

CELL BANKING – PROGRAM CHAIRS:

Yvonne A. Reid, PhD • American Type Culture Collection (ATCC)
Frank Simone • American Type Culture Collection (ATCC)

CONTAMINANT CONTROL – PROGRAM CHAIRS:

Jeri Ann Boose, PhD • Eurofins Lancaster Laboratories, Inc.
Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc.

PROCESS ANALYSIS & AUTOMATION – PROGRAM CHAIRS:

Barry Rosenblatt, PhD • SME Biotech Consulting
Michiel E. Ultee, PhD • Ulteemit BioConsulting

SUNDAY • SEPTEMBER 27, 2015

Welcome Reception

Plus Exhibit Setup at the Waterview Conference Center in the Corporate Executive Board Building

MONDAY • SEPTEMBER 28, 2015

7:00 am – 8:00 am

Registration and Breakfast in the Exhibit Area, plus Exhibit Setup

8:00 am – 8:30 am

Meeting Overview in the Riverview Room

| | Cell Banking Riverview Room View Speaker Abstracts & Bios | Contaminant Control Cityview Room View Speaker Abstracts & Bios | Process Analysis & Automation Districtview South Room View Speaker Abstracts & Bios |
|-----------------------|---|---|--|
| 8:30 am – 9:15 am | Gregory Sykes • American Type Culture Collection – <i>Mitochondrial Multiplex and COI Barcode Analyses as Alternatives to Isoenzymology</i> | Martin H. Wisher, PhD • BioReliance Ltd. <i>The Impact of Next Generation Sequencing on Viral Safety</i> | Boro Dropulić, PhD • Lentigen Technology Inc., a Miltenyi Biotec Company <i>Integration of Work Flows for the Manufacture of CAR T Cell Products</i> |
| 9:15 am – 10:00 am | Linda Fröderberg-Roth, PhD • AstraZeneca R&D – <i>Cell Banking for Pharmaceutical Research</i> | S. Steve Zhou, PhD • MicroBioTest, div. of Microbac Laboratories, Inc. – <i>Use of Surrogates for Viral Inactivation Studies: Do We Have Enough Safety Margin?</i> | Mark F. Witcher, PhD • Integrated Project Services – <i>Building Robust, Well-Structured Biopharmaceutical Design Spaces for Process Analysis, Control, and Understanding</i> |
| 10:00 am – 10:30 am | Morning Break in the Exhibit Area | | |
| 10:30 am – 11:15 am | Technology Workshops in the Riverview Room | Beckman Coulter, Inc. • <i>Transferring a Cell Counting Process — Best Practices</i> | |
| 11:15 am – 12:00 noon | | Biologik Labs • <i>Biohacking and DIYbio</i> | |
| 12:00 noon – 1:30 pm | Lunch in the Exhibit Area | | |
| 1:30 pm – 2:15 pm | John M. Baust, PhD • CPSI Biotech <i>Continued Development of Novel Freezing and Thawing Devices for Improving Cell Cryopreservation</i> | Michael R. Sasges, PhD • Trojan Technologies <i>Clearance of Adventitious Agents from Media in a Disposable Ultraviolet-C Reactor</i> | Wieland Reichelt • Technische Universität Wien – <i>Aspects and Implications of Physiological Process Control</i> |
| 2:15 pm – 3:00 pm | Rosemary J. Versteegen, PhD • International Serum Industry Association – <i>Serum: What, Why, and Where!</i> | Katherine F. Bergmann, PhD • Eurofins Lancaster Laboratories, Inc. – <i>Evaluation of the Infectivity of Vesivirus 2117 in Mammalian Cell Lines</i> | Terry J. Fry, MD • National Cancer Institute <i>Semi-Automated Production of Genetically Modified T Cells for Cancer Immunotherapy</i> |
| 3:00 pm – 3:30 pm | Afternoon Break in the Exhibit Area | | |
| 3:30 pm – 4:15 pm | Shamim Mohammad, PhD • American Type Culture Collection – <i>Strategies for the Development of Human Hybridomas, Cutting Edge Concepts in Therapeutic Antibodies, and Their Applications</i> | Lisa Reilly • Janssen Research & Development, LLC – <i>Platform Host Cell Protein Assay Development, An Overview</i> | Victor Lu, PhD • FDA CBER <i>Regulatory Considerations for Late Phase Product Development of Gene Therapy Investigational Products</i> |
| 4:15 pm – 5:00 pm | John G. Baust, PhD • Binghamton University <i>Media-Free Cell Preservation</i> | Arifa S. Khan, PhD • FDA CBER <i>Viral Safety Strategies for Using Novel Cell Substrates</i> | Jean Peccoud, PhD • Virginia Tech <i>Image-Based Process Control</i> |
| 5:00 pm – 7:00 pm | Reception in the Exhibit Area | | |

ISBioTech 3rd Fall Meeting (continued): TUESDAY • SEPTEMBER 29, 2015

| | Cell Banking Riverview Room | Contaminant Control Cityview Room | Process Analysis & Automation Districtview South Room |
|---------------------------------------|--|--|---|
| 7:30 am – 8:30 am | Breakfast in the Exhibit Area | | |
| 8:30 am – 9:15 am | Haruhiko Murata, MD, PhD • FDA CBER <i>Qualification of Madin-Darby Canine Kidney Cells for Influenza Vaccines</i> | Marcin Łoś, PhD, DSc • Phage Consultants <i>Use of Bacteriophages as Anti-Bacterial Agents in Bioprocesses</i> | Michael Olszowy, PhD • ViroCyt, Inc. <i>Real-Time Virus Quantification Using Direct Affinity-Based Detection</i> |
| 9:15 am – 10:00 am | Ian M. Pope, PhD • Brooks Life Science Systems <i>Protection of Innocents — Unseen Thermal Excursion in Cryogenically Stored Vials</i> | Nouara Sadaoui • InDevR, Inc. <i>Evaluation of Cypher One for Automated Analysis of Hemagglutination and Hemagglutination Inhibition</i> | Barry Rosenblatt, PhD • SME Biotech Consulting – Regulatory and Monetary Drivers for Real Time Analytics |
| 10:00 am – 10:30 am | Morning Break in the Exhibit Area | | |
| 10:30 am – 11:15 am | Afshin Sohrabi, PhD • BioReliance Corporation <i>Selecting the Correct Cell Identity Assays for GMP Product Characterization</i> | James C. Leung, PhD • MIT Center for Biomedical Innovation – A Survey of Industry Data on HTST, UV-C, and Nanofiltration for Media Treatment and Their Efficacy of Removal or Inactivation of Virus | Robert R. Boulanger, PhD • CRB <i>Utilizing Process Closure Analysis as a Tool to Reduce Risk and Operational Costs in Bioprocess Manufacturing</i> |
| 11:15 am – 12:00 noon | Robert N. Ben, PhD • University of Ottawa <i>Ice Recrystallization Inhibitors — A Novel Strategy to Improve Cryopreservation Outcome</i> | Susan M. Liu • Janssen Research & Development, LLC – <i>Demonstrating the Capacity of an Antibody Production Process to Inactivate and Remove Virus</i> | Rajesh K. Gupta, PhD • Biologics Quality & Regulatory Consultants, LLC – <i>Analytical Methods in Monitoring and Managing Manufacturing Processes</i> |
| 12:00 noon – 6:00 pm | Free Afternoon with Recommended Activities | | |
| 6:00 pm – 9:00 pm | “Party Like It’s 1989” Banquet at the Clarendon Ballroom <i>Dress to impress in your favorite ‘80s outfit!</i> | | |
| WEDNESDAY • SEPTEMBER 30, 2015 | | | |
| 7:30 am – 8:30 am | Breakfast in the Exhibit Area | | |
| 8:30 am – 9:15 am | Marcin Łoś, PhD, DSc • Phage Consultants <i>Selection and Characterization of Bacterial Production Cells from a Bacteriophage Perspective</i> | Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc. – <i>Efficacy of Electron Beam for Inactivating Viruses</i> | Hazel Aranha, PhD • Catalent Pharma Solutions, Inc. – <i>Application of Quality by Design to Viral Safety Assurance of Biopharmaceuticals: Are We There Yet?</i> |
| 9:15 am – 10:00 am | Alissa M. Resch, PhD • Coriell Institute for Medical Research – <i>Establishment and Characterization of Cell Lines from Human Populations in the NHGRI Sample Repository</i> | Bing Hu, PhD • Janssen Research & Development, LLC – <i>Real-Time PCR for Analysis of Residual DNA, Virus, and Antibody Binding</i> | Philip Mathuis • Ovizio Imaging Systems NV/SA – <i>In-Process Monitoring of Cell Count and Cell Viability Using Quantitative Microscopy</i> |
| 10:00 am – 10:30 am | Morning Break in the Exhibit Area | | |
| 10:30 am – 11:15 am | Maureen A. Costello, PhD • Costello Consulting, LLC – <i>Regulatory Issues in Cell Banking</i> | Jeri Ann Boose, PhD • Eurofins Lancaster Laboratories, Inc. – <i>Disinfectant Efficacy and Cleaning Validation Studies for Adventitious Agents</i> | Jeffrey Breit, PhD • Bend Research, Inc. <i>Optimization through Integration: Streamlining Bioprocess Definition Using a Novel Lab Environment Focused on Automated Hardware, Process Analytical Technology, and Data Harmonization</i> |
| 11:15 am – 12:00 noon | Kelvin G.M. Brockbank, PhD • Tissue Testing Technologies LLC – <i>Ice-Free Cryopreservation of Tissues When Traditional Freezing Methods Do Not Work</i> | Tony Dang, PhD • Janssen Research & Development, LLC – <i>Virus Neutralization Bioassay Platform: Use of Virus as an Assay Reagent</i> | Kristina Pleitt • Patheon Biologics <i>Single-Use Non-Chromatographic Purification Method for Antibodies</i> |
| 12:00 noon – 1:30 pm | Lunch in the Exhibit Area | | |
| 1:30 pm – 2:15 pm | Jamie Almeida • National Institute of Standards & Technology – <i>NIST’s Efforts in Non-Human Cell Line Authentication</i> | | Dennis Powers • G-CON Manufacturing, Inc. <i>The Future of Facility Design</i> |
| 2:15 pm – 3:00 pm | Yvonne A. Reid, PhD • American Type Culture Collection – <i>Cell Line Authentication for Preclinical Research</i> | | Kim L. Nelson, PhD • CRB – <i>Process Analytical Technology Challenges in the Age of Disposables</i> |
| 3:00 pm – 3:30 pm | Afternoon Break in the Exhibit Area (Exhibit Teardown begins at 3:30 pm) | | |
| 3:30 pm – 5:00 pm | Panel Discussion: Product Development From Beginning to End in the Riverview Room | | |
| 5:00 pm | Meeting Adjourns | | |