



# Viral Vectors & Vaccines

# 4<sup>th</sup> Spring Meeting

# Cellular Therapies

# Baculovirus Expression Technology

**March 10–12, 2014 • Washington, DC USA**

SUNDAY • MARCH 9, 2014			
3:30 pm – 6:30 pm	Welcome Reception, plus Exhibit and Poster Setup at the Mead Center		
MONDAY • MARCH 10, 2014			
7:00 am – 8:00 am	Registration and Breakfast in the Exhibit Area, plus Exhibit and Poster Setup		
8:00 am – 8:30 am	Meeting Overview in Kogod Cradle		
	<b>Baculovirus Expression Technology</b> Kogod Cradle <a href="#">View Speaker Abstracts &amp; Bios</a>	<b>Cellular Therapies</b> Classroom <a href="#">View Speaker Abstracts &amp; Bios</a>	<b>Viral Vectors and Vaccines</b> Rehearsal Studio <a href="#">View Speaker Abstracts &amp; Bios</a>
8:30 am – 9:15 am	<b>Donald L. Jarvis, PhD</b> • University of Wyoming <i>Advanced Recombinant Glycoprotein Production in the Baculovirus-Insect Cell System</i>	<b>Harry L. Malech, MD</b> • NIH National Institute of Allergy and Infectious Diseases (NIAID) – <i>Generation of Neutrophils and Monocytes from Induced Pluripotent Stem Cells: Potential Therapeutic Utility</i>	<b>Yvonne Genzel, PhD</b> • Max-Planck-Institute for Dynamics of Complex Technical Systems – <i>New Cell Substrates for Virus and Viral Vector Production</i>
9:15 am – 10:00 am	<b>Amine A. Kamen, PhD</b> • McGill University – <i>High Cell Density Insect Cell Culture as a New Generation Process for Manufacturing Viral Vectors and Vaccines</i>	<b>Jessica L. Lo Surdo, PhD</b> • FDA CBER <i>Toward Improved Characterization of Stem Cells for Use in Cellular Therapies: Quantitative Approaches to Better Assess Quality Attributes</i>	<b>Robert M. Kotin, PhD</b> • Voyager Therapeutics <i>Progress Report on Systemic Delivery of rAAV9-U7 Vector in the Golden Retriever Muscular Dystrophy Canine Model of Duchenne Muscular Dystrophy</i>
10:00 am – 10:30 am	Morning Break in the Exhibit Area		
10:30 am – 11:00 am	<b>Technology Workshops:</b>	Aldevron	InDevR
11:00 am – 11:30 am		Expression Systems, LLC	BIA Separations
11:30 am – 12:00 noon			Novasep
12:00 noon – 1:30 pm	Lunch in the Exhibit Area (Poster Presentations from 1:00 pm – 1:30 pm)		
1:30 pm – 2:15 pm	<b>Gale E. Smith, PhD</b> • Novavax, Inc. – <i>Development of an Insect Cell Derived Influenza A(H7N9) Virus-Like Particle (VLP) Vaccine: From Gene to Man</i>	<b>Madhusudan V. Peshwa, PhD</b> • MaxCyte Inc. <i>Translational Development of Messenger RNA Encoded Chimeric Antigen Receptor Engineered Onco-Immunotherapies</i>	<b>Denise K. Gavin, PhD</b> • FDA CBER <i>Regulatory Considerations for Adeno-Associated Viruses</i>
2:15 pm – 3:00 pm	<b>Loy E. Volkman, PhD</b> • University of California, Berkeley – <i>The Twist to Baculovirus Replication and Hyperexpression</i>	<b>Dale Ando, MD</b> • Sangamo BioSciences, Inc. <i>Reconstituting HIV Immunity with CCR5 Modified Autologous CD4 T Cells to Eradicate HIV</i>	<b>Amine A. Kamen, PhD</b> • McGill University <i>Influenza Vaccine Manufacturing Technologies: Antigens and Expression Systems Comparison</i>
3:00 pm – 3:30 pm	Afternoon Break in the Exhibit Area		
3:30 pm – 4:15 pm	<b>Arifa S. Khan, PhD</b> • FDA CBER <i>Challenges of Novel Virus Detection in Vaccine Cell Substrates</i>	<b>Racheli Ofir, PhD</b> • Pluristem Therapeutics Inc. <i>PLX, Placental-Derived Adherent Stromal Cells – Manufacturing and Properties</i>	<b>Victor Lu, PhD</b> • FDA CBER <i>Regulatory Considerations for Lentiviral Vectors for Human Use</i>
4:15 pm – 5:00 pm	<b>Charles Richardson, PhD</b> • Takeda Pharmaceuticals U.S.A., Inc. – <i>Scale-Up and Manufacturing of Norovirus Virus-Like Particles</i>	<b>Bruce L. Levine, PhD</b> • University of Pennsylvania <i>Chimeric Antigen Receptor (CAR) Modified T Cells Targeted Against Cancer: CAR Delivery and Clinical Update</i>	<b>J. Fraser Wright, PhD</b> • The Children's Hospital of Philadelphia – <i>Advancing Gene Therapy Product CMC Through Late Stage Clinical Development</i>
5:00 pm – 5:45 pm	<b>Panel Discussion in Kogod Cradle: Potential and Pitfalls for Cellular, VLP, and Gene Vector Vaccines</b> <ul style="list-style-type: none"> <li>• Daniel Takefman, PhD • FDA CBER</li> <li>• Robin Levis, PhD • FDA CBER</li> <li>• Robin A. Robinson, PhD • FDA HHS</li> <li>• Phillip B. Maples, PhD • Laurus Bio, LLC</li> </ul>		
6:00 pm – 8:00 pm	Reception in the Exhibit Area		

**ISBioTech 4th Spring Meeting (continued): TUESDAY • MARCH 11, 2014**

	<b>Baculovirus Expression Technology</b> Kogod Cradle	<b>Cellular Therapies</b> Classroom	<b>Viral Vectors and Vaccines</b> Rehearsal Studio
7:30 am – 8:30 am	<b>Breakfast in the Exhibit Area</b>		
8:30 am – 9:15 am	<b>Gary W. Blissard, PhD</b> • Boyce Thompson Institute for Plant Research – <i>The Interplay Among Genomes of the Baculovirus AcMNPV and the Host Cell Line Tnms42 at the Transcriptome Level</i>	<b>Kelvin G.M. Brockbank, PhD</b> • Cell and Tissue Systems, Inc. – <i>3D Preservation of Natural Tissues and Engineered Constructs</i>	<b>Axel Schambach, MD, PhD</b> • Hannover Medical School – <i>Biosafety Challenges for Use of Retro- and Lentiviral Vectors in Gene Therapy</i>
9:15 am – 10:00 am	<b>Corben P. Pijlman, PhD</b> • Wageningen University <i>Baculovirus Production of Enveloped Virus-Like Particle Vaccines</i>	<b>Harry C. Ledebur, Jr., PhD</b> • Axonia Medical, Inc. <i>Stretch Growth of Tissue-Engineered Nerve Grafts</i>	<b>Cécile Bauche, PhD</b> • THERAVECTYS SA <i>Lentiviral-Based Anti-HIV Therapeutic Vaccine: Design, Preclinical Studies, and Phase I/II Clinical Trial Preliminary Results</i>
10:00 am – 10:30 am	<b>Morning Break in the Exhibit Area</b>		
10:30 am – 11:15 am	<b>Renée Lapointe, PhD</b> • Sylvar Technologies Inc. <i>The Use of Evolutionary and Pathogenesis Studies in the Registration of Baculovirus-Based Insect Control Products</i>	<b>Ian K. McNiece, PhD</b> • MD Anderson Cancer Center <i>Development of Autologous and Allogeneic Stem Cell Products for Clinical Therapies</i>	<b>Douglas J. Jolly, PhD</b> • Tocagen Inc. <i>Production of a Replicating Retroviral Vector for Clinical Use</i>
11:15 am – 12:00 noon	<b>Robert Boulanger, PhD</b> • Protein Sciences Corporation – <i>Start-Up to Scale-Up in 100 Days: Rapid Modification of an Existing Microbial Fermentation Facility for Influenza Vaccine Production</i>	<b>Fred Miesowicz, PhD</b> • Argos Therapeutics, Inc. <i>Clinical Development of Autologous Dendritic Cells for Active Immunotherapy: The Challenges and Promise in Metastatic Renal Cell Carcinomas</i>	<b>Patric S. Lundberg, PhD</b> • Eastern Virginia Medical School – <i>Genetics, the Forgotten Variable</i>
12:00 noon – 12:45 pm	<b>AAV Baculovirus Reference Material Working Group Meeting in the Classroom</b>		
12:45 pm – 6:00 pm	<b>Free Afternoon with Recommended Activities</b>		
6:00 pm – 9:00 pm	<b>“South Pacific” Banquet at the Mead Center in the Molly Smith Study</b>		
<b>WEDNESDAY • MARCH 12, 2014</b>			
7:30 am – 8:30 am	<b>Breakfast in the Exhibit Area</b>		
8:30 am – 9:15 am	<b>Shu Wang, PhD</b> • National University of Singapore <i>Baculoviral Transduction for Cellular Reprogramming and Stable Genetic Modification of Human Pluripotent Stem Cells</i>	<b>Mary Pat Moyer, PhD</b> • INCELL Corporation, LLC <i>New Cell Therapies, Tools, and Product Pipelines</i>	<b>Jacek Lubelski, PhD</b> • uniQure B.V. <i>Insect Cell Based AAV Production: An Update on Process Optimizations</i>
9:15 am – 10:00 am	<b>Christopher W. Kemp, PhD and April Birch</b> • Kempbio, Inc. – <i>Advances in the Use of BacMam Transduced Mammalian Cells for the Large-Scale Expression of Proteins and Virus-Like Particles</i>	<b>Brian Niland, PhD</b> • FDA CBER <i>Characterization of Cellular Therapies: Regulatory Considerations</i>	<b>James Miskin, PhD</b> • Oxford BioMedica plc <i>Lentiviral Vectors: Summary of Experience Gained from Multiple Clinical Trials</i>
10:00 am – 10:30 am	<b>Morning Break in the Exhibit Area</b>		
10:30 am – 11:15 am	<b>Yu-Chen “Andy” Hu, PhD</b> • National Tsing Hua University, Taiwan – <i>Baculovirus as a Tool for Vaccine Development</i>	<b>David F. Stroncek, MD</b> • NIH Clinical Center, Department of Transfusion Medicine <i>Recent Advances in Adoptive T Cell Therapy</i>	<b>Mercedes Segura, PhD</b> • bluebird bio Inc. <i>Overview of Downstream Processing Strategies for Lentiviral Vectors</i>
11:15 am – 12:00 noon	<b>Thera Mulvanía, PhD</b> • Expression Systems, LLC <i>Purification of Recombinant Baculovirus by End Point Dilution and gp64 Screening</i>	<b>Andrew Picken, PhD</b> • Loughborough University <i>Minimizing Cryopreservation Risks for Stem Cell Therapy Bioprocessing</i>	<b>Vladimir A. Slepushkin, MD, PhD</b> • Lentigen Corporation – <i>Qualification of Lot Release Assays for Lentiviral Vectors</i>
12:00 noon – 1:30 pm	<b>Lunch in the Exhibit Area (Poster Presentations from 1:00 pm – 1:30 pm)</b>		
1:30 pm – 2:15 pm	<b>Dominic Esposito, PhD</b> • Leidos Biomedical Research, Inc. – <i>Improved Baculovirus Technologies for Protein Production in the Insect Cell Expression System</i>	<b>Thomas A. Brieva, PhD</b> • Celgene Cellular Therapeutics – <i>Designing Scalable Processes for Cell Therapies</i>	<b>Mark J. Federspiel, PhD</b> • Mayo Clinic – <i>Novel Production and Purification Processes for Oncolytic Viruses</i>
2:15 pm – 3:00 pm	<b>Holly J. Popham, PhD</b> • AgBiTech – <i>Development and Agricultural Use of Baculoviruses</i>	<b>Phillip B. Maples, PhD</b> • Laurus Bio, LLC <i>Cancer Vaccines / Immunotherapy Approaches</i>	<b>John T. Gray, PhD</b> • St. Jude Children’s Research Hospital – <i>Clinical Grade Lentiviral Vector Production from Stable Cell Lines</i>
3:00 pm – 3:30 pm	<b>Afternoon Break in the Exhibit Area (Exhibit and Poster Teardown begins at 3:30 pm)</b>		
3:30 pm – 4:15 pm	<b>Kari Airene, PhD</b> • University of Eastern Finland, A.I. Virtanen Institute – <i>Baculovirus Receptors and Signaling in Mammalian Cells</i>	<b>Margarida Serra, PhD</b> • iBET – <i>Integrating Bioprocess Optimization and Omics Tools Towards the Design of Novel Stem Cell Therapies for Cardiac Repair</i>	<b>Christine Le Bec, PhD</b> • Génethon <i>Analytical Methods to Measure Full and Empty AAV Particles</i>
4:15 pm – 5:00 pm	<b>Otto-Wilhelm Merten, PhD</b> • Génethon <i>Towards Large-Scale AAV Vector Production — The Use of Insect Cell/Baculovirus Technology: Developments, Optimisations, and Perspectives</i>	<b>Heather L. Brown</b> • Cord Blood Registry <i>Collection, Processing, and Storage of Umbilical Cord Blood Stem Cells</i>	
5:00 pm	<b>Meeting Adjourns</b>		