Advancing Manufacture of Cell and Gene Therapies VI

Coronado, California, USA 27-31 January 2019

Editors:

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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 Fernanda Masri (Technology Expert for Regenerative Medicine, Workshop Chairs: 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) Barry Buckland (Chief Executive Officer, BiologicB) ECI Liaison: 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) Elizabeth Cheeseman (Bioprocess Modeling Research Associate, Student Liaison: 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[']!'B#5 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 **Biomanufacturing cardiac cells from human pluripotent stem cells !** 'ÞÆ 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 AG Elena Costariol (PhD Candidate, University College London, UK)
- 09:40 10:00 Animal component free cell culture media development: The approach from the North ÄH Panos Chrysanthopoulos (Development Engineer/ Scientist II, CCRM, Canada)
- 10:00 10:30 **Transitioning from manual to stirred-tank bioreactor manufacturing of IDCT, An allogeneiccell 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** AP EDE 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** A 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 A 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 A 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 Ё中邸E Allan Kaspar (Sr VP, Research & Development, AveXis)
15:30 – 17:30	Session 2: Engineering challenges of <i>in vivo</i> 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 '!'여편 Fernanda Masri and Michael Greene
15:40 - 16:00	Taking an engineering approach to empower breakthrough therapies '!'中即E 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 purificationÄar€ Eni Sterjanaj (Downstream Scientist, Pall, USA)
17:10 - 17:30	Scaling up lentiviral vector production from stable producer cellsÄäG€ Vanja Misic (Development Scientist, CCRM, Canada)
17:30 – 18:30	Poster Snapshots Session 1 AP EDE 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 EGF 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 ଅଁନୟି LiYing Yang (Head of MSAT, Lonza)
09:35-09:55	Identification of CAR T Cell Critical Quality Attributes and Critical Process Parameters V \circ 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 EA
10:15 – 10:35	Effecting clinical starting material quality and the impact to downstream '! 'Þ⑰E 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 3ÄÄÞÐE Jan Joseph Melenhorst (Adjunct Associate Professor of Pathology and Laboratory Medicine, University of Pennsylvania, USA)
12:05 – 13:10	<u>Session 4: Product characterization and analytics</u> (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

Tuesdav. 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 !' PEE 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 ËÁ € 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 EAF 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 🛱 G 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,

16:10 – 18:20 **Poster session (with coffee and snacks)** (Sponsored by the Cell and Gene Therapy Catapult)

USA)

- 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 Ex Ex Exercise Barbon 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, Sartorious 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 A De
10:35 – 10:55	Efficient model driven design of cell-based product manufacturing !'I H 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 🛱 l 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 <i>ex vivo !</i> Å Í Á William Miller (Professor of Chemical & Biological Engineering, Northwestern University, USA)
11:35 – 13:00	Lunch and networking
13:00 – 15:05	<u>Session 6: Bioprocess modeling</u> 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 Ä Î Tom Brieva (Senior Director of Process Development, Celgene, USA)
13:30 – 13:55	Novel supply chain and process modeling for cell therapy manufacturing and distribution AA I 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 manufactureÄA J 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 $\overleftrightarrow{\mathbb{A}} \in$ David Zhang (Chief Executive Officer, Bio-G, USA)
14:45 – 15:05	Automated data management strategies drive cell therapy success 🛱 F Christophe Suchet (Chief Product Officer, Vineti, 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従P的E Neil Tiwari (Chief Digital Officer, Novartis, USA)
16:05 – 16:35	Leveraging digital solutions to predict disease and patient access to transformative therapies Expose 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 AD DE 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 Εφ 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

- BIO regulates the ex vivo expansion and function of hematopoietic stem cells by inhibiting GSK-3β?
 G
 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 ! H Dhinakar Kompala (Sudhin Biopharma Company, USA)
- Use of the Nanobridge system for the Rapid Production of Pluipotent Stem Cells and Neural Progenitor Cells !'I Í Peter P. Gray (AIBN, University of Queensland, Australia)
- 4. Challenges and opportunities for closed processing in autologous CAR-T manufacturing 🛱 Î 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 !ÂÌ Carlos Rodrigues (IST Lisbon, Portugal)
- 7. Pancreas organoids for type I diabetes mellitus Is it feasible as a cell therapy? !'Ï J Bart van Dijk (Lonza, Netherlands)
- Establishment and evaluation of the suspension culture system for umbilical cordderived mesenchymal stromal cells !Å € 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 A F 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 ! G Alexander S. Klarer (Hitachi Chemical Advanced Therapeutic Solutions, USA)
- 11. WITHDRAWN
- **12. Developing a novel microchannel emulsification device for diabetes cell therapy** '!'Ì HÁ Christina Bitar (McGill University, Canada)
- 13. A scalable xeno-free microcarrier suspension bioreactor system for regenerative 'A A 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 !'ì í 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)
- 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)
- 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)