

VIRAL VECTORS & VACCINES

Program Chairs:

Otto-Wilhelm Merten, PhD • Généthon
Mehdi Gasmı, PhD • Avalanche Biotechnologies

CELLULAR THERAPIES

Program Chair:

Phillip B. Maples, PhD • Laurus Bio, LLC

BACULOVIRUS EXPRESSION TECHNOLOGY

Program Chairs:

Kari Airene, PhD • University of Eastern Finland,
A.I. Virtanen Institute
Dominic Esposito, PhD • Frederick National Laboratory
for Cancer Research

SUNDAY • MARCH 8, 2015

4:00 pm – 7:00 pm

Welcome Reception
Plus Exhibit Setup at The Mead Center for American Theater (Arena Stage)

MONDAY • MARCH 9, 2015

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 Kreeger Theater

Viral Vectors and Vaccines Rehearsal Hall

[View Speaker Abstracts & Bios](#)

Cellular Therapies Classroom

[View Speaker Abstracts & Bios](#)

Baculovirus Expression Technology Kreeger Theater

[View Speaker Abstracts & Bios](#)

8:30 am – 9:15 am

Michael Havert, PhD • FDA CBER
Environmental Assessment Expectations for Gene Therapies, Viral Vectors, and Related Products

Laura E. Dickinson, PhD • Gemstone Biotherapeutics, LLC – *Bipotent Vascular Cells Co-Derived from Human Pluripotent Stem Cells*

Anandita Seth, PhD • Lonza Houston, Inc.
Application of Viral Titer Assay in the Development of a Scalable Baculovirus-Based AAV Production Process

9:15 am – 10:00 am

Leopold Grillberger, PhD • Baxter Innovations GmbH – *Novel Avian Cell Line for Human Vaccine and Vector Production*

Swati Pradhan-Bhatt, PhD • Christiana Care Health System – *Tissue Engineering and Regeneration of Glandular Organs: Strategies and Challenges*

Robin Levis, PhD • FDA CBER
Overview of US FDA Regulatory Framework and Licensure Pathways: Baculovirus Expressed Vaccine Antigens and Global Vaccine Development

10:00 am – 10:30 am

Morning Break in the Exhibit Area

10:30 am – 11:15am

Technology Workshops:

Novasep (in the Rehearsal Hall)
The Technical Challenges of Viral Vectors Manufacturing or the Twelve Labors of Hercules

ViroCyt, Inc. (in the Kreeger Theater)
Real-Time Virus Particle Quantification: Accelerating the Pace of Research, Development, and Production

11:15 am – 12:00 noon

BIA Separations (in the Rehearsal Hall)
Enhanced Productivity in Developing and Manufacturing Viral Vectors and Vaccines Using Monolithic Columns

Aldevron, LLC (in the Kreeger Theater)
Manufacturing of Ancillary Materials for Preclinical Through Clinical Applications

12:00 noon – 1:30 pm

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

1:30 pm – 2:15 pm

Maria Cristina Galli, PhD • Istituto Superiore di Sanità, Italy – *Developing AAV-Based Gene Therapy Medicinal Products: A European Perspective*

Mark Szczyпка, PhD • Pall Life Sciences
Generation of Therapeutically-Active Cells Using Microcarrier-Based Expansion in Bioreactors

Lionel Galibert, PhD • Généthon
Optimizing the Baculovirus Backbone for rAAV Production

2:15 pm – 3:00 pm

Carlos Augusto Pereira, PhD • Instituto Butantan
Insect Cell Culture in a Disposable Fixed-Bed Bioreactor: Productivity and Scaling-Up Perspectives

Brian Niland, PhD • FDA CBER
Regulatory Issues of Cellular Therapy Product Development

Monique M. van Oers, PhD • Wageningen University – *The Effect of Temperature on the Folding of Vertebrate Glycoproteins in Insect Cells*

3:00 pm – 3:30 pm

Afternoon Break in the Exhibit Area

3:30 pm – 4:15 pm

Sergei Zolotukhin, PhD • University of Florida
OneBac System for Scale-Up Production of Recombinant Adeno-Associated Virus (rAAV) Vectors

Ma Sha, PhD • Eppendorf, Inc. – *Solving a Stem Cell Therapy Bottleneck – Production of Multi-Billion Mesenchymal Stem Cells in Single-Use Vessels*

Ana Margarida Palma Teixeira, PhD • Instituto de Biologia Experimental e Tecnológica (IBET) – *Novel Insect Cell Platforms for Fast Expression of Complex Proteins by Targeted Gene Integration*

4:15 pm – 5:00 pm

Jakob Reiser, PhD • FDA CBER
Manufacturing Issues During Late Phase Development of Gene Therapy Products

Mahendra Rao, MD, PhD • The New York Stem Cell Foundation (NYSCEF) – *Manufacturing iPC-Based Cell Products — Issues and Solutions*

Samuel P. Simons • Protein Sciences Corporation
Improved Yield of Recombinant Hemagglutinin (rHA) for Production of the Flublok® Recombinant Influenza Vaccine

5:00 pm – 5:45 pm

Jean Peccoud, PhD • Virginia Bioinformatics Institute (VBI), Virginia Tech – *Rule-Based Design of Expression Vectors Using GenoCAD*

Thomas A. Brieva, PhD • Celgene Cellular Therapeutics – *Using Process Modeling to Direct Cell Therapy Manufacturing Development Towards Commercial Success*

Verne A. Luckow, PhD, JD • Ware, Fressola, Maguire & Barber LLP – *Reflections on the America Invents Act (AIA) of 2011 and the Biologics Price Competition and Innovation Act (BPCIA) of 2010: Where Are We Now?*

6:00 pm – 8:00 pm

Reception in the Exhibit Area

ISBioTech 5th Spring Meeting (continued): TUESDAY • MARCH 10, 2015

	Viral Vectors & Vaccines Rehearsal Hall	Cellular Therapies Classroom	Baculovirus Expression Technology Kreeger Theater
7:30 am – 8:30 am	Breakfast in the Exhibit Area		
8:30 am – 9:15 am	Johannes C.M. Van der Loo, PhD • Cincinnati Children's Hospital Medical Center – <i>Foamy Virus Vector Scale-Up for Clinical Application</i>	Phillip B. Maples, PhD • Laurus Bio, LLC on behalf of Axonia Medical, Inc. <i>Three-Dimensional Nerve Constructs</i>	Timothy J. Hahn, PhD • Novavax, Inc. <i>Rapid Manufacture and Release of a GMP Batch of Zaire Ebola Virus Glycoprotein Vaccine Made Using Recombinant Baculovirus-Sf9 Insect Cell Culture Technology</i>
9:15 am – 10:00 am	Haifeng Chen, PhD • Virovek, Inc. <i>Manufacturing AAV Vectors in Insect Cells: The Reliable Way Towards Commercialization</i>	Kelvin G.M. Brockbank, PhD • Tissue Testing Technologies LLC – <i>Cryopreservation of 2D and 3D Tissue Cultures for Chemical Testing and Regenerative Medicine</i>	Wei Xia Ang • A*STAR - Institute of Bioengineering and Nanotechnology (IBN), Singapore – <i>Baculovirus as an Immunotherapeutic Agent and a Gene Transfer Vector for Bladder Cancer Therapy</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:15 am	Ozan S. Kumru, PhD • University of Kansas <i>Characterization of an Oncolytic Herpes Simplex Virus Drug Candidate</i>	Ian K. McNiece, PhD • MD Anderson Cancer Center <i>Applications of Cellular Therapies for Cancer Patients</i>	Christopher W. Kemp, PhD and April Birch Kempbio, Inc. – <i>Development of a High Cell Density Protocol for BacMam Transductions of HEK-293 and CHO Cells for the Production of rlgG and VLPs</i>
11:15 am – 12:00 noon	Hanna P. Lesch, PhD • FKD Therapies Oy <i>Process Development and Clinical Production of Viral Vectors for Phase I and Beyond</i>	Boro Dropulić, PhD • Lentigen Technology Inc., a Miltenyi Biotec Company – <i>Towards a Commercial Process for the Manufacture of Ex Vivo Gene Therapy Products: CAR Engineered T Cells for Leukemia Therapy</i>	Dominic Esposito, PhD • Frederick National Laboratory for Cancer Research – <i>Engineering the Baculovirus Genome to Improve Recombinant Protein Expression</i>
12:00 noon – 12:45 pm		Harry L. Malech, MD • National Institutes of Health <i>Targeted Gene Delivery for iPS Cells</i>	
12:45 pm – 1:45 pm	Lentivirus Reference Material Working Group Meeting in the Rehearsal Hall		
1:45 pm – 6:00 pm	Free Afternoon with Recommended Activities		
6:00 pm – 9:00 pm	Luck o' the Irish Banquet in the Molly Smith Study		
WEDNESDAY • MARCH 11, 2015			
7:30 am – 8:30 am	Breakfast in the Exhibit Area		
8:30 am – 9:15 am	David R. Knop, PhD • Applied Genetic Technologies Corporation (AGTC) – <i>AAV Manufacturing Using Herpes-Assisted Vector Expansion</i>	John M. Baust, PhD • CPSI Biotech <i>Impact of Novel Rapid Freezing and Thawing Devices on Improving Cryopreserved Cell Product Recovery</i>	Yu-Chen "Andy" Hu, PhD • National Tsing Hua University – <i>Development of Hybrid Baculoviruses for Sustained Expression: Applications in Regenerative Medicine and Cancer Therapy</i>
9:15 am – 10:00 am	Klaus Kühnlcke, PhD • EUFETS GmbH <i>High Titer Production of GMP-Grade Self-Inactivating (SIN) Gamma-Retroviral Vectors</i>	Nikolay Korokhov, PhD • BioReliance Corporation <i>BioSafety Testing in Support of Gene Therapy</i>	Robert D. Possee, PhD • Oxford Expression Technologies – <i>Selecting the Most Efficient Baculovirus Expression Vector for Recombinant Protein Production</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:15 am	Matthias Hebben, PhD • Généthon <i>Pre-Industrial Manufacturing of Lentiviral Vectors by Transient Transfection in Single-Use Systems</i>	Mohammad A. Heidarani, PhD • FDA CBER <i>Cell Therapy Product Manufacturing Considerations</i>	Sha Ha, PhD • Merck Research Laboratories <i>Biophysical and Biochemical Characterization of Recombinant Proteins and VLPs as Vaccine Candidates</i>
11:15 am – 12:00 noon	Jacek Lubelski, PhD • uniQure N.V. <i>uniQure's Production Platform, From Gene to Gene Therapy Product</i>	Daniel Simão • Instituto de Biologia Experimental e Tecnológica (iBET) – <i>Human 3D Neural In Vitro Model for Assessment of Gene Therapy Vectors</i>	Arifa S. Khan, PhD • FDA CBER – <i>Characterizing Retro-Elements Expressed In, and Produced From, Sf9 Cells</i>
12:00 noon – 1:30 pm	Lunch in the Exhibit Area (Poster Session from 1:00 pm – 1:30 pm)		
1:30 pm – 2:15 pm	Barbara A. Thorne, PhD • Celladon Corporation <i>Towards Industrial Scale Manufacturing of MYDICAR®: AAV1/SERCA2a for Heart Failure</i>	David F. Stroncek, MD • NIH Clinical Center <i>Anti-CD19 CAR T Cell Manufacturing and Clinical Outcomes: Promise and Problems</i>	Thera Mulvanian, PhD • Expression Systems, LLC <i>rAAV Production Using Linearized and Bacmid-Based Baculovirus Expression Vectors</i>
2:15 pm – 3:00 pm	Isabelle Rivière, PhD • Memorial Sloan Kettering Cancer Center – <i>Large-Scale Clinical Grade Retroviral Vector Production Using a Fixed-Bed Bioreactor</i>	Kathryn L. Pollock • University of Minnesota <i>Using Algorithms to Accelerate and Optimize Cellular Preservation Protocols</i>	Gale E. Smith, PhD • Novavax, Inc. <i>Expression and Immunity of a Recombinant 2014 Guinea Ebola Glycoprotein (GP) Nanoparticle Vaccine Produced in Sf9 Insect Cells</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	Kevin Briggs • SAFC Carlsbad Inc. <i>Adenovirus Vector, Two 50 L Productions: Established Techniques Contrasted with Disposable Purification Technology</i>	J. Joseph Melenhorst, PhD • University of Pennsylvania – <i>Chimeric Antigen Receptor-Directed T Cell Therapy: From Boutique to Mainstay Therapy of Cancer</i>	Donald L. Jarvis, PhD • University of Wyoming <i>Glycoengineering Insect Cell Lines and Baculovirus Vectors for Recombinant Glycoprotein Production</i>
4:15 pm – 5:00 pm	Panel Discussion: Encapsulation of Foreign DNA into AAV Vectors Produced with Different Production Systems (HEK293, Baculovirus, and Others)	Dale Ando, MD • Sangamo BioSciences, Inc. <i>HIV T Cell Program Using Gene Editing of the CCR5 Gene</i>	
5:00 pm	Meeting Adjourns		

All meals and events in the program are included with the registration fee.
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