

2nd Fall Meeting
Cell Banking
Contaminant Control
Rapid Scale-Up & In-Process Testing

FOR:
Antibodies
rProteins
Vaccines
Conjugates

October 27-29, 2014 • Rosslyn, Virginia USA

CELL BANKING – PROGRAM CHAIR:

Yvonne A. Reid, 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.

RAPID SCALE-UP & IN-PROCESS TESTING – PROGRAM CHAIR:

Barry Rosenblatt, PhD • SME Biotech Consulting

SUNDAY • OCTOBER 26, 2014

Welcome Reception

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

MONDAY • OCTOBER 27, 2014

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
Districtview South Room

[View Speaker Abstracts & Bios](#)

Rapid Scale-Up & In-Process Testing
Cityview Room

[View Speaker Abstracts & Bios](#)

8:30 am – 9:15 am

Edward Frey • Janssen Research & Development, LLC – *Cold Chain Custody: Management and Controls to Maintain Mammalian Cell Bank Integrity*

Penny L. Post, PhD • Protein Sciences Corporation – *Control of Process-Related Impurities for a Recombinant Seasonal Influenza Vaccine*

Alexander N. Kotov, MD, PhD • Aeras Development of a Chimpanzee Adenovector Technology Platform for Scalable Tuberculosis Vaccine Production

9:15 am – 10:00 am

Fang Tian, PhD • American Type Culture Collection (ATCC) – *Best Practices in Cell Banking*

Michael Brewer • Life Technologies *Validation Strategies for Real Time qPCR-Based Mycoplasma Detection Assays*

Rajesh K. Gupta, PhD • Biologics Quality & Regulatory Consultants, LLC – *Role of Environmental Monitoring and Microbiological Testing During Manufacture of Cell Culture Based Biologics*

10:00 am – 10:30 am

Morning Break in the Exhibit Area

10:30 am – 11:00 am

Beckman Coulter, Inc.: *Optimizing Cell Viability Analysis in an Automated Cell Counter*

11:00 am – 11:30 am

Technology Workshops
in the Riverview Room

ViroCyt, LLC: *Real-Time Virus Particle Quantification: Accelerating the Pace of Research, Development, and Production*

11:30 am – 12:00 noon

BIA Separations: *Enhanced Productivity in Developing and Manufacturing Viral Vectors and Vaccines Using Monolithic Columns*

12:00 noon – 1:30 pm

Lunch in the Exhibit Area (plus Poster Session from 1:00 pm – 1:30 pm in the Riverview Foyer)

1:30 pm – 2:15 pm

Katherine F. Bergmann, PhD • Eurofins Lancaster Laboratories, Inc. – *Virus Inactivation with Ultraviolet Electromagnetic Radiation - Subtype C*

Kurt A. Brorson, PhD • FDA CDER *PAT and the Future of Biotechnology*

2:15 pm – 3:00 pm

Baolin Zhang, PhD • FDA CDER *A Regulator's Perspectives on Cell Banks for Manufacturing Therapeutic Proteins*

Todd L. Talarico, PhD • Medicago USA *The Use of UVC for Viral Inactivation in a VLP Vaccine Manufacturing Process*

Joan Hilly Foster • Batavia Bioservices *Application of High-Throughput Technologies to Accelerate Pre-Clinical Product Development*

3:00 pm – 3:30 pm

Afternoon Break in the Exhibit Area

3:30 pm – 4:15 pm

Marcia A. Coyne • Genentech, Inc. *Cell Banking Benchmarking Survey Results*

Matthew L. Dickson, PhD • MedImmune, LLC *Adventitious Virus Inactivation During Equipment Cleaning in Suspension and on Product-Contact Surfaces*

Patrick Sagmeister • EXPUTECH GmbH *Mechanistic Tools to Speed Up Bioprocess Development*

4:15 pm – 5:00 pm

John M. Baust, PhD • CPSI Biotech *Development of Novel Devices for the Controlled and Rapid Freezing and Thawing of Viable Cell Products*

Heather D. Malicki, PhD • WuXi AppTec Inc. *Enhancing Adventitious Agent Control Strategies with Next Generation Sequencing Methods*

Rob Noel, PhD • Pall Life Sciences *Step-By-Step Towards Scalable Continuous Integrated Processing*

5:00 pm – 7:00 pm

Reception in the Exhibit Area

ISBioTech 2nd Fall Meeting (continued): TUESDAY • OCTOBER 28, 2014

	Cell Banking Riverview Room	Contaminant Control Districtview South Room	Rapid Scale-Up & In-Process Testing Cityview Room
7:30 am – 8:30 am	Breakfast in the Exhibit Area		
8:30 am – 9:15 am	Manohar R. Furtado, PhD • Biology For Global Good, LLC – <i>SNP Analysis for Cell Line Authentication</i>	Audrey Chang, PhD • BioReliance Corporation <i>Porcine Circovirus: Four Years Later, a CSO's Perspective</i>	Robert Boulanger, PhD • Protein Sciences Corporation – <i>Rapid Modification of an Existing Microbial Fermentation Facility for Influenza Production</i>
9:15 am – 10:00 am	Daniele M. Gilkes, PhD • Johns Hopkins University – <i>The Extracellular Matrix as a Driver for Cell Phenotyping</i>	Karen D. Smith • RJ Lee Group, Inc. <i>Investigating Foreign Particulate Matter Contamination in Pharmaceuticals</i>	Lidija Urbas, PhD • BIA Separations <i>Convective Interaction Media Chromatography as Process Analytical Technology (PAT) Tools for Efficient and Robust Manufacturing of Biopharmaceuticals</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:15 am	Stephanie P. Laidig • Janssen Research & Development, LLC – <i>Outsourcing Cell Bank Production</i>	Michelle E. Cree, PhD • Catalent Pharma Solutions, Inc. – <i>Elemental Impurities – New Regulatory Expectations and Solutions</i>	Mark F. Witcher, PhD • Integrated Project Services – <i>Using Lifecycle Validation and Quality by Design (QbD) to Efficiently Progress from Pre-Investigational New Drug (IND) to Commercial Manufacturing</i>
11:15 am – 12:00 noon	Yvonne A. Reid, PhD • American Type Culture Collection (ATCC) – <i>Authentication of Human Cell Lines by STR Profiling</i>	James C. Leung, PhD • Massachusetts Institute of Technology (MIT) – <i>An Update on the Activities of the Consortium on Adventitious Agent Contamination in Biomanufacturing</i>	Sue W. Clarke • ImmBio Ltd. <i>Next Generation Vaccines: Development of a Novel Streptococcus pneumoniae Multivalent Protein Vaccine</i>
12:00 noon – 6:00 pm	Free Afternoon with Recommended Activities		
6:00 pm – 9:00 pm	Halloween Banquet at Artisphere		
WEDNESDAY • OCTOBER 29, 2014			
7:30 am – 8:30 am	Breakfast in the Exhibit Area		
8:30 am – 9:15 am	Paul J. Price, PhD • Media Design Consultant <i>Best Practices for Cell Culture Media Design and Processes</i>	Michael R. Sasges • Trojan Technologies <i>UV Disinfection of Cell Culture Media: The Effect on Composition and Cell Growth</i>	Phillip B. Maples, PhD • Laurus Bio, LLC <i>Rapid Product Development and Facility Design for Complex Biologics</i>
9:15 am – 10:00 am	Arifa S. Khan, PhD • FDA CBER <i>Identification of a Novel Rhabdovirus in Sf9 Cell Lines</i>	Houman Dehghani, PhD • Amgen Inc. <i>Evaluation of Growth Properties of Different Strains of Mouse Minute Virus in Two Different Test Systems</i>	Barry Rosenblatt, PhD • SME Biotech Consulting – <i>Program Review and Chair's Perspective</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:15 am	Kenneth H. Warrington, Jr., PhD • SGS Life Science Services – <i>Viral Safety Approaches for Influenza Vaccine Manufacturing: Egg & Cell Culture-Based Vaccines</i>	Patrick McCarthy • EMD Millipore <i>A Successful Validation and Submission Case Study of an Alternative Rapid Mycoplasma Testing Method for Biopharmaceutical Products</i>	Jeff Horsman • Mettler-Toledo AutoChem, Inc. – <i>In-Situ Process Analytical Technology Tools and Systems for the Biopharmaceutical Industry</i>
11:15 am – 12:00 noon	Kelvin G.M. Brockbank, PhD • Cell and Tissue Systems, Inc. – <i>Cryopreservation of Cells When DMSO is Not Adequate</i>	Hazel Aranha, PhD • Catalent Pharma Solutions, Inc. – <i>Virus Safety of Biopharmaceuticals: Reality or Myth</i>	R. Barry Holtz, PhD • InterveXion Therapeutics – <i>Developing Predictive Tools as Part of Quality by Design (QbD) for Rapid Scale-Up of Processes and Facilities</i>
12:00 noon – 1:30 pm	Lunch in the Exhibit Area		
1:30 pm – 2:15 pm	Leonard P. Freedman, PhD • Global Biological Standards Institute – <i>Irreproducibility: Changing the Policies and Culture of Cell Authentication</i>	Kathryn Martin Remington, PhD • BioReliance Corporation – <i>The Efficacy of Disinfection Procedures for the Control of Contaminants</i>	Christopher W. Kemp, PhD • Kempbio, Inc. <i>Tracking Baculovirus Levels in Upstream and Downstream Processes in Real-Time</i>
2:15 pm – 3:00 pm	James Gombold, PhD • Charles River Laboratories – <i>A Systematic Evaluation of In Vitro and In Vivo Adventitious Virus Assays for the Detection of Viral Contamination of Cell Banks and Biological Products</i>	Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc. – <i>Models Designed for Heat Inactivation of Viruses: Three Application Scenarios</i>	Rocco Vendegna • Ajinomoto Althea, Inc. <i>Cell Banking: Achieving the Best Possible Outcome</i>
3:00 pm – 3:30 pm	Afternoon Break in the Exhibit Area (Exhibit Teardown begins at 3:30 pm)		
3:30 pm – 4:15 pm	Ian M. Pope, PhD • CRYO Associates, Inc. <i>The Multi-Talented Repository</i>		
4:15 pm	Meeting Adjourns		