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:** Raw Materials Focus Day	**Workshop 2:** Comparability for ATMPs
	8:30am – Registration	**8:30am – Registration**
	9.00am - Starting Materials and Standards for Cell Therapies The Division of Advanced Therapies at NIBSC is houses the UK Stem Cell Bank. The Bank collects, archives, and distributes human ES lines produced in the UK, plus a number generated outside the UK—and makes them available for researchers and commercial developers. We are currently generating a series of hES lines in GLP facilities to EUTCD-grade, to act as starting material for the production of cellular therapies. In conjunction, we are developing a regulator-ready data portfolio to accompany each line, with a view to facilitating the development of clinical grade materials. In conjunction with our role as a repository for human pluripotent stem cells, we are the leading producer of WHO standards, responsible for roughly 85% of such standards world-wide. We are well placed, therefore, to coordinate the production of clinical grade materials with our experience in the production of standards and cell assays towards the clinical development of cell therapies. In this presentation, I shall outline our work in the production of pluripotent cells and their derivatives, the generation of data portfolios to support regulatory submissions of those cells, and our first steps towards the generation of physical standards for cell therapies. **Jack Price, *Division of Advanced therapies*, National Institute for Biological Standards and Control, UK** **9.45am - Quality Management for Raw Materials**	**9:00am** – Workshop begins Christopher Bravery, *Director,* **Consulting on Advanced Biologicals Ltd**, UK Karin Hoogendoorn, *Scientist ATMP Product Development*, **Leiden University Medical Centre (LUMC),** The Netherlands Change is inevitable and necessary both in development and over the post-approval product lifecycle. Whenever changes are made it is necessary to confirm they do not adversely impact the quality and therefore safety and efficacy of the product; this requires data beyond meeting current specifications. With any biological product this is challenging, for cell, gene and tissue products that cannot be fully characterised the challenges are greater still. Concerns about comparability undertaken during development are common issues raised during review and often delay market approval or contribute to failure. This course explains what comparability is and how to develop a successful comparability protocol. Workshop Learning Overview: - What is comparability? - Why is meeting existing specifications not comparability? - How do I apply the principles of comparability to highly variable products? - Case studies: Common mistakes with comparability and their consequences. - Interactive exercise: Spot the weaknesses and propose improvements to a worked comparability study.

	• Quality Agreements – what is expected and needed • Quality audits – luxury or a must • Quality of raw material – should we go for GMP grade? • Setting internal specifications • Testing of raw material **Jakub Cierny, *Senior Quality Compliance Manager*, Sotio AS, Czech Republic** **10.30am – Morning Coffee and Networking** **11.00am - Oversight of 3rd Party Raw Material and Biological Starting Material Suppliers for Cell Therapy Manufacturing** For medicinal products derived from Cellular and Gene Therapy manufacturing, establishing quality controls on biological starting materials and other raw materials varies from traditional raw material quality controls in common biopharmaceutical manufacturing especially when the starting materials originate from human tissue or directly from human origins. In a cell and gene therapy manufacturing process, there may be customized raw materials such as media and ancillary materials. The expectation of meeting EMA guidances on testing for purity, potency, consistency and stability has unique challenges which are weighed against the impact of the material to the manufacturing process and the safety concerns for the patient who receives the finished product. Evaluations of safety critical features may be emphasized more so than other analytical testing methodologies. For biological starting material, the traditional EMA guidance in EudraLex, Volume 4 for Medcinal Products, Annex 2, Table 1 defers to the guidances in Directive 2004/23/EC and recent EudraLex Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products (effective 22 May 2018). The overight of suppliers of these two materials will be contrasted to show similarities and differences in the management and quality control concerns for both.	

	Joseph Carosi, *Associate Director, External CMO QA for Cell and Gene Therapies,* Novartis, USA **11.45am - Implementation of Serum-Free Medium in a Chimeric Antigen Receptor T Cell Manufacturing Process** Many early autologous chimeric antigen receptor (CAR) T cell manufacturing processes relied on the addition of complex animal-derived materials (ADM), such as human and bovine sera, to support T cell expansion. In addition to country of origin sourcing controls and viral testing, viral inactivation treatments, such gamma irradiation, are recommended to further mitigate the risk of adventitious agents. However, irradiation of serum may lower its performance, thereby further increasing the variability associated with complex ADMs. The implementation of serum-free medium (SFM) may significantly reduce the variability and challenges associated with complexes ADMs, while simplifying sourcing and manufacturing. Selection and implementation of SFM in a CAR T cell manufacturing platform presents several challenges. First, the limited availability of patient T cells requires the use of healthy donor cells as a surrogate to screen large numbers of SFM formulations. Second, CAR T cell manufacturing processes may not allow for the gradual adaptation of T cells to SFM conditions. Finally, rather than tailoring a SFM formulation to a single cell line, it must provide sufficient robustness to support CAR T cell manufacturing across a diverse patient population. Overall, the strategy and design considerations towards the selection and implementation of SFM in a CAR T cell manufacturing platform to support future programs will be discussed. **Pascal Beauchesne, *Principal Scientist, Technology Strategy & Innovation*, Juno Therapeutics, USA** **12.15pm – Serum Traceability – how can you tell what is in your bottle?** **Jenny Murray, *Managing Director*, Life Science Group Ltd, *Chair*, International Serum Industry Association (ISIA), UK**	

12:45pm – Sessions Wrap Up and Questions

13.00 Lunch and Networking

13.45 Buses Leave for Site Visit

14.00 – Sanquin Site Visit

Sanquin is a knowledge-driven not-for-profit organization that supplies life-saving products and focuses on health care needs. Research helps us find new solutions for medical problems in the fields of transfusion medicine, hematology and immunology. We are constantly aware of our responsibility to donors – to handle their gift carefully, efficiently and responsibly – and to patients – whose safety and wellbeing is a priority.
With almost 3,000 committed colleagues and more than 330,000 blood donors, Sanquin can provide a better life for 300,000 Dutch patients each year.

In addition to collecting, processing and distributing blood products, Sanquin also:

- produces plasma pharmaceuticals,
- develops blood group and immune reagents,
- performs a multitude of diagnostic services,
- conducts high-quality scientific research,
- collect, process, cryopreserve and distribute (stem)cell products
- and provides education and training.

Sanquin is the only blood organization in the world to offer this combination of in-house medical, pharmaceutical and scientific knowledge and expertise.

Over the course of this 2-hour tour, attendees will get to see and hear about, on a tour on Sanquin's new state of the art facility:

- Blood bank
- Reagents
- Diagnostics
- Cell Therapy Laboratory

Places Are capped at 25 so please register early

[redacted]	**Patrick Burger, *Project Leader Laboratory for Cell Therapy*, Sanquin Research, The Netherlands**	

CONFERENCE DAY ONE
4th December 2018

STREAM 1	STREAM 2	STREAM 3
Manufacturing and Process Development – Analytical Strategies, Design Space, QbD and Cost of Goods Considerations	**Facility Design, Manufacturing Networks and End to End Solutions for Commercial Success**	**Clinical Development for Cell, Gene and Immunotherapies** **STREAM 4**

7.40am - Registration

8.40am - Chairperson's Opening remarks
Miguel Forte, CEO, Zelluna Immunotherapy, Norway

Joint Plenary Session
Industry 4.0 - Integration of manufacturing
& Delivery into healthcare

8.45am – Innovative solutions from Industry 4.0
- Potential to providing real-time visibility
- Control across complex cell and gene therapy supply chains
- QbD
- How can industry 4.0 drive the industry towards increased industrialization?

Confirmed speaker: Michael M. Hay, *President & CEO*, CCRM, Canada

9:05am – Designing production facilities of the future
- Case study
- How can facilities be produced to meet the potential demand of cell and viral vectors
- What needs to change and what innovations are being made

Confirmed speaker: Geoff Hodge, *Chief Technical Officer,* Unum Therapeutics, USA

9.25am – Patient specific therapies and the need for a paradigm shift
- How innovation could lead to a more flexible process based on having enhanced product and process understanding
- How would this then be adaptable to manage critical sources of variability
- Potential for Analytical Technologies (PAT) comprised of sensors with multivariate data analytics and control algorithms as well as electronic data records and enterprise systems to enable efficient knowledge sharing across components in the supply chain

Confirmed speaker: Ohad Karnieli, CEO & Co-Founder, ATVIO Biotech, Israel

09.45am – Spotlight presentation from GE Healthcare

10:05am – Spotlight presentation from Lonza

10:20am - Discussion Panel: What do industry need to innovate the cell and viral vector industries?
- What innovations do industry need to make it possible to treat 100's of patients?

- What can vendors do to innovate platforms they currently provide?
- Where do the gap's lie?
- What is can be done to prevent demand outgrowing capacity?

Confirmed speakers:

1. **Ohad Karnieli, CEO & Co-Founder, ATVIO Biotech, Israel**
2. **Michael M. Hay, President & CEO, CCRM, Canada**
3. **Geoff Hodge, *Chief Technical Officer,* Unum Therapeutics, USA**
4. **Stewart Craig, *Chief Manufacturing Officer,* Orchard Therapeutics, USA**
5. **Benjamin Le Quéré, Business Manager, Bioprocessing Solutions, Saint-Gobain, France**

10.45am - Morning Coffee and Networking

<table>
<tr><th>Late Morning Session

Monitoring quality across the process - Process and automated analytics for cell therapies</th><th>Late Morning Session

Strategies and Facility Design for Commercial Stage Manufacturing – End to end Solutions</th><th>Late Morning Session

Current Pipeline Updates</th></tr>
<tr><td colspan="2">11.15am - A forward look at the future of cell therapy manufacturing

• What does the future of manufacturing look like?
• Review of different technologies out there
• Where do the gaps lie?

Confirmed speaker: Jon Gunther, Supply Chain, Strategic Sourcing, Juno Therapeutics, USA</td><td>11.15am – Zelluna Immunotherapy Case Study

Confirmed speaker: Arjan Roozen, CTO, Zelluna Immunotherapy, Norway</td></tr>
<tr><td>11.50am – Case study: Equivalence testing for a multi-plate potency assay of viral vector

Confirmed speaker: Sara Paulo, Analytical Specialist, FinVector Oy, Finland</td><td>11.50am - Implementation of an affordable and scalable manufacturing strategy

• Case study

Confirmed speaker: Bas Leewis, MSAT Manager, MeriaGTx, UK</td><td>11.50am – Gamma-Delta T Cell Case Study

Confirmed speaker: Michael Leek, CEO, TC Biopharm, UK</td></tr>
</table>

12. 25pm – Spotlight presentation from Miltenyi Biotech	**12.25pm** – Viral Safety in Viral Therapeutics • No pH inactivation • No viral removal by nano filtration • Preventive measures in MCB/WCB and MVB/WVB • No animal derived raw materials • Suspension cell culture processes • Affinity chromatography for viral therapeutics • Sterile filtration of media and buffer • Sanitization of resins and membranes **Confirmed speaker: Rolf G. Werner, Labor Dr. Merk & Kollegen, Germany**	**12.25pm – Spotlight presentation from Fujifilm**
12.55 - Lunch, Networking and Live Labs		
Early Afternoon Session Analytics Associated with Cell Therapy Bioprocessing – Process Modelling and Design Space	**Early Afternoon Session** Strategies and Facility Design for Commercial Stage Manufacturing – End to end Solutions	**Early Afternoon Session** Current Pipeline Updates
2.10pm – Dual Dialogue: Combination of analytical methods for characterization of viral vectors • Analytical methods used in development and production of vectors for gene therapy	**2.10pm** – Case study: Use of stir tank bioreactor and BEVS technology to produce at 500L scale **Confirmed speaker: Juan Pablo Labbrozzi, Lead Scientist, Process Development, uniQure, The Netherlands**	**2.10pm** – Celyad Case Study **Confirmed speaker: Sophie Agaugue, R&D Manager, Celyad, Belgium**

• Quantification with molecular methods • Need for standards in analytical methods for vectors **Confirmed speakers:** **Jessica Alsiö, *Regulatory CMC Senior Manager*, Cell and Gene Therapy, Novartis, Switzerland** **Katy Barglow, *Director, Process Sciences and Analytical Development,* 4D Molecular Therapeutics, USA**	**2.45pm** - Panel discussion: What can cell therapy manufacturers learn from MAbs to save time and money on the path to commercial scale manufacturing *Knect365 is looking for a mix of both cell and Mab manufacturers to join the discussion panel looking at:* • Where current gaps lie in cell therapy manufacturing – do MAb manufacturers have advice on how to fill these • What technologies and process improvements can the cell therapy industry take away from their counterparts • Feedback and discussion on how to improve current processes **Christopher Bravery, Director, Consulting on Advanced Biologicals Ltd, UK** **Karin Hoogendoorn, Scientist ATMP Product Development, Leiden University Medical Centre (LUMC), The Netherlands** **Greg Stromberg, *Associate Director, Global Manufacturing Sciences,* Biogen, USA** **Houssam Alosta, *Senior Manager, Bioprocess Engineering*, BlueRock Therapeutics**	**2.45pm** – Case study: ART-I02, a gene therapy vector for arthritis **Confirmed speaker: Janneke Muelenberg, COO, Arthogen, The Netherlands**

3.20pm – Spotlight presentation from Pall	**3.20pm** – Agility by Design: a new strategy to address the cell & gene therapy manufacturing challenges **Confirmed speaker: Romain de Rauville, *Business Development Manager,* MaSTherCell, Belgium**	**3.20pm** – Spotlight presentation Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. By joining us in sponsoring and exhibiting at this event, you will be able to: • Use an exhibition stand to meet new clients in the main networking area • Raise your corporate profile and shape your corporate image with logo placement • Ensure market presence as a thought leader with a speaking position **For sponsorship and exhibition opportunities please contact: Michael Dunnet, Tel: +44 (0)20 7017 7870; Email: michael.dunnet@knect365.com**
3.40pm –Spotlight presentation from CellGenix	**3.40pm –** A presentation from Anemocyte **Confirmed speaker: Stefano Baila, *Director of Operations & Business Development*, Anemocyte, Italy**	**3.35pm –** Spotlight presentation Use this event to raise your corporate profile and demonstrate your products and services to our targeted, multidisciplinary audience. By joining us in sponsoring and exhibiting at this event, you will be able to: • Use an exhibition stand to meet new clients in the main networking area • Raise your corporate profile and shape your corporate image with logo placement • Ensure market presence as a thought leader with a speaking position **For sponsorship and exhibition opportunities please contact: Michael Dunnet, Tel: +44 (0)20 7017 7870; Email:** michael.dunnet@knect365.com
3.50pm - Afternoon Coffee		
Late Afternoon Session Analytical Testing and Quality Systems	**Late Afternoon Session** Internal Vs. External Manufacturing and CMO/CDMO	**Late Afternoon Session** Current Pipeline Updates

<table>
<tr><td></td><td>Management throughout Development Lifecycle</td><td></td></tr>
<tr><td>4.20pm – Principles, implications and benefits of applying QbD to analytics

• Characterising the product
• Case study tisagenlecleucel, a CAR T cell product

Confirmed speaker: Margit Jeschke, Global Head, Analytical Stewardship and CMC Correlational, Novartis, Switzerland</td><td>4.20pm – Dual Dialogue: When to make the decision to either insource or outsource

• When is the best time to make the decision on in sourcing vs. outsourcing?
• What are the limitations of building your capabilities in house?
• What are the benefits vs. the costs?
• Pros and cons of both models
• What is better for large vs. small companies?
• What sort of bioprocess equipment makes sense for CMO’s opposed to therapeutic companies?
• Enterprise solutions vs. ability to customise

Confirmed speakers:

1. Lior Raviv, Vice President Development, Pluristem, Israel
2. Greg Stromberg, Associate Director, Global Manufacturing Sciences, Biogen, USA</td><td>4.20pm – Transforming cell therapy with gene editing: the case of “off-the-shelf” engineered CAR-T in the clinic

Gene-editing has enabled off-the-shelf allogeneic CAR-T product candidates to reach the clinic. It is also endowing engineered cells with multiple new features, enhancing their capabilities and functions to better address cancer. Hindsight in industrializing 3 different such gene-edited immuno-oncology products now in active trials, and the human clinical experience with the first cases in ongoing studies signal practical avenues for their further deployment and shed light on the transformative role they will play in the anti-cancer arsenal.

Confirmed speaker: David Sourdive, VP, Corporate Development, Cellectis, France

4.55pm - Discovery of Novel TcRs for Cancer Therapy

Confirmed speaker: Andy Hurwitz, Vice President, Head of Preclinical Research, AgenTus Therapeutics, USA</td></tr>
<tr><td colspan="3">5.30pm - Chairperson’s Closing Remarks</td></tr>
<tr><td colspan="3">5.40pm - Rapid Quantification of Adeno-Associated Virus and Lentivirus Vectors

Viral vectors such as adeno-associated virus (AAV) and lentivirus are currently in use for gene and cell therapies. Rapid and accurate enumeration of these viral particles is critical for the safety and efficacy of these promising new therapies. However, obtaining this information can be a challenge as current techniques are slow and imprecise. ELISA tests are subjective and the variability depends on the operator. qPCR takes hours and ultimately only delivers a genome count. While vector genomes/mL is required for dosing, further characterization of the vector formulations is required for patient safety. Furthermore, the amount of time involved in these methods makes them challenging for use in in-process monitoring of vector growth and formulation. The Virus Counter 3100® platform using antibody-based ViroTag® reagents from Sartorius Virus Analytics offers a rapid and precise solution to these problems.

Here, we show how the new ViroTag AAV8-9 and ViroTag VSV-G can be used to quantify crude and purified AAV-8, AAV-9, and VSV-G pseudo-typed lentivirus vectors. Using a patented no-wash assay and the Virus Counter 3100 platform, biologically relevant total particle counts can be obtained in three minutes following a</td></tr>
</table>

30 minute incubation. The speed and precision of this technique makes it practical for in-process monitoring as well as characterization of a final formulation. **Confirmed speaker: Rebecca Montange, *Scientist*, Sartorius Virus Analytics, USA**
6.00pm - Closing Plenary Session – TITLE TBC
6.30pm - Networking Drinks and Evening Social Event

CONFERENCE DAY TWO

5th December 2018

STREAM 1	STREAM 2	STREAM 3
Manufacturing and Process Development – Analytical Strategies, Design Space and Cost of Goods Considerations	**Facility Design, Manufacturing Networks and End to End Solutions for Commercial Success**	**Clinical Development for Cell, Gene and Immunotherapies STREAM 4**

8.25am – Chairperson's Opening Remarks

Anthony Davies, *Founder & CEO*, Dark Horse Consulting, USA

Joint Plenary Session

Regulatory Updates and Recent Progress: US, Japan and EU

8.30am – Title TBC

Jean -Luc Golnez, *GMP Inspector*, FAMHP, Belgium (pending final confirmation)

8.50 - International standardization efforts for accelerating the development and commercialization of cell and gene therapy products

Confirmed speaker: Sheng Lin-Gibson, *Deputy Chief,* National Institutes of Standards & Technology, USA

9.10am – Breakfast Surgery – FDA, EMA and PMDA Pinch Points

Knect365 is looking for 5-6 panellists, comprised of suppliers, manufacturers and regulators to join this breakfast surgery. Attendees will have the opportunity to submit their 'pinch' points anonymously to the panel in advance and this session will provide the perfect opportunity to hear from the experts on expectations

Topics to be covered include:

1. Statistical tools for data assessments
2. GMP for ATMP's – the new guideline and what it means for industry
3. Raw materials and viral safety considerations
4. Analytics and CMC – Potency assays, comparability etc.
5. Interactions with competent authorities for drugs, tissues & cells
6. Compendial testing – safety testing, and sterility

Confirmed speakers:

7. **Andreea Barbu, *Assoc. Prof., Pharmaceutical Assessor*, Pharmaceutics and Biotechnology, MPA, Sweden**
8. **Jean -Luc Golnez, *GMP Inspector*, FAMHP, Belgium (pending final confirmation)**
9. **Catherine Cancian, VP Pharmaceutical Operations, GenSight Biologics, France**
10. **Sheng Lin-Gibson, Deputy Chief, National Institutes of Standards & Technology, USA**
11. **Francesco Cicirello, Chairperson PIC/S Working Group on Annex 2 Revision, *Inspector,* Australia**

9.45am – Spotlight presentation from ThermoFisher Scientific

10.05am – Spotlight presentation (15 mins)

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10.20am - Morning Coffee

Late Morning Session Process Automation and Closed Systems – Applications and Case Studies	**Late Morning Session** Centralised and De-Centralised Manufacturing Networks	**Late Morning Session** Process Validation and Supply Chain Strategies in the Clinic
11.05am – Enabling commercial scale-out of T-cell manufacturing • What are the key challenges in scaling an autologous process for commercial? • The role of closed systems in scalability • Understanding and controlling Key Quality Attributes **Confirmed speaker: Smaragda Angelidou, *Cell & Gene Therapy Medicine and Process Delivery Leader, Platform Technology and Sciences,* GSK, UK**	**11.05am** – Revision of PIC/S Annex 2 for ATMP, challenges with automation and facilitation of cross-border manufacturing **Invited speaker: Francesco Cicirello, Chairperson PIC/S Working Group on Annex Revision, *Inspector,* Australia (invited)**	**11.05am** – The link between process development and GMP production • What do you need to take into consideration when developing your process to then take it to GMP? • Regulatory guidelines and experience on interpreting these **Confirmed speaker: Catherine Cancian, VP Pharmaceutical Operations, GenSight Biologics, France**
11:40am - Adopting Various Manufacturing Closed Systems to Gene Modified T Cell Therapies • Immatics developed a proprietary tumor antigen targets discovery • platform, XPRESIDENT® • The platform identifies novel tumor-specific targets and TCR candidate. • It also screens TCR candidates based on these targets against off-target • toxicities in absence of reliable in vivo models • Natural and engineered TCRs against these tumor targets have been used • in various Immatics' Adoptive Cellular Therapy programs in "First In Man" • clinical trials		**11.40am** – Ensuring enough supply and magnitude in terms of patient and dose increases **Suggested speaker:**

<table>
<tr><td colspan="2">

- Extensive process development was carried out using primary T cells
- derived from multiple healthy donors and cancer patients to optimize
- each step in the manufacturing of TCR T cells for 3 clinical trials (IMA101,
- IMA201, IMA202, and IMA203)
- Manufacturing for engineered TCR T cell therapies has been adapted into
- 3 different closed systems with for future phases of clinical trials with
- excellent results

Confirmed speaker: Ali Mohamed, VP, CMC, Immatics, USA

</td><td></td></tr>
<tr><td>**12.15pm** – A presentation from Vivabiocell</td><td>**12.15pm –** Characterization of viral vector samples at different process steps; morphology, integrity, purity and percentage full

Confirmed Speaker: Vanessa Carvalho, Senior Scientist, Vironova, The Netherlands</td><td>**12.15pm – Spotlight presentation from Miltenyi**</td></tr>
<tr><td>**12.30pm –** Enhancing economic reality for cell based medicine through manufacturing optimization

Confirmed Speaker: Benjamin Le Quéré, Business Manager, Bioprocessing Solutions, Saint-Gobain, France</td><td>**12:30pm** – Spinning Membrane Filtration: Applications in Washing, Concentrating, and Fill/Finish Manufacturing for Cell and Gene Therapies

Confirmed speaker: Steven Binninger, *EU Cell Therapy Leader,* Fresenius Kabi, Germany</td><td></td></tr>
<tr><td colspan="3">**12.45pm - Lunch and Networking**</td></tr>
<tr><td>**Early Afternoon Session**

Reducing the Cost of Manufacturing – Costs of Goods Calculations and Considerations</td><td>**Early Afternoon Session**

Facility Design and Flexibility for Efficient Cell Therapy Manufacturing</td><td>Early Afternoon Session

Collaboration for End-to- End Solutions in Preclinical and Clinical Research
Early Afternoon Session</td></tr>
</table>

2.00pm – Designing a manufacturing facility to meet scaling up requirements • Case study **Confirmed speaker: Amanda Skulte, *Cell & Gene Therapy Product Steward*, Novartis**		**2.00pm** – Low Cost Automation to Drive Efficiency and Reproducibility: Case Studies - When should investments into automation be made? - Early in POC for long term process? **Confirmed speaker: Shashi Murthy, *Professor of Chemical Engineering*, Northeastern University, USA**
2.35pm - Scale Up Case Study: VSV-GP **Confirmed speaker: Dethardt Müller, Head of CMC, ViraTherapeutics GmbH, Austria**	**2.35pm** – Solving challenges in development, manufacture and delivery of cell and gene therapies **Confirmed speaker: Stewart Craig, *Chief Manufacturing Officer,* Orchard Therapeutics, USA**	

3.10pm – Spotlight presentation**s**

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3.30pm – Spotlight presentation

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15.30pm – TITLE

3.40pm - Afternoon Coffee		
Late Afternoon Session	**Late Afternoon Session**	**Late Afternoon Session**

Manufacturing and Process Development Strategies – Solutions for Efficient Scale Up and Scale Out	Analysing the Capabilities of Blood Centres, Blood Banks and Collection Centers in Large Scale Manufacturing	Cell Therapy Clinical Progression and Key Business Deals and Partnership Milestones
4.10pm – Meeting the challenge of delivering allogeneic therapies in the commercial sector • What is the future for autologous therapies? • Are they commercially viable • What are the strategies for ensuring that they are? **Confirmed speaker: Robert Leach, *Quality Control Manager,* Cellectis, France**	**4.10pm** – Industry expectations and management at collection centres • What expectations do manufacturers have for their sites? • What resource challenges does this pose? • What would make it easier from a facility perspective for the site? **Slot reserved for Be the Match Biotherapies**	**4.10pm** – Current state of play for the cell therapy industry in the clinic – stats and facts • Current state of the pipeline, including key company players and trends in approved products and therapies in development by delivery method (in vivo vs. ex vivo, and vector types), phase, and therapy area • Deal-making trends in gene therapy, reviewing key transactions and changes over time in volume and value across three main categories of financings, alliances, and acquisition • Access and reimbursement challenges, discussion of prospects for innovative payment models, payer views on value/evidence needs and pricing benchmarks **Confirmed speaker: Tijana Ignjatovic, *Senior Director, Trends and Market Access*, Data Monitor Health, UK**
4.45pm – Creating sustainable process development strategies for Gene Therapy products **Confirmed speaker: Juan Bort Hernandez, *Head of Early Stage Development,* Shire, Austria**	**4.45pm –** Capabilities of blood centres and banks – Could they be CMO's of the future? • What are the capabilities of blood centres and the blood banking industries? • What is the leverage for them to become CMO's? • What changes need to be made to infrastructure to make this happen? **Confirmed speaker: Veronica Albertini, *Chief Scientific Officer,* Swiss StemCells Biotech, Switzerland**	**4.45pm –** Please move to another track
5.20pm - End of Day Two		

MAIN CONFERENCE DAY THREE
6TH December 2018

Logistics, Supply Chain, and Cryopreservation Techniques

8.55am - Chairperson's Opening remarks

9.00am – Cryobiology – effects of freezing and thawing on cell viability

- Case study on the effect freezing and thawing has on cell viability
- how do you measure viability and what is the most reliable value?

Confirmed speaker: Mandana Haack-Sørensen, Head of Production, Rigshospitalet, Denmark

9:30am – Adipose-derived Stromal Vascular Fraction for clinical use

Confirmed speaker: Gianni Soldati, President, Swiss Stem Cell Bank, Switzerland

10.00 – Spotlight presentation

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10:30am - Morning Coffee and Networking

Late Morning Session

Vein-to Vein Supply Chain and Transportation Considerations

11.00am – Cryopreservation considerations when moving from clinical phase to commercial phase manufacturing

- What is required when reaching marketing/commercial stage with regards to cryopreservation?
- Small amount of doses vs. commercial scale amount
- What considerations must be made?
- Challenges and opportunities?

Confirmed speaker: Carmen Brenner, *QC Manager*, Bone Therapeutics, Belgium

11.30am - Successful CAR-T delivery to the patient– quality perspectives on manufacturability & the supply chain
Confirmed speaker: Sarah Snykers, *QC Manager*, Celyad, Belgium

12:00pm – Building Cell Therapy Supply Chain in Europe

- Introduce specificities of Cell Therapy versus traditional pharma : personalized medicine, manufacturing (short), logistics, supply chain (make to order)
- Solutions for the specific needs of Cell Therapy: integrated delivery solution, white-glove logistics, chain of identity and custody
- Re-definition of supply chain and key to success in EU

Confirmed speaker: Tamás Masztis, Senior Director, EU Supply Chain, Kite Pharma EU B.V., The Netherlands

12.30pm – Spotlight presentation

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1:00pm – Networking Luncheon in the Poster & Exhibition Hall

Early Afternoon Session

Analytical Considerations in Supply Chain – Particulates, Extractables and Leachables

2.00pm –Best practise for managing particulates and visible inspections

- Particulate issues with regards to large scale production
- Guidelines/regulatory expectations
- Filter capabilities
- Risk assessment approaches
- How does this link into COGs?

Confirmed speaker: Erik J. Woods, *Co-Founder and Chief Science Officer,* Ossium Health Inc., USA

2.30pm - Leachable profiles of final product containers

- Single use systems and extractable and leachable concerns
- Additional testing requirements on final product following cryopreservation
- How can the potential for leachables be demonstrated?
- What are the right products to test?
- What containers need to be tested

Suggested speaker:

3:00pm - Afternoon Coffee and Networking

3:30pm - Logistics Discussion Panel: Analysing where the gaps lie

Interactive Discussion Panel on the below topics:

- Product distribution
- Injection technologies/ Administration techniques
- Thawing technologies
- Global supply chain strategies (including raw materials)

• Forward thinking and preparations for commercialisation
4.00pm – Chairpersons Closing Remarks
4.05pm – End of Conference