

THE WATERSIDE CONFERENCE™

CRITICAL CAPABILITIES FOR
BIOLOGIC PRODUCTION

NOVEMBER 4-6, 2019
NORFOLK, VIRGINIA USA

Cell Banking & Characterization

Chaired By:

Fang Tian, PhD

American Type Culture Collection (ATCC)

Linda Fröderberg Roth, PhD

AstraZeneca R&D

Haruhiko Murata, MD, PhD

FDA CBER

Advances in Bioprocess Development

Chaired By:

Swapnil Bhargava, PhD

Seattle Genetics, Inc.

Daisie Ogawa

Boehringer Ingelheim Corporation

Raw Materials Science & Control

Chaired By:

David Kolwyck

Biogen

Kevin P. Kent, PhD

Boehringer Ingelheim Animal Health

Contaminant Control

Chaired By:

Jeri Ann Boose, PhD

Eurofins Lancaster Laboratories, Inc.

Raymond Nims, PhD

RMC Pharmaceutical Solutions, Inc.

SUNDAY • NOVEMBER 3, 2019

4:00 pm – 7:00 pm

Welcome Reception and Registration in the Foyer, Fourth Floor

MONDAY • NOVEMBER 4, 2019

7:00 am – 8:00 am

Registration and Breakfast in the Foyer, Fourth Floor

8:00 am – 8:30 am

Meeting Overview in Salon A, Fourth Floor

8:30 am – 9:15 am

Cell Banking & Characterization Salon B, Fourth Floor

High-Speed and High-Throughput Image Cytometry Assays to Investigate CRISPR/Cas9-Mediated Site-Specific Gene Expression, Cell Cycle, Apoptosis, and Reactive Oxygen Species in CHO Cells
Jean Qiu, PhD
Nexcelom Bioscience LLC

Advances in Bioprocess Development Salon C, Fourth Floor

CHO Cell Culture Process Optimization at Low Glucose Concentrations for mAb Production
Rohan Patel
MedImmune, A member of the AstraZeneca Group

Raw Materials Science & Control Salon F, Fourth Floor

Analytical Insights from Raw Material Testing of Cell Culture Media Components
Elizabeth C. Dodson
Thermo Fisher Scientific

Contaminant Control Salon A, Fourth Floor

Surface Decontamination: Removal or Inactivation? Spray, Wipe, or Vapor?
S. Steve Zhou, PhD
MicroBioTest, div. of Microbac Laboratories, Inc.

9:15 am – 10:00 am

Facilitating the Introduction of New Vaccines: Addressing DNA Oncogenicity Concerns with Novel Cell Substrates
Keith Peden, PhD
FDA CBER

Feeding TCA Cycle Intermediates Improves Lactate Consumption and Antibody Production in CHO Cell Cultures
Xiaolin Zhang, PhD
Merck & Co., Inc.

Implementation of an Integrated Approach for Fingerprinting Cell Culture Media
Kathryn Aron, PhD
Bristol-Myers Squibb Company

Best Practices for Planning and Conducting Extractable and Leachable Studies
Charles E. Ducker, PhD
Eurofins Lancaster Laboratories, Inc.

10:00 am – 10:30 am

Morning Break in the Exhibit Area

All of the meals, events, and activities shown in the program are included with your registration fee.

The Waterside Conference (continued): MONDAY • NOVEMBER 4, 2019

	Cell Banking & Characterization <i>Salon B, Fourth Floor</i>	Advances in Bioprocess Development <i>Salon C, Fourth Floor</i>	Raw Materials Science & Control <i>Salon F, Fourth Floor</i>	Contaminant Control <i>Salon A, Fourth Floor</i>
10:30 am – 11:15 am	<i>A Nature Inspired DMSO-, Protein-, and Serum-Free Chemically-Defined Biopreservation Solution, the New Horizon of Precision in Cell Manufacturing and Processing</i> Xiaoxi Wei, PhD X-Therma Inc.	<i>Potency Assay Basics and Application to Process Development</i> Jyoti Velayudhan, PhD Seattle Genetics, Inc.	<i>From Chemically to Functionally Defined: A Development Strategy to Reduce Raw Material Introduced Process Variability in Cell Culture Media</i> Matthias Brunner, PhD Boehringer Ingelheim GmbH	<i>Detection of Viral Contamination in Cell Culture by Targeted Amplicon Sequencing Using an Automated Next-Generation Sequencing Workflow with Simplified Data Analysis</i> Elena Bolchakova Thermo Fisher Scientific
11:15 am – 12:00 noon	<i>Gene Editing to Improve Upstream and Downstream Production of HIV Vaccines</i> Phillip W. Berman, PhD University of California, Santa Cruz	<i>High-Throughput Screening of High-Producing CHO Cell Lines for Biomufacturing of Biologics</i> Simon Joubert, PhD National Research Council Canada (NRC)	<i>New Approaches to Advancing a Raw Material Variability Strategy</i> Stefan Yohe, PhD Genentech, a Member of the Roche Group	<i>Background NGS Data for Sample Matrix and Reference Control Standards Using Nanopore Sequencing</i> Serge Monpoeho, PhD Regeneron Pharmaceuticals, Inc.
12:00 noon – 1:30 pm	Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm) <i>Sponsored by Wyatt Technology Corporation</i>			
1:30 pm – 2:15 pm	<i>Development of an Allelic Ladder for Mouse Cell Line Authentication</i> Jamie Almeida National Institute of Standards & Technology (NIST)	<i>Use of Stable Pools for Drug Substance Production to Support Non-Clinical Studies to Accelerate the Timeline – A Case Study</i> Li Zhang Amgen Inc.	<i>Complex Raw Material and Spent Cell Media Analyses to Support Bioprocess Development and Troubleshooting Activities</i> Frederic Girard, PhD Eurofins Spinnovation Analytical	<i>Robust Parvovirus (MVM) Clearance Using Anion Exchange Membrane Adsorbers</i> Sherri Dolan Sartorius Stedim North America Inc.
2:15 pm – 3:00 pm	<i>Regulatory Considerations for Characterizing Cell Substrates</i> Anissa Cheung FDA CBER	<i>Seed Train Intensification with High Density Cell Banks and N-1 Perfusion</i> Jessica Maier Boehringer Ingelheim Corporation	<i>Analysis of Cell Media Degradation and Variations With a New At-Line Analyzer</i> Glenn A. Harris, PhD 908 Devices Inc.	
3:00 pm – 3:30 pm	Afternoon Break in the Exhibit Area			
3:30 pm – 4:15 pm	<i>Precision Genome Engineering of Mammalian Host Cell Lines for Enhanced Viral Production</i> Elizabeth Turner Gillies, PhD American Type Culture Collection (ATCC)	Technology Workshop <i>Cellaca™ MX: A Novel Instrument for High-Throughput, High-Speed Cell Counting, Concentration, and Viability</i> Jean Qiu, PhD Nexcelom Bioscience LLC	Technology Workshop <i>Managing Change Control Using a System Risk Structure (SRS)-Based Quality Risk Management (QRM) Exercise</i> Mark F. Witcher, PhD Brevitas Consulting Inc.	Technology Workshop <i>Bridging the Gap: A Biopharmaceutical Processing Workforce Development Continuum</i> Ronald G. Kander, PhD Thomas Jefferson University
5:00 pm – 7:00 pm	Reception in the Exhibit Area			

TUESDAY • NOVEMBER 5, 2019

7:30 am – 8:30 am	Breakfast in the Exhibit Area			
8:30 am – 9:15 am	<i>Legacy Challenges of the Modern Biobank</i> Donna M. Altamuro Coriell Institute for Medical Research	<i>Get Off the Critical Path: Long-Term Cell Banking Strategies and Working with Fast Timelines</i> James Lambropoulos Biogen	<i>Industry-Wide Benchmarking on Standardization of Trace Elements in Cell Culture Media</i> Balasubramanian Ramanathan, PhD Janssen Pharmaceuticals, Inc.	<i>Update on Validation Considerations for Rapid Mycoplasma Detection Using qPCR: Regulatory Queries and Responses</i> Michael Brewer Thermo Fisher Scientific
9:15 am – 10:00 am	<i>Nanowarming of Thin and Thick Walled Arteries in 30–50 mL Volumes — The First Step Towards Organ Cryopreservation</i> Kelvin GM Brockbank, PhD Tissue Testing Technologies LLC	<i>Utilizing High-Throughput Stable Transfections to Eliminate Transient Transfections for Sequence Variant Analysis</i> Pauline Smidt Just Biotherapeutics, Inc.	<i>A Quality by Design Approach to Assess Critical Raw Materials</i> Harika Vemula, PhD Merck KGaA	<i>Facility Segregation for Downstream Processing of Plasma-Derived and Recombinant Products</i> Michael Burdick, PhD CSL Behring
10:00 am – 10:30 am	Morning Break in the Exhibit Area			

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	Cell Banking & Characterization Salon B, Fourth Floor	Advances in Bioprocess Development Salon C, Fourth Floor	Raw Materials Science & Control Salon F, Fourth Floor	Contaminant Control Salon A, Fourth Floor
10:30 am – 11:15 am	<i>The Zeitgeist of Our Time: Reagent Quality is the Cornerstone of Research Excellence</i> Sonia Houghton Cryosphere Services	<i>Developing and Validating Manufacturing Processes for 21st Century Biopharmaceutical Products</i> Mark F. Witcher, PhD Brevitas Consulting Inc.	<i>Reference Materials for Viral Gene Vectors</i> Keith L. Carson ISBioTech	<i>AAV Gene Therapy for Tay-Sachs Disease: Lessons Learned from Preclinical to Clinical Vector Production for an Expanded Access Clinical Trial</i> Miguel Sena Esteves University of Massachusetts Medical School
11:15 am – 12:00 noon	<i>Imposter Cell Lines – A Continuing Threat to the Validity of Biomedical Research</i> Christopher Korch, PhD University of Colorado School of Medicine		<i>Elemental Metal Variance in Cell Culture Raw Materials: Analytical Method Design and Application</i> Chris Grinnell Biogen	<i>Viral Clearance and Aggregate Polish for Clinical Monoclonal Antibodies Using Hydrophobic Interaction Chromatography</i> John J. Li, PhD Thermo Fisher Scientific

Free Afternoon with Recommended Group Activities:

12:00 noon – 6:00 pm **Guided Bike Tour of the Elizabeth River Trail • Guided Historical Walking Tour • Glass Blowing Workshop** at the [Chrysler Glass Studio](#) • **River Cruise** on the [Victory Rover](#) • **Admission to** [Nauticus and the Battleship Wisconsin](#)

Speakeasy Jazz Banquet at the [Historic Martin Mansion](#)

Sponsored by Pall Biotech

WEDNESDAY • NOVEMBER 6, 2019

Breakfast in the Exhibit Area				
7:30 am – 8:30 am				
8:30 am – 9:15 am	<i>Best Practices and International Standards for Cell Banking</i> Fang Tian, PhD American Type Culture Collection (ATCC)	<i>Ensuring Bioreactor Scale-Down Models are Representative of Clinical and Commercial-Scale with Respect to Misincorporations</i> John Bushey Seattle Genetics, Inc.	<i>Innovative Molecules to Simplify Fed-Batch Processes and Ensure Batch-to-Batch Consistency</i> Janike Ehret Merck KGaA	<i>Scientific Considerations for the Analysis of Host Cell Proteins</i> John Smith, PhD and Jacob Serfass, PhD Eurofins Lancaster Laboratories, Inc.
9:15 am – 10:00 am	<i>Next-Generation Strategies for Enhanced Cryopreservation Outcome</i> John M. Baust, PhD CPSI Biotech	<i>Investigating Atypical Cell Culture Performance and Charge Variant Profile of a Monoclonal Antibody from a Large-Scale Mammalian Cell Culture Process</i> Jeffrey Ly Merck & Co., Inc.	<i>Application of Data Analytics to Better Understand and Control Raw Material Variation</i> Susan Burke, PhD Amgen Inc.	<i>Beyond LAL: The rFC and MAT Assays</i> Allen L. Burgenson Lonza Walkersville, Inc.
10:00 am – 10:30 am	Morning Break in the Exhibit Area			
10:30 am – 11:15 am	<i>Multiscale Technologies for Enhancing Cryopreservation</i> Xiaoming “Shawn” He, PhD University of Maryland	<i>Continuous Manufacturing from Perfusion to Capture Step</i> Mike Ford Biogen	<i>Impact of Raw Material Variability on Gene Therapy Modalities</i> Aaron C. Mack, PhD Biogen	<i>Atypical False Positive Observed During In Vitro Virus Assay for MAb Adventitious Virus Screening</i> Serge Monpoeho, PhD Regeneron Pharmaceuticals, Inc.
11:15 am – 12:00 noon	<i>Biobanking Pluripotent Stem Cells for Research, Diagnostics, and Therapy</i> Glyn N. Stacey International Stem Cell Banking Initiative (ISCB)		<i>Raw Material Variability in Hydrolysates — Room For Improvement?</i> Chaya M. Kataru, PhD Kerry Bio-Science	<i>Efficacy of Microbicides for Inactivation of Ebola-Makona Virus in an Organic Load</i> Raymond Nims, PhD RMC Pharmaceutical Solutions, Inc.
12:00 noon – 1:30 pm	Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm)			
1:30 pm – 2:15 pm	<i>Cell Banking — A Requirement in Pharmaceutical Research</i> Linda Fröderberg Roth, PhD AstraZeneca R&D			
2:15 pm – 3:00 pm	<i>Utility of Basement Membrane Extract in the Evaluation of Tumorigenicity Associated with Vaccine Cell Substrates</i> Haruhiko Murata, MD, PhD FDA CBER			
3:00 pm – 3:30 pm	Afternoon Break in the Foyer, Fourth Floor			
3:30 pm – 4:15 pm	Poster Finalist Presentations, Discussion, and Award in Salon B, Fourth Floor			
4:15 pm	Meeting Adjourns			

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Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 11/2/19