



Viral Vectors & Vaccines

Chaired By:

Otto-Wilhelm Merten, PhD

Miltenyi Biotec Inc.

J. Fraser Wright, PhD

Stanford University

Cellular Therapies

Chaired By:

Martin A. Giedlin, PhD

Senti Biosciences

María Mercedes Segura, PhD

ElevateBio

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)

SUNDAY • MARCH 13, 2022

4:00 pm – 7:00 pm

Welcome Reception and Registration in the Foyer, Fourth Floor

MONDAY • MARCH 14, 2022

7:00 am – 8:00 am

Registration and Breakfast in the Foyer, Fourth Floor

8:00 am – 8:30 am

Meeting Overview in Salon A/B/C, Fourth Floor

8:30 am – 9:10 am

<p>Viral Vectors & Vaccines Salon A/B/C, Fourth Floor</p>	<p>Cellular Therapies Paul D. Fraim Center for Excellence, Fourth Floor</p>	<p>Baculovirus Expression Technology Salon G/H, Fourth Floor</p>
<p><i>Harnessing AAV Membrane-Associated Accessory Protein to Improve Vector Supply and Quality</i> Kari Airene, PhD Kuopio Center for Gene and Cell Therapy (KCT)</p>	<p><i>CAR-NK for Hepatocellular Carcinoma</i> Dongfang Liu, PhD Rutgers-New Jersey Medical School (NJMS)</p>	<p><i>Influenza VLP Vaccine Production Done Better: The Perks of Innovating Upstream, Downstream, Storage, and Analytics</i> António Roldão, PhD Instituto de Biologia Experimental e Tecnológica (iBET)</p>

9:10 am – 9:20 am

Water Break

All of the presentations and events shown in the program are included with your registration fee.
Times are Eastern Daylight Time (EDT). Eastern Standard Time (EST) switches to EDT on Sunday, March 13th.

	Viral Vectors & Vaccines Salon A/B/C, Fourth Floor	Cellular Therapies Paul D. Fraim Center for Excellence, Fourth Floor	Baculovirus Expression Technology Salon G/H, Fourth Floor
9:20 am – 10:00 am	<i>Advances in Lentiviral Vector Design and Production Leading to Improved Purity, Potency, and the Generation of Stable Producer Cell Lines for CAR T-Cell Therapy</i> Nicholas Clarkson, PhD Oxford BioMedica plc	<i>Cell Therapy Technology Transfer Approach and Challenges</i> Vijay Patel ElevateBio	<i>Scalable and GMP-Favorable Production of Hepatitis E Nanoparticle Using Linearized Bacmid Expression Systems and a Liquid Chromatography Purification Process</i> Chun C. Chen, PhD Astrid Pharma
10:00 am – 10:30 am	Morning Break in the Exhibit Hall		
10:30 am – 11:00 am	Technology Workshop Salon A/B/C, Fourth Floor Patheon, part of Thermo Fisher Scientific <i>Viral Vector Seamless Solutions from Discovery to the Clinic</i>	Technology Workshop Paul D. Fraim Center for Excellence, Fourth Floor Miltenyi Biotec <i>De-Risking GMP Lentiviral Vector Manufacturing — Leveraging a Proven Platform Process</i>	Technology Workshop Salon G/H, Fourth Floor Pall Biotech <i>Scalable Purification of Recombinant Adeno-Associated Viral Vectors</i>
11:00 am – 11:30 am	Technology Workshop Salon A/B/C, Fourth Floor BIA Separations, a Sartorius company <i>AAV Manufacturing Process Development Using Orthogonal Analytical Methods</i>	Technology Workshop Paul D. Fraim Center for Excellence, Fourth Floor Thermo Fisher Scientific <i>Scalable Production of Adeno-Associated Virus (AAV) in the Gibco™ AAV-MAX Helper-Free AAV Production System</i>	
11:30 am – 12:00 noon	Technology Workshop Salon A/B/C, Fourth Floor Aldevron <i>Manufacturing Considerations for Successful Gene Therapy Development: Beginning With the End in Mind</i>	Technology Workshop Paul D. Fraim Center for Excellence, Fourth Floor Avid Bioservices, Inc. <i>Beyond the Service Offering of a CDMO</i>	Technology Workshop Salon G/H, Fourth Floor Lonza <i>Introducing Lonza's AAV Suspension Transient Transfection Platform to De-Risk Your Path to Clinic</i>
12:00 noon – 1:30 pm	Lunch in the Exhibit Hall • (Poster Session from 1:00 – 1:30 pm)		
	Viral Vectors & Vaccines Salon A/B/C, Fourth Floor	Cellular Therapies Paul D. Fraim Center for Excellence, Fourth Floor	Baculovirus Expression Technology Salon G/H, Fourth Floor
1:30 pm – 2:10 pm	<i>Process Development for Newcastle Disease Virus-Vectored Vaccines in Serum-Free Vero Cell Suspension Cultures</i> Amine A. Kamen, PhD McGill University	<i>Digital Frameworks for Structured CMC and Control Strategy Management</i> Yash Sabharwal, PhD CherryCircle Software, Inc. (QbDVision)	<i>Global Licensure Strategy and Considerations for BEVS Vaccines</i> Penny L. Post, PhD Sanofi US
2:10 pm – 2:20 pm	Water Break		
2:20 pm – 3:00 pm	<i>Helper Virus-Free AAV Production Using Fully Stable Producer Cells</i> Tobias Bonifert, PhD Cevec Pharmaceuticals GmbH	<i>Regulatory Considerations for Source Materials in Cell Therapy Products</i> Haritha Vallabhaneni, PhD FDA CBER	<i>A Two-Component Nanoparticle Vaccine Displaying Glycosylated SARS-CoV-2 Spike S1 Produced in Insect Cells</i> Linda van Oosten Wageningen University
3:00 pm – 3:30 pm	Afternoon Break in the Exhibit Hall		
3:30 pm – 4:10 pm	<i>NIST Update on Lentivirus and Adenovirus Reference Material Projects</i> Jamie Almeida and Edward Kwee, PhD National Institute of Standards & Technology (NIST)	<i>CRISPR-Cas9 RNP Editing of Primary Cells via Electromechanical Transport Phenomena</i> Ta-Chun Hang, PhD Kytopen Corp	<i>Optimization of Insect Cell Platform for Producing Vaccines</i> Indresh K. Srivastava, PhD Novavax, Inc.

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4:10 pm – 4:20 pm

Water Break

Viral Vectors & Vaccines
Salon A/B/C, Fourth Floor

Cellular Therapies
Paul D. Fraim Center for Excellence, Fourth Floor

Baculovirus Expression Technology
Salon G/H, Fourth Floor

4:20 pm – 5:00 pm

Recombinant AAV Vectors for In Vivo Gene Therapy — Reducing Immunogenicity Through Improved Vector Design and Manufacturing
J. Fraser Wright, PhD
Stanford University

Model-Driven Design of Culture Media
Sakis Mantalaris, PhD
Georgia Institute of Technology

A Baculovirus-Expressed Covid-19 Vaccine
Nikolai Petrovsky, PhD
Vaxine Pty Ltd

6:00 pm – 8:00 pm

Reception in the Exhibit Hall

TUESDAY • MARCH 15, 2022

7:30 am – 8:30 am

Breakfast in the Exhibit Hall

Viral Vectors & Vaccines
Salon A/B/C, Fourth Floor

Cellular Therapies
Paul D. Fraim Center for Excellence, Fourth Floor

Baculovirus Expression Technology
Salon G/H, Fourth Floor

8:30 am – 9:10 am

Auto-Regulation of the Adenoviral Major Late Promoter Enables Increased AAV Per Cell Productivity and Enhances Particle Infectivity
Ryan Cawood, PhD
OXGENE, a WuXi Advanced Therapies company

High-Throughput Characterization of Stability and Potency of Gene Therapy Hematopoietic Stem/ Progenitor Cell Products
Mariana Loperfido, PhD
AVROBIO

Assessing the Biosafety Profiles of Sf-rhabdovirus and Its Caterpillar-Derived Progenitor
Donald L. Jarvis, PhD
University of Wyoming

9:10 am – 9:20 am

Water Break

9:20 am – 10:00 am

Collaborative NIH Programs to Accelerate AAV Gene Therapy Clinical Trials
PJ Brooks, PhD
National Institutes of Health (NIH)

Beyond Automation: The Future of Cell Therapy Manufacturing
John Paul Tomtishen, III
Cellares Inc.

The MultiBac Platform in the University of Bristol COVID Emergency Response
Imre Berger, PhD
University of Bristol

10:00 am – 10:30 am

Morning Break in the Exhibit Hall

10:30 am – 11:10 am

Scalable and High-Yield Production of Extracellular Vesicles by Turbulence Stimulation for Regenerative Medicine: Proof-of-Concept in Five Animal Models
Amanda K.A. Silva, PharmD, PhD
Université Paris Diderot

Working Effectively with a CDMO to Bring Innovative Cell Therapies to Clinic and to Market
Kenneth LeClair, PhD
Lykan Bioscience

Polycistronic Baculovirus Co-Expression of Chaperones to Enhance Recombinant Protein Production in Insect Cells
Dominic Esposito, PhD
Frederick National Laboratory for Cancer Research (FNLCR)

11:10 am – 11:20 am

Water Break

11:20 am – 12:00 noon

A Streamlined Manufacturing Process for Lentiviral Vector Production
Aziza P. Manceur, PhD
National Research Council Canada (NRC)

Characterization of Cellular Therapy Products
Saravanan Karumbayaram, PhD
FDA CBER

Complex Complexes: Glycoproteins, Oligomericity, and Instability Oh My!
Carter A. Mitchell, PhD
Kemp Proteins, LLC

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Free Afternoon with Recommended Group Activities

Lunch on your own!

12:00 noon – 6:00 pm

- **Glass Blowing Workshop** at the [Chrysler Glass Studio](#) •
- **Guided Walking Tour of the Historic Freemason Neighborhood** •
- Admission to [Nauticus and the Battleship Wisconsin](#) with a **Guided Tour of the Hampton Roads Naval Museum** •
- **Guided Bike Tour of the Elizabeth River Trail** •
- **Local Food and Drinks Tour** •

See the registration desk to sign up for activities (first come, first served)!

6:00 pm – 9:00 pm

Great Gatsby Jazz Banquet at the [Hermitage Museum & Gardens](#) • **Sponsored by BIA Separations**

Shuttle transportation provided!

WEDNESDAY • MARCH 16, 2022

7:30 am – 8:30 am

Breakfast in the Exhibit Hall

8:30 am – 9:00 am

Technology Workshop
Salon A/B/C, Fourth Floor
Miltenyi Biotec
Automation of Cell Therapy Manufacturing Using the CliniMACS Prodigy

Technology Workshop
Paul D. Fraim Center for Excellence, Fourth Floor
Lonza
Process Development Excellence to De-Risk and Accelerate Commercialization of Cell and Gene Therapies

9:00 am – 9:30 am

Technology Workshop
Salon A/B/C, Fourth Floor
Myriade
VIDEODROP: Ideal Tool for Lentiviral Vector Bioproduction Follow-Up

Technology Workshop
Paul D. Fraim Center for Excellence, Fourth Floor
Univercells Technologies
Intensified Viral Manufacturing With Integrated, Scalable Fixed-Bed Technology

Technology Workshop
Salon G/H, Fourth Floor
CherryCircle Software, Inc. (QbDVision)
Digital Maturity for CMC Operations — Strategies & Successes

9:30 am – 10:00 am

Technology Workshop
Salon A/B/C, Fourth Floor
Charles River
From Concept to Clinic: End-to-End Support of Cell and Gene Therapy Product Development

Technology Workshop
Paul D. Fraim Center for Excellence, Fourth Floor
MilliporeSigma
A Rhabdovirus-Negative (Sf-RVN®) Platform is a Safer BEVS Alternative for Production of Recombinant Protein and AAV

Technology Workshop
Salon G/H, Fourth Floor
Thermo Fisher Scientific
Feeder-Free Expansion and Closed, Automated Wash and Concentration of Human NK Cells

10:00 am – 10:30 am

Morning Break in the Exhibit Hall

Viral Vectors & Vaccines
Salon A/B/C, Fourth Floor

Cellular Therapies
Paul D. Fraim Center for Excellence, Fourth Floor

Baculovirus Expression Technology
Salon G/H, Fourth Floor

10:30 am – 11:10 am

An Improved DNA Control Strategy for Engineered Exosomes
Michael Doherty
Codiak BioSciences

Development Considerations of Transitioning From Fresh to Cryopreserved Apheresis Starting Material for Autologous Cell and Gene Therapy
Craig Jones
bluebird bio Inc.

A Fast, Transient, and Baculovirus-Free Protein and VLP Production System in Insect Cells
Maren Schubert, PhD
Technical University Braunschweig

11:10 am – 11:20 am

Water Break

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11:20 am – 12:00 noon	<i>CMC Considerations for Viral Vectors</i> Anurag Sharma, PhD FDA CBER	<i>Development of an Improved Targeted, Non-Viral Ex Vivo Cell Manufacturing Process</i> Ines Mende, PhD PACT pharma	<i>Analysis of Malaria-Mosquito Interaction Using the Baculovirus Expression System</i> Jun Li, PhD Florida International University
12:00 noon – 1:30 pm	Lunch in the Exhibit Hall • (Poster Session from 1:00 – 1:30 pm)		
1:30 pm – 2:10 pm	<i>Production and Purification of a Lentiviral Vector Reference Material</i> Sushma G. Puttaswamaiah, PhD National Research Council Canada (NRC)	<i>Explainable AI to Accelerate Drug Discovery and Development</i> Steven Banerjee NExTNet Inc.	<i>Antibody Responses to SARS-CoV-2 Vaccination and Infection</i> Florian Krammer, PhD Icahn School of Medicine at Mount Sinai
2:10 pm – 2:20 pm	Water Break		
2:20 pm – 3:00 pm	<i>Innovative Facility Options in an Era of Urgent Capacity Needs</i> Peter Makowskyj G-CON Manufacturing, Inc.	<i>Process Development and Scale-Up for Gene Circuit Engineered CAR-NK Cell Manufacturing</i> Travis Wood Senti Biosciences	<i>Lac Inducible Baculovirus Expression Vector Optimization of Virion Capsid Protein Ratios Shows Adeno-Associated Virus Capsid Assembly is Not Entirely Stochastic and That Overabundance of VP1 and VP2 Affects Potency and Packaging of Genomes into the Capsid</i> Jeffrey Morley Slack, PhD Voyager Therapeutics
3:00 pm – 3:30 pm	Afternoon Break in the Foyer, Fourth Floor		
3:30 pm – 4:10 pm	<i>Comparison of Highly Pure rAAV9 Vector Stocks Produced in Suspension by PEI Transfection or HSV Infection Reveals Striking Quantitative and Qualitative Differences</i> Nathalie A. Clément, PhD Unicorn Consultations, LLC	<i>Accelerating Cell-Based Therapy Development with Microfluidic Immunoassay Technology</i> James Sharkey Gyros US Inc.	<i>A Synthetic Baculovirus Expression Vector for Recombinant AAV Production</i> Christopher Nguyen, PhD Voyager Therapeutics
4:10 pm – 4:20 pm	Water Break		
4:20 pm – 5:00 pm	Poster Finalist Presentations and Awards in the Paul D. Fraim Center for Excellence		
5:00 pm	Meeting Adjourns		

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Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice. REV 03/09/2022