

**10<sup>TH</sup> SPRING MEETING REDUX**  
**VIRTUAL**

**MARCH 15-17, 2021**

**Viral Vectors & Vaccines**

*Chaired By:*

**María Mercedes Segura, PhD**

AVROBIO

**Lawrence C. Thompson, PhD**

Pfizer, Inc.

**Otto-Wilhelm Merten, PhD**

Miltenyi Biotec Inc.

**Cellular Therapies**

*Chaired By:*

**Martin A. Giedlin, PhD**

PACT pharma

**Baculovirus Expression Technology**

*Chaired By:*

**Dominic Esposito, PhD**

Frederick National Laboratory for Cancer Research

**António M. Roldão, PhD**

Instituto de Biologia Experimental e Tecnológica (iBET)

**MONDAY • MARCH 15, 2021**

9:00 am – 9:15 am

**Intro/Overview**

9:15 am – 9:30 am

**Break**

**Viral Vectors & Vaccines**

**Cellular Therapies**

**Baculovirus Expression Technology**

9:30 am – 10:10 am

*Functional Roles of the Novel AAV Membrane-Associated Accessory Protein*

**Lionel Galibert, PhD**

Kuopio Center for Gene and Cell Therapy

*Autologous Cell Therapy Manufacturing Innovation and Industry 4.0 Solutions*

**Ohad Karnieli, PhD**

AdvaBio Ltd.

*BacMam-Mediated In Situ Modification of Recombinant Proteins*

**Christopher W. Kemp, PhD**

Kemp Proteins, LLC

10:10 am – 10:25 am

**Break**

10:25 am – 11:05 am

*Development and Validation of Analytical Methods for GTx Commercialization*

**Vesselin Mitaksov**

Pfizer, Inc.

*Recommendations for the Development of Allogeneic CAR T-Cell Products — A CBER Perspective*

**Anna Kwilas, PhD**

FDA CBER

*Screening and Production of Human Proteins Using Baculovirus and BacMam*

**Nicola A. Burgess-Brown, PhD**

University of Oxford

11:05 am – 11:20 am

**Break**

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The ISBioTech 10th Spring Meeting Redux (continued): MONDAY • MARCH 15, 2021

11:20 am – 11:50 am	<b>Technology Workshop</b> Paragon Gene Therapy, now a part of Catalent	<b>Technology Workshop</b> <i>How to Mitigate Contamination Risk for Viral Vector Large-Scale Production</i> Pall Biotech	<b>Technology Workshop</b> <i>Considerations for Plasmid DNA in Gene Therapy: Evaluating the Impact of How Materials are Used on Design, Characterization, and Specifications</i> Aldevron
11:50 am – 12:40 pm	<b>Lunch</b>		
12:40 pm – 1:10 pm	<b>Technology Workshop</b> <i>Protein or Not? Advanced High-Throughput Aggregate Analysis with the Aura</i> Halo Labs	<b>Technology Workshop</b> <i>Scaling Up Viral Vector and Vaccine Manufacturing with the VHU®</i> Artemis Biosystems	<b>Technology Workshop</b> <i>HumanKine FGF Basic — A Case Study</i> Proteintech Group, Inc
1:10 pm – 1:25 pm	<b>Break</b>		
	<b>Viral Vectors &amp; Vaccines</b>	<b>Cellular Therapies</b>	<b>Baculovirus Expression Technology</b>
1:25 pm – 2:05 pm	<i>Scale-Up of rAAV Production Using Stable Producer Cell Lines</i> <b>Juliana Coronel, PhD</b> Cevec Pharmaceuticals GmbH	<i>Automation in Delivery Technologies to Empower Breakthrough Therapies</i> <b>Anil Narasimha, PhD</b> Mekonos	<i>Baculovirus-Cell Interactions in the Insect Midgut: Transcriptome Profiling and Envelope Protein Trafficking</i> <b>Gary W. Blissard, PhD</b> Boyce Thompson Institute
2:05 pm – 2:20 pm	<b>Break</b>		
2:20 pm – 3:00 pm	<i>Development and Validation of a Potency Assay for a Viral-Based Gene Therapy Product</i> <b>Rashmi Prasad, PhD</b> MassBiologics	<i>Spearheading a Paradigm Shift in Cell Therapy Manufacturing</i> <b>Fabian Gerlinghaus</b> Cellares Inc.	<i>Process Intensification for a Human Recombinant Influenza Vaccine</i> <b>Nikolai Khramtsov, PhD</b> Protein Sciences Corporation, A Sanofi Company
3:00 pm – 3:15 pm	<b>Break</b>		
3:15 pm – 4:00 pm	<b>Lentiviral Vector Reference Material Project Update</b>		

TUESDAY • MARCH 16, 2021

9:00 am – 9:15 am	<b>Intro/Overview</b>
9:15 am – 9:30 am	<b>Break</b>

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	Viral Vectors & Vaccines	Cellular Therapies	Baculovirus Expression Technology
9:30 am – 10:10 am	<b>Juan Carlos Ramirez, PhD</b> VIVEbiotech	<i>Considerations for the Development of Gene-Edited Stem Cell Therapies</i> <b>Brent Morse</b> Vor Biopharma	<b>Arifa S. Khan, PhD</b> FDA CBER
10:10 am – 10:25 am	<b>Break</b>		
10:25 am – 11:05 am	<i>Developing a Potency Assay for a Proprietary AAV-Based Genome Editing Platform Technology</i> <b>Matthias Hebben, PhD</b> LogicBio Therapeutics	<i>New Nanotechnology for Efficient Non-Viral Gene Delivery to Cells Ex Vivo</i> <b>Christopher Ballas, PhD</b> Innovative Cellular Therapeutics Co., Ltd.	<i>Development and Optimisation of Virus-Like Particle Vaccines Against Pathogenic Arboviruses</i> <b>Sandra R. Abbo and Linda van Oosten</b> Wageningen University
11:05 am – 11:20 am	<b>Break</b>		
11:20 am – 11:50 am	<b>Technology Workshop</b> <i>Videodrop, a New Tool for Measuring Size and Concentration of Nanoparticles in 40s in a Single Drop</i> <b>Myriade</b>	<b>Technology Workshop</b> <i>Quantification of Viral and Non-Viral Vector CQAs</i> <b>Wyatt Technology Corporation</b>	<b>Technology Workshop</b> <i>Chromatographic Tools for the Optimization of IVT Reaction and mRNA Purification Process Improvement</i> <b>BIA Separations, a Sartorius company</b>
11:50 am – 12:40 pm	<b>Lunch</b>		
	Viral Vectors & Vaccines	Cellular Therapies	Baculovirus Expression Technology
12:40 pm – 1:20 pm	<i>Routine Size, Mass, Aggregate Level, Total Concentration and Empty:Full Ratio Determinations for AAV Particles by SEC-MALS</i> <b>Darren W. Begley, PhD</b> Beam Therapeutics	<i>Building Effective Control Strategies for Cellular Therapy and Other Complex Biopharmaceutical Products</i> <b>Mark F. Witcher, PhD</b> Exyte	<i>Use of Recombinant Proteins and Particles for Molecular Studies and Novel Vaccines</i> <b>Polly Roy, PhD</b> London School of Hygiene & Tropical Medicine
1:20 pm – 1:35 pm	<b>Break</b>		
1:35 pm – 2:15 pm	<i>Accelerating Cell and Gene Therapy Clinical Pipelines and Path to Commercialization with a Robust Lentiviral Vector Platform and a Scalable Manufacturing Process</i> <b>Kevin Beck, PhD</b> Lentigen Technology Inc., a Miltenyi Biotec Company	<b>Nebojsa Milovic, PhD</b> Takeda Pharmaceuticals U.S.A., Inc.	<i>Baculovirus-Sf9 System for the Manufacture of SARS-CoV-2 Vaccine</i> <b>Gale E. Smith, PhD</b> Novavax, Inc.
2:15 pm – 2:30 pm	<b>Break</b>		
2:30 pm – 3:00 pm	<b>Technology Workshop</b> <b>Beckman Coulter Life Sciences</b>	<b>Technology Workshop</b> <i>Design, Manufacturing, and Analytics of New AAV Reference Standards — A Case Study</i> <b>Vigene Biosciences</b>	<b>Technology Workshop</b> <b>Thermo Fisher Scientific</b>
3:00 pm – 3:15 pm	<b>Break</b>		
3:15 pm – 3:45 pm	<b>Technology Workshop</b> <i>Scalable, High-Titer Production of Adeno-Associated Virus in the Gibco™ AAV-MAX Helper-Free AAV Production System</i> <b>Thermo Fisher Scientific</b>	<b>Technology Workshop</b> <b>Beckman Coulter Life Sciences</b>	<b>Technology Workshop</b> <b>GlycoBac LLC</b>

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9:00 am – 9:15 am	Intro/Overview		
9:15 am – 9:30 am	Break		
9:30 am – 10:00 am	<b>Technology Workshop</b> <i>Next-Generation Transfection Reagent for Large-Scale AAV Manufacturing</i> <b>Polyplus-transfection SA</b>	<b>Technology Workshop</b> <i>ExpiSF™: A Versatile Chemically-Defined Sf9/Baculovirus Expression System</i> <b>Thermo Fisher Scientific</b>	<b>Technology Workshop</b> <b>Lonza</b>
10:00 am – 10:15 am	Break		
10:15 am – 10:45 am	<b>Technology Workshop</b> <i>AAV Manufacturing Platform and In-Process Controls</i> <b>BIA Separations, a Sartorius company</b>	<b>Technology Workshop</b> <b>Mirus Bio LLC</b>	<b>Technology Workshop</b> <b>UNIVERCELLS</b>
10:45 am – 11:00 am	Break		
	<b>Viral Vectors &amp; Vaccines</b>	<b>Cellular Therapies</b>	<b>Baculovirus Expression Technology</b>
11:00 am – 11:40 am	<i>rVSV-Vectored Vaccine Production in Vero Cells</i> <b>Sascha Kiesslich</b> McGill University	<i>Optimizing Cell Manufacturing Processes for the Treatment of Severe Genetic Diseases and Cancer</i> <b>Elizabeth Pratico, PhD</b> bluebird bio Inc.	<i>Baculovirus-Based Vaccines for Rift Valley Fever Virus</i> <b>Jürgen A. Richt, DVM, PhD</b> Kansas State University
11:40 am – 12:30 pm	Lunch		
12:30 pm – 1:10 pm	<b>Nicholas Clarkson, PhD</b> Oxford BioMedica plc	<i>Machine Learning Applications for the Characterization of Particle Profiles of Therapeutic Products</i> <b>Amber H. Fradkin, PhD</b> KBI Biopharma	<i>Vaccine and Viral Vector Production Using the Baculovirus-Insect Cell Expression System: AAV Case Study</i> <b>Pranavkumar Joshi, PhD</b> McGill University
1:10 pm – 1:25 pm	Break		
1:25 pm – 2:05 pm	<i>Impact of rAAV Titer Accuracy for Translational Studies</i> <b>Zhu Zhen Pirot, PhD</b> Kriya Therapeutics	<i>Advanced Therapies, Clinical Holds, and Strategies to Avoid</i> <b>Debra A. Webster, PhD</b> BlueRock Therapeutics	<i>Ongoing Work for Expression of Difficult-to-Express Proteins and Protein Complexes</i> <b>Yuichiro Takagi, PhD</b> Indiana University School of Medicine
2:05 pm – 2:20 pm	Break		
2:20 pm – 3:00 pm	<i>AAV Vector and Manufacturing Process Design Considerations: A 2021 Perspective</i> <b>John Fraser Wright, PhD</b> Stanford University	<i>Development of a GMP Relevant Process for Gene Circuit Engineered Allogeneic CAR-NK Cell Therapies in Oncology</i> <b>Philip Lee, PhD</b> Senti Biosciences	<i>New Technologies for Robust and Efficient Large-Scale Production of Recombinant Multi-Protein Complexes</i> <b>Jill O. Fuss, PhD</b> Lawrence Berkeley National Laboratory
3:00 pm – 3:15 pm	Break		
3:15 pm – 4:15 pm	Roundtable		

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Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 03/02/2021