



Cell Line Development & Banking + Rapid Scale-Up & Testing

PROGRAM CHAIR:

James Moldenhauer – Eli Lilly & Company

SCIENTIFIC ADVISORY COMMITTEE:

Arifa S. Khan, PhD – FDA CBER

James Moldenhauer – Eli Lilly & Company

Claudia W. Buser, PhD – Genzyme Corp., a Sanofi company

PROGRAM CHAIR:

Keith L. Carson – ISBioTech

SCIENTIFIC ADVISORY COMMITTEE:

Jeri Ann Boose, PhD – Eurofins Lancaster Laboratories, Inc.

Anthony S. Lubiniecki, ScD – Janssen Research & Development, LLC

SUNDAY • OCTOBER 13, 2013

3:00 pm – 7:00 pm **Welcome Reception at Meeting Venue, plus Exhibit Setup**

MONDAY • OCTOBER 14, 2013

7:00 am – 8:00 am **Registration, Breakfast in Meeting Foyer, plus Exhibit Setup**

8:00 am – 8:30 am **Meeting Overview in Riverview Room**

**CELL LINE DEVELOPMENT
& BANKING Riverview Room**

**RAPID SCALE-UP &
TESTING Cityview Room**

8:30 am – 9:15 am **Speaker Presentations**

Maureen A. Costello, PhD • Seraphim Life Sciences, LLC
Cell Banks and Process Control

Lajos Baranyi, PhD • Lentigen Corporation
Rapid Scale-Up and Testing of Virus-Like Particle Vaccines Using a Lentivirus Platform

9:15 am – 10:00 am **Speaker Presentations**

James Moldenhauer • Eli Lilly & Company
Facility Design and Operations for Multi-Platform Cell Banking

Nadine M. Ritter, PhD • Biologics Consulting Group, Inc.
Use of Process Analytical Technology to Manage Host Cell Proteins

10:00 am – 10:30 am **Morning Break in Exhibit Area** / 10:30 am – 11:15 am **Technology Workshop in Riverview Room**

Biolog

11:15 am – 12:00 noon **Technology Workshop in Riverview Room**

TAP Biosystems

12:00 noon – 1:30 pm **Lunch in Exhibit Area** (Poster Presentations from 1:00 pm – 1:30 pm) /
1:30 pm – 2:15 pm **Keynote Presentation in Riverview Room**

Trends in the Development and Commercialization of Antibody Products

2:15 pm – 3:00 pm **Speaker Presentations**

FDA speaker unable to present due to government shutdown

Rajesh K. Gupta, PhD • Biologics Quality & Regulatory Consultants, LLC • *Scientific and Regulatory Aspects of Methods for Cell Culture-Based Biological Products in Ensuring Safety and Building Quality*

3:00 pm – 3:30 pm **Afternoon Break in Exhibit Area** / 3:30 pm – 4:15 pm **Speaker Presentations**

Yvonne A. Reid, PhD • American Type Culture Collection
Misidentification of Human Cell Lines Used for Cell Banking

Joseph M. Lee, PhD • BioReliance Corporation
BioSafety Testing in Support of Gene Therapy and Regenerative Medicine – from the Contract Service Organization Perspective

4:15 pm – 5:00 pm **Speaker Presentations**

Marcia A. Coyne • Genentech, Inc.
Novel Technologies for Reducing Time from Cell Bank to Scale-Up

Timothy J. Hahn, PhD • Novavax, Inc.
Rapid Manufacture and Release of a GMP Batch of Avian Influenza A (H7N9) Virus-Like Particle Vaccine within Three Months

6:00 pm – 8:00 pm **Reception in Exhibit Area**

CELL LINE DEVELOPMENT & BANKING
Riverview Room

RAPID SCALE-UP & TESTING
Cityview Room

TUESDAY • OCTOBER 15, 2013

7:30 am – 8:30 am **Breakfast in the Exhibit Area** / 8:30 am – 9:15 am **Speaker Presentations**

Penny L. Post, PhD • Protein Sciences Corporation
Development and Qualification of a Serum-Free Insect Cell Line for Use in Commercial Manufacturing

Steffen Kreye • GLYCOTOPE GmbH
GlycoExpress: A Toolbox for the High Yield Production of Glyco-Optimized Fully Human Biopharmaceuticals

9:15 am – 10:00 am **Speaker Presentations**

Michael J. Hantman, PhD • Charles River Laboratories
Multi-Modal Synergy in Biosafety Testing and Cell Line Characterization

Christopher W. Kemp, PhD • Kempbio, Inc.
Bioprocess Schemes for Rapid Process Development and Manufacturing Campaigns

10:00 am – 10:30 am **Morning Break in Exhibit Area** / 10:30 am – 11:15 am **Speaker Presentations**

Stephanie P. Laidig • Janssen Research & Development, LLC
Understanding Cell Bank Stability and Managing a Stability Program

Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc.
Worst-Case Model Viruses for Inactivation Approaches: It's Not Just About Parvoviruses!

11:15 am – 12:00 noon **Speaker Presentations**

FDA speaker unable to present due to government shutdown

Barry Rosenblatt, PhD • SME Biotech Consulting
So, You Want to Develop a New Biologic?

12:00 noon – 6:00 pm **Free Afternoon with Recommended Activities**

6:00 pm – 9:00 pm **Banquet at Artisphere**

WEDNESDAY • OCTOBER 16, 2013

7:30 am – 8:30 am **Breakfast in the Exhibit Area** / 8:30 am – 9:15 am **Speaker Presentations**

Kenneth H. Warrington, Jr., PhD • SGS Life Science Services
Cell Bank Biosafety/Analytical Characterization: Methods & Regulatory Expectations

Mark F. Witcher, PhD • Integrated Project Services
Advantages of Single-Use-Systems in Process Scale-Up

9:15 am – 10:00 am **Speaker Presentations**

Darrell Sleep, PhD • Novozymes Biopharma
Developing Yeast Strains as a Simple, Stable, Scalable, and Flexible Manufacturing Platform

Heather Beyer, PhD • Eurofins Lancaster Laboratories, Inc.
Virus Inactivation by UVC Treatment

10:00 am – 10:30 am **Morning Break in Exhibit Area** / 10:30 am – 11:15 am **Speaker Presentations**

Kelvin G.M. Brockbank, PhD • Cell and Tissue Systems, Inc.
Development of Frozen Multiwell "Cryoplates" with Viable Cells for High-Throughput Testing Applications

Sung Ho Hahm, PhD • Rafagen, Inc.
Genetic Engineering of CHO Cells for an Increase in Transgene Expression and a Better Fit in Scale-Up Production

11:15 am – 12:00 noon **Speaker Presentations**

Ian M. Pope, PhD • CRYO Associates, Inc.
Cryogenic Storage Strategy – Green Storage – Protecting the Environment and Maximising the Integrity of Stored Biologicals for Viability and Analytics

Weihong Wang, PhD • Eurofins Lancaster Laboratories, Inc.
Cell Based Potency Assays: From Development to Outsourcing

12:00 noon – 12:45 pm **Speaker Presentations**

Jeffrey A. Shaman, PhD • GENEWIZ Inc.
What's in My Bank? Approaches to Adventitious Virus, Microbial, and Cell Line Testing

Frederick M. Boyce, MD, PhD • Massachusetts General Hospital
Rapid Generation of Recombinant Baculoviruses Using Ver3 BacMam Vectors

12:45 pm – 2:15 pm **Lunch in Exhibit Area**

2:15 pm **Meeting Adjourns**