

# 2<sup>nd</sup> Global Cell & Gene Therapy Summit

July 07-09, 2025 (Hybrid)  
Holiday Inn & Suites, Orlando, FL

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Join the meeting: <https://us06web.zoom.us/j/89811420618?pwd=Zygp81u7LHj3F1NOEcaJ6zg0X6mS.1>

Meeting ID: **898 1142 0618**

Passcode: **662059**

08:00 On-site Registrations

08:50 Introduction and Opening Remarks

## Advancements in Cell and Stem Cell-based Therapies

**Chair:** Arun Srivastava, University of Florida, FL

09:00 **Keynote: Considerations for Allogeneic Dopaminergic Cell Products for Parkinson's Disease**  
**Howard Federoff**, Chief Medical Officer and Co-founder, Kenai Therapeutics, TX

09:30 **A Novel Proteomic Assay for Monitoring Cell Transplantation**  
**Eric Schuur**, Chief Executive Officer and Founder, HepaTx Corporation, CA

09:50 **Emerging Novel Technologies to Enable *in vivo* Cell Engineering as an Alternative to Traditional Cell Therapies**  
**Guobao Chen**, Principal Research Scientist, AbbVie, MA

10:10 **Pioneering Spinal Cord Injury Treatment: NurExone's Innovative Exosome-based siRNA Therapy with FDA Endorsement and Expanding Pipeline for Neuronal Regeneration**  
**Lior Shaltiel**, Chief Executive Officer, NurExone Biologic, Israel

10:30 ***In vitro* Assays to Study Neuroprotection and Axon Regeneration in Human Neurons Differentiated from Neurogenin-2 Engineered Induced Pluripotent Stem Cells**  
**Maheswara Reddy Emani**, Principal Scientist, Genentech, SF

## 10:50 Networking (Coffee) Break

## Advancing Cell-based Immunotherapies: CAR-T, TCR-T and Beyond

**Chairs:** Neena Haider, Shifa Precision, MA  
Meg DeAngelis, University at Buffalo, NY

11:20 **Keynote: Strategies to Advance CAR-T Cell Therapy Development**  
**Maryland Franklin**, Vice President and Enterprise Head of Cell & Gene Therapy, Labcorp, MI

11:50 **High-fidelity, Precise Gene Editing with Cas-CLOVER Technology for Allogeneic CAR-T Cell Therapy**  
**Meena Narayanan**, Process Analytical Scientist, Poseida Therapeutics, CA

12:10 **From Bench to Batch Release: Building a Reporter Gene Based Potency Assay for TCR-T Cell Therapy**  
**Boning Zhang**, Senior Scientist, TScan Therapeutics, MA

12:30 **A Unique Immuno-cell Therapy Platform That Can Overcome IO Treatment Resistance**  
**Alex Blyth**, Founder and Chief Executive Officer, Lift Biosciences, United Kingdom

12:50 **Exhibitor Talk: Considerations for Donor Starting Material Characterization**  
**Rob Tressler**, Chief Scientific Officer, Excellos, SD

## 13:10 Lunch

# Cell and Gene Therapy Research Advancements: From Basics to Clinical Applications

**Chair:** Mikko Turunen, RNatives Inc, Finland

- 14:10 **Keynote: Elucidating Genomic Mechanisms in Human Tissues to Inform Appropriate Therapeutics for Age-related Macular Degeneration**  
**Meg DeAngelis**, Endowed Chair and Professor, University at Buffalo, NY
- 14:40 **Keynote: Restoring Sight: Modifier Gene Therapies from Mechanistic Insight to Therapeutic Reality**  
**Neena Haider**, Founder, Shifa Precision, MA
- 15:10 **Development of Genome-modified NextGen AAV Vectors**  
**Arun Srivastava**, Professor, University of Florida, FL
- 15:30 **rAAV8 Encapsidated HMR-001 Mediates High Efficiency of Viral Transduction and Bleeding Normalization in HA Mice**  
**Xiaomo Wu**, PI-Dermatology Hospital of Fuzhou and Co-founder of Humvira Therapeutics, China
- 15:50 **Cell and Gene Therapy Development for Hereditary Connective Tissue Diseases: Overcoming Dominant Negative Phenotype**  
**Erik Foehr**, President, BioTether Sciences Inc., SF
- 16:10 **Synthetic DNA for Cell & Gene Therapy, and Vaccine Applications**  
**Patrick Thiaville**, Vice President of Science and Technology, 4basebio, FL
- 16:30 **mRNA Therapeutics for Cardiovascular Diseases**  
**Ajit Magadum**, Assistant Professor, University of South Florida, FL

## 16:50 Networking (Coffee) Break

## Gene Therapy: Methods, Strategies & Clinical Applications


**Chair:** Patrick Thiaville, 4basebio, FL

- 17:20 **Keynote: Nuclear microRNA Gene Therapy: Use of AI-assisted Discovery Platform for Transcriptional Regulation**  
**Mikko Turunen**, Chief Scientific Officer, RNatives Inc., Finland
- 17:50 **Modifier Gene Therapy Platform for the Treatment of Ocular Diseases**  
**Arun Upadhyay**, Chief Scientific Officer and Head of Research & Development, Ocugen, PA
- 18:10 **Nuclease-free Genome Editing with AAV-B19 Hybrid and Chimeric Vectors**  
**Arun Srivastava**, Professor of Medical Genetics, University of Florida, FL

## 18:30 Poster Presentation and Networking Drinks

- CGT-1 **Morpholino Based Modification in sgRNA Showed Efficient CRISPR-Cas Gene Editing in HeLa and SH-SY-5Y Cells**  
**Saheli Ganguly**, University of Colorado Boulder, CO
- CGT-2 **Anti-pan AAV - New Versatile Antibody for the Detection of Various AAV Serotypes Including Novel Capsids**  
**Katja Betts**, Progen, Germany
- CGT-3 **Closing the Final Steps in Hematopoietic Stem Cell Therapy Manufacturing: An FDA-supported Approach to Process Automation and Closure**  
**Matthew Tauras**, Vor Bio Inc., MA



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- CGT-4 **Overcoming Challenges of Gene-edited Hematopoietic Stem Cell Manufacturing: Enhancing Yield Through Donor Mobilization Regimen and Cell Culture Conditions**  
**Kylee Klinkowski**, Vor Bio Inc., MA
- CGT-5 **Harnessing Non-coding RNAs for the Advancement in Gene Therapy**  
**Jack Coleman**, Enzo Life Sciences, NY
- CGT-6 **Favorable Complement Profile of AAVrh10: Clinical Monitoring Experience from Three Gene Therapy Studies Across Two Programs**  
**Xiomara Rosales**, Lexeo Therapeutics, NY

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08:50 Introduction and Opening Remarks

## Scaling Up CGT: Manufacturing Innovation, Commercialization Strategies & Global Accessibility

**Chairs:** **Daniel Gibson**, Catapult, United Kingdom  
**Alicia D Henn**, BioSpherix, LLC, NY

09:00 **Keynote: From Development to Commercialisation: What is the Key to Success?**  
**Alessandra De Riva**, Head of Process Development and R&D, Advent Bioservices, United Kingdom

09:30 **Digital and Automation: Accelerating Innovation in CGT Industrialisation**  
**Daniel Gibson**, Head of Collaborations- Cell and Gene Therapy, Catapult, United Kingdom

09:50 **Key Considerations for Successfully Commercialization a Cell & Gene Product**  
**Cassandra Perkins**, Director Value & Access Channel Distribution Consulting; Cell & Gene Therapy Consulting, Syneos Health, NC

10:10 **Innovative Platforms, Strategies and a Peek into the Commercial Future**  
**Stefan Sandstrom**, Founder and Chief Executive Officer, BioSector Ltd., Japan

## 10:30 Networking (Coffee) Break

11:00 **Exhibitor Talk: Bringing Biopharma Processing To Life**  
**Rob Blackman**, Product Sales Manager, Parker Hannifin, NC

11:20 **Cytocentric Conditions for Decentralized Biomanufacturing**  
**Alicia Henn**, Chief Scientific Officer, BioSpherix, Ltd., NY

11:40 **Exhibitor Talk: Enhancing Cell & Gene Therapy Manufacturing with BatchLine Lite MES: A Collaborative Success Story with Vector BioMed**  
**Carlo de Vera**, Manufacturing Director, Vector BioMed, MD  
**Neil Wetherall**, Managing Director, BatchLine, United Kingdom

12:00 **Shipping Validation 101: A Phase-appropriate Approach for Cell and Gene Therapies**  
**Carson Dickey**, Engineering Manager, Modality Solutions, TX

12:20 **Developing an Advanced Sterility Assay for CGT Products on the QIAcuity dPCR Platform**  
**Frederick Kweh**, Co-founder and CTSO, KweHealth, LLC, FL

12:40 **Can Data-driven Manufacturing Fuel Global Access for Cell Therapies?**  
**Nirupama (Rupa) Pike**, Sr. Director and Global Head of Strategic Alliances, Catalent Pharma Solutions, NJ

## 13:00 Lunch

## Optimizing AAV Manufacturing: Engineering, Processing, Analysis and Quality Control

**Chair:** **Mark Davis**, Minaris Advanced Therapies, PA

14:00 **Keynote: Viral Vector Innovation: Improving Quality, Productivity, and Gene Size Capacity**  
**Sebastien Ribault**, Chief Business Officer, Oxford Biomedica, France



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- 14:30 **Novel Cell Engineering Platform for High-yield AAV Production and Improved Manufacturability via Engineered HEK-293 Cells**  
**Larry Forman**, Founder and Chief Executive Officer, CHO Plus, Inc., CA
- 14:50 **The Need for an Unbiased Assay to Detect and Quantify Replication Competent AAV in Clinical Vector Products**  
**Pierre Axel Vinot**, Director, CMC Portfolio Management, SparingVision, France
- 15:10 **Transformative Advances in Viral Vector Manufacturing: Unlocking Commercial Scalability, Consistency and Cost-effectiveness with Tet-Off PCL Innovation**  
**Susan D'Costa**, Chief Technical and Commercial Officer, Genezen, IN & MA
- 15:30 **An AAV GMP Manufacturing Solution for Large Clinical Demand Indications**  
**Timothy Fenn**, Vice President, Lexeo Therapeutics, CT
- 15:50 **High-efficiency, Single-use Chromatography Solutions for Scalable Viral Vector Purification**  
**Sanjeev Saxena**, Chief Commercial Officer, Sepragen Corporation, CA
- 16:10 **Development of Next-generation Xcite AAV Stable Producer Cell Lines**  
**Bingnan Gu**, Senior Director and Head of R&D Viral Vector and Cell Therapy, Lonza, TX
- 16:30 **How to Enhance AAV Yield with a Single Clone Producer Cell Line, Optimized Plasmid Design, and the TESSA® Production Platform**  
**Mark Davis**, Scientist Viral Vector, Minaris Advanced Therapies, PA

## 16:50 Networking (Coffee) Break

- 17:20 **Panel Discussion I: Breaking Barriers in Viral Vectors & CAR-T and Gene Therapy Manufacturing: Innovations for Scalability and Affordability**  
**Moderator:** **Niranjan Kumar**, Chief Executive Officer & President, ABSINCGROUP, PA  
**Panelists:** **Larry Forman**, Founder and Chief Executive Officer, CHO Plus, Inc., CA  
**Sanjeev Saxena**, Chief Commercial Officer, Sepragen Corp., CA  
**Nidhi Kotecha**, Program Director, Regulatory Affairs, Gates Institute, CO  
**Alessandra De Riva**, Head of Process Development and R&D, Advent Bioservices, United Kingdom  
**Susan D'Costa**, Chief Technical and Commercial Officer, Genezen, IN & MA

## 19:00 Networking Dinner (\*Ticket Required)

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08:45 Introduction and Opening Remarks

## Regulatory Landscape and Commercialization Strategies

**Chair:** **Nidhi Kotecha**, Gates Institute, CO

08:50 **Keynote: Optimizing Technology Transfer and Federal Partnerships to Advance Cell and Gene Therapy Innovation**

**Courtney Silverthorn**, Vice President, Strategic Alliances and Innovation, FNIH, MD

09:20 **Successful Commercialization Strategies for Cell and Gene Therapy Products in America's Dynamic Market; Lessons Learned from Recent Product Launches**

**Kevin Cast**, Partner, Archbow Consulting, FL

09:40 **Exhibitor Talk: Navigating Regulatory Success in Cell and Gene Therapy Development**

**Jason Mercer**, Strategic Regulatory Innovator, Facet Life Sciences, NC

10:00 **Nonclinical Regulatory Considerations for Cell Therapy Development: Early Development and IND Stage**

**Ziyan Zhang**, Consultant, Eliquent Life Sciences, DC

## 10:20 Networking (Coffee) Break

10:50 **Concept to Cure: Integrate Safety/Tox and CMC to Streamline Clinical Development and Commercialization for Advanced Therapies**

**David Alvarado**, Business Development Manager, Gene Therapy CDMO, Charles River, AZ

11:10 **Regulatory, Commercialization and Community Engagement for jCell, an Investigational Allogeneic Cell Therapy for Treatment of Retinitis Pigmentosa**

**John Sholar**, Chief Executive Officer, jCyte, CA

11:30 **Exhibitor Talk: Safeguarding Every CGT Sample – An Integrated Stability & Sustainability Outsourcing Model**

**Ryan Smith**, Global Head of Sales, Astorion, United Kingdom

11:50 **Exhibitor Talk: From Lab to Launch: Case Studies Demonstrating Scalable Solutions for Complex Cell Engineering Workflows**

**Megan Embrey**, Senior Field Application Scientist, MaxCyte, Inc., MD

12:10 **Exhibitor Talk: The Future of Cell Culture Media: Pioneering Artificial Human Platelet Lysate for Scalable, Xeno-free Bioproduction**

**Jungsoo Park**, Senior Vice President, Global Marketing and Sales, PL BioScience GmbH, Germany

12:30 **Panel Discussion II: Collaborative Approaches: Industry-Academia Partnerships in CGT Manufacturing**

**Moderator:** **Nidhi Kotecha**, Program Director, Regulatory Affairs, Gates Institute, CO

**Panelists:** **Alessandra De Riva**, Head of Process Development and R&D, Advent Bioservices, United Kingdom

**Kevin Cast**, Partner, Archbow Consulting, FL

**Stefan Sandstrom**, Founder and Chief Executive Officer, BioSector Ltd., Japan

**Courtney Silverthorn**, Vice President, Strategic Alliances and Innovation, FNIH, MD

**Mikko Turunen**, Chief Scientific Officer, RNatives Inc., Finland

## 13:10 Lunch & Departure





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# BATCHLINE

## BatchLine Lite MES

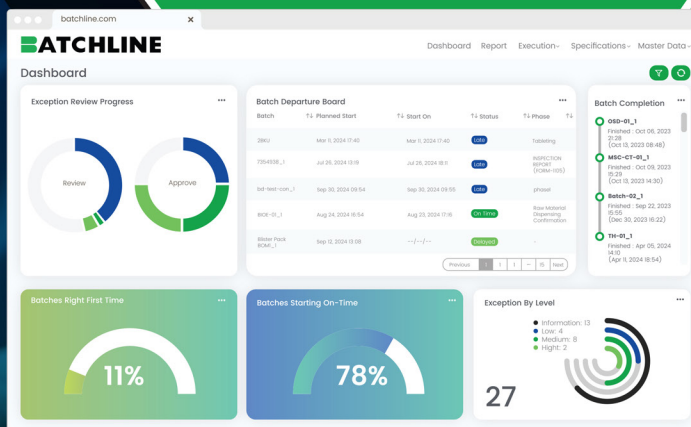
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Digital solution to  
streamline operations,  
and enhance productivity



### Logbooks

Take the pain out of  
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A modern tool that's  
intuitive and easy to use



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simplified and cost  
effective integrations



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## EXCELLOS™



**Better Inputs. Smarter Development. Faster Paths to Patients.**

### Cell Characterization for CAR T/NK Advancement

The current landscape is experiencing a boom in the number of cell therapy-based clinical trials. We are excited to see the plethora of CAR T/NK therapies in this tract but dismayed by the limited number receiving FDA approval. Here at Excellos, we are generating high quality research to better elucidate the features of starting material used to create highly advanced CAR T/NK therapies. We aim to go beyond typical cell and donor screening to create a comprehensive immune cell profile for each donor as well as an assessment of the metabolic and effector potential of their cells. Featuring proprietary Excellos 360 cell characterization, you can achieve:

- Improved clinical outcomes
- Lower therapeutic dosage
- Reduced cost of goods associated with cell and gene therapy manufacturing

### Immunotherapy Process Development

Excellos offers comprehensive process development services to transform your innovative cell therapy concept into a cGMP-compliant product. We collaborate with you to design critical quality attributes, optimize each manufacturing step, and execute performance qualification as part of our seamless technology transfer package. Our expertise in cell isolation and expansion, transduction/transfection, and assay development enables a smooth transition to large-scale cGMP manufacturing with an emphasis on product quality and integrity.

- Efficient technology transfer
- Process development expertise
- Custom assay development

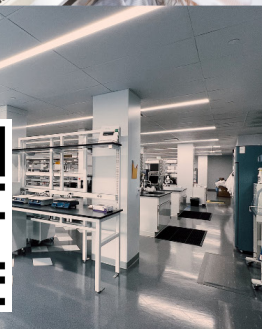
### cGMP Manufacturing

Excellos supports a complete suite of five 150-7 cleanrooms for cGMP manufacturing of clinical and commercial cellular therapies. We offer competitive starting material sourcing and novel characterization platforms. Our end-to-end services are designed to handle each critical step precisely. Additional services, including quality control release testing and stability programs, will elevate your experience. We are committed to partnering with you to achieve compliance with regulatory requirements and ensure the highest quality of production.

- ISO 7 Cleanroom suite (6,400 sq. ft.)
- Starting material sourcing and characterization
- Extensive cGMP & compliance experience

### Specialized in Advancing TIL Therapies

For over a decade, we have been manufacturing high-quality, irradiated feeder cells to support the TIL industry. These are available in RUO- and GMP- grade to support the continuum of developmental to commercial therapeutic campaigns. Our assay development and quality control teams have created dedicated release assays to ensure safety for downstream manufacturing of TILs. Importantly, our roots in blood banking have led unparalleled expertise in donor management and starting material sourcing, so we are able to scale with client needs.



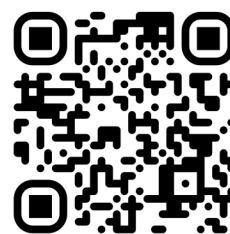
**Jessica Wanamaker, VP of Business Development** • [info@excellos.com](mailto:info@excellos.com) • [www.excellos.com](http://www.excellos.com)





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### REGULATORY STRATEGY AND FDA SUBMISSIONS

- *Plan and implement aggressive, data-driven cell and gene therapy programs - Fast track, breakthrough, orphan, RMAT, accelerated approval*
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- *Prepare and submit applications to FDA - IND, NDA/BLA, DMF*

### STRATEGIC STATISTICS SERVICES

- *Strategic use of innovative and efficient trial designs, including n=1, interim analysis, early stopping, basket, umbrella, and multiple adaptation*
- *Strategic endpoint selection, endpoint optimization, and biomarker validation*
- *Use of simulations and modeling to reduce sample size, increase trial success, and save time and money*

### ASSET VALUATION AND OPTIMIZATION SERVICES

- *Identify and optimize asset value for marketing or value-driven divestiture*
- *Preparation of compelling pitch decks to attract and secure investment*
- *Targeted guidance to grow asset value to achieve long-term financial success*



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You need to reach your next value inflection faster to be first to market. At MaxCyte, we understand your journey and invest in your success from day 1, bringing best-in-class electroporation technology, unmatched scientific support, and cell engineering expertise. We guide you from concept all the way through commercialization and beyond. With our dedicated partnership, you can speed up and de-risk your development and manufacturing process, accelerating your path to delivering life-changing therapies to patients.

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 **MaxCyte®** Let's Build Better Cells Together™

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# PromoCell

## PromoCell: Your Shortcut to GMP Confidence

At PromoCell, we bridge the gap between science and clinical implementation with Excipient GMP-grade cell culture media manufacturing tailored for research institutions, and red biotechnology innovators. Our services and products are designed to seamlessly transition from discovery to clinical applications and beyond, ensuring you have the resources you need at every stage of your journey.

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- **Comprehensive Support:** From research to clinical applications, we provide the resources and guidance needed at every stage of your journey.

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