

**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?
Kathryn Martin Remington, PhD
MilliporeSigma BioReliance® Services

A Case Study for Automated Sampling, Feedback Control, and Predictive Modeling of a CHO Cell Culture Process
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

Contamination Control in Bioprocessing: Filtration Challenges and Solutions During Microbial and Viral Clearance Operations
Hazel Aranha, PhD
Sartorius Stedim North America Inc.

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 – 11:15 am

Technology Workshops
Peacock Salon A

Quality Risk Management (QRM): A Prospective Approach Based on Evaluating Causal Mechanisms Using a System Risk Structure (SRS)
Mark F. Witcher, PhD
NNE

11:15 am – 12:00 noon

Development of MicroRNAs as Diagnostic and Therapeutic Tools for Prostate Cancer
Aurora E. Kerscher, PhD
Eastern Virginia Medical School (EVMS)

12:00 noon – 1:30 pm

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

1:30 pm – 2:15 pm

Human Cell Line Authentication
Douglas R. 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

Quality Considerations for Reference Materials
Nahid Turan, PhD
Coriell Institute for Medical Research

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

New Testing and Treatment Methods for Animal Sera
Rosemary J. Versteegen, PhD
International Serum Industry Association

Breaking Down the Walls – Integrated Process and Automation Design with Concurrent Engineering
Dwight J. Lammers
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> Alissa M. Resch, PhD Coriell Institute for Medical Research	<i>A New Era of Adventitious Virus Detection: The Rewards and Challenges of Implementing Change</i> Cassandra Braxton, PhD Biogen	<i>Developments in Digital Biomanufacturing</i> William G. Whitford GE Healthcare
9:15 am – 10:00 am	<i>Cell Banking Best Practices for Mammalian and Bacterial Cell Lines for Biotherapeutics</i> 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	<i>Generating New Cancer Cell Line Models and Using Existing Authenticated Models to Build a Cancer Dependency Map</i> Jennifer Roth Broad Institute	<i>Demonstration of Porcine Circovirus Type 2 Inactivation by the Low pH Step of the Trypsin Manufacturing Process Using a New Infectivity Assay</i> Kathryn Martin Remington, PhD MilliporeSigma BioReliance® Services	<i>Adaptive Process Control Techniques for Next Generation Biologics and Biomanufacturing of the Future</i> Simon J. Saxby Stratophase Ltd.
11:15 am – 12:00 noon	<i>Complex 3D Co-Cultures: Toward Robust and Uniform Assays in 3D</i> Brian Manning, PhD InSphero Inc.	<i>Ultraviolet Irradiation of Adventitious Agents for the Biopharmaceutical Industry</i> Sarah Meunier, PhD University of Waterloo	<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, A Sanofi Company	<i>Importance of Facility Fitness in Aging Facilities</i> Marc Pelletier, PhD CRB
9:15 am – 10:00 am	<i>The Genetic Testing Reference Materials Coordination Program (GeT-RM): Translating Reference Material Needs into Reality!</i> Lisa V. Kalman, PhD Centers for Disease Control & Prevention	<i>I Can See It, Now What Is It? A Guide for What Happens After Visual Inspection</i> 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, PhD 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 Jr., PhD 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	<i>Endotoxin Detection in Cell/Gene Therapy and Combination Products</i> Allen L. Burgenson Lonza Walkersville, Inc.	<i>Monitoring and Controlling Viable Biomass in Bioprocesses Using Dielectric Spectroscopy for PAT Control</i> Aditya Bhat, PhD Aber Instruments Ltd.
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 MacIsaac Bristol-Myers Squibb Company	<i>New Topics for an Old Mycoplasma Technology</i> Shayn Armstrong, PhD Bionique Testing Laboratories, Inc.	<i>Process Automation System Design with a Purpose</i> Dwight J. Lammers NNE
2:15 pm – 3:00 pm	<i>Characterization and Banking of CRISPR-Generated Isogenic Cell Lines</i> Fang Tian, PhD American Type Culture Collection	<i>An Arms Race Between Bacteria and Bacteriophages — Will This War Ever End?</i> Marcin Łoś, PhD Phage Consultants	<i>Continuous Bioprocessing – Turning a Vision into Reality</i> Julie Grace Pall Life Sciences
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		