



Viral Vectors & Vaccines

Chaired By:

Otto-Wilhelm Merten, PhD

Miltenyi Biotec Inc.

Nathalie A. Clément, PhD

Unicorn Consultations, LLC

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 19, 2023

4:00 pm – 7:00 pm

Welcome Reception and Registration in the Foyer, Fourth Floor

MONDAY • MARCH 20, 2023

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

Viral Vectors & Vaccines

Salon A/B/C, Fourth Floor

Cellular Therapies

Paul D. Fraim Center for Excellence, Fourth Floor

Baculovirus Expression Technology

Salon F/G/H, Fourth Floor

8:30 am – 9:10 am

Building a Flexible Platform for the Manufacture of AAV Drug Substance

Nicholas DiGioia

Alexion Pharmaceuticals, Inc.

Venture Beyond Today's Approach: A Unique Cell Engineering Platform for Rapid, Reliable, and Safe Therapeutic Development

Cenk Sumen, PhD

MaxCyte Inc.

CRISPR-Aided Baculovirus Genome Probing for Bettering the BEVS Production Platform

Marc G. Aucoin, PhD

University of Waterloo

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) switched to EDT on Sunday, March 12th.

	Viral Vectors & Vaccines Salon A/B/C, Fourth Floor	Cellular Therapies Paul D. Fraim Center for Excellence, Fourth Floor	Baculovirus Expression Technology Salon F/G/H, Fourth Floor
9:20 am – 10:00 am	<i>Stabilization of Biologic Drugs Within a Film Matrix</i> Maria A. Croyle, PhD University of Texas at Austin	<i>Analytical Strategies for Cell-Based Gene Therapies with Parvoviral Vector Gene Delivery</i> Gillian Payne, PhD Carbon Biosciences	<i>Baculovirus Expression Systems: Regulatory Considerations</i> Robin Levis, PhD FDA CBER
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 Gyros US Inc. <i>Accelerate Downstream Process Development with Automated Analysis of Viral Vector Titer and Process-Related Impurities</i>	Technology Workshop Paul D. Fraim Center for Excellence, Fourth Floor NextNet Inc. <i>Sapiens: A Novel Platform to Accelerate Search into Real Discovery</i>	Technology Workshop Salon F/G/H, Fourth Floor Expression Systems, LLC, An ANGUS company <i>Tools for the Application of the Baculovirus and Insect Host Cell System</i>
11:00 am – 11:30 am	Technology Workshop Salon A/B/C, Fourth Floor Teknova <i>RNA-Based Fluorescent Detection of AAV Infection for Process Optimization</i>	Technology Workshop Paul D. Fraim Center for Excellence, Fourth Floor Charles River <i>Pain Points to Potential: Positioning Process and Analytical Development for Next-Gen Cell Therapies</i>	Technology Workshop Salon F/G/H, Fourth Floor Univercells Technologies <i>Accelerating Development of Gene Therapies Through Truly Scalable Technologies</i>
11:30 am – 12:00 noon	Technology Workshop Salon A/B/C, Fourth Floor GenScript ProBio <i>Development and Manufacturing Strategy for DNA-Based Drug/Vaccine Candidates</i>	Technology Workshop Paul D. Fraim Center for Excellence, Fourth Floor QbDVision, Inc. <i>Digital Strategies for Biotech Product Development and Lifecycle Management</i>	Technology Workshop Salon F/G/H, Fourth Floor Lonza Inc. <i>AAV Platform for Viral Vector Production Using Suspension HEK293 Cell Line</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 F/G/H, Fourth Floor
1:30 pm – 2:10 pm	<i>CFD Modeling of Plasmid/Cationic Polymer Complexation to Develop a Scalable Triple-Transient Transfection Process</i> Oliver Meade Resilience	<i>Assays for Cell Therapy Products and Raw Material Qualification</i> Benjamin A. Clarke, PhD US Pharmacopeial Convention (USP)	<i>Platform Development for AAV Manufacturing with the Baculovirus Expression Vector System (BEVS)</i> Bas van de Waterbeemd, PhD uniQure Biopharma B.V.
2:10 pm – 2:20 pm	Water Break		
2:20 pm – 3:00 pm	<i>CMC Considerations for Adenoviral Vectors</i> Anurag Sharma, PhD FDA CBER	<i>Using Relational Risk Analysis for Building Contamination Control Strategies</i> Mark F. Witcher, PhD Exyte	<i>The Ups and Downs of Baculovirus Very Late (Polyhedrin and p10) Gene Promoters</i> Robert D. Possee, PhD Oxford Expression Technologies
3:00 pm – 3:30 pm	Afternoon Break in the Exhibit Hall		
3:30 pm – 4:10 pm	<i>From Cellular Senescence to an Extracellular Vesicle Toolbox</i> Johannes Grillari, PhD LBG Ludwig Boltzmann Institute for Traumatology, The Research Center in Cooperation with AUVA (LBI)	<i>Characterization of Autologous Engineered Tregs for Early Stage Clinical Trials</i> Stephen Sofen, PhD Abata Therapeutics	<i>Modified Baculovirus Backbone for Recombinant Seasonal Influenza Vaccine</i> Nikolai Khramtsov, PhD Protein Sciences Corporation, A Sanofi Company

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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 F/G/H, Fourth Floor
<i>Rapid Optimisations for Cell and Gene Therapy Applications</i> R. André Raposo, PhD Oxford BioMedica plc	<i>Sourcing Biomaterials; Delivering Impactful Value — A Meaningful Regulation and Testing Review</i> Zachry R. Vavra Versiti Inc.	<i>Strategies for Recombinant Protein Expression and Reconstitution of Multi-Protein Complexes Using the Baculovirus Expression System</i> Arnaud Poterszman, PhD L'institut de Génétique et de Biologie Moléculaire et Cellulaire (IGBMC)

4:20 pm – 5:00 pm

6:00 pm – 8:00 pm

Reception and Lentiviral Vector Reference Material (LVV-RM) Awards in the Exhibit Hall

TUESDAY • MARCH 21, 2023

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 F/G/H, Fourth Floor
<i>An Expertise Core Facility for Multimodal Characterization of Extracellular Vesicles for Therapeutic and Diagnostic Purposes</i> Lise Abiven, PhD IVETH Expertise Facility	<i>Non-Viral Gene Engineering of Cellular Therapies</i> David L. Hermanson, PhD Bio-Techne	<i>Upstream Strategies To Maximize Downstream Yield of AAV Produced in Insect Cells</i> Brooks Hayes, PhD Expression Systems, LLC, An ANGUS company

8:30 am – 9:10 am

9:10 am – 9:20 am

Water Break

<i>Continuous Production Of Retroviral Vectors In High Cell Density Culture</i> Marc Hein, PhD Max Planck Institute for Dynamics of Complex Technical Systems	<i>Adventitious Agent Control in the Manufacture of Cell and Gene Therapy Products</i> Hazel Aranha, PhD GAEA Resources Inc.	<i>Baculovirus Expression Technology for the Production of Virus-Like Particles as Vaccine Candidates</i> Nico Lingg, PhD Austrian Centre of Industrial Biotechnology GmbH (ACIB)
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9:20 am – 10:00 am

10:00 am – 10:30 am

Morning Break in the Exhibit Hall

<i>An Inducible Stable, Helper Virus- and Transfection-Free AAV Manufacturing Platform</i> Nicole Faust, PhD Cevec Pharmaceuticals GmbH, now part of Cytiva	<i>Advancing the Manufacture of Human Pluripotent Stem Cell-Based Products for Cardiac Regenerative Medicine</i> Maria Margarida de Carvalho Negrão Serra, PhD Instituto de Biologia Experimental e Tecnológica (iBET)	<i>Baculovirus Technology Produced SARS-CoV-2 Spike Protein Vaccine Induces Broad, High Affinity and Durable Protective Immunity</i> Gale E. Smith, PhD Novavax, Inc.
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10:30 am – 11:10 am

11:10 am – 11:20 am

Water Break

Panel Discussion: Viral Vector Reference Materials

Keith L. Carson, ChE, MBA (Moderator)
ISBioTech

11:20 am – 12:20 pm

<i>LVV Reference Material</i> Andrew E. Timmons, PhD FDA CBER	<i>Lentiviral Vector Production</i> Aziza Manceur, PhD National Research Council Canada (NRC)	<i>Ad5 Reference Material</i> Anurag Sharma, PhD FDA CBER	<i>Viral Vector Reference Materials</i> Jamie Almeida National Institute of Standards & Technology (NIST)
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Free Afternoon with Recommended Group Activities (included with your registration)

Lunch on your own!

12:20 pm – 6:00 pm

- Pedal Trolley Tour of Historic Downtown Norfolk •
- Improv 101 Class at [Push Comedy Theater](#) •
- Admission to [Nauticus and the Battleship Wisconsin](#) with a **Guided Tour of the Hampton Roads Naval Museum** •
- Victory Rover Cruise of the Elizabeth River •
- Guided Tour of the [Chrysler Museum](#) Collection •

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

6:00 pm – 9:00 pm

Disco Dancing Banquet at the Pagoda & Oriental Garden

included with your registration

WEDNESDAY • MARCH 22, 2023

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
Thermo Fisher Scientific
Scalable Production of AAV from Shake Flasks to 1000L Single Use Bioreactors Using the Gibco™ CTS™ AAV-MAX Production System

Technology Workshop
Salon F/G/H, Fourth Floor
PlasmidFactory GmbH & Co. KG
Large Scale Plasmid DNA Production in High Quality

9:00 am – 9:30 am

Technology Workshop
Salon A/B/C, Fourth Floor
ElevateBio
LentiPeak: A Robust and Scalable Platform Process for GMP Manufacturing of Lentiviral Vectors

Technology Workshop
Paul D. Fraim Center for Excellence, Fourth Floor
Thermo Fisher Scientific
Feeder Free Expansion and Closed, Automated Wash and Concentration of a Clinically Relevant Number of Human NK Cells

Technology Workshop
Salon F/G/H, Fourth Floor
MilliporeSigma
The Sf-RVN® Platform Applied to B1IC

9:30 am – 10:00 am

Technology Workshop
Salon A/B/C, Fourth Floor
Charles River
Implementing Sustainable Manufacturing Strategies to Accelerate Gene Therapies

Technology Workshop
Paul D. Fraim Center for Excellence, Fourth Floor
CPSI Biotech
Improving Cell Recovery Following Cryopreservation: Incorporating Molecular and Device-Based Strategies

Technology Workshop
Salon F/G/H, Fourth Floor
Pall Biotech
Scale-Up Separation of Full and Empty AAV Capsids Using Mustang Q Membrane Chromatography

10:00 am – 10:30 am

Morning Break in the Exhibit Hall

10:30 am – 11:10 am

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

Viral Safety Testing Strategies for Advanced Therapy Medicinal Products
Horst Ruppach, PhD
Charles River Laboratories

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

Case Study: Impact of Manufacturing Process Changes on the In Vitro Function and In Vivo Efficacy of Gene-Modified CAR/TCR T-cells
Dawn Maier
ElevateBio

Baculovirus Expression Technology
Salon F/G/H, Fourth Floor

A Multi-Locus Rescue System for Reconstitution of Recombinant Baculovirus Expression Vectors
Christopher Nguyen, PhD
Voyager Therapeutics

11:10 am – 11:20 am

Water Break

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11:20 am – 12:00 noon	<i>Progress and Challenges in Manufacturing of Lentiviral Vectors</i> Vladimir A. Slepushkin, MD, PhD MedTherapy Biotechnology Incorporated	<i>Process Closure: The Impact on the Manufacturing Risk, Flexibility, and Facility Design for ATMPs</i> Jeffery N. Odum Genesis AEC	<i>A Tale of Two Transcriptomic Responses in Agricultural Pests Via Host Defenses and Viral Replication</i> Pramod Pantha, PhD Louisiana State 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>Using an Equivalence Approach to Establish Lot Release Limits for Vector Dose During Pre-Clinical Studies and Early Phase Clinical Trials</i> Nancy Sajjadi Sajjadi Consulting	<i>Driving Cell Therapy Innovation through End-to-End, Robotic Automation</i> Victoria Hodgson Cellares Inc.	<i>Utilizing a Streamlined Automated Workflow to QC Baculovirus Expression</i> Jennifer M. Shipman Merck Research Laboratories
2:10 pm – 2:20 pm	Water Break		
2:20 pm – 3:00 pm	<i>Autonomous Parvovirus Vectors for Gene Therapy</i> Sebastian Aguirre, PhD Carbon Biosciences	<i>Transfection Optimization for Primary Cells with Electromechanical Transfection Technology</i> John Zhao Kytopen Corp	<i>Single-Cell and Bulk Transcriptomics of Insect Cells During Production of AAV and Influenza HA-VLPs</i> Antônio M. M. Roldão, PhD Instituto de Biologia Experimental e Tecnológica (iBET)
3:00 pm – 3:30 pm	Afternoon Break in the Foyer, Fourth Floor		
3:30 pm – 4:30 pm	Poster Finalist Presentations and Awards in the Paul D. Fraim Center for Excellence		
4:30 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 03/18/2023