

**PROGRAM CHAIR:**

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**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**