

Program

Scale-Up and Manufacturing of Cell-Based Therapies

January 11 – 13, 2012
San Diego, CA, USA

Conference Chairs:

Chris Mason
University College London

Lars Nielsen
University of Queensland

Greg Russotti
Celgene Cellular Therapeutics



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Wednesday, January 11, 2012

- 12:00 – 14:00 Registration (Rousseau Foyer, 1st Floor)
- 14:00 – 14:15 Welcome (Rousseau Center, 1st Floor)
- 14:15 – 14:20 Introduction to plenary
- 14:20 – 15:00 **Plenary 1**
Cellular Therapies and PROVENGE® (sipuleucel-T)
Heidi Hagen, Dendreon, USA
- Session1: Process Technologies**
Chairs: Peter Zandstra, University of Toronto, Canada
Dolores Baksh, Organogenesis, USA
- 15:00 – 15:25 **Engineering human tissues**
Gordana Vunjak-Novakovic (invited), Columbia University, USA
- 15:25 – 15:50 **Impact of technology decisions on product characteristics**
Frida Grynspan (invited), Collplant, Israel
- 15:50 – 16:15 **Long term maintenance of human liver cell spheroids with canalicular polarity and drug-responsive phenotype in perfusion bioreactor cultures**
Catarina Brito, Instituto de Biologia Experimental e Tecnológica, Portugal
- 16:15 – 16:40 **Small scale “high-throughput” bioreactors for process development and optimizing and controlling growth and differentiation of human embryonic stem cells**
Tiffany D Rau, Pall Corporation, USA
- 16:40 – 17:05 **Physical or chemical inhibition of focal adhesions improves megakaryocytic cell line ploidy and proplatelet formation: implications for in vitro platelet production**
William M. Miller, Northwestern University, USA

NOTES

- *Technical Sessions will be held in Rousseau Center on the 1st Floor. Poster sessions will be in the Toucan Room on the 2nd Floor.*
- *Breakfasts and lunches will be in Rousseau East and West. If weather permits, lunches can be taken outside to Beach South.*
- *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 5 minutes for questions and discussion.*
- *Please do not smoke at any conference functions.*
- *Turn your cellular telephones to vibrate or off during technical sessions.*
- *Be sure to make any corrections to your name/contact information on the Master Participant List or confirm (by your initials) that the listing is correct. A corrected copy will be sent to all participants after the conference.*

Wednesday, January 11, 2012 (continued)

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|---------------|---|
| 17:05 – 17:35 | Coffee break (Toucan Room) |
| | Poster boards available for set up |
| 17:35 – 18:25 | Poster Snapshots |
| 18:25 – 18:30 | Introduction to Plenary |
| 18:30 – 19:10 | <u>Plenary 2</u>
Parallels with vaccines
John Aunins, Janis Biologics, LLC, USA |
| 19:10 – 20:25 | Dinner (Macaw Room) |
| 20:25 – 23:00 | Dessert + Posters / Social Hour (Toucan Room) |

Thursday, January 12, 2012

07:30 – 08:30 Breakfast

Session 2: Process Development Challenges for Allogeneic Cell Therapies

Chairs: Thomas Brieva, Celgene Cellular Therapeutics, USA
Joaquim Cabral, Technical University of Lisbon, Portugal

08:30 – 08:55 **Bioprocess engineering from nL clonal cultures to >1,000 L bioreactors for transplantation**

Jamie Piret (invited), University of British Columbia, Canada

08:55 – 09:20 **Hypoxic culture minimizes teratoma formation by embryonic stem cell derivatives**
Clark K. Colton (invited), Massachusetts Institute of Technology, USA

09:20 – 09:45 **Larger scale expansion of human mesenchymal stem cells on microcarriers**
Chris J. Hewitt, Loughborough University, United Kingdom

09:45 – 10:10 **Scalable expansion of human mesenchymal stem cells using a microcarrier-based system under serum-free and xeno-free conditions**
Claudia Lobato da Silva, Technical University of Lisbon, Portugal

10:10 – 10:40 Coffee Break

Session 3: Process Development Challenges for Autologous Cell Therapies

Chairs: Robert Preti, Progenitor Cell Therapy, USA
Farlan Veraitch, University College London, United Kingdom

10:40 – 11:05 **Dealing with a batch size of one dose - novel manufacturing solutions for patient-specific cell therapy**
Brian Hampson (invited), Aastrom, USA

11:05 – 11:30 **Engineering T lymphocytes that engraft, expand in vivo, persist, and function**
Bruce Levine (invited), University of Pennsylvania, USA

11:30 – 11:55 **Challenges in ex-vivo expansion of cell therapy products and automated manufacturing**
David Newble, TAP Biosystems, United Kingdom

11:55 – 12:20 **Robust, scalable, CGMP compliant, non-viral approach to engineer cellular function as platform for enhancing the potency of cell therapy products for oncology and regenerative medicine applications**
Madhusudan V. Peshwa, MaxCyte, Inc., USA

12:20 – 14:00 Lunch

14:00 – 15:30 Networking

15:30 – 16:00 Coffee Break

Session 4: Product Purification, Formulation & Storage

Chairs: Ravinder Bhatia, J&J, USA
Allison Hubel, University of Minnesota, USA

16:00 – 16:25 **In-vitro anhydrobiosis, teaching mammalian cells to survive without water, how close are we?**
Sachi Norman (invited), Core Dynamics, USA

Thursday, January 12, 2012 (continued)

- 16:25 – 16:50 ***In silico* approaches to optimal cryopreservation for cell therapy products**
Jens Karlsson (invited), Villanova University, USA
- 16:50 – 17:15 **96-well platform for high-throughput mapping of cryopreservation design space**
Brian Murphy, Celgene Cellular Therapeutics, USA
- 17:15 – 17:40 **An ultra scale-down discovery tool to speed route to bioprocessing of new cell therapy preparations**
Michael Hoare, University College London, United Kingdom
- 17:40 – 17:45 Introduction to Plenary
- 17:45 – 18:30 **Plenary 3**
Rapid expansion of human blood stem cells by automated control of inhibitory feedback signaling
Peter Zandstra, University of Toronto, Canada
- 19:00 – 21:00 Conference Dinner (Rousseau East and West)
- 21:00 – 22:30 Poster Session and Social Hour (Toucan Room)

Friday, January 13, 2012

- 07:30 – 09:00 Breakfast
- Session 5: Product Characterization**
Chairs: Kim Warren, Lonza, USA
Bill Miller, Northwestern University, USA
- 09:00 – 09:25 **High throughput methods to identify biomarkers for the characterization of cellular therapies**
David Stroncek (invited), National Institute of Health, USA
- 09:25 – 09:50 **Potency assay development for characterization of multistem, an adult bone marrow stromal cell therapy product**
Wouter vant Hof (invited), Athersys, USA
- 09:50 – 10:15 **Development of unique characterization assays for cellular therapy and regenerative medicine products**
Candace Brayfield, Genzyme, USA
- 10:15 – 10:20 Introduction to Plenary
- 10:20 – 11:00 **Plenary 4**
Applying bioprocessing concepts and technologies to develop commercial-scale cell therapy manufacturing processes
John Rowley, Lonza, USA
- 11:00 – 11:30 Coffee Break
- Session 6: Business Models**
Chairs: Robert Deans, Athersys, USA
Chris Mason, University College London, United Kingdom
- 11:30 – 11:55 **Development of cellular therapies - the role of academia**
Ian McNiece (invited), University of Miami, USA
- 11:55 – 12:20 **Considerations in scale up of autologous and allogeneic cell therapies: implications to cost of goods**
Bob Preti (invited), Progenitor Cell Therapy, USA
- 12:20 – 12:45 **Cell therapy value systems modelling including manufacturing costs**
Mark J McCall, Loughborough University, United Kingdom
- 12:45 – 13:00 Farewell
- 13:00 – 14:00 Lunch

Poster Presentations

1. **Bioprocess forces and their impact on adherent mammalian cells: potential benefits for bone regeneration therapies**
Ivan Wall, University College London, United Kingdom
2. **Novel strategies for 3D neural culture and gene delivery: towards human central nervous system in vitro models for preclinical research**
Catarina Brito, Instituto de Biologia Experimental e Tecnológica, Portugal
3. **Bioengineering strategies for the development of robust and integrated processes for expansion and cryopreservation of human pluripotent stem cells**
Catarina Brito, Instituto de Biologia Experimental e Tecnológica, Portugal
4. **Design and operation of a bioreactor system for the expansion of mouse embryonic stem cell-derived neural stem cells on microcarriers**
Maria Margarida Diogo, Technical University of Lisbon, Portugal
5. **The large scale expansion and exploitation of pluripotent stem cells for regenerative medicine purposes: beyond the T flask**
Andrew J. Want, Loughborough University, United Kingdom
6. **Effect of dissolved oxygen tension and medium exchange on the in vitro proliferation and metabolism of human mesenchymal stem cells: a quantitative approach**
Chris J. Hewitt, Loughborough University, United Kingdom
7. **Optimization of processing and expansion for mesenchymal stem cells from umbilical cord tissue**
Andreea Ifimia, Loughborough University, United Kingdom
8. **Unique challenges in autologous cellular immunotherapies: improving cell culture medium robustness**
Pascal R Beauchesne, Dendreon Corporation, USA
9. **Effect of cold storage and mechanical vibration on human mesenchymal stem cell therapeutic products transported in suspension**
Mark McCall, Loughborough University, United Kingdom
10. **Fit-for-purpose development towards the validation of a multicolor flow cytometry assay for cellular product release**
Brian Murphy, Celgene Cellular Therapeutics, USA
11. **Characterisation of human embryonic stem cell (HESC) culture.**
Andrew J. Want, Loughborough University, United Kingdom
12. **Control of human embryonic stem cell growth and differentiation via automation and parallel mini-bioreactors**
Andrew B.J. Prowse, The Australian Institute for Bioengineering and Nanotechnology, Australia
13. **Novel cryopreservative solution free from mammal factors**
Satoshi Terada, University of Fukui, Japan
14. **Developing scalable and standardised manufacturing methods for human mesenchymal stem cells**
Qasim A. Rafiq, Loughborough University, United Kingdom

15. **Evaluation of continuous, scalable cell concentration and wash systems for cell therapies**
Lauren DePalma, Celgene Cellular Therapeutics, USA
16. **An optimisation tool (AMBR) for defining the critical to quality production parameters and their specifications for large scale production of erythrocytes from human cord blood derived hematopoietic stem cells**
Katie Glen, Loughborough University, United Kingdom
17. **A quality by design (QBD) approach to risk reduction and optimisation for a unit operation of cell therapy manufacture**
Robert Thomas, Loughborough University, United Kingdom
18. **Development of a custom serum-free, xeno-free medium to support the isolation and expansion of human multipotent adult progenitor cells (MAPC)**
Andrew Campbell, Life Technologies Corp., USA
19. **Serum-free and spheroidal culture propagates and expands undifferentiated multipotent mesenchymal stem cells in suspension**
Andrew Campbell, Life Technologies Corp., USA
20. **Virally inactivated allogeneic human platelet-derived growth factor mixture: a new xeno-free medium supplement**
William Milligan, GwoWei Technology Co., Ltd., Canada
21. **Xpansion multi-plate bioreactor: the scalable solution for adherent stem cell expansion**
Matthieu Egloff, ATMI LifeSciences, Belgium
22. **Production of pluripotent cells in a high-density acoustic-perfused bioreactor**
Ricardo P. Baptista, University of Toronto, Canada
23. **Engineering the bioequivalence of a process change from cryobags to cryovials**
Daniel DeWitt, Celgene Cellular Therapeutics, USA
24. **Single use bioreactor system for large scale production of erythrocytes from human cord blood derived hematopoietic stem cells**
Rebecca Moore, Celgene Cellular Therapeutics, USA
25. **Scalable expansion of human mesenchymal stem cells using a microcarrier-based system under serum-free and xeno-free conditions**
Claudia Lobato da Silva, Technical University of Lisbon, Portugal
26. **Suspension format differentiation of human ES cells to pancreatic progenitors that rescue chemically-induced hyperglycemia in mice**
Holly Young, ViaCyte, USA
27. **Hypoxic culture of human pluripotent cells is permissible using mouse embryonic fibroblasts**
Jennifer Badger, University College London, United Kingdom
28. **Design, development and detailed examination of an expanded bed reactor for the seeding of embryonic stem cells to microcarriers**
Tristan Pritchard-Meaker, University College London