

4th Fall Meeting

Contaminant Control Cell & Tissue Banking Process Analysis & Automation

FOR:

- Antibodies
- Viral Vectors
- rProteins
- Vaccines
- Cellular Therapies

December 12-14, 2016 • Virginia Beach, VA USA

CELL & TISSUE BANKING – PROGRAM CHAIRS:

Yvonne A. Reid, PhD • American Type Culture Collection (ATCC)
Alissa M. Resch, PhD • Coriell Institute for Medical Research

CONTAMINANT CONTROL – PROGRAM CHAIRS:

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

PROCESS ANALYSIS & AUTOMATION – PROGRAM CHAIRS:

Jeffrey Breit, PhD • Capsugel
Robert R. Boulanger, PhD • CRB

SUNDAY • DECEMBER 11, 2016

Welcome Reception in the Peacock Foyer
Registration and Exhibit Set-Up

MONDAY • DECEMBER 12, 2016

Registration and Breakfast in the Exhibit Area, plus Exhibit Setup

Meeting Overview in Peacock Salon A

Cell & Tissue Banking
Peacock Salon A

[View Speaker Abstracts & Bios](#)

Contaminant Control
Courtney Terrace

[View Speaker Abstracts & Bios](#)

Process Analysis & Automation
Spotswood Arms

[View Speaker Abstracts & Bios](#)

8:30 am – 9:15 am

Jamie Almeida • National Institute of Standards & Technology – *Mouse Cell Line Authentication Consortium*

Antonio J. Scatena • Gateway Analytical LLC
Case Studies in Foreign Particulate Contamination Identification

Richard S. Rogers, PhD • Just Biotherapeutics, Inc. – *Leveraging the Multi-Attribute Method (MAM) to Improve Biotherapeutic Characterization*

9:15 am – 10:00 am

Kristina L. Green, PhD • Coriell Institute for Medical Research – *Order from Chaos: Use of Short Tandem Repeat (STR) Analysis for Human Cell Line Authentication*

Katherine F. Bergmann, PhD • Eurofins Lancaster Laboratories, Inc. – *Viral Clearance Studies for Tissue-Based Products*

Marissa Nasshan • Ovizio Imaging Systems NV/SA – *Process Analytical Technologies for Bioproduction Monitoring and Control — Case Study of Inline and Automated Cell Counting*

10:00 am – 10:30 am

Morning Break in the Exhibit Area

10:30 am – 11:00 am

The Intellectual Property Law Office of Verne A. Luckow, LLC • *Assessing the Impact of the America Invents Act (AIA) on Institutions Having an Interest in the Life Sciences*

11:00 am – 11:30 am

Technology Workshops
in Peacock Salon A

NNE Pharmaplan • *Designing the Next Generation of Biopharmaceutical Manufacturing Facilities Based on Design-to-Operate and Enterprise Lifecycle Concepts*

11:30 am – 12:00 noon

Ron Villanueva • Virginia House of Delegates 21st District; Co-Chair, Virginia Bioscience Legislative Caucus

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

Deborah Lee Dormady Letham, PhD • Charles River Laboratories
Cell Line — Know Thyself

Victor Lu, PhD • FDA CBER
Regulatory Considerations for Lentiviral Vector Safety and Potency

Tara Barreira • Merrimack Pharmaceuticals, Inc. – *When Novel Molecules Meet Bioreactor Realities: A Case Study in Scale-Up Challenges and Innovative Solutions*

2:15 pm – 3:00 pm

Richard Adair, PhD • SGS Vitrology
Cell Substrate Characterisation: In Vitro-Based Virus Detection Methods

Hazel Aranha PhD • Sartorius Stedim North America Inc. – *Virus Removal Filtration: Impact of Operational Parameters on Robustness of Virus Clearance*

Sebastijan Peljhan, PhD • BIA Separations
HPLC Fingerprinting Approach for Increased Speed and Flexibility of Process Analytical Technology

3:00 pm – 3:30 pm

Afternoon Break in the Exhibit Area

3:30 pm – 4:15 pm

Yvonne A. Reid, PhD • American Type Culture Collection (ATCC) – *Comprehensive Overview of Cell Line Authentication for Pre-Clinical Research*

Todd L. Talarico, PhD • Medicago USA
A Case Study for Adventitious Agent Clearance in an Influenza Vaccine Produced in Plants

Lisa J. Graham, PhD • Alkemy Innovation Inc.
The Future of Data Visualization is Now: How to Drive Innovation Through Newly Enabled Process Analysis Techniques

4:15 pm – 5:00 pm

Lisa V. Kalman, PhD • Centers for Disease Control & Prevention – *The Genetic Testing Reference Materials Coordination Program (GeTRM): Translating Reference Material Needs Into Reality!*

Marcin Łoś, PhD, DSc • Phage Consultants
Recovery After Phage Contamination — is a White Glove Test Essential?

Robert P. Hendrix • CRB – *A Design Case Study Upgrading a Commercial Manufacturing Facility: Using Lean Six Sigma Principles, Process Engineering, and Upgrades to Process Automation and Control Strategies to Minimize Utility Costs and Facility Soft Costs for Critical Manufacturing Operations*

5:00 pm – 7:00 pm

Reception in the Exhibit Area

ISBioTech 4th Fall Meeting (continued): TUESDAY • DECEMBER 13, 2016

	Cell & Tissue Banking Peacock Salon A	Contaminant Control Courtney Terrace	Process Analysis & Automation Spotswood Arms
7:30 am – 8:30 am	Breakfast in the Exhibit Area		
8:30 am – 9:15 am	Gregory R. Sykes • American Type Culture Collection (ATCC) – <i>Mitochondria-Targeting PCR and CO1 Barcode Sequence Analyses as Alternatives to Isoenzymology</i>	Emma V. Dare, PhD • University of Waterloo <i>Dissolved Oxygen Impact on CHO Medium Ultraviolet Irradiation</i>	Clinton B. Pepper, PhD • Capsugel <i>Accelerate Cell Culture Development Using the Modular Automated Sampling Technology (MAST) Platform</i>
9:15 am – 10:00 am	William E. Grizzle, MD, PhD • Cooperative Human Tissue Network – <i>Availability of Human Tissues to Support Biomedical Research</i>	S. Steve Zhou, PhD • MicroBioTest, div. of Microbac Laboratories, Inc. – <i>Inactivation and Disinfection of Zika Virus on Surfaces</i>	Adam Elhofy, PhD • Essential Pharmaceuticals, LLC – <i>Glycolytic Complexity and Pattern Consistency Can be Improved by Using Novel Lipid Delivery</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:15 am	Maghboeba Mosavel, PhD • Virginia Commonwealth University – <i>Community Engagement and Biobanking: The GTE_x Ethical, Legal, and Social Implications (ELSI) Sub-Study</i>	Robert R. Donatelli • Eurofins Lancaster Laboratories, Inc. – <i>Testing of Host Cell Impurities: Scientific Considerations and Regulatory Expectation</i>	Patrick Sagmeister, PhD • EXPUTECH GmbH <i>Data Science for Biopharma Manufacturing: Improving Technology Transfers</i>
11:15 am – 12:00 noon	Nahid Turan, PhD • Coriell Institute for Medical Research – <i>Reference Samples for Human Genome Sequencing</i>	Donald L. Jarvis, PhD • GlycoBac LLC <i>Contamination Control Up-Front: Isolation and Characterization of an Sf-Rhabdovirus-Negative Cell Line for the Baculovirus-Insect Cell Expression System</i>	Mary Jo Wojtusik, PhD • LEWA Process Technologies, Inc. – <i>Buffer In-Line Dilution: Superior Performance with Volume-Based Control Systems</i>
12:00 noon – 12:45 pm			Mark F. Witcher, PhD • NNE Pharmaplan <i>Improving Process Analysis, Understanding, and Control of Biopharmaceutical Processes by Using a Well-Structured Design Space</i>
12:45 pm – 6:00 pm	Free Afternoon with Recommended Group Activity		
6:00 pm – 9:00 pm	Under the Sea Banquet at the Virginia Aquarium & Marine Science Center		
WEDNESDAY • DECEMBER 14, 2016			
7:30 am – 8:30 am	Breakfast in the Exhibit Area		
8:30 am – 9:15 am	John M. Baust, PhD • CPSI Biotech <i>Improving Processing and Recovery of Cryopreserved Cell and Tissues</i>	Rosemary J. Versteegen, PhD • International Serum Industry Association – <i>Risk Mitigation Strategies for Animal Sera Used in Cell Culture</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	Kelvin G.M. Brockbank, PhD • Tissue Testing Technologies LLC – <i>Recent Advances in Viable Ice-Free Vitrification for Cryopreservation of Cardiovascular Tissues</i>	Daniel Strauss, PhD • Asahi Kasei Bioprocess America, Inc. – <i>Direct Demonstration of Scalability of Virus Removal Filter Performance</i>	Mark A. Brower, PhD • Merck & Co., Inc. <i>Integration of PAT Tools into Continuous Biomanufacturing: Steps Toward Feedback Control and Real-Time Release</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:15 am	Yvonne A. Reid, PhD • American Type Culture Collection (ATCC) – <i>DNA Typing of Human Cell Lines: Historical Perspective</i>	Michael Brewer • Life Technologies <i>Design and Performance of a System for the Detection and Identification of Adventitious Agents in CHO Manufacturing</i>	Ravi Shankar • Endress+Hauser Inc. <i>Process Sensor Technology Moves into Process Development Laboratories</i>
11:15 am – 12:00 noon	Ian M. Pope, PhD • Brooks Life Science Systems – <i>Cold Chain Management — Transient Warming Control During Sample Handling</i>	Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc. – <i>Worst Case Model Viruses for Low and High pH Inactivation</i>	Craig T. Robinson • Repligen Corporation <i>Supporting Emerging Trends in Upstream Cell Culture Processing Objectives</i>
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	Alissa M. Resch, PhD • Coriell Institute for Medical Research – <i>Importance of DNA and Tissue Samples for Clinical Diagnostic Testing</i>	Panel Discussion: <i>Managing Cell & Tissue Contaminants</i>	Christopher W. Kemp, PhD • Kempbio, Inc. <i>Monitoring Virus and VLP Loads in Biological Process Fluids</i>
2:15 pm – 3:00 pm	Ashley Bowman • LifeNet Health <i>Human Tissues and Cells for Biomedical and Pharmaceutical Research</i>		John Poppleton • Applikon Biotechnology, Inc. – <i>Monitoring and Controlling Viable Biomass in Bioprocesses Using Dielectric Spectroscopy for PAT Control</i>
3:00 pm – 3:30 pm	Afternoon Break in the Exhibit Area (Exhibit Teardown begins at 3:30 pm)		
3:30 pm	Meeting Adjourns		

Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice.