

2nd Annual

Bioprocessing of Advanced Cellular Therapies Congress

8th - 9th June 2017, Radisson Blu Edwardian Heathrow Hotel, London, UK

Event overview:

After the success of Bioprocessing of Advanced Cellular Therapies Congress (BACT), MarketsandMarkets is pleased to announce the **2nd Annual Bioprocessing of Advanced Cellular Therapies Congress** at **Radisson Blu Edwardian Heathrow Hotel, London, UK**.

Research Organizations and Pharma companies have been investing big time into the promise of cellular therapies and all signs point to the need to accelerate the process of moving from lab to patient using advanced manufacturing processes and solutions to commercialization.

With this objective, making the shift from manual processes to automation, bridging the gap between research lab and market place, and using novel and advanced technologies will be the key aspects for manufacturers to answer the challenge of scale-out.

The 2nd Annual BACT taking place on the **8th and 9th June, 2017 in London, UK** focuses on this holistic approach by discussing the next generation bioprocessing, strategies, technologies and solutions to work together for this constantly evolving field.

Highlights:

- ☛ Manufacturing and **Scale-up** of Cellular Therapies
- ☛ Novel **technologies** to manufacture Cell and Gene therapy
- ☛ Novel **biomaterials** technology to facilitate downstream processing
- ☛ Bioprocess challenges for manufacture of **exosomes**
- ☛ **Next generation bioprocessing** and in-line metrics
- ☛ **Online monitoring tools** for bioprocessing
- ☛ **Optimization** and **automation** of processes
- ☛ **Inferential process control** and implementation of **PAT**
- ☛ **Bioprocess Modelling**, Commercialization and Regulatory Issues
- ☛ Overcoming challenges in **Logistics** and Supply Chain



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Scientific Advisors 2017



Steve Oh
Director, Stem Cell Bioprocessing,
BTI, Singapore



Damian Marshall
Head of Analytical Development,
CT Catapult, United Kingdom



Bo Kara,
Head Process Development, Cell &
Gene Therapy Platform CMC,
GSK, United Kingdom



Otto-Wilhelm Merten
Head of the Applied Vectorology and
Innovation group,
Généthon, France



Tiago Aguiar
Process
Development,
Autolus Ltd., United Kingdom

Esteemed Speakers



Manuel J T Carrondo
Professor of Chemical and Biochemical
Engineering, FCT-UNL
Vice-President, IBET, Portugal



Maya Fürstenau-Sharp
Field Marketing Manager EU
**Sartorius Stedim Biotech GmbH,
Deutschland**



Ben Mantle
UK & Ireland Area Manager
Chemometec A/S, United Kingdom



Steve Oh
Director, Stem Cell Bioprocessing
BTI, Singapore



Silke Wissing
Director R&D
**CEVEC Pharmaceuticals GmbH,
Germany**



Damian Marshall
Head of Analytical Development
CT Catapult, United Kingdom



Ohad Karnieli
CEO and Co-Founder
ATVIO Biotechnology, Israel



Stephen Hague
European ddPCR Specialist
**Bio-Rad Laboratories Ltd, United
Kingdom**



Nina Kotsopoulou,
Director, Process Development
Autolus, United Kingdom



Mardon McFarlane
Team Leader, Process R&D
Oxford BioMedica, United Kingdom



Ivan Wall
Senior Lecturer, Cell Therapy Bioprocessing
UCL, United Kingdom



David Brindley
Senior Research Fellow in Healthcare
Translation
University of Oxford, United Kingdom



Takis Athanasopoulos
Head of Transgene Delivery as part of the Cell
& Gene Therapy Research & Development
platform
GSK, United Kingdom



Nick Gaddum
Lead Devices & Delivery Scientist
CT Catapult, United Kingdom



Gabrielle Humphrey
Technical Lead, MSAT
Oxford BioMedica, United Kingdom



Andrea Ducci
Senior Lecturer, Dept of Mechanical
Engineering, Faculty of Engineering Science
UCL, United Kingdom



Timothy O'Brien
Director of the Regenerative Medicine Institute,
NUI, Galway and GUH, Ireland



Daniel G. Bracewell
Professor of Bioprocess Analysis & Doctoral
Admissions Tutor, Department of Biochemical
Engineering
UCL, United Kingdom



Suzanne Farid
Professor, Bioprocess Systems Engineering
**University College London, United
Kingdom**



John Elliot
Investigator
NIST, USA



Toby Proctor
Research Engineer, Haematology Department
**UCL Medical School, Royal Free Campus,
United Kingdom**



Tania Chilima
Senior Doctoral Researcher, Department of
Biochemical Engineering.
**University College London, United
Kingdom**

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Day 1 – Thursday 8th June

08:00 **Registration and Refreshments**

08:50 **MarketsandMarkets' Welcome Address**

08:55 **Opening remarks by the chair**
Steve Oh, Director, Stem Cell Bioprocessing, **BTI, Singapore**

Manufacturing & Scale-up of Cellular Therapies

09:00 **Single use technologies for manufacturing cells and cell products for therapy**

- Biodegradable microcarriers for expansion and implantation
- Serum free media for suspension cultures
- Microfluidics for cell separation
- Novel cell potency assays

Steve Oh, Director, Stem Cell Bioprocessing, **BTI, Singapore**

09:30 **Cell & Gene Therapies: From Discovery Research to Manufacturing and Commercialization, so a title talk could be similar Why do we need cell/gene therapy and what are the challenges (CGT)?**

- Where/How do you want to apply CGT?
- Commercialisation of Ex-vivo Cell Gene Therapy Products: Establishing Processes, Manufacturing and Supply Chains

Takis Athanasopoulos, Head of Transgene Delivery as part of the Cell & Gene Therapy Research & Development platform, **GSK, United Kingdom**

10:00 **Approaches for improved viral vector manufacture**

- Effective transition from R&D to clinical manufacture
- Successful scale-up design using single-use flow path & disposable equipment
- Implementation of dual supply in vector manufacturing

Dr. Gabrielle Humphrey, Technical Lead, MSAT, **Oxford BioMedica, United Kingdom**

10:30 **Company Introduction: Chemometec**

Ben Mantle, UK & Ireland Area Manager, **Chemometec A/S, United Kingdom**



10:35 *Morning Refreshments and Poster Presentation | One-to-One Networking Meetings*

11:10 **CAP-GT, Novel Human Suspension Cell Lines for Scalable Production of Viral Vectors**

- Regulatory endorsed human suspension cell lines as a platform for the production of Lentiviral, AAV, and Adenoviral vectors
- Scalable and cost-effective gene therapy vector production
- Development of stable packing cell lines

Silke Wissing, Director R&D, **CEVEC Pharmaceuticals GmbH, Germany**

11:40 **Investigation into stirred tank bioreactor agitation configurations to maintain the suspension of cells**

- Development of the TAP Sartorius 250ml scale, single-use stirred tank bioreactor
- Computational Fluid Dynamics (CFD) simulation of dynamic fluid structures within the vessel, validated using Particle Tracking Velocimetry (PIV) applied to an experimental replica stirred tank bioreactor
- CFD simulation of geometric variations to explore different means of agitation

Dr. Nick Gaddum, Lead Devices & Delivery Scientist, **CT Catapult**

12:10 **Workshop by Bio-Rad: Droplet Digital PCR: Rare molecule detection & Bioprocessing**

- Droplet Digital PCR enables rare molecule detection.
- Validation of cell line generation using ddPCR.
- Detection of Residual Host cell DNA during biomanufacture.

Stephen Hague, European ddPCR Specialist, **Bio-Rad Laboratories Ltd, United Kingdom**



13:10 *Lunch and Poster Presentation | One-to-One Networking Meetings*

14:10 **Cost of goods and facility optimisation for successful commercialisation of CAR T-cell products**

- Manufacturing strategies to achieve feasible business models for cell therapies.
- Cost-benefit of autologous versus allogeneic cell products – where is the switch point?
- Selecting a facility network configuration for autologous cell therapies

Suzanne Farid, Professor, Bioprocess Systems Engineering, **University College London, United Kingdom** and
Tania Chilima, Senior Doctoral Researcher, Department of Biochemical Engineering, **University College London, United Kingdom**

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- 14:40 Challenges of autologous MSC therapy in patients with advanced disease**
- MSCs have angiogenic and immunomodulatory properties and may be used in the treatment of ischemic disorders such as critical limb ischemia (CLI)
 - Use of autologous and allogeneic approaches will be discussed
 - MSC isolation from patients with CLI has reduced yields, abnormal cell proliferation kinetics and karyotypic abnormalities. The implication for autologous MSC therapy in patients with advanced disease will be discussed.
- Timothy O'Brien**, Director of the Regenerative Medicine Institute, **NUI, Galway and GUH, Ireland**
- 15:10 Purification and concentration of Stem Cells**
- Removal of process contaminants prior to use
 - Novel technologies and reconcentration
 - Ensuring differentiation
- Manuel J T Carrondo**, Professor of Chemical and Biochemical Engineering, FCT-UNL, Vice-President, **IBET, Portugal**
- 15:40 CAR-T CMC strategies**
- Vector and genetically modified process definition and development
 - Vector and Drug Product release and characterisation testing
 - Process changes and comparability studies
- Nina Kotsopoulou**, Director, Process Development, **Autolus, United Kingdom**
- 16:10 Afternoon Refreshments and Poster Presentation | One-to-One Networking Meetings**
- 16:55 Sponsorship Provider Presentation; Please contact Steve Hambrook at Steve.h@marketsandmarkets.com**
- 17:10 Strategies to aid successful and scalable viral vector manufacturing processes**
- Overcoming challenges in developing viral vector processes
 - Scale-up approaches within R&D
 - The pursuit of second generation capture steps
- Mardon McFarlane**, Team Leader, Process R&D, **Oxford BioMedica, United Kingdom**
- 17:40 Bioprocess challenges for manufacture of exosomes**
- Exosomes are emerging as a potentially groundbreaking new type of therapeutic
 - They have in numerous cases been shown to promote the same functional recovery as the parent stem cells that secreted them
 - A significant barrier to creation of robust exosome therapies is controlled production and subsequent purification in large enough quantities to be clinically meaningful
 - Current manufacturing challenges, trends and areas of active research need to be considered
- Ivan Wall**, Senior Lecturer, **Cell Therapy Bioprocessing, UCL, United Kingdom**
- 18:10 Closing remarks by the chair**
- 18:15 Networking and Drinks Reception**

End of Day 1

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Day 2 – Friday 9th June

08:00 **Registration and Refreshments**

08:50 **MarketsandMarkets' Welcome Address**

08:55 **Opening remarks by the chair**
Ohad Karnieli, CEO and Co-Founder, **ATVIO Biotechnology, Israel**

Next Generation Bioprocessing & In-Line Metrics

09:00 **Process Analytical Technologies to support cell therapy manufacture**

- Strategies to screen and identify in-process markers which can be used to monitor product quality
- The role of multivariate analysis for monitoring complex processes
- How inferential monitoring can be used to assess product quality

Damian Marshall, Head of Analytical Development, **CT Catapult, United Kingdom**

09:30 **Mixing and Microcarriers suspension in lab scale shaken reactors**

- Mixing modelling from small to mid-scale disposable flasks
- Scale up/down approach
- Critical speed for microcarriers full suspension

Andrea Ducci, Senior Lecturer, Dept of Mechanical Engineering, Faculty of Engineering Science, **UCL, United Kingdom**

10:00 **Panel Discussion: Can autologous therapies be as profitable as allogenic?**

- Risk for the patient
- Do we really need autologous therapies?
- How to efficiently scale-out?

Panelists:
-**Steve Oh**, Director, Stem Cell Bioprocessing, **BTI, Singapore**
-**Maya Fürstenau-Sharp**, Field Marketing Manager EU, **Sartorius Stedim Biotech GmbH, Deutschland**
-**Daniel G. Bracewell**, Professor of Bioprocess Analysis & Doctoral Admissions Tutor, Department of Biochemical Engineering, **UCL, United Kingdom**

10:40 *Morning Refreshments and Poster Presentation | One-to-One Networking Meetings*

11:25 **Presentation by Biospherix**

11:55 **Bioreactors and disposable technologies for ATMP production**

- Challenges in adopting new manufacturing technologies in GMP facilities.
- Off-the-shelf vs bespoke solutions; product specific approaches for different ATMP types.
- Future perspectives on "near-patient" manufacturing solutions

Toby Proctor, Research Engineer, Haematology Department, **UCL Medical School, Royal Free Campus, United Kingdom**

12:25 **Optimization and automation of processes for cost reduction**

- Identifying Critical bottle necks in cell therapy manufacturing. Risk assessment based approach
- Designing a Process development road map and plan
- Optional solutions and case studies

Ohad Karnieli, CEO and Co-Founder, **ATVIO Biotechnology, Israel**

12:55 **Sponsorship Provider Presentation; Please contact Steve Hambrook at steve.h@marketsandmarkets.com**

13:10 *Lunch and Poster Presentation | One-to-One Networking Meetings*

14:10 **Enabling ATMP Commercialization through Automation, PAT Innovations and Bioanalytics**

- Addressing autologous therapeutic variability through automated control loop technologies
- Implementing online process analytic technologies (PAT) to aid closure of manufacturing systems
- Potential for improved bioanalytical testing strategies

Maya Fürstenau-Sharp, Field Marketing Manager EU, **Sartorius Stedim Biotech GmbH, Deutschland**

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14:40 **Viral vector bioprocessing – towards scalable platform processes**

- Product related impurity e.g. empty vectors
- The design of adsorption based separations
- Comparison of AAV, adeno and lenti based virus vector challenges

Daniel G. Bracewell, Professor of Bioprocess Analysis & Doctoral Admissions Tutor, Department of Biochemical Engineering, **UCL, United Kingdom**

15:10 **Evaluating Stem Cell Culture and Treatment as a Manufacturing Process**

- Industrialization of cell culture and treatment protocols is critical for transitioning cellular therapies and regenerative medicine products into a manufacturing paradigm.
- Inherent to the manufacturing is the need to consider high quality cell-based assays that can serve as both in-line process controls and product potency assays.
- The application of measurement assurance strategies to cellular measurements can improve the comparability of results from cell based assays and facilitate transitioning stem cell culturing and treatment into a more controlled process.

John Elliot, Investigator, **NIST, USA**

15:40 **Sponsorship Provider Presentation; Please contact Steve Hambrook at Steve.h@marketsandmarkets.com**

16:10 *Afternoon Refreshments and Poster Presentation*

16:40 **The Critical and Changing Interface of Regulation and Bioprocessing: Adaptive Trial Pathways**

- Large numbers of cell and gene therapies are pursuing adaptive clinical trial approaches to expedite their path to market
- Consequently, the point at which a product developer must 'lock down' their manufacturing strategy has moved earlier in the translation pathway
- The presentation will discuss implications of adaptive licensing for biomanufacturing development

David Brindley, Senior Research Fellow in Healthcare Translation, **University of Oxford, United Kingdom**

17:10 **Logistics and supply chain considerations for overcoming delays in commercialization**

- Identifying the critical Cell therapy logistics bottle necks from vain to vain. Risk assessment based approach
- Introducing integrated early stage process development focused on logistic issues
- Optional solutions Case studies

Ohad Karnieli, CEO and Co-Founder, **ATVIO Biotechnology, Israel**

17:40 **End of Conference**

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