

Cell & Tissue Banking Contaminant Control Process Analysis & Automation

December 11-13, 2017 • Virginia Beach, VA USA

Cell & Tissue Banking – Program Chairs:

Alissa M. Resch, PhD • Coriell Institute for Medical Research
Fang Tian, PhD • 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:

Robert R. Boulanger, PhD • CRB
Jeffery N. Odum • NNE

SUNDAY • DECEMBER 10, 2017

3:00 pm – 6:00 pm

Welcome Reception and Registration in the Peacock Foyer

MONDAY • DECEMBER 11, 2017

7:00 am – 8:00 am

Registration and Breakfast in Peacock Salon C

8:00 am – 8:30 am

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

Next-Generation Cancer Models: Challenges in Scale-Up and Cell Banking for Global Distribution

James M. Clinton, PhD
American Type Culture Collection

Viral Safety Testing: In Vitro, In Vivo, In Vogue?

Audrey Chang, PhD
BioReliance

Rapid Process Development for a Miniature-Scale Culture System

Matthew T. McRae, PhD
Nova Biomedical

9:15 am – 10:00 am

Mouse Cell Line Authentication Consortium Update

Jamie Almeida
National Institute of Standards & Technology

New Testing and Treatment Methods for Animal Sera

Rosemary J. Versteegen, PhD
International Serum Industry Association

Process Analytics for Gene Therapy Vector Production

Sebastijan Peljhan, PhD • BIA Separations

10:00 am – 10:30 am

Morning Break in Peacock Salon C

10:30 am – 11:00 am

Technology Workshops

Peacock Salon A

Quality Risk Management (QRM): A Prospective Approach Based on Evaluating Causal Mechanisms Using a System Risk Structure (SRS)

NNE

Workshop Pending

Workshop Pending

11:00 am – 11:30 am

11:30 am – 12:00 noon

Lunch and Local Handmade Holiday Market in Peacock Salon C (Poster Session from 1:00 – 1:30 pm)

12:00 noon – 1:30 pm

Human Cell Line Authentication

Douglas Storts, PhD
Promega Corporation

Heat Inactivation of Virus: Expect the "Unexpected"

S. Steve Zhou, PhD
MicroBioTest, div. of Microbac Laboratories, Inc.

Novel Process Analytical Technology (PAT)

Applications Using Advanced Imaging Technology
Tod Canty
JM Canty, Inc.

2:15 pm – 3:00 pm

Development of Reference Materials for Genetic Testing from Biorepository Samples: GeT-RM Program

Lisa V. Kalman, PhD
Centers for Disease Control & Prevention

Determining Subvisible Particulate Matter in Therapeutic Protein Injections

Zachary Beck
Eurofins Lancaster Laboratories, Inc.

Automated Manufacturing Solutions for Patient-Scale Therapies

Yaling Shi, PhD
Lonza Walkersville, Inc.

3:00 pm – 3:30 pm

Afternoon Break in Peacock Salon C

3:30 pm – 4:15 pm

Best Practices to Consider for Naming Cell Lines

Yvonne A. Reid, PhD
Program Chair Emeritus

Detection of Virus in CHO Culture by Ultra-High Multiplex PCR and Next Generation Sequencing

Michael Brewer
Thermo Fisher Scientific

Multi-Parametric Control Strategies for Enabling Continuous Biomanufacturing

Christoph Herwig, PhD
Technische Universität Wien

4:15 pm – 5:00 pm

Adventitious Agent Risk Mitigation: Engineering Minute Virus of Mice Resistance into CHO Cells

Joaquina Mascarenhas, PhD
MilliporeSigma

Contamination Control in Bioprocessing: Filtration Challenges and Solutions During Microbial and Viral Clearance Operations

Hazel Aranha, PhD
Sartorius Stedim North America Inc.

Breaking Down the Walls – Integrated Process and Automation Design with Concurrent Engineering

Gilad Langer, PhD
NNE

5:00 pm – 7:00 pm

Reception in Peacock Salon C

	Cell & Tissue Banking Peacock Salon A	Contaminant Control Courtney Terrace	Process Analysis & Automation Spotswood Arms
7:30 am – 8:30 am		Breakfast in Peacock Salon C	
8:30 am – 9:15 am	<i>Establishment and Maintenance of iPSC Distribution Banks</i> Shuo-Hung “Jack” Hsiao, PhD Coriell Institute for Medical Research	<i>An Arms Race Between Bacteria and Bacteriophages — Will This War Ever End?</i> Marcin Łoś, PhD Phage Consultants	<i>Developments in Digital Biomanufacturing</i> William G. Whitford GE Healthcare
9:15 am – 10:00 am	Kamalpreet Arora, PhD US Pharmacopeial Convention	<i>Virus-Free Insect Cell Lines for Baculovirus-Mediated Recombinant Protein Production</i> Donald L. Jarvis, PhD GlycoBac LLC	<i>In-Line, Automated Monitoring with Viral Detection, A Case Study</i> Marissa Nasshan Ovizio Imaging Systems NV/SA
10:00 am – 10:30 am		Morning Break in Peacock Salon C	
10:30 am – 11:15 am	Paula Keskula Broad Institute	Kathryn Martin Remington, PhD BioReliance	<i>Adaptive Process Control Techniques for Next Generation Biologics and Biomanufacturing of the Future</i> Sam Watts, PhD Stratophase Ltd.
11:15 am – 12:00 noon	Fang Tian, PhD American Type Culture Collection	Houman Dehghani Amgen Inc.	<i>Developing Control Strategies for Maintaining Cleanroom Environments by Using a System Risk Structure (SRS) for a Quality Risk Management (QRM) Analysis</i> Mark F. Witcher, PhD NNE
12:00 noon – 6:00 pm	Free Afternoon with Recommended Group Activity: Guided Visit to Cape Henry Lighthouse and Beach Hike (1:30 – 4:30 pm)		
6:00 pm – 9:00 pm	Banquet at the Virginia Museum of Contemporary Art		

WEDNESDAY • DECEMBER 13, 2017

	Cell & Tissue Banking Peacock Salon A	Contaminant Control Courtney Terrace	Process Analysis & Automation Spotswood Arms
7:30 am – 8:30 am		Breakfast in Peacock Salon C	
8:30 am – 9:15 am	<i>Strategies and Trends for Improving Sample Quality Following Cryopreservation</i> John M. Baust, PhD CPSI Biotech	<i>Viral Safety Testing of Insect Cells for Production of Influenza Vaccines</i> Penny L. Post, PhD Protein Sciences Corporation	Marc Pelletier, PhD CRB
9:15 am – 10:00 am	<i>Quality Considerations for Reference Materials</i> Nahid Turan, PhD Coriell Institute for Medical Research	Antonio J. Scatena Gateway Analytical LLC	<i>Continuous Process Verification — Asset Health and Performance</i> Ravi Shankar Endress+Hauser Inc.
10:00 am – 10:30 am		Morning Break in Peacock Salon C	
10:30 am – 11:15 am	<i>Cell Line Authentication: Species Identity and Purity Analysis Using Next Generation Sequencing</i> Christine Mitchell WuXi AppTec Inc.	<i>Differential Retention of Parvoviruses by Virus Filtration</i> Michael Burdick, PhD CSL Behring	<i>Counter-Current Chromatography and Its Use in Bioprocessing</i> Sheldon E. Broedel Athena Environmental Sciences, Inc.
11:15 am – 12:00 noon	<i>Ice-Free Cryopreservation of Natural and Engineered Tissues</i> Kelvin G.M. Brockbank, PhD Tissue Testing Technologies LLC	Allen L. Burgenson Lonza Walkersville, Inc.	Speaker Pending
12:00 noon – 1:30 pm	Lunch in Peacock Salon C (Poster Session from 1:00 – 1:30 pm)		
1:30 pm – 2:15 pm	<i>A Master Cell Bank (MCB) Troubleshooting Case Study: Challenges and Process Improvements with Comprehensive Root Cause Analysis</i> Glenn Maclsaac Bristol-Myers Squibb Company	Shayn Armstrong, PhD Bionique Testing Laboratories, Inc.	Speaker Pending
2:15 pm – 3:00 pm	Speaker Pending	<i>A New Era of Adventitious Virus Detection: The Rewards and Challenges of Implementing Change</i> Cassandra Lambeth Braxton, PhD Biogen	Speaker Pending
3:00 pm – 3:30 pm	Afternoon Break in Peacock Salon C		
3:30 pm – 5:00 pm	Panel Discussion		
5:00 pm	Meeting Adjourns		

Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 10/17/17