<table>
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| Cell Banking & Characterization           | 8:00 am – 8:30 am | 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  
CHO Cell Culture Process Optimization at Low Glucose Concentrations for mAB Production  
Rohan Patel  
Medimmune, A member of the AstraZeneca Group  
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.  
Analytical Insights from Raw Material Testing of Cell Culture Media Components  
Elizabeth C. Dodson  
Thermo Fisher Scientific |
The Waterside Conference (continued): MONDAY - NOVEMBER 4, 2019

10:30 am – 11:15 am
Cell Banking & Characterization
Salon B, Fourth Floor
- A Nature Inspired DMSO-, Protein-, and Serum-Free Chemically-Defined Biopreservation Solution, the New Horizon of Precision in Cell Manufacturing and Processing
  Xiao Wei, PhD
  X-Therma Inc.
- Potency Assay Basics and Application to Process Development
  Jyoti Velayudhan, PhD
  Seattle Genetics, Inc.

11:15 am – 12:00 noon
Legacy Challenges of the Modern Biobank
Salon C, Fourth Floor
- Gene Editing to Improve Upstream and Downstream Production of HIV Vaccines
  Phillip W. Berman, PhD
  University of California, Santa Cruz
- High-Throughput Screening of High-Producing CHO Cell Lines for Biomanufacturing of Biologics
  Simon Joubert, PhD
  National Research Council Canada (NRC)

12:00 noon – 1:30 pm
Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm)
Sponsored by Wyatt Technology Corporation
- Use of Stable Pools for Drug Substance Production to Support Non-Clinical Studies to Accelerate the Timeline – A Case Study
  Li Zhang
  Amgen Inc.
- Seed Train Intensification with High Density Cell Banks and N-1 Perfusion
  Jessica Maier
  Boehringer Ingelheim Corporation
- Analysis of Cell Media Degradation and Variations With a New At-Line Analyzer
  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
Advances in Bioprocess Development
Salon C, Fourth Floor
- Use of Stable Pools for Drug Substance Production to Support Non-Clinical Studies to Accelerate the Timeline – A Case Study
  Li Zhang
  Amgen Inc.
- Seed Train Intensification with High Density Cell Banks and N-1 Perfusion
  Jessica Maier
  Boehringer Ingelheim Corporation
- Analysis of Cell Media Degradation and Variations With a New At-Line Analyzer
  Glenn A. Harris, PhD
  908 Devices Inc.

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
Legacy Challenges of the Modern Biobank
Salon A, Fourth Floor
- Legacy Challenges of the Modern Biobank
  Donna M. Altamuro
  Coriell Institute for Medical Research
- Get Off the Critical Path: Long-Term Cell Banking Strategies and Working with Fast Timelines
  James Lambropoulos
  Biogen
- Industry-Wide Benchmarking on Standardization of Trace Elements in Cell Culture Media
  Balasubramanian Ramanathan, PhD
  Janssen Pharmaceuticals, Inc.
- Update on Validation Considerations for Rapid Mycoplasma Detection Using qPCR: Regulatory Queries and Responses
  Michael Brewer
  Thermo Fisher Scientific

9:15 am – 10:00 am
Cell Banking & Characterization
Salon B, Fourth Floor
- Nanowarming of Thin and Thick Walled Arteries in 30–50 mL Volumes — The First Step Towards Organ Cryopreservation
  Kelvin GM Brockbank, PhD
  Tissue Testing Technologies LLC
- Utilizing High-Throughput Stable Transfections to Eliminate Transient Transfections for Sequence Variant Analysis
  Pauline Smidt
  Just Biotherapeutics, Inc.
- A Quality by Design Approach to Assess Critical Raw Materials
  Harika Vemula, PhD
  Merck KGaA
- Facility Segregation for Downstream Processing of Plasma-Derived and Recombinant Products
  Michael Burdick, PhD
  CSL Behring

10:00 am – 10:30 am
Continuing 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): TUESDAY - NOVEMBER 5, 2019

10:30 am – 11:15 am
The Zeitgeist of Our Time: Reagent Quality is the Cornerstone of Research Excellence
Sonia Houghton
Cryosphere Services

Advances in Bioprocess Development
Salon C, Fourth Floor
Developing and Validating Manufacturing Processes for 21st Century Biopharmaceutical Products
Mark F. Witcher, PhD
Brevitas Consulting Inc.

Raw Materials Science & Control
Salon F, Fourth Floor
Reference Materials for Viral Gene Vectors
Keith L. Carson
JSBiotech

Contaminant Control
Salon A, Fourth Floor
AAV Gene Therapy for Tay-Sachs Disease: Lessons Learned from Preclinical to Clinical Vector Production for an Expanded Access Clinical Trial
Miguel Sena Esteves
University of Massachusetts Medical School

11:15 am – 12:00 noon
Imposter Cell Lines – A Continuing Threat to the Validity of Biomedical Research
Christopher Korch, PhD
University of Colorado School of Medicine

Free Afternoon with Recommended Group Activities:
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

7:30 am – 8:30 am
Breakfast in the Exhibit Area

8:30 am – 9:15 am
Best Practices and International Standards for Cell Banking
Fang Tian, PhD
American Type Culture Collection (ATCC)

Ensuring Bioreactor Scale-Down Models are Representative of Clinical and Commercial-Scale with Respect to Misincorporations
John Bushey
Seattle Genetics, Inc.

Innovative Molecules to Simplify Fed-Batch Processes and Ensure Batch-to-Batch Consistency
Janike Ehret
Merck KGaA

Scientific Considerations for the Analysis of Host Cell Proteins
John Smith, PhD and Jacob Serfass, PhD
Eurofins Lancaster Laboratories, Inc.

9:15 am – 10:00 am
Next-Generation Strategies for Enhanced Cryopreservation Outcome
John M. Baust, PhD
CPSI Biotech

Investigating Atypical Cell Culture Performance and Charge Variant Profile of a Monoclonal Antibody from a Large-Scale Mammalian Cell Culture Process
Jeffrey Ly
Merck & Co., Inc.

Application of Data Analytics to Better Understand and Control Raw Material Variation
Susan Burke, PhD
Amgen Inc.

Beyond LAL: The rFC and MAT Assays
Allen L. Burgenson
Lonza Walkersville, Inc.

10:00 am – 10:30 am
Morning Break in the Exhibit Area

10:30 am – 11:15 am
Multiscale Technologies for Enhancing Cryopreservation
Xiaoming "Shawn" He, PhD
University of Maryland

Continuous Manufacturing from Perfusion to Capture Step
Mike Ford
Biogen

Impact of Raw Material Variability on Gene Therapy Modalities
Aaron C. Mack, PhD
Biogen

Atypical False Positive Observed During In Vitro Virus Assay for MAB Adventitious Virus Screening
Serge Mongeoo, PhD
Regeneron Pharmaceuticals, Inc.

11:15 am – 12:00 noon
Biobanking Pluripotent Stem Cells for Research, Diagnostics, and Therapy
Glyn N. Stacey
International Stem Cell Banking Initiative (ISCB)

Utility of Basement Membrane Extract in the Evaluation of Tumorigenicity Associated with Vaccine Cell Substrates
Haruhiko Murata, MD, PhD
FDA CBER

Raw Material Variability in Hydrolysates — Room For Improvement?
Chaya M. Kataru, PhD
Kerry Bio-Science

Efficacy of Microbicidal Actives for Inactivation of Ebola-Makona Virus in an Organic Load
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
Cell Banking — A Requirement in Pharmaceutical Research
Linda Fröderberg Roth, PhD
AstraZeneca R&D

Utility of Basement Membrane Extract in the Evaluation of Tumorigenicity Associated with Vaccine Cell Substrates
Haruhiko Murata, MD, PhD
FDA CBER

2:15 pm – 3:00 pm
Impact of Raw Material Variability on Gene Therapy Modalities
Aaron C. Mack, PhD
Biogen

Atypical False Positive Observed During In Vitro Virus Assay for MAB Adventitious Virus Screening
Serge Mongeoo, PhD
Regeneron Pharmaceuticals, Inc.

3:00 pm – 3:30 pm
Poster Finalist Presentations, Discussion, and Award in Salon B, Fourth Floor

Meeting Adjourns

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

Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 10/29/19