### Process Analysis & Automation
**Chair by:**
Barry Rosenblatt, PhD  
SME Biotech Consulting  
Robert R. Boulanger, PhD  
CRB

### Expansion & Expression
**Chair by:**
Swapnil Bhargava, PhD  
Seattle Genetics, Inc.  
Blair McNeill, PhD  
Roviant Sciences, Inc.

### Cell Line Characterization & Banking
**Chair by:**
Fang Tian, PhD  
American Type Culture Collection (ATCC)  
Alissa M. Resch, PhD  
Coriell Institute for Medical Research

### Contaminant Control
**Chair by:**
Jeri Ann Boose, PhD  
Eurofins Lancaster Laboratories, Inc.  
Raymond Nims, PhD  
RMC Pharmaceutical Solutions, Inc.

### Raw Materials Science & Control
**Chair by:**
David Kolwycz  
Biogen  
Henry Lin, PhD  
Merck & Co., Inc.

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**SUNDAY • NOVEMBER 11, 2018**

- **4:00 pm – 7:00 pm** 
  Welcome Reception and Registration in the Main Ballroom Foyer, Fourth Floor

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**MONDAY • NOVEMBER 12, 2018**

- **7:00 am – 8:00 am** 
  Registration and Breakfast in the Main Ballroom Foyer, Fourth Floor

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<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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</thead>
<tbody>
<tr>
<td>8:00 am – 8:30 am</td>
<td>Meeting Overview in Salon A, Fourth Floor</td>
</tr>
</tbody>
</table>
| 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.  
  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 Kolwycz  
  Biogen  
  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  
  Virus Risk Mitigation in Cell Culture Media Using Virus Retentive Membranes  
  Sherri Dolan  
  Sartorius Stedim Biotech |
| 10:00 am – 10:30 am | Morning Break in the Exhibit Area |

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**Saturday Night Gala Dinner**

- **7:00 pm – 10:00 pm** 
  Riverfront Palladium Theater

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**Sunday Night BioPony Open Bar Reception**

- **7:00 pm – 9:00 pm** 
  Riverfront Palladium Theater

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**Monday Morning Break in the Exhibit Area**
<table>
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<tr>
<td>10:30 am – 11:15 am</td>
<td>Deploying Automated Buffer Production for cGMP Use</td>
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<tr>
<td></td>
<td>Iona Erlandsson</td>
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<td>GE Healthcare Bio-Sciences AB</td>
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<td>The Cumate-Inducible Switch for Static CHO Pool and Clone Generation</td>
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<td></td>
<td>Yves Durocher, PhD</td>
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<td>National Research Council Canada</td>
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<tr>
<td>11:15 am – 12:00 noon</td>
<td>Development of a Targeted Integration System for Therapeutic Protein Expression</td>
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<td></td>
<td>Sherman Ku, PhD</td>
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<td>Just Biotherapeutics, Inc.</td>
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<tr>
<td>12:00 noon – 1:30 pm</td>
<td>Assuring Fitness-for-Purpose in Biobanking: Standards Development in ISO/TC276 Biotechnology</td>
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<tr>
<td></td>
<td>Clare M. Allocca</td>
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<td></td>
<td>National Institute of Standards &amp; Technology (NIST)</td>
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<tr>
<td>1:30 pm – 2:15 pm</td>
<td>A Multipronged Approach to Develop an In-House Chemically-Defined Media System for a CHO Fed-Batch Process</td>
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<tr>
<td></td>
<td>David Lee</td>
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<td>Seattle Genetics, Inc.</td>
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<tr>
<td>2:15 pm – 3:00 pm</td>
<td>Contract Services Session</td>
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<td>Viral Filtration in Continuous Bioprocessing: Considerations for Filter Design Space and Validation</td>
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<td>3:00 pm – 3:30 pm</td>
<td>Afternoon Break in the Exhibit Area</td>
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<tr>
<td>3:30 pm – 4:15 pm</td>
<td>Continuous Processing Session</td>
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<td>4:15 pm – 5:00 pm</td>
<td>Continuous Processing in Biomanufacturing: Case Studies in Biologic Development Scale-Down Models and Manufacturing</td>
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<td>Breakfast in the Exhibit Area</td>
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<td>8:30 am – 9:15 am</td>
<td>Process Design and Scaling of Multi-Column Chromatography for Capture of Monoclonal Antibodies</td>
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<td>9:15 am – 10:00 am</td>
<td>Optimization of Neutralizing Antibody Conditions for Adverse Viral Tests of Micro-RNA Attenuated Oncolytic Herpes Simplex Virus</td>
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<td>Laura Viggiano Salta</td>
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<td>Oncorus</td>
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<td>Troubleshooting as an Alternative to DMSO for Cryopreservation of Cells</td>
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<td>10:30 am – 11:15 am</td>
<td>Development of an Efficient Hepatitis E Virus Cell Culture Infectivity Assay for Evaluating the Clearance Capacity of Biological Manufacturing Processes</td>
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<td>Michael Burdick, PhD</td>
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<td>CSL Behring</td>
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<td>11:15 am – 12:00 noon</td>
<td>Phage Contamination in a Fermentation Facility: What Can be Done, Except for Burning It Down, to Stop the Phage?</td>
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<td>Marcin Lois, PhD</td>
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<td>DSc</td>
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<td>Establishing an Attribute-Focused Approach to Raw Materials</td>
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The Waterside Conference™ (continued): TUESDAY - NOVEMBER 13, 2018

10:30 am – 11:15 am

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?
Mark F. Witcher, PhD
Semi-Retired Engineer/Executive

Next Generation Manufacturing for Biologics: Integration of a Hybrid Model for Continuous Manufacturing Concepts into a Clinical Facility
Michael C. Borys, PhD
Bristol-Myers Squibb Company

The Importance of Biobanking for Precision Medicine and Public Health
Jim Vaught, PhD
Biopreservation and Biobanking

Approach to Pre- and Post-Viral Clearance Room Segregation
Serge Monpoeho, PhD
Regeneron Pharmaceuticals, Inc.

Raw Material Investigations for Managing Variability in Charge Variant Profiles of a Monoclonal Antibody
Jonathan Cacciatore, PhD
Merck & Co., Inc.

11:15 am – 12:00 noon

Flexible Bioprocess Design for Maximizing Upstream Throughput
Eric A. Rudolph
ABEC, Inc.

Evaluation of New and Current Process Intensification Scenarios For Predicting the Most Cost-Effective Processes
Priyanka Gupta
Sartorius Stedim Biotech

Cell Count, Viability, and Cell Health Characterization Using Image Cytometry
Jean Qiu, PhD
Nexcelom Bioscience LLC

Source Determination Testing of Foreign and Unknown Particulate Matter in Pharmaceutical Products
Antonio J. Scatena
Gateway Analytical LLC

Free Afternoon with Recommended Group Activities:

River Cruise on the Victory Rover • Admission to Nauticus and the Battleship Wisconsin • Guided Historical Walking Tour • Glass Blowing Workshop at the Chrysler Glass Studio

Mad Hatter Banquet at the Granby Theater

12:00 noon – 6:00 pm

Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm)

6:00 pm – 9:00 pm

Afternoon Break in the Exhibit Area

Meeting Adjourns

Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 11/10/18