

### 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

### 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  
*Regulatory Expectations for Baculovirus Expressed Products*

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

**Hanna P. Lesch, PhD** • FKD Therapies Oy  
*Process Development and Clinical Production of Viral Vectors for Phase I and Beyond*

**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 (NYSCF) – *Manufacturing iPSC-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

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

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

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