PRE-CONFERENCE FOCUS DAYS **28th November 2016**		
Additional Information: - There are two streams - Both workshops will finish no later than 16:00 - Refreshments, documents and a lunch will be provided	**Workshop 1:** **Next Generation Therapies and Technology Platforms**	**Workshop 2:** **Comparability Testing for ATMPs**
	9:30am – Registration	**8:30am – Registration**
	10:00am – Workshop begins James Smith, *Research Associate,* **CAMSI Translational Stem Cell Consortium**, Associate **IP Asset Ventures**, UK David Brindley, *Senior Research Fellow*, **University of Oxford**, *Managing Partner,* **IPAV**, UK - Exosomes, micro-vesicles and other extracellular vesicles (EVs): what's the difference? - Opportunities in exosomes: therapeutics, diagnostics and delivery vehicles - Commercial environment - recent investments and R&D in exosomes and 'ones to watch' - Intellectual property landscape: navigating a complex maze - Outlook: where are we now and where will we be in 5 years time?	**9:00am** – Workshop begins Christopher Bravery, *Director,* **Consulting on Advanced Biologicals Ltd**, UK Karin Hoodendoorn, **Quality RA**, The Netherlands - Introduction to comparability - Regulatory framework - Process and product characterisation - Comparability expectations during clinical development and post-approval - Examples of changes and comparability strategies - Case study exercise

CONFERENCE DAY ONE
29th November 2016

STREAM 1	STREAM 2	STREAM 3	STREAM 4
Cell, Gene and Immunotherapy Manufacturing, Process Optimization and Analytics	**Cell, Gene and Immunotherapy Manufacturing, Process Automation and Cold Chain**	**Preclinical Strategies for Cell, Gene and Immunotherapies**	**Clinical Development for Cell, Gene and Immunotherapies**
8.00am - Registration			
8.55am - Chairperson's Opening remarks			
Joint Plenary Session The realities of manufacturing CAR-T cells			
9.25am – Presentation from Novartis **Jason Hamilton, *Senior Fellow*, Cell and Gene Therapy, Novartis, USA**			
9.25am - Leveraging Cellectis' gene edited CAR-T platform to industrialize off-the-shelf allogeneic pharmaceuticals **David Sourdive, *EVP Corporate Development & Manufacturing*, Cellectis, France**			
9.45am - Juno´s cell handling platform for efficient production of gene-modified T cells **Lothar Germeroth, *SVP, Managing Director*, Juno Therapeutics, USA**			
10.05am - Discussion panel: Successful CAR-T strategies - CAR-T cell growth - Input on CAR-T clinical research - Feedback/updates on current status and developments - Applications and different strategies for development			
10.30am - Morning Coffee and Networking			
Late Morning Session Process Technologies and Validation	**Late Morning Session** Bioprocessing Technologies for Large Scale Production	**Late Morning Session** A Closer Look at Current Development Pipelines	**Late Morning Session** Clinical Strategies for Moving Products Through the Clinic
11. 15am - Comparability study set up when changing of manufacturer : guideline, study and agency feedback - GS010 example	**11.15am** - Developing a stringent, commercially viable manufacturing strategy: Anticipating your end point **Alain Pralong, *Senior Vice President, Manufacturing***	**11.15am** - Preclinical update from GeneQuine Biotherapeutics GmbH: Gene Therapy for Osteoarthritis **Kilian Guse, *CEO*, GeneQuine**	**11.15am** - Regulatory expectations for the generation of clinical evidence

Nitza Thomasson, *Chief Preclinical Officer,* GenSight Biologics, France	***Operations*, Cell Medica, UK**	**Biotherapeutics GmbH, Germany**	**Suggested speaker:**
11.50am - Using Commercial Manufacturing Requirements to Guide Process Development **Sharon Chen, *Senior Director of Process Development,* Athersys, Inc., USA**	**11.50am** - Scalable platforms – creating a standard for commercial production **Jeffrey Bartlett, *Chief Scientific Officer, SVP,* Research and Development, Calimmune, Inc., USA**	**11.50am** - Preclinical update from Newcastle University: Alginate-encapsulation for the storage and therapeutic delivery of adipose-derived stem cells **Che John Connon, *Professor of Tissue Engineering,* Faculty of Medicine, Newcastle University, UK**	**11.50am** - From academia / CRO then to CMO : product characterization versus potential product evolution **Jean-Phillipe Combal, *COO*, GenSight Biologics, France**
12. 25pm – Towards the commercial manufacture of CAR-T cells: Scaling-up Lentiviral Vector manufacturing using serum-free suspension bioreactor processes and the production of CAR-T cells using an automated cell processing device **Boro Dropulic, *Chief Science Officer and General Manager*, Lentigen Technology Inc., A Miltenyi Biotec Company, USA**	**12.25pm** – A presentation from Merck **Antoine Heron, Merck, Germany** **12.40** – A presentation from Pall	**12.25pm –** Developing DNA and Stable Cell Line Solutions for Maximising Lentivirus Production **Ryan Cawood, *CEO*, Oxford Genetics, UK**	**12.25pm –** A presentation from Thermo Fisher Scientific
12.55 - Lunch, Networking and Live Labs	**12.55 - Lunch, Networking and Live Labs**	**12.55 - Lunch, Networking and Live Labs**	**12.55 - Lunch, Networking and Live Labs**
Early Afternoon Session Process Technologies and Validation	**Early Afternoon Session** Bioprocessing Technologies for Large Scale Production	**Early Afternoon Session** A Closer Look at Current Development Pipelines	**Early Afternoon Session** Translational Medicine and drug delivery
2.10pm - Process optimisation and development – ensuring successful launch into large scale manufacturing	**2.10pm** - Applying bioprocessing technologies for large scale manufacturing	**2.10pm** - Moving into the clinic – the GOSH experience **Sue Swift, *QA Officer Gene Therapy*, Great Ormond Street Hospital**	**2.10pm** - Successfully anticipating transferability and manufacturability

Lior Raviv, *Development Director,* Pluristem Therapeutics Inc., Israel	**Matthias Hebben, *Head, Bioprocess Development,* Genethon, France**	**for Children NHS Foundation Trust, UK**	**Ludek Sojka, *Chief Operating Officer*, Sotio a.s., Czech Republic**
2.45pm - Making cell therapy process changes: Why, how, and when? **Greg Russoti, Vice President, Technical Operations, Celgene Cellular Therapeutics, USA**	**2.45pm** - Challenges for the manufacture of autologous ex-vivo cell gene therapy products **Tarik Senussi, *Manager: Lead Upstream Process Development Scientist*, Cell & Gene Therapy Platform CMC, GSK, UK**	**2.45pm** - Adult stem cell derived organoids for Cell Therapy **Rob Vries, *Managing Director*, foundation Hubrecht Organoid Technology (HUB), The Netherlands**	**2.45pm** - Delivery and formulation round tables The delegates will be split into groups of 5-10 to discuss points looking at formulation and delivery at a clinical level
3.20pm - High resolution monolithic support - enabling tool for understanding viral particle structure and its purity **Aleš Štrancar, CEO, BIA Separations, Slovenia**	**3.20pm** – Innovative solutions dedicated to cell and gene therapy automation **Olivier Waridel, Biosafe S.A., Switzerland**	**3.20pm - Spotlight presentations** Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. **For sponsorship and exhibition opportunities please contact: Luke Pickering, Tel: +44(0)20 3377 3553; Email:luke.pickering@informa.com**	**3.20pm - Spotlight presentations** Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. **For sponsorship and exhibition opportunities please contact: Luke Pickering, Tel: +44(0)20 3377 3553; Email:luke.pickering@informa.com**
3.35pm – A presentation from Saint Gobain	**3.35pm** – A presentation from MasTHerCell **Alexandre Lennaertz, Development Engineer, MaSTherCell, Belgium**		
3.50pm - Afternoon Coffee			
Late Afternoon Session Cell, Gene and Immunotherapy Raw Materials and Analytics	**Late Afternoon Session** Scaling Up/Out and Industrialisation	**Late Afternoon Session** A Closer Look at Current Development Pipelines	**Late Afternoon Session** Clinical Case Studies, Partnerships for Successful Clinical Development and Orphan Similarity

4.20pm - Analytical comparability to demonstrate the similarity of the product after changes in manufacturing process – Gene therapy case study **Minna Hassinen,** ***Analytical Director,*** **FinVector, Finland**	**4.20pm –** Compare and contrast: scale-up VS. scale-out – how to revolutionise current practise **Toon Lambrechts,** ***PhD researcher,*** **KU Leuven, Brussels**	**4.20pm** - Generation of human iPS cells as disease models and therapeutic targets **Balazs Sarkadi,** ***Head of Department, Research Centre for Natural Sciences,*** **Hungarian Academy of Sciences, Hungary**	**4.20pm** - From Bench to Bedside – An academic perspective **Eleanor Berrie,** ***Qualified Person, Clinical BioManufacturing Facility,*** **University of Oxford, UK**
4.55pm - Defining what analytical testing needs to be done – looking at the QA side of product manufacturing **Josh Sorafine,** ***Associate Director, Clinical QC Operations*****, bluebird bio, USA**	**4.55pm** - Understanding scale-out systems – how to keep costs down **Donna Rill,** ***Chief Development Officer,*** **Opexa Therapeutics, USA**	**4.55pm** - Expanded cell endocardiac transplantation - Phase I/IIb clinical trial **Anthony Criquet,** ***Chief Medical Officer,*** **CellProthera, France**	**4.55pm** - A closer look at orphan similarity – incentives for orphan drugs **Alex Bloom,** ***Director, Regulatory Affairs (EU),*** **Cell Medica, UK**
5.30pm - Chairperson's Closing Remarks			
5.40pm - Closing Plenary Session The Eulogy of Toby Peach *'I was born on 18th December 1988. I dressed up as a bandicoot once. I was diagnosed with cancer 2,102,000 minutes ago…'* One in two of us will experience cancer first-hand and now Toby Peach brings this universal issue to the stage. The Eulogy of Toby Peach is the story of his journey with Hodgkin's Lymphoma, a cancer of the lymph nodes that he faced at the age of 19 and again at 21. Toby didn't know what cancer was, what happens when it's treated and the effects it can have. A Eulogy is a celebration of life - we will all need one; Toby is just delivering his now. Join Toby as he enters the (not so) exclusive Cancer Club; sample chemotherapy cocktails, select the perfect funeral playlist and marvel at Willy Wonka's life-saving stem cell machine. From diagnosis to remission, relapse and treatment, experience a young man's journey with cancer in this honest, fascinating and inspiring exploration of modern science and the wonders of the human body. The Eulogy of Toby Peach is a discovery of self-mortality and this original piece explores a true story and an important and difficult subject in a refreshing, insightful and humorous way.			
6.25pm - Networking Drinks and Evening Social Event			

CONFERENCE DAY TWO
30th November 2016

STREAM 1	STREAM 2	STREAM 3	STREAM 4
Cell, Gene and Immunotherapy Manufacturing, Process Optimization and Analytics	**Cell, Gene and Immunotherapy Manufacturing, Process Automation and Cold Chain**	**Preclinical Strategies for Cell, Gene and Immunotherapies**	**Clinical Development for Cell, Gene and Immunotherapies**
8.30am - Registration			
8.55am – Chairperson's Opening Remarks			
9.00am - Joint Plenary Session Regulatory updates and recent progress			
9.00am – EU accelerated and regulatory approval schemes **Anthony Lodge, *Regulatory Affairs Manager*, ATMPS, Cheisi, UK**			
9.20am – Speed to market – making the use of FDA Expedited Programs **Shaun Stapelton, *Head of Regulatory Affairs,* ReNeuron, UK**			
9.40am – Conditional and time-limited approval systems for a new regenerative medicinal product in Japan **Masami Tamuri, *President and CEO,* CoreMed Corporation, Japan**			
10.00am – Development of Animal Component-Free, Chemically Defined Media for Gene and Cell Therapy **Jessie Ni, CSO, Irvine Scientific, USA**			
10.20am - Morning Coffee			
Late Morning Session Cell, Gene and Immunotherapy Raw Materials and Analytics	**Late Morning Session** Scaling Up/Out and Industrialisation	**Late Morning Session** A Closer Look at Current Development Pipelines and Pre-Clinical Regulatory Considerations for Entering the Clinic	**Late Morning Session** Regulatory Expectations for the Generation of Clinical Evidence
11.05am - Compare and contrast: the biggest headaches when developing analytical strategies Informa is looking for 3 speakers – working within	**11.05am** - Transient GMP Lentiviral Vector Manufacture: a multi-batch experience **Lucas Chan, *Head of Production for Advanced Therapy Medicinal Products*, King's College London Clinical Research Facility, UK**	**11.05am** - Preclinical update from Queen's University Belfast **Alan Stitt, *Chair of Experimental Ophthalmology***	**11.05am** - European Union Gene and Cell Therapy support in Horizon 2020 **Confirmed speaker: David Gancberg, *EU Project and Scientific Officer, Novel Medical Developments,* European Commission, Brussels**

cell, gene and immunotherapies to provide short 10 minute presentations where they will compare and contrast the biggest headaches/difficulties they face when developing analytical strategies for their products **Diana Colleluori, *Senior Director, Quality Control,* bluebird bio, USA**			
11.40am - Discussion panel: looking at the need for more robust guidelines on the expectations surrounding characterisation	**11.40am** - Discussion panel: Scaling up/out and industrialisation surgery	**11.40am** - What is needed from preclinical studies so a product can move smoothly into the clinic – A case study from Arthrogen/Vicinivax **Janneke Meulenberg, *COO*, Arthrogen and *CEO*, Vicinivax, The Netherlands**	**11.40am** - Accelerated/ conditional regulatory approvals and post-marketing clinical adoption in cell therapy **Alexey Bersenev, *Director Advanced Cell Therapy Lab,* Yale University, USA**
12.15pm – Raw Materials in the manufacture of Advanced Therapies in Medicinal Products: Quality Attributes and Quality Assurance **Bernd Leistler, CellGenix, Germany**	**12.15pm –** The process of industrialising gene therapies is only just beginning **Dave Wilson*, European Business Development Manager*, Fisher BioServices, A Thermo Fisher Scientific Brand, UK**	**12.15pm - Spotlight presentations** Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. **For sponsorship and exhibition opportunities please contact: Luke Pickering, Tel: +44(0)20 3377 3553; Email:luke.pickering@informa.com**	**12.15pm –** A presentation from Miltenyi
12.45pm - Lunch and Networking			
Early Afternoon Session	**Early Afternoon Session** Process Development, Automation, Closed	Early Afternoon Session Pre-Clinical Regulatory Considerations for	**Early Afternoon Session**

Cell, Gene and Immunotherapy Raw Materials and Analytics	Systems and End-to-End Solutions	Entering the Clinic and Biosafety as the Entry Point	Predicting Optimum Manufacturing Strategy in Clinical Development
2.00pm - CQA assessment: a closer look at critical parameters and building a sufficient control strategy **Anthony Lodge, *Regulatory Affairs Manager*, ATMPS, Cheisi, UK**	**2.00pm** - Perfluorocarbons – potential for successful expansion of bone marrow-derived human mesenchymal stem cells at liquid/liquid interface **Petra Hanga, *Postdoctoral Research Associate*, Centre for Biological Engineering Chemical Engineering Department School of AACME Loughborough University, UK**	**2.00pm** - How to bring cell-based therapies to the clinic – a flexible approach for preclinical development **Tiina Palomäki, *Senior researcher* Finnish medicines agency, Fimea, Finland**	**2.00pm** - Adopting an efficient manufacturing strategy to facilitate commercialisation **Wouter Harink, *Head of Manufacturing,* Kiadis Pharma, Netherlands**
2.35pm - Requirements for raw materials: an Eu perspective **Maria Cristina Galli, EATRIS, Italy**	**2.35pm** - Automation case study: Argos's Therapeutics **Fred Miesowicz, *Consultant* for Argos Therapeutics and *former COO*, USA**	**2.35pm** - Pre-clinical animal models to prove clinical efficacy **J Joseph Melenhorst, *Director, Product Development & Correlative,* Sciences laboratories (PDCS) *Adjunct Associate Professor,* Center for Cellular Immunotherapies, University of Pennsylvania, USA**	**2.35pm** - Adapting business models through clinical development **Miguel Forte, *Chief Operating Officer*, TxCell SA, France**
3.10pm – A presentation from Cook	**3.10pm –** A presentation from Trackcell	**3.10pm - Spotlight presentations** Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. **For sponsorship and exhibition opportunities please contact: Luke Pickering, Tel: +44(0)20 3377 3553;**	**3.10pm - Spotlight presentations** Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. **For sponsorship and exhibition opportunities please contact: Luke Pickering, Tel: +44(0)20 3377 3553;**

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3.40pm - Afternoon Coffee			
Late Afternoon Session Cell, Gene and Immunotherapy Raw Materials and Analytics	**Late Afternoon Session** Transportation, Cold Chain and Cryopreservation	**Late Afternoon Session** Funding Pre-Clinical Studies – Capital Investment & IP Considerations in Clinical Development	
4.10pm - Cost of goods considerations when deciding on your raw materials **Suggested speaker:**	**4.10pm** - GDP: Transportation of Skin (autologous) on 35 +/- 2°C **Rene Stenger, *Head of Production and Qualified Person for Good Distribution Practices (GDP)*, Wyss Zurich, Switzerland**	**4.10pm** - IP – Good and bad practise for re-imbursement **James Smith, *Research Associate* (CAMSI Translational Stem Cell Consortium)** ***Associate* (IP Asset Ventures), UK**	
4.45pm - Discussion panel: Raw material quality, traceability and industry need **Suggested speakers:**	**4.45pm** - Cryopreservation strategies for cell therapies **Suggested speaker:**	**4.45pm** - Funding options: Generating funding from investors, government and other agencies **Lioba Lobmayr, *Founder & Managing Director*, aquila pharma e.U., Austria**	
5.25pm - End of Day Two			

POST CONFERENCE WORKSHOP

1st December 2016

Characterising ATMPs (360mins)

10.00am – Understanding Potency and Developing Potency Assays for ATMP

Christopher Bravery, *Consulting* on Advanced Biologicals Ltd., *Member*, ISCT EU Legal and Regulatory Affairs Committee, UK

Karin Hoogendoorn, *Quality RA*, The Netherlands