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Scale-up and Manufacturing of Cell-based Therapies
V

Proceedings

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Conference Program

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Program

Scale-up and Manufacturing of Cell-based Therapies V

January 15-19, 2017

Hyatt Regency Mission Bay Hotel

San Diego, California

Conference Chairs

Tom Brieva
Celgene Cellular Therapeutics, USA

William Miller
Northwestern University, USA

Chris Mason
University College London, UK



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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

2017 Scale-up and Manufacturing of Cell-Based Therapies Award Winner

Sponsored by Pfizer and ECI

Peter W. Zandstra



Peter Zandstra has demonstrated outstanding achievements in elucidating the factors that regulate stem cell expansion and differentiation. He has also developed a fundamental understanding of the design principles for stem cell bioreactor technologies during nearly two decades at the University of Toronto. Peter's work integrates engineering and biological approaches, and he has contributed to the development of clinically and industrially relevant and academically recognized technologies based on the design of bioprocesses for the growth and differentiation of adult and pluripotent stem cells. Key contributions include:

- High-throughput experimental assays for determining molecular regulators of stem cell behavior
- Conceptual and computational models for molecular regulation of stem cell proliferation and differentiation
- Establishing bioreactor conditions to effectively yield desired stem cell proliferation and differentiation behavior
- Developing approaches to examine physiological and therapeutic effects of culture-expanded stem cells

In addition to his role as a Professor, Dr. Zandstra is interested in innovation and the process by which fundamental research (especially in cell manufacturing and process development) can be catalyzed and translated for health and economic impact. Some of these efforts are manifest in his role as co-founder and Chief Scientific Officer at CCRM (www.ccrm.ca).

CCRM is a Canadian, federally incorporated, not-for-profit organization supporting the development of foundational technologies that accelerate the commercialization of

stem-cell-based products and therapies. Over the last 5 years CCRM has grown to 40+ employees (>75% PhD level), launched 4 companies, and attracted >\$30M in industry funding. Peter has also participated in the founding of two for-profit companies (Inception Lifebank and ExCellThera), and is a scientific advisor for a number of others, including Silvercreek Pharmaceuticals. ExCellThera, launched in 2015, is a clinical stage company that focuses on the development of technologies for robust and cost effective blood-stem-cell-based therapies for leukemia and other blood diseases.

Peter is a spectacular teacher and scientist. His scientific accomplishments set the bar high for the field. He has the novel ideas and inventiveness to come up with entirely new concepts, as well as the intelligence and drive to carry them through to fruition. Few laboratories are having more impact on the field.

This award recognizes outstanding contributors to the development and commercialization of cell-based therapies. Past recipients include Bob Nerem (2014) and Kim Warren (2015).

Conference Sponsors

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Sunday, January 15, 2017

16:00 – 19:00	Conference check-in (Bayview Foyer)
18:00 – 18:10	Welcome to conference Conference Chairs: Tom Brieva (Celgene Cellular Therapeutics) Bill Miller (Northwestern University) Chris Mason (University College London) ECI Liaison: Barry Buckland
18:10 – 18:40	Poster snapshots Session Chairs: Corinne Hoesli (McGill University) Eytan Abraham (Lonza)
18:40 – 18:45	Introduction to Plenary 1 Tom Brieva (Celgene Cellular Therapeutics), ISCT Process and Product Development Subcommittee
18:45 – 19:45	<u>Plenary 1</u> Moving off-the-shelf into patients; development of pluripotent cell-based immunotherapeutics Stewart Abbot, Fate Therapeutics, USA
19:45 – 21:00	Dinner
21:00 – 22:30	Welcome reception and poster session with dessert

Notes

- *Technical sessions will be in the Bayview Ballroom. Poster Sessions will be in the Regatta Pavilion.*
- *Breakfasts and dinners will be in the Regatta Pavilion. Lunches will be on the Bayview/Sunset Terrace.*
- *Audiotaping, videotaping and photography of presentations are prohibited.*
- *Speakers – Please have your presentation loaded onto the conference computer prior to the session start (preferably the day before).*
- *Speakers – Please leave at least 3-5 minutes for questions and discussion. Please do not smoke at any conference functions.*
- *Turn your mobile telephones to vibrate or off during technical sessions.*
- *Please write your name on your program so that it can be returned to you if lost or misplaced.*
- *After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.*

Monday, January 16, 2017

- 07:00 – 08:30 Breakfast buffet
- 08:30 – 11:35 **Session 1: Novel technologies for cell therapy manufacturing**
Sponsored by Panasonic Healthcare Corporation of North America
Session Chairs: Jamie Piret (University of British Columbia)
Jon Rowley (RoosterBio)
- 08:30 – 08:35 Introduction
- 08:35 – 09:00 **Acoustic cell washing and Raman spectroscopy to address cell therapy bioprocess challenges**
Jamie Piret, University of British Columbia, Canada
- 09:00 – 09:25 **Bespoke cell therapy manufacturing platforms - A contradiction in terms?**
Eytan Abraham, Lonza, USA, ISCT Process and Product Development Subcommittee
- 09:25 – 09:45 **DMSO-free method of preserving mesenchymal stem cells (MSCs) that retains high levels of post thaw function**
Katie Pollock, University of Minnesota, USA
- 09:45 – 10:05 **Incorporating quality in engineered tissues using bottom-up niche assemblies**
Ioannis Papantoniou, KU Leuven, Belgium
- 10:05 – 10:25 **Xeno-free production and recovery of human pluripotent stem cells using synthetic dissolvable microcarriers**
Maria Margarida Diogo, University of Lisbon, Portugal
- 10:25 – 10:55 Coffee break
- 10:55 – 11:15 **Magnetic ratcheting cytometry towards manufacturing scale separations of “best in class”**
Coleman T. Murray, University of California, Los Angeles, USA
- 11:15 – 11:35 **Development of a high-dose engineered TCR T cell manufacturing process using automated semi-continuous perfusion bioreactors**
Kenny Choi, Kite Pharma, USA
- 11:35 – 11:40 **Introduction to Plenary 2**
Bill Miller (Northwestern University)
- 11:40 – 12:40 **Plenary 2**
Design of novel materials to regulate stem and progenitor cell expansion and differentiation
Kristi Anseth, University of Colorado, USA
- 12:45 – 14:15 Lunch
- 14:15 – 16:25 Networking and free time (includes industrial promotion session)
- 15:45 – 16:15 **Industrial promotion session**
Session Chairs: Tom Brieva (Celgene Cellular Therapeutics)
Bill Miller (Northwestern University)
- 15:45 – 16:00 **Enabling technology for scalable manufacturing of cell therapy products**
Brian Lee, PBS Biotech, Inc., USA

Monday, January 16, 2017 (continued)

- 16:00 – 16:15 **Total quality approach to cell incubation and processing / scale-up & scale-out**
Kevin Murray, BioSpherix, Ltd., USA
- 16:25 – 18:00 **Session 2: Collaborating with regulatory agencies to define the landscape for emerging cell-based therapies – challenges and lessons learned**
Session Chairs: Bernadette Keane (Keane Consulting)
Mohammad Heidarani (US Food and Drug Administration)
- 16:25 – 16:40 **Industry challenges and questions for regulatory authorities**
Bernadette Keane, Keane Consulting, USA
- 16:40 – 17:05 **Cell therapy product manufacturing considerations**
Mohammad Heidarani, US Food and Drug Administration, USA
- 17:05 – 17:30 **Regulatory aspects of manufacturing and control of genetically modified cells**
Matthias Renner, Paul Ehrlich Institute, Germany
- 17:30 – 18:00 **Panel discussion with questions from the audience**
Topic 1: How to better define the cell-based product CQA and CPP?
Topic 2: Challenges of establishing reliable assays which could be useful in measuring product potency.
Topic 3: How to deal with manufacturing changes including automation introduced during late stages of the product development cycle?
Topic 4: Approaches for establishing product comparability.
Topic 5: Challenges of establishing control over the source materials and ancillary materials.
Topic 6: What is the relationship between the lot release tests and the drug product CQA?
Topic 7: Importance of establishing and distinguishing drug substance from drug product.
- 18:00 – 19:00 **Poster snapshots**
Session Chairs: Corinne Hoesli (McGill University)
Eytan Abraham (Lonza)
- 19:00 – 20:30 Dinner
- 20:30 – 22:00 **Poster session with dessert and social hour**
Sponsored by MilliporeSigma

Tuesday, January 17, 2017

- 07:00 – 08:30 Breakfast buffet
- 08:30 – 10:35 **Session 3: Product characterization and potency**
Session Chairs: Anne Plant (National Institute of Standards and Technology)
Chris Wiwi (Celgene)
- 08:30 – 08:35 Introduction
- 08:35 – 09:00 **A systems approach for CAR T cell therapy product characterization**
Sadik Kassim, Novartis, USA
- 09:00 – 09:25 **Implications of the CAACB virus contamination in biomanufacturing project for cell therapy manufacturers**
Paul Barone, Massachusetts Institute of Technology, USA
- 09:25 – 09:45 **Novel assays for immunotherapy product characterization and potency measurement**
Damian Marshall, Cell and Gene Therapy Catapult, UK
- 09:45 – 10:05 **Metabolism regulation of phenotypic and therapeutic properties of human mesenchymal stem cells**
Teng Ma, Florida State University, USA
- 10:05 – 10:25 **Evaluating the quality of cell counting measurements using experimental design and statistical analysis**
Sumona Sarkar, National Institute of Standards and Technology, USA
- 10:25 – 10:55 Coffee break
- 10:55 – 13:00 **Session 4: Manufacturing CAR T cells and other cancer immunotherapies: challenges and progress**
Sponsored by Sartorius Group North America
Session Chairs: David Stroncek (National Institutes of Health)
Marianna Sabatino (Kite Pharma)
- 10:55 – 11:00 Introduction
- 11:00 – 11:25 **Optimizing CAR T cell therapy for hematologic malignancies**
Terry Fry, National Institutes of Health, USA
- 11:25 – 11:50 **Production of anti-CD19 CAR T cells to support multicenter trials evaluating KTE- C19 in B cell malignancies**
Marianna Sabatino, Kite Pharma, USA
- 11:50 – 12:15 **Removal of myeloid cells from autologous leukocytes used for chimeric antigen receptor (CAR) T cell manufacturing improves final product consistency and yields**
David Stroncek, National Institutes of Health, USA
- 12:15 – 12:40 **Considerations and challenges associated with manufacturing autologous cellular therapies such as Car T Cells**
Dawn Maier, bluebird bio, USA
- 12:40 – 13:00 **Cost effective manufacturing strategies for feasible commercialization of CAR T-cell products**
Tania Chilima, University College London, UK

Tuesday, January 17, 2017 (continued)

- 13:00 – 14:45 Lunch, networking and free time
- 14:45 – 17:45 **Session 5: Gene editing, vector production, synthetic biology, and genetic modification of cells**
Session Chairs: Paula Alves (Instituto de Biologia Experimental e Tecnológica)
Robert Kutner (Rocket Pharma)
- 14:45 – 14:50 Introduction
- 14:50 – 15:15 **Gene therapy for inherited blood diseases, from viral vectors to gene editing**
Fulvio Mavilio, Genethon, France
- 15:15 – 15:40 **Challenges and solutions to quality GMP supply of AAV vectors**
Anandita Seth, Lonza, USA
- 15:40 – 16:05 **Translation of pseudotyped HIV-1-based lentiviral vectors for clinical applications**
Robert Kutner, Rocket Pharma, USA
- 16:05 – 16:35 Coffee break
- 16:35 – 17:00 **Altering, improving, and defining the specificities of CRISPR-Cas nucleases**
Ben Kleinstiver, Joung Lab, Harvard University, USA
- 17:00 – 17:25 **Engineering red blood cells for therapeutic function**
Robert Deans, Rubius Therapeutics, USA
- 17:25 – 17:45 **Exosomes for regenerative medicine – manufacturing challenges and potential applications**
Ivan Wall, University College London, UK
- 18:00 Buses depart for Stone Brewing World Bistro
- 18:15 – 21:15 **Social hour, networking, and grazing dinner at Stone Brewing World Bistro**
(buses will return to the Hyatt beginning at 19:30 and ending at 21:15)

Wednesday, January 18, 2017

- 07:00 – 08:30 Breakfast buffet
- 08:30 – 11:55 **Session 6: Upstream and downstream process characterization, scale-up, comparability, and in-line process monitoring**
Sponsored by Pall Life Sciences
Session Chairs: Joaquim Cabral (University of Lisbon) Fran Meacle (Johnson & Johnson)
- 08:30 – 08:35 Introduction
- 08:35 – 09:00 **Metabolomics and the role of metabolism in stem cell bioprocessing**
Sakis Mantalaris, Imperial College London, UK
- 09:00 – 09:25 **Process scale-up and characterization for a cardiac-derived cell therapy**
Rachel Smith, Capricor Therapeutics, USA
- 09:25 – 09:45 **Clinical scale manufacturing of autologous insulin-producing liver cells for the treatment of diabetes**
Rachel Legmann, Pall Life Sciences, USA
- 09:45 – 10:05 **Characterization and optimization of the nanobridge system for hESC suspension cultures**
Peter Gray, University of Queensland, Australia
- 10:05 – 10:35 Coffee break
- 10:35 – 10:55 **High density ex vivo expansion of stem cell aggregates in stirred perfusion bioreactors**
Ernesto Scibona, ETH Zurich, Switzerland
- 10:55 – 11:15 **Interactive visualization of cell expansion process performance**
Toon Lambrechts, KU Leuven, Belgium
- 11:15 – 11:35 **Process and equipment scale-up of controlled-rate freezing in cell therapy**
Jonathan Rubin, Janssen R&D, USA
- 11:35 – 11:55 **Bioprocess integration for human mesenchymal stem cells: from up to downstream processing scale-up to cell proteome characterization**
Margarida Serra, Instituto de Biologia Experimental e Tecnológica, Portugal
- 12:00 – 15:30 Lunch on your own, networking and free time
- 15:30 – 15:35 **Introduction to Award Lecture**
Bill Miller (Northwestern University)
- 15:35 – 16:35 **Scale-up and Manufacturing of Cell-Based Therapies Award Lecture**
Sponsored by Pfizer and ECI
Engineering stem cell fate for drug development and therapy
Peter Zandstra, University of Toronto, Canada
- 16:35 – 17:05 Coffee Break

Wednesday, January 18, 2017 (continued)

- 17:05 – 18:35 **Session 7: Bioprocess modeling – the road to informed decision-making for successful commercialization**
Session Chairs: Dolores Baksh (GE Healthcare), ISCT Commercialization Committee
Suzanne S. Farid (University College London), ISCT Business Models and COGs Subcommittee
- 17:05 – 17:10 Introduction
- 17:10 – 17:30 **Decision support tools for cost-effective bioprocess design in the cell therapy sector**
Michael Jenkins, University College London, UK
- 17:30 – 17:50 **Utilizing simulation and optimization techniques to evaluate different CAR T cell therapy manufacturing paradigms**
Jon Gunther, Juno Therapeutics, USA
- 17:50 – 18:10 **Dynamic mechanistic modelling and controlled growth factor delivery for optimization of scalable haematopoietic cell processing**
Robert Thomas, Loughborough University, UK
- 18:10 – 18:35 **Panel discussion with questions from the audience**
Topic 1: How do we get management buy-in for modeling and when is the best time to introduce modeling in the development pathway?
Topic 2: What criteria do we consider and optimize for when designing new cell therapy processes?
Topic 3: Will the cell therapy sector reach the point where process models enable process control?
- 18:35 – 19:00 Break
- 19:00 – 21:00 Banquet
- 21:00 – 22:30 Social hour with dessert

Thursday, January 19, 2017

- 06:30 – 08:00 Breakfast buffet
- 08:00 – 08:10 **Introduction to the ISCT Process and Product Development Subcommittee and Plenary 3**
Dominic M. Clarke (Charter Medical)
Eytan Abraham (Lonza)
ISCT Process and Product Development Subcommittee
- 08:10 – 09:10 **Plenary 3**
Sponsored by the ISCT Process and Product Development Subcommittee
How to use computational fluid dynamics in the development of cell therapeutics
Valentin Jossen, Eibl Lab, Zurich University of Applied Science, Switzerland
- 09:10 – 10:05 **Session 8: From method to manufacturing, ramping-up for commercial production**
Sponsored by Eppendorf AG
Session Chairs: Nick Timmins (CCRM)
Greg Russotti (Celgene Cellular Therapeutics)
- 09:10 – 09:15 Introduction
- 09:15 – 09:40 **A penny today or a dollar tomorrow – early stage development for future success**
Nick Timmins, CCRM, Canada
- 09:40 – 10:05 **Cell Therapy Manufacturing: It's about "TIME"**
Donald Powers, Janssen, USA
- 10:05 – 10:10 **Introduction to Plenary 4**
Tom Brieva (Celgene Cellular Therapeutics)
- 10:10 – 11:10 **Plenary 4**
CAR-T manufacturing: delivering on the promise of a transformational therapy
Greg Russotti, Celgene Cellular Therapeutics, USA
- 11:10 – 11:35 Coffee break
- 11:35 – 12:30 **Conference wrap-up and discussion with conference chairs**
- 12:30 Departures

Posters

Scale-up and Manufacturing of Cell-based Therapies V

January 15-19, 2017

Hyatt Regency Mission Bay Hotel

San Diego, California



Engineering Conference International

Poster Presentations

1. **Process development approaches for expansion of adherent stem cells in microcarrier-based bioreactor culture**
Kara Levine, MilliporeSigma, USA
2. **Scale-out of massively parallel patient-specific cell cultures with a modified transportable conditioned cell culture chamber**
Alicia D. Henn, BioSpherix, USA
3. **Umbilical cord matrix derived-mesenchymal stem cell production in microcarrier-based culture systems**
Ana Fernandes-Platzgummer, Instituto Superior Técnico, Universidade de Lisboa, Portugal
4. **Microfluidic tools and high-content imaging for cell therapy bioprocessing**
Ana Valinhas, University College London, United Kingdom
5. **Characterization of a 3D matrix bioreactor for scaled production of human mesenchymal stem cells**
Andrew B. Burns, Keck Graduate Institute, USA
6. **Development of a chemically defined, animal-component-free ex vivo expansion process for activated human T cells**
Annie Ngo, Irvine Scientific, USA
7. **Characterisation and process verification studies in a miniature bioreactor used as a predictive tool to scale-up an industrial process**
Asma Ahmad, University College London, United Kingdom
8. **A novel acoustic cell processing platform for cell concentration and washing**
Bart Lipkens, FloDesign Sonics, USA
9. **Engineering cardiac tissue using human induced pluripotent stem cell derivatives: Proteomic characterization of co-cultures of cardiomyocytes and endothelial cells**
Bernardo Abecasis, IBET, Portugal
10. **Expansion of 3D human induced pluripotent stem cell aggregates in bioreactors: Bioprocess intensification and scaling-up approaches**
Bernardo Abecasis, IBET, Portugal
11. **Computational fluid dynamic modeling of 100ml and scaled-down 10ml stirred suspension bioreactors enables prediction of embryonic stem cell characteristics**
Breanna Shalyn Borys, University of Calgary, Canada
12. **New paradigm of scalable manufacturing for allogeneic cell therapy products**
Brian Lee, PBS Biotech, Inc., USA
13. **Development of a scale-down approach to the scalable culture of induced Pluripotent Stem Cells on microcarriers using single-use Vertical-Wheel™ bioreactors under xeno-free conditions**
Carlos A. V. Rodrigues, Instituto Superior Técnico, Universidade de Lisboa, Portugal
14. **Impact of high extracellular lactate on induced pluripotent stem cell metabolism and pluripotency**
Daniel Odenwelder, Clemson University, USA

15. **Optimization of a scalable single-use manufacturing platform for expansion of high quality human mesenchymal stem cells**
David Splan, Pall Life Sciences, USA
16. **Enabling human pluripotent stem cell derived megakaryocyte manufacture**
Elizabeth Cheeseman, Loughborough University, United Kingdom
17. **Optimized media and workflow for the expansion of human pluripotent stem cells as aggregates in suspension**
Eric J. Jervis, STEMCELL Technologies, Canada
18. **Combined with #48 as # 74**
19. **Scaled-up expansion of equine cord blood mesenchymal stem cells (MSCs) from stirred suspension bioreactors to 100mL computer controlled stirred suspension bioreactors using computational fluid dynamic modeling**
Erin Roberts, University of Calgary, Canada
20. **Maintenance of stemness and optimization of differentiation potentials during in vitro expansion of human adipose-derived stem cells**
EunAh Lee, Kyung Hee University, South Korea
21. **Appraisal of microcarrier suspension dynamics in shaken bioreactors**
Gregorio Rodriguez, University College London, United Kingdom
22. **Large-scale stem cell production system by newly designed bioreactor**
Hideaki Kagawa, FUJIFILM Corporation, Japan
23. **Optimized process for regulatory T cell activation and expansion using Dynabeads™ Treg CD3/CD28 for clinical applications**
Hui Zhang, Thermo Fisher Scientific, Norway
24. **Development of downstream processing options for the commercial scale purification of stem cell derived exosomes**
Ivano L. Colao, University College London, United Kingdom
25. **Economics and quality attributes of hMSC production in xeno-free bioprocessing media**
Jon Rowley, RoosterBio, USA
26. **Improving production of retroviral vector from Pg13 cells for T cell therapy**
Joseph Shiloach, NIDDK/NIH, USA
27. **Manufacturing solutions for robust cell therapy expansion and harvest**
Sandhya Punreddy, MilliporeSigma, USA
28. **Development of microchannel emulsification as a novel cell encapsulation technology**
Karen E. Markwick, McGill University, Canada
29. **A mechanistic model of erythroblast growth inhibition: Optimising red blood cell manufacture**
Katie Glen, Loughborough University, United Kingdom

30. **TRPV-1 activation through thermal and agonist treatment in the process of scalable cardiac differentiation and tissues fabrication is the novel strategy to eliminate undifferentiated iPS cells in the bioengineered cardiac tissues**
Katsuhisa Matsuura, Tokyo Women's Medical University, Japan
31. **Assay automation towards the commercialization of cell therapies**
Kruti H. Shah, Celgene, USA
32. **Industrially-relevant examples using a data analytics strategy to effectively address complex performance challenges**
Lisa Graham, Alkemy Innovation, Inc., USA
33. **Opportunities for applying biomedical production and manufacturing methods to the development of the clean meat industry**
Liz Specht, Good Food Institute, USA
34. **Rapid human T cell expansion using gas-permeable bags in the Eppendorf New Brunswick™ S41i CO2 incubator shaker**
Ma Sha, Eppendorf Inc., USA
35. **Establishing the design space of a filtration-based operation for the concentration of human pluripotent stem cells**
Manuel JT Carrondo, iBET/FCT-NOVA, Portugal
36. **Characterization and fractionation in Aqueous Two-Phase Systems of site-specific PEGylated antibodies: Targeting stem cell separation**
Marco Rito-Palomares, Tecnológico de Monterrey, Mexico
37. **Unveiling human Cardiac Stem Cells regenerative potential in Ischemia/Reperfusion Injury**
Margarida Serra, iBet/ ITQB NOVA, Portugal
38. **Effective hypothermic storage of human pluripotent stem cell-derived cardiomyocytes compatible with global distribution of cells for clinical applications and toxicology testing**
Margarida Serra, iBET, Portugal
39. **Improving production and maturation of cardiomyocytes derived from human pluripotent stem cells: An “-Omics” driven approach**
Margarida Serra, iBET, Portugal
40. **Development and optimization of animal origin-free, serum-free media for human treg manufacturing**
Maria de los Angeles Torres-Castillo, Thermo Fisher Scientific, USA
41. **Scaling up a chemically-defined aggregate-based suspension culture system for neural commitment of human pluripotent stem cells**
Maria Margarida Diogo, Instituto Superior Técnico, Universidade de Lisboa, Portugal
42. **Impact of the hydrodynamic environment on cardiomyocyte differentiation of iPSC**
Martina Micheletti, University College London, United Kingdom
43. **Comprehensive cell manufacturing system based on flexible modular platform**
Masahiro Kino-oka, Osaka University, Japan

44. **The development of scalable bioreactor series for human iPS cell stirred suspension culture**
Masanori Wada, ABLE Corporation, Japan
45. **Designing a banking scale of human induced pluripotent stem cells based on suspension time-dependent quality variations in filling and cryopreservation processes**
Masashi Kagihiro, Sumitomo Dainippon Pharma Co., Ltd., Japan
46. **Economic and operational appraisal of an allogeneic CAR T-cell bioprocess**
Michael J. Jenkins, University College London, United Kingdom
47. **Control of starting material and final product administration of cellular therapies**
Nayyereh Rajaei, Celgene, USA
48. **Combined with #18 as # 74**
49. **Application of quality by design concepts and automation to improve manufacturing process consistency of development and clinical-stage cell therapies**
Peter David Mitchell, Loughborough University, United Kingdom
50. **Process development of human mesenchymal stem cell microcarrier culture using an automated high-throughput microbioreactor**
Qasim Rafiq, Aston University, United Kingdom
51. **Experimental and Computational Fluid Dynamics study of microcarrier suspension during the cultivation of Mesenchymal Stem Cells in an ambr250 bioreactor**
Qasim Rafiq, Aston University, United Kingdom
52. **Investigating the requirement for dual cell co-culture platforms in creating regenerative cell therapies for CNS injury**
Rachael C. Wood, University College London, United Kingdom
53. **Determination of an optimal formulation for CAR-T Cells: Cryopreservation studies using model T-Cells**
Rachel N. Witts, Pfizer, USA
54. **Albumin in cell culture media – An examination of quality and function**
Randall W. Alfano, InVitria, USA
55. **Scalable and controlled presentation of surface immobilised factors from the bone marrow niche for hematopoietic cell expansion**
Rebecca Moore, Loughborough University, United Kingdom
56. **Development of a cost efficient platform for the industrial manufacturing of pluripotent stem cell derived products for cell therapy: Cell expansion is the starting point**
Jahid Hasan, The Cell and Gene Therapy Catapult, United Kingdom
57. **An alternative methodology for a quantitative flow-based cell-mediated in vitro cytotoxicity assay to evaluate immune cell potency**
Sherry Zhou, Celgene Corporation, USA
58. **WITHDRAWN**

59. **Application of the migratory nature of human mesenchymal stem cells to optimise microcarrier-based expansion processes**
Steven Ruck, Loughborough University, United Kingdom
60. **High density culture of human induced pluripotent stem cells through the refinement of medium by dialysis in suspension**
Suman Chandra Nath, Osaka University, Japan
61. **NIST and FDA collaboration on standards development activities and laboratory programs supporting translation of regenerative medicine products**
Sumona Sarkar, NIST, USA
62. **A method for estimating capital investment and facility footprint of cell therapy facilities**
Tania Doroteia Pereira Chilima, University College London, United Kingdom
63. **Aggregation kinetics of human mesenchymal stem cells under wave motion**
Teng Ma, Florida State University, USA
64. **Dissolvable microcarriers for efficient cell production and recovery**
Todd Sciortino, Corning Incorporated, USA
65. **Development of an alternative harvesting method using pH to detach adherent cells from microcarriers**
Tylor Walsh, University of Calgary, Canada
66. **Derivation of endothelial cells and formation of microvasculature from mouse embryonic stem cells**
Alan Jesus Gómez Calderon, Centro Medico Nacional 20 de Noviembre, Mexico
67. **Directed differentiation of inner ear hair cells from mouse embryonic stem cells (E14Tg2a)**
Miguel Ángel Juárez Mancera, Centro Médico Nacional 20 de Noviembre-ISSSTE, Mexico
68. **Experimental and economic evaluation of different culture systems for mesenchymal stromal/stem cell expansion for clinical applications**
Kamilla Swiech, University of Sao Paulo, Brazil
69. **Expansion strategies for human mesenchymal stromal cells cultured under xeno-free conditions**
Kamilla Swiech, University of São Paulo, Brazil
70. **Modification of T lymphocytes with lentiviral vectors for expression of anti-CD19 chimeric antigen receptor (CAR)**
Virginia Picanco Castro, Faculdade de Ciências Farmacêuticas de Ribeirão Preto, Brazil
71. **Optimization of human limbal epithelial stem cell expansion under chemically defined culture conditions**
Mario Antonio Téllez-González, Centro Médico Nacional “20 de Noviembre” – ISSSTE, Mexico
72. **Effects of culture media and suspension expansion technologies in mesenchymal stem cell manufacturing - A computational bioprocess and bioeconomics study**
Carlos A. V. Rodrigues, Institute for Bioengineering and Biosciences, Instituto Superior Tecnico, Portugal

73. **MaxCyte scalable electroporation: A universal cell engineering platform for development of cell-based medicines from R&D to clinic**
Jessica McClure-Kuhar, MaxCyte, USA
74. **Shear susceptibility of human mesenchymal stem cells increases with generation number: Implications for stem cell therapy scale-up and manufacturing**
Peter Amaya and Eric Plencner, The Ohio State University, USA