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

Engineering Conference International
32 Broadway, Suite 314 - New York, NY 10004, USA
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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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Manuel Carrondo, IBET

Peter Gray, The University of Queensland

Bob Nerem, Georgia Institute of Technology

Lars Nielsen, University of Queensland

Greg Russotti, Celgene Cellular Therapeutics

Peter Zandstra, University of Toronto

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Anne Plant, NIST

Mark Powers, Thermo Fisher Scientific

Chris Ramsborg, Juno Therapeutics

Nick Timmins, CCRM

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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 (Insception 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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SQZ Biotechnologies

Thermo Fisher Scientific

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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	**Plenary 1** **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 Heidaran (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 Heidaran, 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

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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. **Enginnering 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 BrunswickTM 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 Ishemia/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 derivedfrom 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