

Program

Advancing Manufacture of Cell and Gene Therapies VI

January 27-31, 2019

Loews Coronado Bay Hotel,
Coronado, California

Conference Chairs

Dolores Baksh
GE Healthcare, USA

Rod Rietze
Novartis, USA

Ivan Wall
Aston University, UK



Engineering Conference International
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Coronado, California, 92118
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Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.

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Previous conferences in this series:

Scale-Up and Manufacturing of Cell-Based Therapies

January 11-13, 2012

San Diego, California

Conference Chairs:

Chris Mason, University College London, UK

Lars Nielsen, University of Queensland, Australia

Greg Russotti, Celgene, USA

Scale-Up and Manufacturing of Cell-Based Therapies II

January 21-23, 2013

San Diego, California

Conference Chairs:

Chris Mason, University College London, UK

Lars Nielsen, University of Queensland, Australia

Greg Russotti, Celgene, USA

Scale-Up and Manufacturing of Cell-Based Therapies III

January 5-9, 2014

San Diego, California

Conference Chairs:

Chris Mason, University College London, UK

Greg Russotti, Celgene, USA

Peter Zandstra, University of Toronto, Canada

Scale-Up and Manufacturing of Cell-Based Therapies IV

January 18-22, 2015

San Diego, CA USA

Conference Chairs:

Chris Mason, University College London, UK

Greg Russotti, Celgene Cellular Therapeutics, USA

Peter Zandstra, University of Toronto, Canada

Thomas Brieva, Celgene Cellular Therapeutics, USA

Scale-Up and Manufacturing of Cell-Based Therapies V

January 15-19, 2017

San Diego, California

Conference Chairs:

Thomas Brieva, Celgene Cellular Therapeutics, USA

Chris Mason, University College London, UK

William Miller, Northwestern University, USA

Greg Russotti to receive the 2019 Award for Advancing Manufacture of Cell and Gene Therapy



The **National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)** and **Engineering Conferences International** are pleased to announce that Greg Russotti of Celgene is the recipient of the 2019 Award for Advancing Manufacture of Cell and Gene Therapy. The award will be presented at the Advancing Manufacture of Cell and Gene Therapy VI conference, January 27-31, 2019 in Coronado, California.

Greg Russotti has established himself as a world leader in the field of cell therapy technical development and manufacturing. He joined Celgene over 12 years ago, just as Celgene began major efforts in the cell therapy field. He was initially responsible for process and analytical development of all cell-based processes at Celgene and was soon appointed CMC lead for Celgene's placental cell therapy product, PDA-001, with accountability for all technical operations activities, including process and analytical development, clinical production, quality control, quality assurance, and supply chain. Greg later took on functional responsibility for the aforementioned areas for all cell and tissue-based products.

Greg led Celgene's technical development efforts to drive five different cell therapy products to IND and clinical stage, including two different placental cell therapy products, cord blood-derived Natural Killer cells, autologous cytotoxic T lymphocytes, and autologous CAR T cells. Greg was awarded Celgene's most prestigious internal award, the John W. Jackson Leadership Award, in 2011 for driving Celgene's decision to build in-house cell therapy manufacturing capabilities and leading Celgene in the cell therapy space. This award is given to only one employee in the company each year.

Greg is known globally as a leader in the field, having given over 25 invited presentations and keynote lectures, including two presentations at the FDA, and one at the EMA. He has participated in various panel discussions and has given webinars at the largest cell therapy conferences in the US, Canada, and Europe. Greg was the meeting co-chair for first four Annual ECI Scale-up and Manufacturing of Cell-Based Therapies conferences, from 2012 to 2015, helping shape and build the conference. He remains actively involved as a Steering Committee member.

Greg is actively involved in various national consortia. His roles include:

- Celgene's technical cell therapy lead on NIIMBL
- Executive Committee member of the NSF-funded Center for the Manufacturing of Advanced Therapeutics, being led by the Georgia Tech
- Industrial Executive Board Chairman of the Marcus Center for the Commercialization of Cell Therapies (\$27MM facility) at Georgia Tech
- Executive Committee member of NIST-funded American Technology Cell Therapy Manufacturing Consortium, led by the Georgia Research Alliance
- Advisory Board Member of the Cell Therapy Facility at the NJ Institute of Innovation (at NJIT)

Greg has maintained a strong relationship with the academic community by serving in the following roles:

- Industrial Advisory Board Member in Rutgers University's Biomedical Engineering and Biochemical/Chemical Engineering Departments
- Guest lecturer in various classes at Rutgers and in past years at Princeton, Columbia, Georgia Tech, NC State, NJIT, and Michigan State
- Lecturer at the International Advanced Course on Regenerative Medicine Manufacturing, hosted by Technical University of Lisbon, Loughborough University, and Georgia Tech University, in 2013 in Portugal and in 2016 in Hilton Head, NC

Greg also designed, organized and taught a graduate level topics-based course, "Bioprocess Engineering: Fundamental and Real World Perspectives" in Rutgers University's Biomedical Engineering and Chemical/Biochemical Engineering Departments from 2000 until 2010, after which he passed the torch to others who have since led this course, which continues to enjoy success. For his active involvement in the Rutgers community and his leadership in the cell therapy field, Greg was awarded the Rutgers Engineering School Distinguished Alumnus Medal of Excellence in Education and Research in 2013. This award is given by Rutgers School of Engineering to one recipient per year.

Prior to joining Celgene in 2006, Greg spent 15 years at Merck Research Laboratories developing products that included live virus vaccines, monoclonal antibodies, recombinant vaccines, and microbially-produced natural products. He worked on development, scale-up, and tech transfer of cell culture, microbial fermentation, and downstream isolation processes to clinical and commercial manufacturing facilities. Greg received his B.S. and M.S. degrees in Chemical Engineering from Rensselaer Polytechnic Institute and his Ph.D. in Chemical and Biochemical Engineering from Rutgers University.

Currently, Greg has functional responsibility for all cell therapy development areas at Celgene, including cell culture, isolation and formulation process development, analytical development, product attributes sciences, development operations, which includes high throughput testing and data automation, clinical manufacturing QC, and manufacturing sciences, which supports clinical and commercial manufacturing.

Conference Sponsors

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Locations and Notes

- *Technical sessions will be in the Commodore CDE. Poster Sessions will be in the Bay Pavilion.*
- *Breakfasts and lunches will be in the Bay Pavilion.*
- *Dinner on Sunday and Monday will be in the Bay Pavilion. The conference banquet will be in the Commodore Ballroom.*
- *The ECI office is in the Boardroom.*
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Sunday, January 27, 2019

- 09:00 – 17:00 **Pre-conference workshop** (Commodore A)
Developing a toolkit to engineer viral vector manufacturing and next generation gene therapies
- Workshop Chairs: Fernanda Masri (Technology Expert for Regenerative Medicine, Sartorius Stedim, UK)
 Michael Greene (Executive Director, Mustang Bio, USA)
- 16:00 – 19:00 **Conference check-in** (Atrium)
- 18:00 – 18:10 **Welcome** (Commodore C, D, E)
ECI Liaison: Barry Buckland (Chief Executive Officer, BiologicB)
- Conference Chairs: Dolores Baksh (Innovation Leader, GE Healthcare, USA)
 Rod Rietze (Director, Strategic Development & Innovation, Novartis)
 Ivan Wall (Professor in Regenerative Medicine, Aston University, UK)
- Student Liaison: Elizabeth Cheeseman (Bioprocess Modeling Research Associate, Loughborough University, UK)
- 18:10 – 19:30 **Plenary 1 – Fireside chat: Delivering commercial cell products**
- 18:10 – 18:15 Introduction
Session Chairs: Dolores Baksh
 Rod Rietze
- 18:15 – 19:30 **Plenary 1**
Timothy Moore (EVP Technical Operations, Kite Pharma – A Gilead Company)
Phil Vanek (GM Cell Therapy Strategy, GE Healthcare)
Greg Russotti (Vice President, Cell Therapy Technical Development, Celgene)
Jan Joseph Melenhorst (University of Pennsylvania)
- 19:30 – 22:00 **Welcome reception and dinner** (Pavilion)

Monday, January 28, 2019 (Part 1)

- 07:00 – 08:30 **Breakfast buffet**
- Chairs introduction**
- 08:30 – 13:00 **[Session 1: Advances in cell processing: New technologies for new therapies](#)**
(Session sponsored by FloDesign Sonics)
- Session Chairs: Jeffery Chalmers (Associate Chair and Professor, Chemical & Biomolecular Engineering, Ohio State University, USA)
 Thomas Heathman (Business Leader, Manufacturing Development, Technology Development & GTP Services, PCT - Hitachi Chemical Advanced Therapeutics Solutions, USA)
- 08:30 – 08:35 **Introduction**
- 08:35 – 09:00 **Biomufacturing cardiac cells from human pluripotent stem cells**
Sean Palecek (Professor of Chemical & Biological Engineering, University of Wisconsin, USA)
- 09:00 – 09:20 **Acoustic cell processing - An innovation in cell therapy manufacturing**
Nina Bauer (VP Business Development, FloDesign Sonics, USA)
- 09:20 – 09:40 **Process development and manufacture of primary human T-cells in scalable, automated stirred-tank bioreactors**
Elena Costariol (PhD Candidate, University College London, UK)
- 09:40 – 10:00 **Animal component free cell culture media development: The approach from the North**
Panos Chrysanthopoulos (Development Engineer/ Scientist II, CCRM, Canada)
- 10:00 – 10:30 **Transitioning from manual to stirred-tank bioreactor manufacturing of IDCT, An allogeneic cell therapy to treat lumbar degenerative disc disease**
Lara Silverman (Director of Research and Development, DiscGenics, USA) & Gary Pigeau (Development Manager - Cell & Gene Therapy, GE Healthcare, USA)
- 10:30 – 11:00 **Morning Break**
(Sponsored by Cambridge Consultants)
- 11:00 – 11:30 **Scale up of iPSC-derived product manufacturing**
Peter Fuhrken (Director of Process Engineering, Fujifilm Cellular Dynamics, USA)
- 11:30 – 11:50 **Enabling large-scale ex vivo production of megakaryocytes and platelets from CD34+ cells using gas-permeable surfaces and microfluidic bioreactors**
Andres F. Martinez (PhD Candidate, Northwestern University, USA)
- 11:50 – 12:10 **Functionalized microcarriers for Enhanced CAR T cell manufacturing**
Nate Dwarshuis (PhD Candidate, Georgia Institute of Technology, USA)
- 12:10 – 12:40 **Scale up of allogeneic cell therapy manufacturing in single-use bioreactors: Challenges, insights and solutions**
Brian Lee (President, PBS Biotech, USA)
- 12:40 – 13:00 **Comparative analysis of FBS containing media and serum free chemically defined media, CellCor for adipose derived stem cells production**
Jooyoun Lee (Head of R&D Center, Xcell Therapeutics, Korea)
- 13:00 – 14:30 **Lunch**

Monday, January 28, 2019 (Part 2)

- 14:30 – 15:30 **Plenary 2: Gene Therapy**
- 14:30 – 14:35 **Introduction to Plenary 2**
- 14:35 – 15:30 **Plenary 2**
Allan Kaspar (Sr VP, Research & Development, AveXis)
- 15:30 – 17:30 **Session 2: Engineering challenges of *in vivo* gene therapy**
(Session sponsored by GE Healthcare)
Session Chairs: Fernanda Masri (Technology Expert for Regenerative Medicine, Sartorius Stedim, UK)
Michael Greene (Executive Director, Mustang Bio, USA)
- 15:30 – 15:40 **Feedback from ECI Workshop: Developing a toolkit to engineer viral vector manufacturing and next generation gene therapies**
Fernanda Masri and Michael Greene
- 15:40 – 16:00 **Taking an engineering approach to empower breakthrough therapies**
Anil Narasimha (Chief Scientific Officer, Mekonos Biotech, USA)
- 16:00 – 16:20 **A single-use chromatographic purification platform for viral gene transfer vectors & viral vaccines**
Pavel Marichal-Gallardo (Bioprocess Engineer, Max Planck Institute for Dynamics of Complex Technical Systems, Germany)
- 16:20 – 16:50 **Afternoon Break**
(Sponsored by CCRM)
- 16:50 – 17:10 **Tangential flow filtration and scalability in viral vector purification**
Eni Sterjanaj (Downstream Scientist, Pall, USA)
- 17:10 – 17:30 **Scaling up lentiviral vector production from stable producer cells**
Vanja Mistic (Development Scientist, CCRM, Canada)
- 17:30 – 18:30 **Poster Snapshots Session 1**
Session Chairs: Corinne Hoesli (Assistant Professor, Cellular Therapy Bioprocess Engineering McGill University, Canada)
Eric Roos (Strategic Alliances Leader, Cell Therapy, Thermo Fisher Scientific, USA)
- 18:30 – 22:30 **Dinner and poster viewing**

Tuesday, January 29, 2019 (Part 1)

- 07:00 – 08:30 **Breakfast buffet**
- Chairs introduction**
- 08:30 – 10:35 **Session 3: Gene-modification of cells for therapy**
(Session sponsored by PBS Biotech)
Session Chairs: Peter Jones (Head of Operational Strategy, Oxford BioMedica, UK)
Sean Palecek (Professor of Chemical and Biological Engineering, University of Wisconsin, Madison, USA)
- 08:30 – 08:35 **Introduction**
- 08:35 – 09:05 **Key engineering challenges in the biomanufacturing of lentiviral viral vectors**
Peter Jones (Head of Technical Operations, Oxford BioMedica, UK)
- 09:05 – 09:35 **Technology transfer of cell and gene therapy products into a new GMP facility: Success factors and key challenges**
LiYing Yang (Head of MSAT, Lonza)
- 09:35 – 09:55 **Identification of CAR T Cell Critical Quality Attributes and Critical Process Parameters**
Ryan Larson (Director, Cell Therapy Product Sciences, Juno Therapeutics, USA)
- 09:55 – 10:15 **The development of a 14-day non-viral engineered CAR T-cell process**
Emi Y. Tokuda (Postdoctoral Fellow, Seattle Children's Research Institute, USA)
- 10:15 – 10:35 **Effecting clinical starting material quality and the impact to downstream processing**
Dominic Clark (Global Head of Cell Therapy, HemaCare Corporation, USA)
- 10:35 – 11:05 **Morning Break**
(Sponsored by FUJIFILM Cellular Dynamics, Inc.)
- 11:05 – 12:05 **Plenary 3: Product characterization and analytics**
- 11:05 – 11:10 **Introduction to Plenary 3**
- 11:10 – 12:05 **Plenary 3**
Jan Joseph Melenhorst (Adjunct Associate Professor of Pathology and Laboratory Medicine, University of Pennsylvania, USA)
- 12:05 – 13:10 **Session 4: Product characterization and analytics**
(Session sponsored by Xcell Therapeutics Inc.)
Session Chairs: Damian Marshall (Director - New and Enabling Technologies Cell and Gene Therapy Catapult, UK)
Erik Rutjens (Head, New and Enabling Technologies, Cell and Gene Therapy Novartis, USA)
- 12:05 – 12:10 **Introduction**
- 12:10 – 12:40 **Raman spectroscopy of cells as a process analytical technology**
Jamie Piret (Professor of Chemical & Biological Engineering, University of British Columbia, Canada)

Tuesday, January 29, 2019 (Part 2)

- 12:40 – 13:10 **The dynamic mass spectrometry probe (DMSP) - Advanced process analytics for therapeutic cell manufacturing, health monitoring and biomarker discovery**
Andrei G. Fedorov (Professor of Mechanical Engineering, Georgia Institute of Technology, USA)
- 13:10 – 14:40 **Lunch**
- 14:40 – 15:40 **Session 4 (continued): Product characterization and analytics**
- 14:40 – 15:00 **Improving functional maturation of human pluripotent stem cells derived cardiomyocytes through metabolic understanding**
Margarida Serra (Research Associate, IBET/ITQB-UNL, University of Lisbon, Portugal)
- 15:00 – 15:20 **Single cell analysis of viral transduction as a novel toolbox for an improved characterization of cell therapy products**
Nicole Nicholas (Senior Analytical Development Scientist, Cell & Gene Therapy Catapult, UK)
- 15:20 – 15:40 **Evaluating the impact of culture conditions on human mesenchymal stem/stromal cell-derived exosomes through FTIR spectroscopy**
Ana Fernandes-Platzgummer (Post-Doctoral Research Fellow, Department of Bioengineering and iBB, University of Lisbon, Portugal)
- 15:40 – 16:10 **Poster snapshots session 2**
Session Chairs: Corinne Hoesli (Assistant Professor, Cellular Therapy Bioprocess Engineering McGill University, Canada)
Eric Roos (Strategic Alliances Leader, Cell Therapy, Thermo Fisher Scientific, USA)
- 16:10 – 18:20 **Poster session (with coffee and snacks)**
(Sponsored by the Cell and Gene Therapy Catapult)
- 18:20 – 18:45 **Free time**
- 18:45 – 22:30 Boat cruise, reception, networking, music and dinner
- 18:45 – 19:15 Boarding reception
- 19:15 Boat departure

Wednesday, January 30, 2019 (Part 1)

- 07:00 – 09:00 **Breakfast buffet**
- Chairs introduction**
- 09:00 – 10:00 **Plenary 4: Big data processing and analytics**
- 09:00 – 09:05 **Introduction to Plenary 4**
- 09:05 – 10:00 **Plenary 4**
James Mault (President and Chief Medical Officer, CQuentia, USA)
- 10:00 – 11:35 **Session 5 - Big data, analytics and control strategies**
Session Chairs: David Pollard (Head of New Materials & Components, Corporate Research, Sartorius Stedim, USA)
Carolyn Yeago (Georgia Institute of Technology, USA)
- 10:00 – 10:05 **Introduction**
- 10:05 – 10:35 **The emerging role for AI in cell and gene therapy manufacture**
Damian Marshall (Director, New & Enabling Technologies, Cell & Gene Therapy Catapult, UK)
- 10:35 – 10:55 **Efficient model driven design of cell-based product manufacturing**
Rob Thomas (Professor of Manufacturing for Cell and Gene Therapies, Loughborough University, UK)
- 10:55 – 11:15 **Automated data capture and monitoring – An analytics toolbox**
Dina Ibrahim (Senior Process Engineer, Kite Pharma, USA)
- 11:15 – 11:35 **Using Gaussian mixture models and machine learning to predict donor- dependent megakaryocytic cell growth and differentiation potential *ex vivo***
William Miller (Professor of Chemical & Biological Engineering, Northwestern University, USA)
- 11:35 – 13:00 **Lunch and networking**
- 13:00 – 15:05 **Session 6: Bioprocess modeling**
Session Chairs: Suzanne Farid (Professor of Bioprocess Systems Engineering, University College London, UK)
Jon Gunther (Head of Supply Chain, Sana Biotechnology, USA)
- 13:00 – 13:05 **Introduction**
- 13:05 – 13:30 **Establishing successful commercial CAR T manufacturing on a short timeline: A process development and planning perspective**
Tom Brieve (Senior Director of Process Development, Celgene, USA)
- 13:30 – 13:55 **Novel supply chain and process modeling for cell therapy manufacturing and distribution**
Chip White (Schneider National Chair in Transportation and Logistics, Georgia Institute of Technology, USA)
- 13:55 – 14:20 **A roadmap to successful commercialization of autologous CAR T-cell products with centralized and bedside manufacture**
Tania Pereira Chilima (Post-Doctoral Research Associate, University College London, UK)

Wednesday, January 30, 2019 (Part 2)

- 14:20 – 14:45 **Modeling of commercial autologous cell therapy manufacturing using simulation and optimization**
David Zhang (Chief Executive Officer, Bio-G, USA)
- 14:45 – 15:05 **Automated data management strategies drive cell therapy success**
Christophe Suchet (Chief Product Officer, Vinatec, USA)
- 15:05 – 15:30 **Afternoon Break**
(Sponsored by Biolife Solutions and Lonza)
- 15:30 – 16:35 **Session 7: Revolutionizing / delivering the pipelines**
Conference Chairs: Dolores Baksh
Rod Rietze
Ivan Wall
- 15:30 – 15:35 **Introduction**
- 15:35 – 16:05 **The tech enabled pharma company**
Neil Tiwari (Chief Digital Officer, Novartis, USA)
- 16:05 – 16:35 **Leveraging digital solutions to predict disease and patient access to transformative therapies**
Ben Newton (Chief Digital Officer, GE Healthcare, USA)
- 16:35 – 17:30 **Advancing manufacture of cell and gene therapies award lecture**
- 16:35 – 16:45 **Introduction and presentation of award**
Barry Buckland (President, ECI Board of Directors)
- 16:45 – 17:30 **Advancing manufacture of cell and gene therapies award lecture**
Greg Russotti (Vice President, Cell Therapy Technical Development, Celgene, USA)
- 17:30 – 19:00 **Free time and networking**
- 19:00 – 19:30 **Banquet reception and networking**
- 19:30 – 21:30 **Conference banquet**

Thalassaemia and gene therapy from a patient's perspective – Why your work is so important
Laurice Levine (β -thalassemia patient and advocate)

Awards and recognition

Thursday, January 31, 2019

- 07:00 – 09:00 **Breakfast and networking**
- 09:00 – 10:30 **Networking**
- 09:00 – 12:00 **Hotel check-out**

Advancing Manufacture of Cell and Gene Therapies VI

Poster Presentations

Advances in cell processing: New technologies for new therapies

- 1. BIO regulates the *ex vivo* expansion and function of hematopoietic stem cells by inhibiting GSK-3 β**
Qihao Sun (East China University of Science and Technology, China)
- 2. Single use disposable BioSettler removes the dead cells and cell debris selectively to increase the viability percentage of mammalian cells (e.g., CAR-T) during expansion**
Dhinakar Kompala (Sudhin Biopharma Company, USA)
- 3. Use of the Nanobridge system for the Rapid Production of Pluripotent Stem Cells and Neural Progenitor Cells**
Peter P. Gray (AIBN, University of Queensland, Australia)
- 4. Challenges and opportunities for closed processing in autologous CAR-T manufacturing**
John Wesner (Juno Therapeutics, USA)
- 5. Scalable generation of cerebellar neurons from pluripotent stem cells**
Carlos Rodrigues (IST Lisbon, Portugal)
- 6. Human pluripotent stem cell expansion in vertical-wheel bioreactors**
Carlos Rodrigues (IST Lisbon, Portugal)
- 7. Pancreas organoids for type I diabetes mellitus - Is it feasible as a cell therapy?**
Bart van Dijk (Lonza, Netherlands)
- 8. Establishment and evaluation of the suspension culture system for umbilical cord-derived mesenchymal stromal cells**
Hikari Hasegawa (ROHTO Pharmaceutical Co., Japan)
- 9. Scalable manufacturing of human mesenchymal stem/stromal cells and derived exosomes in the single-use, vertical-wheel bioreactor system using a human platelet lysate culture supplement**
Ana M. Fernandes-Platzgummer (IST Lisbon, Portugal)
- 10. Viable manufacture of cell therapies through the integration of multiple unit processes onto a counter-flow centrifugation device**
Alexander S. Klarer (Hitachi Chemical Advanced Therapeutic Solutions, USA)
- 11. WITHDRAWN**
- 12. Developing a novel microchannel emulsification device for diabetes cell therapy**
Christina Bitar (McGill University, Canada)
- 13. A scalable xeno-free microcarrier suspension bioreactor system for regenerative medicine biomanufacturing of hMSCs**
Timothy Olsen (RoosterBio Inc., USA)

14. WITHDRAWN

15. WITHDRAWN

16. Further evaluation of a novel COP container system for the cryopreservation of adherent and suspension human cell types

Alexander Lyness (West Pharmaceutical Services, Inc., USA)

17. Enabling stem cell based therapies: Adaptable and scalable manufacturing of human pluripotent stem cells

Haritha Vallabhaneni (Lonza, USA)

18. Maintaining CD4/CD8 ratio and Th1-CTL subsets of chimeric antigen receptor (CAR)-T cells in serum-free culture conditions

Hsin-Lin Lu (Development Center for Biotechnology, Taiwan)

19. Scale-up study for *ex-vivo* expansion of allogeneic natural killer cells in stirred-tank bioreactor

Juyoung Kim (GreenCross LabCell, South Korea)

20. A step closer to industrial scale manufacture of exosomes - Adaptation of clinical grade neural stem cells from 2D to 3D culture

Nicola Goddard (University College London, UK)

21. *In vitro* high expansion of chimeric antigen receptor (CAR)-T cells in serum-free process conditions

Wei-Kuang Chi (Development Center for Biotechnology, Taiwan)

22. Reducing variability in conditions for cell handling improves MSC yields

Ken Rando (BioSpherix, USA)

23. Impact of the dynamic culture system for 3D high cell density neural differentiation of hESC in electrospun PCL scaffolds

Veronique Chotteau (KTH, Sweden)

24. Superior expansion of long-term hematopoietic stem cells using StemPro™ HSC medium kit

Chad MacArthur (Thermo Fisher Scientific, USA)

25. An automated and closed system for patient specific CAR-T cell therapies

Joseph W. O'Connor (Lonza, USA)

26. Automated manufacturing for iPSC-derived retinal pigment epithelial cells

Masahiro Kino-oka (Osaka University, Japan)

27. Isolation and expansion of human bone marrow-derived mesenchymal stem cells (hMSCs) directly on microcarriers in a stirred tank bioreactor

Christopher J. Hewitt (Aston University, UK)

28. Mitigating the risks of adventitious agents in serum: Elimination or viral inactivation

Kelly A. O'Neill (Celgene, USA)

Engineering challenges of in vivo gene therapy

29. **LentiPro stable producer cells: Delivering scalable and reliable lentiviral vector manufacturing**
Manuel Carrondo (IBET, Portugal)
30. **Therapeutic genome editing for Charcot-marie-tooth disease type 1a**
Jae young Lee (ToolGen Inc., South Korea)
31. **Engineering characterization of a versatile vertical-wheel bioreactor for cell and gene therapy**
Matthew Croughan (Matthew S. Croughan Consulting Services, USA)
32. **A novel scalable manufacturing platform for T-cell activation and expansion in adoptive T-cell therapy**
Jian Ling (Southwest Research Institute, USA)
33. **Optimising HEK293T culture for the improved manufacture of gene therapies**
Angharad Evans (Loughborough University, UK)

Gene-modification of cells for therapy

34. **A scalable and physiologically relevant system for human induced pluripotent stem cell expansion and differentiation**
Yuguo Lei (University of Nebraska-Lincoln, USA)
35. **Towards an allogeneic therapy for neural regeneration**
Rachael Wood (Aston University, UK)
36. **Engineering and manufacturing of probiotic E. Coli to treat metabolic disorder**
Eugene Antipov (Synlogic, USA)
37. **Development of a closed CAR-T manufacturing process**
Steven Loo-Yong-Kee (CCRM, Canada)
38. **Leveraging bioprocess platform technology for the development of a robust, scalable, and economic manufacturing process of allogeneic CAR-T cell therapy products**
Bernadette Dahlin (AdicetBio, USA)
39. **Characterization of CAR-T transduction parameters using a lentiviral vector**
Stefanie Shahan (Celgene, USA)
40. **Platelet lysate boosts transgene levels and maintains undifferentiated T cell subtypes following lentiviral delivery to human primary T cells**
Christina Dann (Cook Regentec, USA)
41. **New viral and non-viral platforms for T-cell engineering**
Chad MacArthur (Thermo Fisher Scientific, USA)

Product characterization and analytics

42. **Development of feeder-free PSC culture system enabling translational & clinical research**
Chad MacArthur (Thermo Fisher Scientific, USA)
43. **Xeno-free expansion of late-adherent human olfactory mucosa cells: Towards an allogeneic therapy for neural regeneration**
Gerardo Santiago-Toledo (UCL, UK)
44. **Decoding human cardiac stem cells regenerative potential in acute myocardial infarction**
Margarida Serra (IBET, Portugal)
45. **Advancing the knowledge on immunomodulatory properties of human cardiac stem cells**
Margarida Serra (IBET, Portugal)
46. **Cryopreservation critical process parameters: Impact on post-thaw recovery of cellular product**
Alireza Abazari (BioLife Solutions, USA)
47. **Optimized media and workflow for the expansion of human pluripotent stem cells as aggregates in suspension cultures**
Eric Jervis (STEMCELL Technologies, Canada)
48. **Refining iPSC-based 3D neural cell models and characterization tools to address brain microenvironment-related diseases**
Margarida Serra (IBET, Portugal)

Big data, analytics and control strategies

49. **Metabolite-based model predictive control of cell growth**
Kathleen Van Beylen (KU Leuven, Belgium)
50. **Streamlining cell therapy manufacturing: Automated production and integrated data management**
Sébastien de Bournonville (KU Leuven, Belgium)
51. **Application of quality by design tools to upstream processing of platelet precursor cells to enable *in vitro* manufacture of blood products**
Elizabeth A. Cheeseman (Loughborough University, UK)
52. **Dielectric spectroscopy monitoring of a bioreactor process for hiPSC expansion and differentiation**
Pedro Vicente (IBET, Portugal)

Bioprocess modelling

53. **Scaling up and industrialization the production and purification of viral vectors for therapeutic use: Challenges and progress**
Rachel Legmann (Pall, USA)

- 54. Optimization of HEK293T suspension cultivation with a DoE-approach in ambr®15 microbioreactor**
Franziska Bollmann (Sartorius Stedim Biotech GmbH, Germany)
- 55. Determining the role of lactate in induced pluripotent stem cell metabolism**
Daniel Odenwelder (Clemson University, USA)
- 56. Computational fluid dynamics (CFD) modeling of single-use, vertical-wheel bioreactors as a predictive scale-up tool for large scale stem cell culture**
Breanna Borys (University of Calgary, Canada)
- 57. A cost/quality analysis of primary human T-Cells in different expansion systems**
Marco C. Rotondi (UCL, UK)
- 58. High shear stress from a resonance phenomenon in Wave bioreactor revealed by computational fluid dynamics simulation**
Veronique Chotteau (KHT, Sweden)
- 59. Defining cell culture dynamics in response to growth factor provision for efficient optimization of cell based therapies**
Katie E. Glen (Loughborough University, UK)
- 60. Development of media production processes for CAR-T therapies**
Ryan C. Glussi (Celgene, USA)
- 61. Economics of lentiviral vector processes**
Ruxandra-Maria Comisel (UCL, UK)

Revolutionizing/Delivering the pipelines

- 62. CMC strategy for AAV gene therapies in the age of RMAT designation**
Rajiv Gangurde (Voyager Therapeutics, USA)
- 63. CAR T-cell therapies: The concept of a dynamic supply chain**
Maria Papathanasiou (Imperial College London, UK)
- 64. Advancing the robust manufacture of T-cell therapies through the application of stirred tank bioreactors**
Alexander S. Klarer (Hitachi Chemical Advanced Therapeutic Solutions, USA)
- 65. Automated filtration screening of lentiviral vectors with multiple envelope proteins**
Christopher Perry (UCL, UK)
- 66. Producer cell line engineering for large volume manufacturing of therapeutic AAV**
Jennifer Baerenwald (Biogen, USA)
- 67. Volume reduction, cell washing and affinity cell selection using multi-dimensional acoustic standing wave technology**
Chris Leidel (FloDesign Sonics, USA)