontier for Adventitious Virus Detection</i> <b>Maria M. Bednar, PhD</b> Biogen	<i>An Overview of ATCC Custom Solutions: Capabilities and Highlights</i> <b>Reed Shabman, PhD</b> American Type Culture Collection (ATCC)
11:15 am – 12:00 noon	<i>Using Dynamic Imaging for Foam Control Level Particle Count and Cell Counting</i> <b>Tod Canty</b> JM Canty, Inc.	<b>Joint Session in Expansion &amp; Expression Room</b> <i>Two Cytoplasmic Ubiquitin E3 Ligases and an ER Protease Mediate ER-Associated Degradation of Unfolded Antibody Heavy Chains</i> <b>Danming Tang, PhD</b> Genentech, a Member of the Roche Group		<i>MMV Inactivation by HTST: Beyond the Log10 Reduction Factors</i> <b>Dayue Chen, PhD</b> Eli Lilly & Company	<i>Impact of Impurities in Industrial Cell Culture: Understanding and Managing Variation</i> <b>Cory J. Card</b> GE Healthcare
12:00 noon – 1:30 pm	<b>Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm)</b>				
1:30 pm – 2:15 pm	<b>Roundtable Discussion</b>	<b>Roundtable Discussion</b>	<b>Roundtable Discussion</b>	<i>Investigation of an Adventitious Agent False Positive Test in a Plant-Based Influenza Vaccine</i> <b>Todd L. Talarico, PhD</b> Medicago USA	<i>Using Lifecycle Development Tools Including Risk Analysis for Building Better Infrastructure Systems (e.g., Controlling Raw Materials) or, Getting to Six-Sigma Performance</i> <b>Mark F. Witcher, PhD</b> Semi-Retired Engineer/Executive
2:15 pm – 3:00 pm				<i>Contamination Control in Biomanufacturing: From Monitoring to Disinfection</i> <b>S. Steve Zhou, PhD</b> MicroBioTest, div. of Microbac Laboratories, Inc.	
3:00 pm – 3:30 pm	<b>Afternoon Break in the Exhibit Area</b>				
3:30 pm	<b>Meeting Adjourns</b>				