

5 Days: March 11-15, 2013 • Rosslyn, Virginia USA

APPLICATION Track: Programs At-A-Glance

SUNDAY • MARCH 10, 2013

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

MONDAY • MARCH 11, 2013

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

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

| BACULOVIRUS EXPRESSION TECHNOLOGY Riverview Room | CELLULAR THERAPIES Tera Room | VIRAL VECTORS & VACCINES Cityview Room |
|--|--|---|
| 8:30 am – 9:15 am Speaker Presentations | | |
| Manuel J.T. Carrondo, PhD • Instituto de Biología Experimental e Tecnológica (iBET) — <i>Metabolomics and Proteomics Powering Insect Cells for the Production of Gene Therapy Vectors</i> | Phillip B. Maples, PhD • Gradalis, Inc. <i>FANG™ Autologous Cancer Vaccine in Phase II Clinical Trials: Manufacturing and BioAssay Developments</i> | Mavis Agbandje-McKenna, PhD • University of Florida <i>Structural Virology as a Tool in AAV Vectorology</i> |
| 9:15 am – 10:00 am Speaker Presentations | | |
| Pravin Mahajan, PhD • The Structural Genomics Consortium <i>Baculovirus Expression of Human Integral Membrane Proteins at the SGC</i> | Fred Miesowicz, PhD • Argos Therapeutics, Inc. <i>An Automated Approach for Manufacturing Personalized Dendritic Cell Immunotherapies</i> | Kevin Briggs • SAFC Carlsbad Inc. <i>Validating a Biological Manufacturing Platform</i> |
| 10:00 am – 10:30 am Morning Break in Exhibit Area / 10:30 am – 12:00 noon Technology Workshops | | |
| 10:30 am – 11:00 am | Aldevron | BIA Separations |
| 11:00 am – 11:30 am | | Pall Life Sciences |
| 11:30 am – 12:00 noon | | Eastern Virginia Medical School (EVMS) |
| 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 | | |
| Donald L. Jarvis, PhD • University of Wyoming <i>Protein Glycosylation in the Baculovirus Insect Cell System</i> | Anthony Ting, PhD • Athersys, Inc. <i>Adult Stem Cells for Cardiovascular Disease: Process and Manufacturing Change in Mid-Phase Development</i> | Audrey Chang, PhD • BioReliance Corporation <i>Assay Validation from a Contract Testing Organization Perspective</i> |
| 2:15 pm – 3:00 pm Speaker Presentations | | |
| Robert Ames, PhD • GlaxoSmithKline <i>BacMam: A Versatile Solution for Drug Discovery Bioassays</i> | Ian K. McNiece, PhD • MD Anderson Cancer Center <i>In Vivo and In Vitro Applications of Stromal Cells</i> | Kathryn Rizzo • Protein Sciences Corporation <i>Biosafety Characterization of an Insect Cell Line for GMP Manufacturing</i> |
| 3:00 pm – 3:30 pm Afternoon Break in Exhibit Area / 3:30 pm – 4:15 pm Speaker Presentations | | |
| Gale E. Smith, PhD • Novavax, Inc. <i>Challenges and Evaluation of Influenza and Respiratory Syncytial Virus Nanoparticle Immunogens Produced in Insect Cells</i> | Kanika Chawla, PhD • Cellerant Therapeutics, Inc. <i>Development of a Myeloid Progenitor Cell Therapy for Treatment of Chemotherapy and Radiation Induced Neutropenia</i> | Allison Hagerman • Oncolytics Biotech Inc. <i>Qualification of a Reovirus Production Process: Design through Production</i> |
| 4:15 pm – 5:00 pm Speaker Presentations | | |
| Tsafi Danieli, PhD • The Hebrew University of Jerusalem <i>Enhancing Protein Secretion</i> | Pamela G. Robey, PhD • National Institute of Dental and Craniofacial Research (NIH/NIDCR) <i>Cell Therapy Strategies for Connective Tissue Regeneration</i> | Harald Petry, PhD • uniQure B.V. <i>Hurdles Faced From the Quality Perspective During the Glybera Approval Process</i> |
| 5:00 pm – 5:45 pm Speaker Presentations | | |
| Christopher W. Kemp, PhD • Kempbio, Inc. <i>Bioreactor Scale-Up of BacMam-Transduced CHO-S Cells for the Production of Soluble Recombinant Proteins</i> | | Federico Mingozi, PhD • Genethon <i>Immune Responses to AAV Vectors, Implication for the Design of Gene Transfer Clinical Trials</i> |
| 6:00 pm – 8:00 pm Reception in Exhibit Area | | |
| TUESDAY • MARCH 12, 2013 | | |
| 7:30 am – 8:30 am Breakfast in the Exhibit Area / 8:30 am – 9:15 am Speaker Presentations | | |
| James M. Groarke, PhD • Bortus Biosciences <i>Baculovirus Protein Production for Drug Discovery</i> | Lee K. Roberts, PhD • Roberts Biotech Consulting, LLC — <i>Development of a Dendritic Cell Vaccine Platform for Translational Research</i> | Gabor M. Rubanyi, MD, PhD • Cardium Therapeutics, Inc. <i>Meeting Product Requirements for a Phase III Pivotal Trial and Beyond</i> |

Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice.

TUESDAY • MARCH 12, 2013 (continued)

| BACULOVIRUS EXPRESSION TECHNOLOGY Riverview Room | CELLULAR THERAPIES Tera Room | VIRAL VECTORS & VACCINES Cityview Room |
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| 9:15 am – 10:00 am Speaker Presentations | | |
| Fuad T. Haddadin, PhD • Boehringer Ingelheim Vetmedica, Inc. — <i>Process Improvement of Baculovirus Expression Vector System (BEVS): Methodology and Case-Study</i> | David F. Stroncek, MD • NIH Clinical Center <i>The Manufacture and Potency Testing of Dendritic Cells for Cancer Therapy</i> | Majid Mehtali, PhD • Vivalis — <i>Building on the Unique Biological Properties of Embryonic Stem Cells for the Industrial Manufacture of Human and Veterinary Vaccines</i> |
| 10:00 am – 10:30 am Morning Break in Exhibit Area / 10:30 am – 11:15 am Speaker Presentations | | |
| Yu-Chen “Andy” Hu, PhD • National Tsing Hua University <i>Baculovirus as a Versatile Gene Delivery Vector for Bone and Cartilage Tissue Engineering</i> | Dale Ando, MD • Sangamo BioSciences, Inc. — <i>Ex Vivo Modification and Expansion of Autologous CD4 T Cells in HIV Subjects and Correlation with Long Term In Vivo Persistence and CD4 T Cell Increases</i> | Fulvio Mavilio, PhD • Genethon <i>Interaction Between Lentiviral Gene Transfer Vectors and the Human Genome</i> |
| 11:15 am – 12:00 noon Speaker Presentations | | |
| Penny L. Post, PhD • Protein Sciences Corporation <i>GMP Manufacture of Influenza Vaccines Using the Baculovirus Expression System</i> | Marianna Sabatino, MD • National Institutes of Health (NIH) — <i>Potency and Quality Control for Bone Marrow Stromal Cell-Based Therapies</i> | J. David Pajeroski, PhD • Merck Research Laboratories — <i>Novel Cell Substrate(s) and Single-Use Technology for Manufacture of Viral Vaccines</i> |
| 12:00 noon – 12:45 pm Speaker Presentations | | |
| Felix Tay • National University of Singapore <i>Stable Genetic Modification of Human Pluripotent Stem Cells with Baculoviral Vectors</i> | | Vladimir A. Slepishkin, MD, PhD • Lentigen Corporation — <i>New Developments in Lentiviral Vector Manufacturing</i> |
| 12:45 pm – 6:00 pm Free Afternoon with Recommended Activities | | |
| 6:00 pm – 9:00 pm Banquet at Artisphere | | |
| WEDNESDAY • MARCH 13, 2013 | | |
| 7:30 am – 8:30 am Breakfast in the Exhibit Area / 8:30 am – 9:15 am Speaker Presentations | | |
| Thera Mulvania, PhD • Expression Systems, LLC <i>Strategies for the Purification of HIS-Tagged Proteins from Insect Cell Culture</i> | Harry C. Ledebur, Jr., PhD • Axonia Medical, Inc. <i>Stretch Growth of Tissue-Engineered Nerve Grafts</i> | Mark J. Federspiel, PhD • Mayo Clinic <i>Production and Purification of Oncolytic Measles Viruses for Human Clinical Trials</i> |
| 9:15 am – 10:00 am Speaker Presentations | | |
| Peter Pushko, PhD • Medigen, Inc. <i>Preparation of Multi-Subtype Influenza Virus-Like Particles (VLPs) Using a Baculovirus Expression System</i> | James G. Bender, PhD • ImmunoCellular Therapeutics, Ltd. <i>Development of a Dendritic Cell Vaccine Therapy for Glioblastoma</i> | Sandrine Cigarini • Sanofi Pasteur SA <i>Formulation Challenges in the Development of Viral Vectors and Vaccines</i> |
| 10:00 am – 10:30 am Morning Break in Exhibit Area / 10:30 am – 11:15 am Speaker Presentations | | |
| Robin Levis, PhD • FDA CBER <i>Regulatory Update: Characterization of Products Manufactured With Baculovirus Expression Systems</i> | Marta L. Schilling • Prima BioMed, Ltd <i>The Challenges of Harmonizing cGMP Manufacturing Across Multiple CMOs on Different Continents</i> | John Bell, PhD • Ottawa Hospital Research Institute <i>Targeted Oncolytic and Immunotherapeutic Viruses: Emerging Multi-Mechanistic Biologics for Cancer</i> |
| 11:15 am – 12:00 noon Speaker Presentations | | |
| James Wagner • Merck Research Laboratories <i>Insect Cells for the Production of Human Vaccine Candidates: Three Development Case Studies</i> | Pascal Beauchesne, PhD • Dendreon Corporation <i>Design Considerations in Autologous Cellular Immunotherapy Manufacturing Process Development</i> | Mark Angelino, PhD • bluebird bio Inc. <i>Evolution of a HIV-1 Based Lentiviral Vector Gene Therapy Platform</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 | | |
| Paula Marques Alves, PhD • Instituto de Biologia Experimental e Tecnologica (iBET) — <i>Flipase-Mediated Cassette Exchange in Sf9 Insect Cells for Stable Gene Expression</i> | Eric Dollins, PhD • FDA CBER <i>Characterization of Cellular Therapies: Regulatory Considerations</i> | Barbara A. Thorne, PhD • Celladon Corporation <i>Viral Safety for Viral Vectors</i> |
| 2:15 pm – 3:00 pm Speaker Presentations | | |
| Kim J. Stutzman-Engwall, PhD • Formerly with Pfizer Global R&D <i>BacMam-Mediated Recombinant Protein Expression for Assay Development</i> | Mary Pat Moyer, PhD • INCELL Corporation, LLC <i>Challenges in Manufacturing, Development, and Cryostorage of Autologous and Allogeneic Cell Therapies Derived From Various Tissues</i> | Daniel Takefman, PhD • FDA CBER <i>Manufacturing of Gene Therapies: Getting Your Product Ready for Licensure</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 | | |
| Monique M. van Oers, PhD • Wageningen University <i>Proteins Required for Baculovirus Particle Formation: Relevance for the Development of a Baculovirion-Free Expression System</i> | Lye Theng Lock • Lonza Walkersville, Inc. <i>Case Study of a Transfer of Human Mesenchymal Stem Cell (hMSC) Process from Traditional Multi-Tray Stack to 2D Xpansion Bioreactor</i> | J. Fraser Wright, PhD • The Children's Hospital of Philadelphia <i>Investigational Product Characterization for Phase III Clinical Trials</i> |
| 4:15 pm Meeting Adjourns | | |