

PROGRAM

2nd Global Cell& Gene Therapy Summit

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

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EXCELL S™

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 highquality, 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 assav 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.



IN 19

Jessica Wanamaker, VP of Business Development • info@excellos.com • www.excellos.com

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YOUR PARTNER IN LIFE SCIENCES PRODUCT DEVELOPMENT



REGULATORY STRATEGY AND FDA SUBMISSIONS

- Plan and implement aggressive, data-driven cell and gene therapy programs Fast track, breakthrough, orphan, RMAT, accelerated approval
- o Facilitate and support FDA meetings INTERACT, CPIM, pre-IND, pre-NDA/pre-BLA, Type A, C, D
- 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
- o 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

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

Your Success Is Our Guiding Light

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.

Trust the first and only electroporation platform supporting a commercial non-viral engineered cell therapy.

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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.

PROGRAM OUTLINE

Day 1, July 07, 2025

Opening Remarks Session I: Advancements in Cell and Stem Cell-based Therapies Coffee Break Session II: Advancing Cell-Based Immunotherapies: CAR-T, TCR-T and Beyond Lunch Session III: Cell and Gene Therapy Research Advancements: From Basics to Clinical Applications Coffee Break Session IV: Gene Therapy: Methods, Strategies & Clinical Applications Poster Presentations and Networking Drinks

Day 2, July 08, 2025

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

Coffee Break

Session V: Continues...

Lunch

Session VI: Optimizing AAV Manufacturing: Engineering, Processing, Analysis and Quality Control

Coffee Break

Panel Discussion I: Breaking Barriers in Viral Vectors & CAR-T and Gene Therapy Manufacturing: Innovations for Scalability and Affordability

Networking Dinner*

Day 3, July 09, 2025

Session VII: Regulatory Landscape and Commercialization Strategies

Coffee Break

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

Closing Remarks

Lunch & Departure

Meeting Room: Studio

Join the meeting: https://us06web.zoom.us/j/89811420618?pwd=Zygjp81u7lLhj3F1N0EcaJ6zg0X6mS.1

Meeting ID: 898 1142 0618 Passcode: 662059

@ Fove

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, CA
- 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 @ Foyer

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, Senier Scientist, TScan Therapeutics, MA

Boning Zhang, Senior Scientist, TScan Therapeutics, MA

- 12:30 Virtual: Rejuvenating Innate Immune Competence to Enable CAR-T and Immunotherapies to Eliminate Solid Tumors 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 Group Photo

13:15 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

@ Foyer

@ Foyer

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

- 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

NOTES

Meeting Room: Studio

Join the meeting: https://us06web.zoom.us/j/89811420618?pwd=Zygjp81u7lLhj3F1N0EcaJ6zg0X6mS.1

Meeting ID: 898 1142 0618 Passcode: 662059

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

@ Foyer

- 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

@ Foyer

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

- 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 @ Foyer

 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)

@ Foyer

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2<sup>nd</sup> Global Cell & Gene Therapy Summit | July 07-09, 2025 (Hybrid) | Orlando, FL
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Meeting Room: Studio

Join the meeting: https://us06web.zoom.us/j/89811420618?pwd=Zygjp81u7lLhj3F1N0EcaJ6zg0X6mS.1

Meeting ID: 898 1142 0618 Passcode: 662059

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

@ Foyer

- 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 Exhibitor Talk: Safeguarding Every CGT Sample An Integrated Stability & Sustainability Outsourcing Model

Ryan Smith, Global Head of Sales, Astoriom, United Kingdom

- 11:30 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
- 11:50 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

12:10 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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