



#### Viral Vectors & Vaccines – Program Chairs:

**Otto-Wilhelm Merten, PhD** • Génethon  
**Barbara A. Thorne, PhD** • Thorne Bio-consulting LLC

#### Cellular Therapies – Program Chairs:

**Joseph A. Fraietta, PhD** • University of Pennsylvania  
**Martin A. Giedlin, PhD** • Novartis Pharmaceuticals Corporation

#### Baculovirus Expression Technology – Program Chairs:

**Penny L. Post, PhD** • Protein Sciences Corporation  
**Monique M. van Oers, PhD** • Wageningen University

### SUNDAY • MARCH 5, 2017

3:00 pm – 6:00 pm

**Welcome Reception in the Lower Lobby at the Mead Center for American Theater**  
Registration and Exhibit Set-Up

### MONDAY • MARCH 6, 2017

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 & Vaccines**  
Kreeger Theater  
[View Speaker Abstracts & Bios](#)

**Cellular Therapies**  
Classroom  
[View Speaker Abstracts & Bios](#)

**Baculovirus Expression Technology**  
Ammerman Rehearsal Hall  
[View Speaker Abstracts & Bios](#)

8:30 am – 9:15 am

**Marco Schmeer** • PlasmidFactory GmbH & Co. KG  
*Use of Minicircles for AAV Production*

**Kelvin G.M. Brockbank, PhD** • Tissue Testing Technologies LLC • 202 — *Fundamental Issues in Cryopreservation of Cells and Tissues*

**Amine Kamen, PhD** • McGill University  
*Critical Assessment of Influenza VLP Production in Sf9 and HEK293 Expression Systems*

9:15 am – 10:00 am

**Hugo R. Soares** • Instituto de Biologia Experimental e Tecnológica (iBET) • *Virus-Like Particles as Scaffolds for Vaccine Development: A Case Study of Hepatitis C Virus*

**John M. Baust, PhD** • CPSI Biotech  
*New Technologies for Enhanced Recovery of Cryopreserved Cells and Tissues*

**Clifton E. McPherson, PhD** • Protein Sciences Corporation • *Production of Recombinant Hemagglutinin for Flublok at the 20,000 L Scale*

10:00 am – 10:30 am

Morning Break in the Exhibit Area

10:30 am – 11:00 am

**Technology Workshop • BIA Separations**  
*High Resolution Monolithic Columns — Enabling Tools for Understanding Viral Structures and Their Purity*

**Technology Workshop • MilliporeSigma**  
*Virus Safety for Vaccines, Viral Vectors, and Cell-Based Therapies*

**Technology Workshop • The Intellectual Property Law Office of Verne A. Luckow, LLC**  
*Assessing the 21st Century Cures Act (21st CCA) and Proposals to Review Medical Device and Drug Prices on Institutions Having an Interest in the Life Sciences*

11:00 am – 11:30 am

**Technology Workshop • Novasep**  
*What Should be Anticipated and Implemented to Ensure a Successful Process Transfer: A CMO Perspective with Risk Analysis from Analytical to Process Transfer*

**Technology Workshop • Aldevron**  
*Critical Raw Materials for Cell and Gene Therapy: Manufacturing and Quality Considerations*

**Technology Workshop • Thermo Fisher Scientific**  
*Serum-Free Suspension System for Large-Scale Production of Clinical Grade Lentivirus*

11:30 am – 12:00 noon

**Technology Workshop • Vironova AB**  
*Characterization of Viral Vectors by Electron Microscopy and Image Analysis*

**Technology Workshop • FUJIFILM Diosynth Biotechnologies Texas, LLC** • *Comparison of Adherent Cell Technologies for the Amplification of Virus Stocks and Viral Vectors*

**Technology Workshop • SGS Vitrology**  
*Approaches to Biosafety Testing of Viral Vectors and Vaccines*

12:00 noon – 1:30 pm

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

1:30 pm – 2:15 pm

**Gwendolyn M. Wilmes, PhD** • Dimension Therapeutics • *Potency Assay Development for AAV Vectors*

**Rachel Legmann, PhD** • Pall Life Sciences  
*Clinical-Scale Manufacturing of Autologous Insulin Producing Liver-Derived Cells for the Treatment of Diabetes: Culture Dish to a 200 Plate Bioreactor*

**Tsafi Danieli, PhD** • The Hebrew University of Jerusalem • *Reproducing Irreproducible Results: Lessons Taught from a Self Destructing Protein*

2:15 pm – 3:00 pm

**Marian Bendik** • Shire  
*AAV Vector Quantification Strategy for Clinical Trials*

**Nirali N. Shah, MD** • National Cancer Institute  
*Lessons Learned With CAR T-Cell Therapies for Acute Lymphoblastic Leukemia*

**Luis A. Hernandez, PhD** • Boehringer Ingelheim Vetmedica, Inc. • *Baculovirus-Derived Particle and Subunit Vaccines for Influenza in Swine*

3:00 pm – 3:30 pm

Afternoon Break in the Exhibit Area

3:30 pm – 4:15 pm

**Renukaradhya J. Gourapura, DVM, PhD** • Ohio State University • *Nanotechnology-Based Viral Vaccines to Elicit Cross-Protective Immunity in a Pig Model*

**Kathleen Meyer, PhD** • Sangamo BioSciences, Inc. • *Preclinical Evaluation to Support the First-in-Human Study for Ex Vivo Zinc Finger Nuclease Genome Editing of the CCR5 Locus in Hematopoietic Stem and Progenitor Cells*

**Robin Levis, PhD** • FDA CBER  
*A Regulatory Perspective on Baculovirus Expression Systems*

4:15 pm – 5:00 pm

**Amitabha Deb, PhD** • Novartis Institutes for Biomedical Research • *Stabilizing Lentiviral Vector Formulations for CAR T-Cell Applications*

**Joseph A. Fraietta, PhD** • University of Pennsylvania • *Predictive Correlates of Response to CD19-Directed T-Cell Therapy*

**Wian A. de Jongh, PhD** • ExpreS2ion Biotechnologies • *Development of Malaria Sub-Unit Vaccines Using the Non-Viral Drosophila S2 Insect Cell Expression System*

5:00 pm – 6:00 pm

**Plenary Session in the Kreeger Theater**  
**Arifa S. Khan, PhD** • FDA CBER • *Next Generation Sequencing for Adventitious Virus Detection in Biologics*

6:00 pm – 8:00 pm

Reception in the Exhibit Area

## ISBioTech 7th Spring Meeting (continued): TUESDAY • MARCH 7, 2017

	<b>Viral Vectors &amp; Vaccines</b> Kreger Theater	<b>Cellular Therapies</b> Classroom	<b>Baculovirus Expression Technology</b> Ammerman Rehearsal Hall
7:30 am – 8:30 am	<b>Breakfast in the Exhibit Area</b>		
8:30 am – 9:15 am	<b>Suzanna Melotti</b> • bluebird bio Inc. <i>Physicochemical Characterization of Lentiviral Vectors</i>	<b>Allison Hubel, PhD</b> • University of Minnesota <i>Transforming Preservation of Cells Used Therapeutically: Improved Post-Thaw Function of Mesenchymal Stem Cells</i>	<b>João M.N. Vidigal</b> • Instituto de Biologia Experimental e Tecnológica (iBET) • <i>Insect Cell Platforms for Fast Production of Pseudotype Virus-Like Particles for Drug and Vaccine Development</i>
9:15 am – 10:00 am	<b>Axel Schambach, MD, PhD</b> • Hannover Medical School • <i>Alpharetroviral Self-Inactivating (SIN) Vectors: Biology, Applications, and Production</i>	<b>Cenk Sumen, PhD</b> • PCT, a Caladrius company <i>Successful Manufacturing of CAR T-Cell Therapies: Challenges and Opportunities</i>	<b>Gale E. Smith, PhD</b> • Novavax, Inc. <i>Challenges in the Development of a Zika Virus Envelope Dimer (EnvD) Vaccine in Insect Cells</i>
10:00 am – 10:30 am	<b>Morning Break in the Exhibit Area</b>		
10:30 am – 11:15 am	<b>Michael L. Roberts, PhD</b> • Synpromics Ltd <i>Enhancing Viral Vector Manufacturing and Therapeutic Construct Design with Synthetic Promoters</i>	<b>Michael C. Holmes, PhD</b> • Sangamo BioSciences, Inc. • <i>New Zinc Finger Nuclease Architectures for Precision Genome Engineering</i>	<b>Linda A. King, PhD</b> • Oxford Brookes University <i>BacMam Expression Vectors: Applications in Gene Therapy</i>
11:15 am – 12:00 noon	<b>Matthias Renner, PhD</b> • Paul-Ehrlich-Institut (PEI) <i>Viral Vector Manufacturing and Control: Regulatory Considerations and Challenges</i>	<b>Jeffery N. Odum</b> • NNE <i>The Journey to Design Efficient Cell Therapy Manufacturing Assets</i>	<b>Dieter Palmberger</b> • Austrian Centre of Industrial Biotechnology GmbH (ACIB) • <i>Baculovirus-Based Manufacturing of Large Biomolecular Assemblies in Trichoplusia ni Cells</i>
12:00 noon – 1:30 pm	<b>Lentivirus Reference Standard Working Group Meeting</b>		
12:00 noon – 6:00 pm	<b>Free Afternoon with Recommended Group Activity: Guided Walking Tour of Eastern Market and Capitol Hill</b> <i>Sponsored by Pall Life Sciences</i>		
6:00 pm – 9:00 pm	<b>Flamenco Banquet in the Molly Smith Study</b>		

## WEDNESDAY • MARCH 8, 2017

7:30 am – 8:30 am	<b>Breakfast in the Exhibit Area</b>		
8:30 am – 9:15 am	<b>Elizabeth Larimore, PhD</b> • Immune Design Corp. <i>Process Development and Manufacturing of ZVex, a Lentiviral Vector, for Treatment of Soft Tissue Sarcoma</i>	<b>David F. Stroncek, MD</b> • NIH Clinical Center <i>Chimeric Antigen Receptor T-Cells: Manufacturing Challenges</i>	<b>Donald L. Jarvis, PhD</b> • University of Wyoming <i>Recent Progress Towards Host Cell Improvement in the Baculovirus-Insect Cell System</i>
9:15 am – 10:00 am	<b>Eduard Ayuso, DVM, PhD</b> • Université de Nantes <i>Comparative Studies of AAV2 Manufacturing: Mammalian Versus Insect Cells</i>	<b>Boro Dropulić, PhD</b> • Lentigen Technology Inc., a Miltenyi Biotec Company • <i>Integration of Work Flows for the Manufacture of CAR T-Cell Products</i>	<b>Nicola A. Burgess-Brown, PhD</b> • The Structural Genomics Consortium (SGC) • <i>Optimising Baculovirus and BacMam Expression of Human Membrane Proteins</i>
10:00 am – 10:30 am	<b>Morning Break in the Exhibit Area</b>		
10:30 am – 11:15 am	<b>Joseph G. Joyce, PhD</b> • Merck Research Laboratories • <i>Challenges in the Development and Scale-Up of an Attenuated Live Virus Vaccine Candidate for Human Cytomegalovirus Infection</i>	<b>Ravi Vyzasatya</b> • Lonza Walkersville, Inc. <i>Important Design Considerations for the Development of a cGMP Compliant Manufacturing Process for Cell Therapy Applications</i>	<b>David A. Theilmann, PhD</b> • Agriculture and Agri-Food Canada • <i>The Ins and Outs of Baculovirus Infection: Dissecting the Mechanisms of Nucleocapsid Nuclear Import and Egress</i>
11:15 am – 12:00 noon	<b>Haifeng Chen, PhD</b> • Virovek, Inc. <i>Manufacturing Adeno-Associated Virus (AAV) in Insect Cells: Optimizations to Increase Recombinant Baculovirus (rBV) Stability and AAV Yield</i>	<b>Martin A. Giedlin, PhD</b> • Novartis Pharmaceuticals Corporation • <i>Bench to Commercial-Scale Process Development for a CAR T-Cell Therapy</i>	<b>M. Javad Aman, PhD</b> • Integrated Biotherapeutics, Inc. • <i>Virus-Like Particle-Based Vaccines for Filoviruses Produced in the Baculovirus Expression System: Opportunities and Challenges</i>
12:00 noon – 1:30 pm	<b>Lunch in the Exhibit Area (Poster Session from 1:00 – 1:30 pm)</b>		
1:30 pm – 2:15 pm	<b>Ramjay S. Vatsan, PhD</b> • FDA CBER <i>FDA Update on Regulatory Considerations for AAV, CAR T-Cell, and Genome Edited Products</i>	<b>Kenny Choi</b> • Kite Pharma, Inc. <i>Establishing Process Control for the Production of Autologous CAR T-Cells to Support Multicenter Studies in Leukemia</i>	<b>Sergei Zolotukhin, PhD</b> • University of Florida <i>Direct Head-to-Head Evaluation of Recombinant Adeno-Associated Viral (rAAV) Vectors Manufactured in Human Versus Insect Cells</i>
2:15 pm – 3:00 pm	<b>Els Verhoeven</b> • Ens de Lyon <i>New Lentiviral Vector Pseudotypes for Gene Therapy of Human Hematopoietic Cells</i>	<b>Ilya Shestopalov, PhD</b> • bluebird bio Inc. <i>Advanced Cellular Analytics for CD34 Drug Products</i>	<b>Robert L. Harrison</b> • USDA Agricultural Research Service • <i>Baculovirus Expression of Insecticidal Proteins</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>Matthias Hebben, PhD</b> • Généthon <i>Large-Scale Manufacturing of AAV Vectors: Scale-Up and Transfer of AAV Production Process for Crigler-Najjar Syndrome Gene Therapy</i>	<b>Leyla Diaz, PhD</b> • BioReliance Corporation <i>Testing Approaches for Cell-Based Therapeutics: Rapid Testing and Regulatory Expectations</i>	<b>Brian Paszkiet</b> • Thermo Fisher Scientific <i>A Yeastolate-Free Baculovirus-Based Expression System for Enhanced Protein Production in Sf9 Cells</i>
4:15 pm – 5:00 pm	<b>Nitin Garg</b> • Applied Genetic Technologies Corporation (AGTC) • <i>Bioreactor Production of Recombinant Herpes Simplex Virus</i>	<b>Brian Bischoff</b> • Cellular Therapy Solutions, LLC <i>Development of a Microfluidic Device for the Removal of Glycerol from Cultured Red Blood Cells</i>	<b>Monique M. van Oers, PhD</b> • Wageningen University • <i>Per Os Infectivity Factors (PIF) are Essential Proteins of Occlusion-Derived Viruses (ODVs), the 'Other' Baculovirus Particles</i>
5:00 pm – 5:45 pm	<b>Eevi M. Lipponen</b> • FinVector Vision Therapies OY • <i>Process Development for Large-Scale Lentivirus Production in an Adherent iCELLis 500 Bioreactor</i>		
5:45 pm	<b>Meeting Adjourns</b>		

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

REV 3/6/17