

Preliminary Program
(January 22, 2024)

***Advancing Manufacture of Cell and
Gene Therapies VIII***

February 4 – 8, 2024
Loews Coronado Bay Hotel
Coronado, CA, USA

Conference Chairs:

Fernanda Masri
Cytomos, UK

Carolyn Yeago
CY Solutions LLC, USA

Gargi Maheshwari
BMS, USA

John Moscariello
BMS, USA



Engineering Conferences International
369 Lexington Avenue, 3rd Floor #389
New York, NY 10017, USA
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Saturday, February 3, 2024

19:30 Welcome Reception

Sunday, February 4, 2024

08:30 – 16:15 **Pre-Conference Workshop**
Building a flexible manufacturing strategy to navigate turbulent global markets
Chairs: Taby Ahsan, City of Hope, USA
Anne-Lise Brondel, Kyowa Kirin, USA
Mercedes Segura, Elevate Bio, USA
Veena Warikoo, AstraZeneca, USA

14:30 Conference check-in

16:45 – 17:00 Conference welcome
Chairs: Fernanda Masri, Cytomos, United Kingdom
Carolyn Yeago, CY Solutions LLC, USA
Gargi Maheshwari, BMS, USA
John Moscariello, BMS, USA

ECI Technical Liaison: Barry Buckland, NIIMBL, USA

Student Liaison: Bryan Wang, TreeFrog Therapeutics, USA

17:00 – 18:00 **Fireside Chat**
A recap of the last 2 years and outlook into the future of cell and gene therapies
Moderator: Fernanda Masri, Cytomos, United Kingdom
Panelists: Gregg Nyberg, Landmark Bio, USA
Bryan Poltilove, PBS Biotech, USA

18:00 – 18:30 Break

18:30 – 20:00 Dinner

Monday, February 5, 2024

- 07:00 – 08:30 Breakfast
- Session 1: Viral Vector and Gene Editing Platforms – Progress and Challenges in Process Development, Manufacturing, Product Characterization and Technology Landscape**
Chairs: Tania Pereira Chilima, Independent Consultant, Switzerland
Daniel M Marasco, Eli Lilly and Company, USA
- 08:30 – 09:05 **Keynote**
Time is muscle: Platform advancement for swift time-to-market in AAV manufacturing
Jiuyi Lu, Sarepta Therapeutics, USA
- 09:05 – 09:25 **Continuous processing of viral gene therapy vectors**
Caryn Heldt, Michigan Technological University, USA
- 09:25 – 09:45 **Leveraging a RNA-based lipid nanoparticle (LNP) gene writer system to generate Chimeric Antigen Receptor T cells (CAR-T) for in vitro and in vivo tumor activity**
Jason Rodriguez, Tessera Therapeutics, USA
- 09:45 – 10:20 **Keynote**
TBD
Bruno Figueroa, Sanofi, USA
- 10:20 – 11:05 Coffee Break / Opportunity to visit sponsor tables
- 11:05 – 11:25 **Enhancing rAAV biomanufacturing: Process intensification strategies for streamlined upstream and downstream processing**
António Roldão, iBET, Portugal
- 11:25 – 12:00 **Keynote**
Novel single plasmid technology for AAV production in HEK-293 suspension cells
Alina Venereo Sanchez, VVector Bio, Canada
- 12:00 – 12:20 **Towards a scalable AAV vector production at high volumetric efficiency**
Prasanna Srinivasan, Massachusetts Institute of Technology, USA
- 12:20 – 12:35 Panel Session
- 12:35 – 14:05 Lunch
- Session 2: Advances in Cell Therapy Manufacturing Technology to Enable Autologous and Allogeneic Applications**
Sponsored by PBS Biotech
Chairs: Bruno Marques, Century Therapeutics, USA
Samin Akbari, Sartorius, USA
- 14:05 – 14:40 **Keynote**
Fit for purpose, DMSO-free preservation of cellular therapies
Alison Hubel, University of Minnesota, USA

Monday, February 5, 2024 (continued)

- 14:40 – 15:00 **High-density microbioreactor process designed for automated point-of-care manufacturing of CAR T cells**
Wei-Xiang Sin, Singapore-MIT Alliance for Research and Technology Centre (SMART), Singapore
- 15:00 – 15:20 **Scalable allogeneic CAR-T manufacturing: Perfusion optimization, multi-liter scale-up and automated harvesting in single-use stirred-tank bioreactors**
Pierre Springuel, University College London, United Kingdom
- 15:20 – 15:40 **Producing lpsc derived functional Cd8+ T-cells in scalable stirred tank bioreactors**
Liz Csaszar, Notch Therapeutics, Canada
- 15:40 – 16:00 **Assessing robust bioprocess design through modulation of process input variables in the expansion of human induced pluripotent stem cell aggregates in Vertical-Wheel(R) bioreactors**
Tiffany Dang, University of Calgary, Canada
- 16:00 – 16:45 Coffee Break / Opportunity to visit sponsor tables
Sponsored by Cell and Gene Therapy Catapult
- 16:45 – 17:20 **Keynote**
Powerful characterization of cell therapies via whole and single-cell next-generation sequencing
Tom Brieva, Resilience, USA
- 17:20 – 17:40 **Optimizing the generation of hematopoietic progenitor cells from pluripotent stem cells in dynamic suspension culture**
Thristan Paulo Taberna, University of British Columbia, Canada,
- 17:40 – 18:00 **Combined Wnt activation and oxygen modulation enhance the manufacture and scale-up of pluripotent stem cell-derived cardiomyocytes in bioreactors**
Pedro Vicente, iBET, Portugal
- 18:00 – 18:20 **Towards a scalable, closed and automated platform for the production of cost-efficient allogeneic cell therapies: showcase of an exemplar iNK process**
Márcia F. Mata, Cell and Gene Therapy Catapult, United Kingdom
- 18:20 – 18:30 Break
- 18:30 – 19:30 **Poster Session** with refreshments & open bar (beer and wine)
Sponsored by Takeda
- 19:30 Dinner on your own

Tuesday, February 6, 2024

- 07:00 – 08:30 Breakfast
- Session 2: Advances in Cell Therapy Manufacturing Technology to Enable Autologous and Allogeneic Applications (continued)**
Chairs: Bruno Marques, Century Therapeutics, USA
Samin Akbari, Sartorius, USA
- 08:30 – 09:05 **Keynote**
Bioprocessing of stem-cell derived allogeneic cell therapy products: enabling large-scale manufacturing
Mats Åkesson, Novo Nordisk, Denmark
- 09:05 – 09:25 **Stem cell-derived pancreatic Islet encapsulation technologies for immobilized culture and transplantation**
Corinne A. Hoesli, McGill University, Canada
- 09:25 – 09:45 **Cell culture media-based cryo-formulations containing dimethyl sulfoxide minimize cryopreservation-induced cell damage in iPSC-derived effector cells**
Victoria Karakis, Century Therapeutics, USA
- 09:45 – 10:05 **Effects of temperature fluctuations on cryopreserved human induced pluripotent stem cells Post-thaw viability and cryo-Raman observation**
Jun Okuda, Osaka University, Japan
- 10:05 – 10:20 Panel Session
- 10:20 – 11:05 Coffee Break / Opportunity to visit sponsor tables
Sponsored by Resilience
- Session 3: Digitization, Process Control, and Closed-system Automation in Cell and Gene Therapies**
Chairs: Antinea Chair, Cellares, USA
Stephen Balakirsky, Georgia Tech Research Institute, USA
- 11:05 – 11:40 **Keynote**
Modular sensing, automation, and control for the production of cellular therapies
Stephen Balakirsky, Georgia Tech Research Institute, USA
- 11:40 – 12:00 **Digital twin-enabled feedback-controlled bioreactors with integrated process analytics for biomanufacturing of cell therapies**
Bryan Wang, TreeFrog Therapeutics, USA
- 12:00 – 12:35 **Keynote**
TBD
- 12:35 – 12:55 **Scaling AAV viral vector production processes up to manufacturing scale utilizing dynadribe single-use bioreactors**
Paula Decaria, Thermo Fisher Scientific, USA
- 12:55 – 14:25 Lunch with **Poster Session**

Tuesday, February 6, 2024 (continued)

- 14:25 – 14:45 **Cell placement in culture vessel after seeding is CPP in induction culture of retina pigment epithelial cells derived from iPSC**
Masahiro Kino-oka, Osaka University, Japan
- 14:45 – 15:20 **Keynote**
Metabolic control, adaptive culturing, and AI predictions, a new generation of cell culturing devices, ADVA X3 case study
Ohad Karnieli, ADVA Biotechnology, Israel
- 15:20 – 15:40 **Towards in-silico scale-up of cell and gene therapy manufacturing**
Christian Witz, SimVantage, Austria
- 15:40 – 15:55 Panel Session
- 15:55 – 16:40 Coffee Break / Opportunity to visit sponsor tables
- Session 4: In-Process and Analytical Control Strategies for Cell and Gene Therapies**
Sponsored by Genentech
Chairs: Paula Alves, iBET, Portugal
 Tomas Kowski, Umoja Therapeutics, USA
- 16:40 – 17:15 **Keynote**
Evolving CAR cell therapy engineering: Challenges & opportunities
Isabelle Riviere, Takeda, USA
- 17:15 – 17:35 **Rapid noninvasive analytical tool for cell and gene therapy products**
Marc Taraban, University of Maryland, USA
- 17:35 – 18:00 **Chris Hewitt Award Lecture**
Predicting and enhancing cardiac potential of iPSC-derived cardiac progenitor cells through integrated multi-omic analysis
Aaron Simmons, University of Wisconsin-Madison, USA
- 18:00 – 18:30 Break
- 18:30 – 23:00 Social event – Stone Brewery

Wednesday, February 7, 2024

- 07:00 – 08:30 Breakfast
- Session 4: In-Process and Analytical Control Strategies for Cell and Gene Therapies (continued)**
Chairs: Paula Alves, iBET, Portugal
Tomas Kowski, Umoja Therapeutics, USA
- 08:30 – 09:05 **Keynote**
TBD
Richard Rogers, Umoja Biopharma, USA
- 09:05 – 09:25 **TBD**
- 09:25 – 10:00 **Keynote**
Leveraging cell and gene therapy products' quality through a bioanalytics avenue
Patricia Gomes-Alves, iBET, Portugal
- 10:00 – 10:20 **Novel analytics for rapid adventitious agent detection in cell and gene therapy manufacturing**
Stacy Springs, Massachusetts Institute of Technology, USA
- 10:20 – 11:05 Coffee Break / Opportunity to visit sponsor tables
- 11:05 – 11:40 **Keynote**
New methods and approaches for the analysis of new therapeutic modalities
Sunny Zhou, Northeastern University, USA
- 11:40 – 12:00 **Process analytical utility of Raman microscopy for cell therapy manufacturing**
James M. Piret, University of British Columbia, Canada
- 12:00 – 12:15 Panel Session
- 12:15 – 13:45 Lunch
- 13:45 – 14:15 **Advancing Manufacture of Cell and Gene Therapies Award Lecture**
R&D supporting translation of cell based biotherapeutics
Paula Alves, iBET, Portugal
- 14:15 – 15:00 Coffee Break
- Session 5: Critical Early Decisions in Regulatory Strategies and Standards to Facilitate Product Development**
Chairs: Taby Ahsan, City of Hope, USA
Eytan Abraham, Resilience, USA
- 15:00 – 15:35 **Keynote**
NIST flow cytometry standards consortium enables quantitative and comparable characterization of cell and gene therapies
Lili Wang, NIST, USA

Wednesday, February 7, 2024 (continued)

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| 15:35 – 16:10 | Keynote
Reducing regulatory risk with CMC strategy using gene therapy platforms
Doris Snow, Resilience, USA |
| 16:10 – 16:45 | Keynote
Regulatory updates and trends in cell and gene therapy
Kimberly Benton, Dark Horse Consulting, USA |
| 16:45 – 16:50 | Workshop output
Anne-Lise Brondel, Kyowa Kirin, USA and Taby Ahsan, City of Hope, USA |
| 16:50 – 17:30 | Panel Discussion |
| 17:30 – 19:00 | Break |
| 19:00 | Conference Banquet |

Thursday, February 8, 2024

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| 07:00 | Breakfast and Departure |
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