Program

Scale-Up and Manufacturing of Cell-Based Therapies II

January 21 – 23, 2013
San Diego, CA, USA

Conference Chairs:

Chris Mason
University College London

Lars Nielsen
University of Queensland

Greg Russotti
Celgene Cellular Therapeutics

Engineering Conferences International
32 Broadway, Suite 314 - New York, NY 10004, USA
Phone: 1 - 212 - 514 - 6760, Fax: 1 - 212 - 514 - 6030
www.engconfintl.org – info@engconfintl.org

Hyatt Regency Mission Bay Spa and Marina - San Diego

1441 Quivira Road,

San Diego, California, USA 92109

Tel: +1 619 224 1234 Fax: +1 619 224 034

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Monday, January 21, 2013

12:00 – 14:00	Conference registration (Mission Foyer)
14:00 – 14:15	Welcome Conference Chairs ECI Liaison (Barry Buckland)
14:15 – 14:20	Introduction to plenary
14:20 – 15:00	**Plenary 1** **Stem Cell Culture Engineering –Process Scale-up and beyond** Wei-Shou Hu, University of Minnesota **Session1: Product Definition and Analytics** Chairs: Bill Miller, Northwestern University Bob Deans, Athersys
15:00 – 15:25	**Implementation of Epigenetic Screens to Characterize MultiStem®, An Allogeneic Cell Therapy Product** Bart Vaes (invited), Athersys
15:25 – 15:50	**Analysis of tissue cell composition by single-cell gene-expression PCR** Piero Dalerba (invited), Stanford University
15:50 – 16:10	**Enumeral Biomedical Corp's high-throughput single cell analysis platform: applications to bioprocess and cell therapy development** Arthur Tinkelenberg, Enumeral Biomedical Corp.
16:10 – 16:30	**Immunoinformatic Analysis of Chinese Hamster Ovary (CHO) Protein Contaminants in Therapeutic Protein Formulations** Annie De Groot, EpiVax, Inc. and University of Rhode Island
16:30 – 16:50	**hES-Derived Clonal Embryonic Progenitor Cell Lines: A Novel Point of Scalability** Michael West, BioTime
16:50– 17:20	Coffee break

NOTES

- Audiotaping, videotaping and photography of presentations are strictly prohibited.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
- Technical sessions will be in Mission I/II. Poster sessions will be in Mission III.
- Breakfasts and lunches will be in the Regatta Pavilion. The banquet on Tuesday will be in Bayview III.
- Be sure to check your contact information on the Participant List in this program and make any corrections to your name/contact information online. A corrected copy will be sent to all participants after the conference.
- Speakers – Please leave at least 5 minutes for questions and discussion. Be available for discussion during meals and social periods

Monday, January 21, 2013 (continued)

17:20 – 18:10 **Poster Snapshots**

Key considerations when scaling-up cell culture for therapies
Iwan T. Roberts, University College London, United Kingdom

Pressurised tracheal decellularisation for tissue engineering purposes
Leanne Partington, University College London, United Kingdom

A hypoxic expansion step, prior to differentiation of mouse embryonic stem cells, robustly increases the formation of meso- and endodermal specific cell types
Kate Fynes, University College London, United Kingdom

Predicting the cost-effectiveness of cell expansion technologies for commercial allogeneic cell therapies
Sally Hassan, University College London, United Kingdom

Aqueous two-phase system bioengineering strategies to establish novel bioprocess for the potential recovery of stem cells
Mirna Gonzalez, Tecnológico de Monterrey, Mexico

Bioengineering approaches for production, purification and cryopreservation of iPSC-derived cardiomyocytes
Margarida Serra, ITQB-UNL/IBET, Portugal

Culture supplement obtained from rice bran for improving serum-free culture
Satoshi Terada, University of Fukui, Japan

18:10 – 18:15 Introduction to plenary

18:15 – 18:55 **Plenary 2**
Mesenchymal Stem Cell Therapy for Protection and Repair of Injured Vital Organs
Martin Yarmush, Massachusetts General Hospital

18:55 – 20:30 Dinner (Bayview III)

20:30 – 22:30 **Poster Session and Social Hour (with desserts)**
Chairs: Jeffrey Karp, Harvard Medical School
Todd McDevitt, Georgia Institute of Technology

Tuesday, January 22, 2013

07:00 – 08:55	Breakfast
	Session 2: Process Development ***Sponsored by ATMI LifeSciences*** Chairs: Joaquim Cabral, Technical University of Lisbon Jon Rowley, Lonza
08:55 – 09:00	Introduction by ATMI LifeSciences (Jose Castillo)
09:00 – 09:25	**Development and Characterization of Serum Free Suspension Culture T-cell Manufacturing Processes** Jason Carsten (invited), Fred Hutchinson Cancer Research Center
09:25 – 09:50	**Producing Gene Modified Autologous Stem Cell Products for HIV Therapy** David Digiusto (invited), City of Hope
09:50 – 10:10	**Efficient CAR-T Cell Manufacturing Process for Clinical Applications** Pradip Bajgain, Baylor University
10:10 – 10:30	**Significant Interaction Effects Between Inoculation Density and Agitation Rate in Stirred Suspension Bioreactor Cultures of Human Embryonic Stem Cells** Megan Hunt, University of Calgary
10:30 – 11:00	Coffee Break
11:00 – 11:25	**Scale-Out and Scale-Up of iPSC Derivation and Culture Processes for Pluripotent Stem Cell Manufacturing** Wen Bo Wang (invited), Cellular Dynamics
11:25 – 11:50	**Bioreactors in cell therapy, the advantages of high-throughput culturing technologies and the downstream challenges** Ohad Karnieli (invited), Pluristem
11:50 – 12:10	**Dynamic Culture of Human Mesenchymal Stem Cells in Defined Conditions Not Only Supports Rapid Cell Expansion But Also Enhances Their Therapeutic Benefit For Treating Central Nervous Systems Diseases** Krishna M. Panchalingam, University of Calgary
12:10 – 12:30	**Design and Engineering of Scalable Stirred-Tank Bioreactors for the Manufacture of Culture-Adherent Allogeneic Cell Therapies** Thomas Brieva, Celgene
12:30 – 13:30	Lunch
13:30 – 15:30	Networking / Free time
15:30 – 16:00	Coffee Break
	Session 3: Business Models Chairs: Lee Buckler, The Cell Therapy Group Chris Mason, University College London

Tuesday, January 22, 2013 (continued)

16:00 – 16:25	**Autologous Cell Therapy at the Point-Of-Care: Building a Global Business** Doug Arm (invited), Cytori
16:25 – 16:50	**Commercialization Considerations for an Allogenic Cell Therapy** Dean Tozer (invited), ABH/Shire
16:50 – 17:10	**Cell Therapy Facility Design** Robert Preti, Progenitor Cell Therapy
17:10 – 17:30	**Downstream Process Technology Roadmap for Scaling Allogeneic Cell Therapy Bioprocesses** Jacob Pattasseril, Lonza
17:30 – 17:35	Introduction to Plenary
17:35 – 18:15	**Plenary 3** **Effective Trial Design for Cell Therapy Clinical Trials** Greg Bonfiglio, Proteus Ventures
19:00 – 21:00	Conference Dinner
21:00 – 22:30	Social Hour / Poster Session

Wednesday, January 23, 2013

07:00 – 09:00	Breakfast
	Session 4: Product Delivery & Administration Chairs: Brian Murphy, Celgene Bruce Levine, University of Pennsylvania
09:00 – 09:25	**Manufacturing Cellular Products for Phase 1 Trials** Adrian Gee (invited), Baylor College of Medicine
09:25 – 09:50	**Supply and Administration of Ixmyelocel-T, a Patient-Specific Cell Therapy** Brian Hampson (invited), Aastrom
09:50 – 10:10	**Scale-Up and Performance Qualification of the Cooling Step of a Cryopreserved Myeloid Progenitor Cell Therapy Filled in Cryobags** David Frey, Cellerant Therapeutics
10:10 – 10:30	**Chimeric Antigen Receptor (CAR) Modified T Cells Targeted Against Cancer: CAR Delivery and Clinical Update** Bruce Levine, University of Pennsylvania
10:30 – 11:00	Coffee Break
	Session 5: Novel Tools, Technologies and Products Chairs: Dawn Applegate, Regenemed Michael Shuler, Cornell University
11:00– 11:25	**Using Cell Cultures and Microscale Systems In Drug Development** Michael Shuler (invited), Cornell University
11:25 – 11:50	**3D Bioprinting: An Innovative Tool for Creating Scaffold-free Human Tissues** Craig Halberstadt, Organovo
11:50 – 12:10	**Human neural in vitro models for preclinical research: 3D culture systems for neural differentiation and genetic modification of human stem cells** Paula Alves, IBET
12:10 – 12:30	**Flexible modular platform available for manufacturing of cell sheet** Masahiro Kino-oka, Osaka University
12:30 – 12:35	Closing Remarks / Farewell
12:35 – 13:30	Lunch

Poster List

1. **Integrative approaches to decipher human cardiac stem cells receptome and secretome contribution to cardiac regeneration**
   Manuel Carrondo, ITQB-UNL/IBET, Portugal

2. **Scalable and integrated strategies for the downstream processing of human mesenchymal stem cells**
   Margarida Serra, ITQB-UNL/IBET, Portugal

3. **Towards a clinical-grade bioprocess for the large-scale production of human pluripotent stem cells**
   Margarida Serra, ITQB-UNL/IBET, Portugal

4. **Bioengineering approaches for production, purification and cryopreservation of iPSC-derived cardiomyocytes**
   Margarida Serra, ITQB-UNL/IBET, Portugal

5. **Orbital mixing as an alternative to stirred-tank bioreactors for scale-up and commercial production of cell-based therapies**
   David Laidlaw, Kuhner Shaker Inc., Switzerland

6. **A hypoxic expansion step, prior to differentiation of mouse embryonic stem cells, robustly increases the formation of meso- and endodermal specific cell types**
   Kate Fynes, University College London, United Kingdom

7. **Engraftment of adult mesenchymal stromal cells used for cell therapy is dependent on functional Neuropilin 1**
   Owen William Bain, University College London, United Kingdom

8. **Chip bioreactor system for monitoring of mature process in long-term culture of retinal pigment epithelial cells**
   Masakazu Inamori, Osaka University, Japan

9. **Aqueous two-phase system bioengineering strategies to establish novel bioprocess for the potential recovery of stem cells**
   Mirna Gonzalez, Tecnológico de Monterrey, Mexico

10. **Non-invasive image analysis for quality by design approaches to cell based therapy manufacturing**
    David Smith, Loughborough University, United Kingdom

11. **Enhancing bone marrow cell engraftment and potency in hypoxia using ligands of the notch signalling pathway in vitro**
    Giulia Detela, University College London, United Kingdom

12. **Culture supplement obtained from rice bran for improving serum-free culture**
    Satoshi Terada, University of Fukui, Japan

13. **Impact of cell seeding density on early neuronal differentiation of human pluripotent cells**
    John Thwaites, University College London, United Kingdom

14. **Transfer of hepatic progenitor stem cell culture process from multiple-tray stacks to the xpansion™ multiplate bioreactor**
    Matthieu Egloff, ATMI LifeSciences, Belgium

15. **The development of small scale bioreactor system for human iPS cell culture**
    Masanori Wada, ABLE Co., Japan

16. **Pressurised tracheal decellularisation for tissue engineering purposes**
    Leanne Partington, University College London, United Kingdom

17. **A Quality by Design (QbD) approach to human embryonic stem cell (hESC) cryopreservation**
    Peter David Mitchell, Loughborough University, United Kingdom

18. **Serum-free media development for suspension culture of human mesenchymal stem cells**
    Yuan Wen, Life Technologies Corporation, USA

19. **Development of a perfused-bioreactor process for high-density culture of NK-92 cells for immunotherapy**
    Ricardo P. Baptista, CCRM-Centre for Commercialization of Regenerative Medicine, Canada

20. **Development of preservation media for enhanced stabilisation and storage of cells during manufacture and administration**
    Jennifer Man, University College London, United Kingdom

21. **Expansion and differentiation of human embryonic stem cells on an automated microwell platform**
    Nathalie Moens, University College London, United Kingdom

22. **Dental pulp stem cell homing in tooth repair**
    Yvonne Wai Yee Pang, University College London, United Kingdom

23. **Key considerations when scaling-up cell culture for therapies**
    Iwan T. Roberts, University College London, United Kingdom

24. **Challenges and solutions for scalable cultivation of anchorage dependent cells for cell-based therapies in single use bioreactor**
    Brian Lee, PBS Biotech, Inc., USA

25. **Evaluating the effect of standard cryopreservation protocols on long-term cell survival and quality**
    Karen Coopman, Loughborough University, United Kingdom

26. **Litre-scale expansion and harvest of human mesenchymal stem cells on microcarriers in a stirred-tank bioreactor**
Karen Coopman, Loughborough University, United Kingdom

27. **Cell-sheet-based bioengineered human cardiac tissue using pluripotent stem cells for heart repair and disease models**
Katsuhisa Matsuura, Tokyo Women's Medical University, Japan

28. **Evaluation of microcarrier-based suspension cultures for human induced pluripotent stem cells**
Maria Margarida Diogo, Instituto Superior Tecnico - Institute for Biotechnology and Bioengineering, Portugal

29. **Production of high-ploidy megakaryocytic cells and functional platelets in culture using a 3-phase process**
William M. Miller, Northwestern University, USA

30. **Dynamic control over the mechanical microenvironment during early neuronal differentiation of mouse embryonic stem cells**
Shahzad Ali, University College London, United Kingdom

31. **Human mesenchymal stem cell attachment and expansion on synthetic microcarriers in defined, serum-free medium**
Todd Sciortino, Corning Inc., USA

32. **A high density xeno-free bioreactor culture system for the clinical-scale expansion of human mesenchymal stem/stromal cells**
Claudia Lobato da Silva, Instituto Superior Tecnico - Institute for Biotechnology and Bioengineering, Portugal

33. **A new viral inactivated human platelet lysate supplement (hpgf c18) demonstrated to be an effective, serum-free, xeno-free replacement for fbs in culturing mesenchymal stem cells**
Claudia Lobato da Silva, Instituto Superior Tecnico - Institute for Biotechnology and Bioengineering, Portugal

34. **Overcoming the challenges of scale-up & scale-out through automation**
Kim Bure, TAP Biosystems, United Kingdom

35. **Membrane separation of human cells for therapy using ultra-scale down technology as a predictive tool for scale-up**
Fernanda Masri Rabin, University College London, United Kingdom

36. **A xeno-free virally-inactivated human platelet lysate-based microcarrier coating for the expansion of human mesenchymal stem/stromal cells in a stirred culture system**
Joaquim Cabral, Instituto Superior Tecnico, Portugal

37. **Development of an ultra scale down normal flow filtration device for the recovery of human cells for therapy**
Chris Longster, University College London, United Kingdom

38. **From Gene Expression to In Vivo Models – Characterization and Potential Therapeutic Properties of Placenta Derived Mesenchymal-Like Adherent Stromal Cells**
Eytan Abraham, Pluristem, Israel

39. **Predicting the cost-effectiveness of cell expansion technologies for commercial allogeneic cell therapies**
Sally Hassan, University College London, United Kingdom