

April 2-4, 2012 • Rosslyn, Virginia USA

Program At-A-Glance

SUNDAY • APRIL 1, 2012

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

MONDAY • APRIL 2, 2012

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

8:00 am – 8:30 am **Meeting Overview (Riverview Room)**

BACULOVIRUS EXPRESSION Track
Riverview Room

ANTIBODIES & RECOMBINANT PROTEINS Track
University South Room

VIRAL VECTORS & VACCINES Track
Cityview Room

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

Frederick M. Boyce, MD, PhD • Massachusetts General Hospital — *Recent Advances in BacMam Vectors*

Michael Brewer • Life Technologies
Strategies for Use of Rapid, Real-Time PCR Assays for Contaminant Detection in Biopharmaceutical Manufacturing

Barrie J. Carter, PhD • Carter BioConsulting
Success in Gene Therapy: Progress, Prospects, and Challenges

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

Nicola Burgess-Brown, PhD • The Structural Genomics Consortium — *High-Throughput Expression of Human Proteins in Insect Cells*

Mark Plavsic, DVM, PhD • Genzyme Corporation
Raw Material Treatment by Gamma Irradiation and Analytical Considerations

Peter K. Working, PhD • WorkingAdvisors, LLC
Requirements and Issues Faced – Product Characterization and Manufacturing for Phase III Viral Therapy Products

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

Donald L. Jarvis, PhD • University of Wyoming
Glycosylation Pathways in the Baculovirus-Insect Cell System

Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc.
Cell Authentication: Part of an Overall Cell Characterization Paradigm

J. Fraser Wright, PhD • The Children's Hospital of Philadelphia
Advancing Investigation Product Chemistry, Manufacturing, and Controls to Support Accelerating Clinical Progress in Therapeutic Gene Transfer

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

Malcolm J. Fraser, Jr., PhD • University of Notre Dame
Developing the Lepidopteran piggyBac Transposon for Genetic Engineering of Animals and Cell Cultures

Yvonne A. Reid, PhD • ATCC
Authentication of Human Cell Lines by STR Profiling

Charlotte Dyring, PhD • ExpreS²ion Biotechnologies
Development of a Placental Malaria Vaccine Using a Drosophila S2 Protein Expression Platform

12:00 noon – 1:30 pm **Lunch in Exhibit Area (Poster Presentations from 1:00 pm – 1:30 pm)**

1:30 pm – 3:00 pm **Technology Workshops**

Riverview Room

Cityview Room

1:30 pm – 2:00 pm

BIA Separations

2:00 pm – 2:30 pm

Alfa Wassermann Separation Technologies

2:30 pm – 3:00 pm

Refine Technology

Thermo Fisher Scientific

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

Robin Levis, PhD • FDA CBER
Current Regulatory Considerations Related to Antigen Production Using Baculovirus Expression Systems

Bill Lawrence • Amgen Inc.
Evaluation and Applications of a Rapid Nucleic Acid Based Universal Biosensor System for Detection of Adventitious Contaminants in Cell Culture

Larry A. Couture, PhD • City of Hope
Process Development for Vectors

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

Gale E. Smith, PhD • Novavax, Inc.
Genetic Engineering, GMP Manufacture, and Clinical Evaluation of a Respiratory Syncytial Virus Recombinant Fusion (F) Particle-Based Vaccine Made in Sf9 Cells

Vladimir Chizhikov, PhD • FDA CBER
Conventional and Alternative Approaches to Mycoplasma Testing of Cell Substrates: Pros and Cons

Richard O. Snyder, PhD • University of Florida, CERHB
Translational Research Support and Education: Moving Gene Therapies from Research into the Clinic

5:00 pm – 5:45 pm **Plenary Session (Riverview Room)**

Verne A. Luckow, PhD, JD • Polster, Lieder, Woodruff & Lucchesi, L.C.
Opportunities Provided by the Biologics Price Competition and Innovation Act of 2009 for the Sponsors of Innovative and Follow-On-Biologics and Their Service Providers

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

ISBioTech 2nd Annual Meeting: TUESDAY • APRIL 3, 2012

| BACULOVIRUS EXPRESSION Track Riverview Room | ANTIBODIES & RECOMBINANT PROTEINS Track University South Room | VIRAL VECTORS & VACCINES Track Cityview Room |
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| 7:30 am – 8:30 am Breakfast in the Exhibit Area / 8:30 am – 9:15 am Speaker Presentations | | |
| Suzanne M. Thiem, PhD • Michigan State University – Department of Entomology/Department of Microbiology and Molecular Genetics – <i>Progressing Toward Improved Membrane Protein Expression by Baculoviruses</i> | John L. Kolman, PhD • BioReliance Corporation <i>Massively Parallel Sequencing for Comprehensive Detection of Adventitious Agents</i> | Gwendolyn Binder-Scholl, PhD • Adaptimmune LLC <i>Engineered T Cell Therapy with Affinity Enhanced T Cell Receptors</i> |
| 9:15 am – 10:00 am Speaker Presentations | | |
| Loy E. Volkman, PhD • University of California, Berkeley <i>Actin and Baculovirus Biology</i> | Daniel Shelly, PhD • Novozymes Biopharma <i>Improving Circulatory Half-Life of APIs with Enhanced Recombinant Albumins via Conjugation and Albumin Fusion Technology</i> | Otto-Wilhelm Merten, PhD • Genethon <i>Large-Scale Production of AAV and LV Vectors</i> |
| 10:00 am – 10:30 am Morning Break in Exhibit Area / 10:30 am – 11:15 am Speaker Presentations | | |
| Penny L. Post, PhD • Protein Sciences Corporation <i>Safety Testing and Use of the Baculovirus Expression Vector System for GMP Manufacturing</i> | Euan W. Milne • Vitrology <i>Electron Microscopy in Biosafety: The Whys, Wherefores, and How a Picture is Worth a Thousand Words</i> | Carlos E. Ibañez, PhD • Tocagen Inc. <i>Preclinical and Product Development of a Retroviral Replicating Vector, Toca 511, in Phase I Trials in Patients with Recurrent High-Grade Glioma</i> |
| 11:15 am – 12:00 noon Speaker Presentations | | |
| Dominic Esposito, PhD • SAIC-Frederick, Inc. <i>Enhancing Protein Production with the Baculovirus Expression System Through Vector Engineering and Microscale Expression</i> | Gregory Sykes • American Type Culture Collection (ATCC) <i>Cell Culture Species Identification Through Molecular Genetics</i> | Wolfgang Klump, PhD • SAFC Pharma <i>Evolution of Validation Studies for a Titer Assay</i> |
| 12:00 noon – 6:00 pm | | |
| Free Afternoon with Recommended Activities – Visit the BioProcessing Journal exhibit (Tabletop #4) for suggestions and group sign-up sheets | | |
| 6:00 pm – 9:00 pm Banquet at the National Postal Museum | | |
| WEDNESDAY • APRIL 4, 2012 | | |
| BACULOVIRUS EXPRESSION Track Riverview Room | ANTIBODIES & RECOMBINANT PROTEINS Track University South Room | VIRAL VECTORS & VACCINES Track Cityview Room |
| 7:30 am – 8:30 am Breakfast in the Exhibit Area / 8:30 am – 9:15 am Speaker Presentations | | |
| Ross Taylor, PhD • LigoCyte Pharmaceuticals, Inc. <i>Production of Norovirus Virus-Like Particles in the Baculovirus Expression System from Benchtop to GMP Manufacturing</i> | Tina S. Morris, PhD • US Pharmacopeial Convention <i>Overview of USP's New General Information Chapter <1050.1> Design, Evaluation, and Characterization of Viral Clearance Procedures</i> | Elie Hanania, PhD • SAFC Pharma <i>Project Tech Transfer: How to Ensure Success</i> |
| 9:15 am – 10:00 am Speaker Presentations | | |
| April Birch • Kempbio, Inc. <i>Efforts in the Development of a Large-Scale Mammalian Expression Platform Based on BacMam Technology</i> | Kenneth H. Warrington, Jr., PhD • Meridian Life Science, Inc. <i>Challenge Viruses and the "Challenges" Associated with Their Production</i> | Daniel Galbraith, PhD • BioOutsource Ltd. <i>Overcoming Difficulties When QC Testing Viral Vectors</i> |
| 10:00 am – 10:30 am Morning Break in Exhibit Area / 10:30 am – 11:15 am Speaker Presentations | | |
| Brooks Hayes • Expression Systems, LLC <i>Current Trends Using the Baculovirus Vector and Host Cell Expression System for Commercial Applications</i> | Jeri Ann Boose, PhD • Lancaster Laboratories Inc. <i>Risk Mitigation Strategies for Non-Enveloped Viruses</i> | Patric Lundberg, PhD • Eastern Virginia Medical School <i>Sex Hormone Regulation of HSV Gene Expression: Considerations for In Vitro and In Vivo Pathogen Studies and Gene Vector Use</i> |
| 11:15 am – 12:00 noon Speaker Presentations | | |
| Monique M. van Oers, PhD • Wageningen University – Laboratory of Virology – <i>The Development of a Baculovirus-Virion Free Expression System: Exploitation of the Minor Capsid Protein VP80</i> | S. Steve Zhou, PhD • MicroBioTest <i>Control of Microbial Contamination in Bio-Manufacturing: Risks, Measures, and Testing</i> | Robert Schrock, PhD • Lonza Houston, Inc. <i>Expectations and Realities: Cell-Based Potency Assays</i> |
| 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 Speaker Presentations | | |
| Subhash Kalluri • Izon Science Ltd. <i>Quantification and Characterization of Baculovirus Using Nanopore-Based Sensors</i> | Miguel Noguerras, PhD • Abbott Medical Optics Inc. <i>Life Cycle of Rapid Methods for the Detection of Microorganisms</i> | Paul W. Shabram • PaxVax, Inc. <i>Adenovirus 4 Infectious Titer Using Flow Cytometry</i> |
| 2:15 pm – 3:00 pm Speaker Presentations | | |
| Bruce A. Webb, PhD • The University of Kentucky <i>Function and Versatility of Vankyrin Genes in Mediating Enhancement of Baculovirus Expression Vector Protein Production</i> | Marcin Los, PhD, DSc • Phage Consultants <i>A Wolf in Sheep's Clothing or Vice Versa? Implications of DE3 Prophage Applications in Protein Production</i> | Vladimir A. Slepushkin, MD, PhD • Lentigen Corporation <i>New Developments in the Manufacturing of Lentiviral Vectors</i> |
| 3:00 pm – 3:30 pm Afternoon Break in Exhibit Area (Exhibit teardown begins at 3:30 pm) / 3:30 pm – 4:15 pm Speaker Presentations | | |
| George W. Buchman, PhD • Chesapeake PERL Inc. <i>Recombinant Human Paraoxonase 1 Expressed by Baculovirus Infection of Whole Insect Larvae: A Potential Therapeutic for Lipidemia and Stroke</i> | Robert J. Duff, PhD • Lancaster Laboratories Inc. <i>Analytical Methods for Characterization of Antibody-Drug Conjugates: Challenges and Assessments of Heterogeneity and Stability</i> | Arifa S. Khan PhD • FDA CBER <i>Cell Substrate Safety Issues in the Production of Gene Therapy Vectors and Viral Vaccines</i> |
| 4:15 pm – 5:00 pm Speaker Presentations | | |
| John Zeng, PhD • Dendreon Corporation <i>Challenges and Strategy in Large-Scale Insect Cell-Baculovirus Technology for Vaccine Production</i> | Asri Gaduh • Amgen Inc. <i>Effectiveness of HTST as a Barrier to Adventitious Agent Contaminations</i> | Robert M. Kotin, PhD • US NIH/National Heart, Lung, and Blood Institute — <i>Large-Scale Recombinant Adeno-Associated Virus Production in Sf9 Cells</i> |
| 5:00 pm Meeting Adjourns | | |