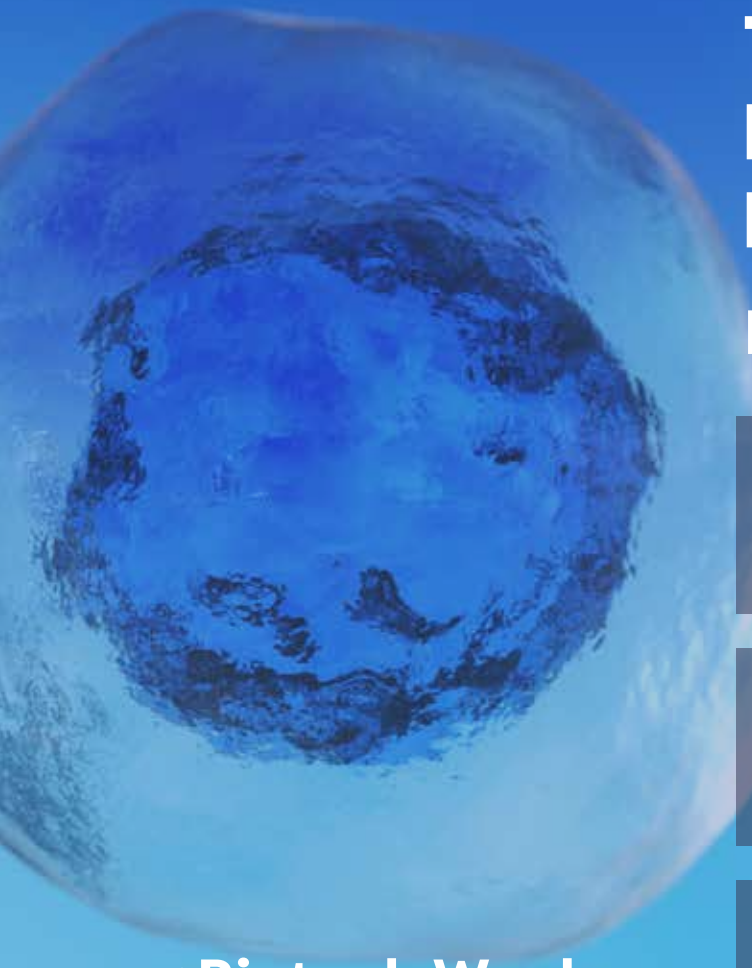
Cell & Gene Therapy Bioprocessing & Commercialization

September 4-7, 2018
Hynes Convention Center
Boston, MA



Part of **Biotech Week Boston**

TRANSFORMING INNOVATIVE RESEARCH TO DRIVE THE FUTURE OF CELL & GENE THERAPY MANUFACTURING AND COMMERCIALIZATION

Real-World Insights. Trusted Resources. Novel Solutions.

50+ New companies attended in 2017 – Were you one of them?

300+ Attendees hit Boston in 2017 - This year will be bigger and better

70:30 Buyer:Seller Ratio

KNect365 Life Sciences

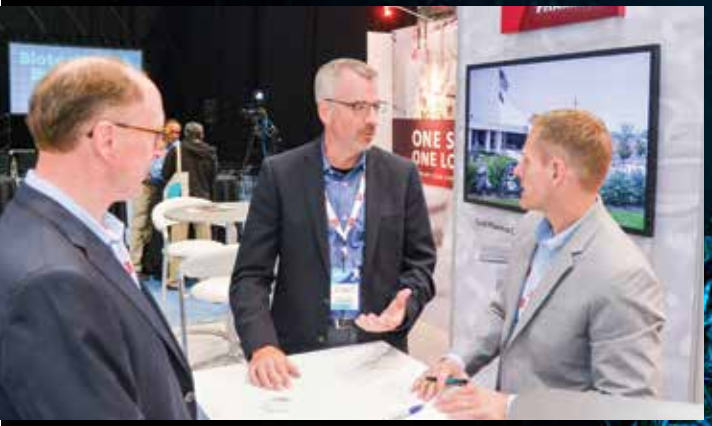
Register by June 29 and Save $400 **www.CellGeneEvent.com**

BIOPROCESSING:

- Investigate monitoring quality across your process with PAT, QbD and novel analytical methods
- Get top tips on the application of process automation and closed systems in manufacturing
- Dive into costs of goods calculations and considerations

COMMERCIALIZATION:

- Making the decision to either insource or outsource manufacturing? What's the best choice?
- Hear the latest on designing a manufacturing facility to meet scaling up and out requirements
- Put yourself in the shoes of Novartis or Kite – a retrospective look at 2017



CLINICAL:

- Get the latest on current development pipelines –optimise preclinical models and examine novel targets
- Pick up knowledge on pre-clinical regulatory and process considerations for entering the clinic
- Push the boundaries of collaboration for end-to-end solutions in preclinical and clinical research

LOGISTICS, SUPPLY CHAIN, AND CRYOPRESERVATION:

- Immerse yourself in cryopreservation – considerations when moving from clinical phase to commercial
- Understand vein-to-vein supply chain and transportation strategies
- Master chain of identity, analytical considerations and patient specific batches

Pre-Conference Workshops • Tuesday, September 4, 2018 • 9.00 - 6.00pm or 12:00 - 6:00pm

Workshop 1: Raw Materials Focus Day

Topics to be covered include:

- Elimination of variations, especially in starting and raw materials/ ancillary materials and manual manufacturing steps
- GMP-grade raw materials
- Regulatory guidance surrounding raw materials - USP Chapter <1043>, <92> and EMA's Ph. Eur. General Chapter 5.2.12
- Automated systems linked to the removal of variation in raw materials
- Developments in manufacturing augmenting a greater need for higher quality raw materials and customised raw materials
- Assessment of origin and impurity profiles
- Best practise for providing documented evidence of purity, potency, consistency and stability
- Supplier agreements and ensuring sufficient supply chain for large scale commercial manufacturing
- Analytical testing

Omer Butt, Director, CMC Regulatory Affairs, **Athersys, Inc,** *USA*

Mithu Majumder, Project Manager, **RoosterBio Inc.,** *USA*

Rosemary Versteegen, CEO, **ISIA,** *USA*

Workshop 2: Process Development and Manufacturing Scale Up for Engineered Tissues

12.00 *Registration*

1:00 **Chairperson's Opening Remarks**
Tom Bollenbach, Ph.D., Chief Technology Officer, **Advanced Regenerative Manufacturing Institute**

1:15 **Keynote Address – Engineered Tissue Manufacturing: The Failures of the Past are the Lessons for Today**

1:45 **What CBER Wants to See in the Development of a Robust, Scalable Manufacturing Process for Engineered Tissues**

2:15 **Multi-platform-based Characterization of Cell and Tissue Processes: Application of DOE and QbD Principles**

2:45 **Role of Data Management and Artificial Intelligence in Automation of Biomanufacturing Process Development**

3:15 *Networking Refreshment Break*

3:45 **Integrated, Closed System PAT Analytics for Advanced Auto Feedback Control of CPPs in Single Use Bioreactors – Reactive Analytics**

4:15 **Automation and Robotics in Large-Scale Engineered Tissue Manufacturing**

4:45 **Cost Considerations in Scaling up Adherent Cell Culture**

5:15 **Panel Discussion – Title TBD**

5:50 **Chairperson's Closing Remarks and Look Ahead**

6:00 *Reception*

Workshop 3: Cell & Gene Connect – Partnering Track

9:00 *Continental Breakfast*

10:00 **Welcome Remarks & Opening Panel: Evolving Landscape of Cell & Gene Therapies**

11:30 **Panel Discussion: New Partnering Models: R&D, Hospitals, Manufacturer**

12:30 **Lunch Presentations**

1:30 **Panel Discussion: Public/Private Partnerships**

2:30 **Panel Discussion: Market Access**

3:45 **Presentations**

5:00 **Panel Discussion: Next Generation Therapies**

6:00 *Reception*

Partnering meetings will take place from 11:30 am - 6:00 pm

7:00	*Registration and Coffee*		
	PLENARY SESSION		
8:00	**Chairperson's Remarks** **Miguel Forte,** CEO, **Zelluna Immunotherapy,** *Norway*		
	Beyond First Generation CAR-Ts - Manufacturing Gene-Edited CAR-Ts, NK Cells and TCRs		
8:05	**CASE STUDY: Novartis – Beyond CD19** • Feedback on pipelines and candidates beyond first generation CAR-T's • What has been learned from 2017 success and what is next		
8:25	**CASE STUDY: Adaptimmune – SPEAR T-cells** • Case study on TCR candidates **Dan Williams,** VP Research and Technology Operations, **Adaptimmune,** *UK*		
8:45	**CASE STUDY: Treatments Attacking Solid and Blood Borne Tumors**		
9:05	**PANEL DISCUSSION: What Can Be Learned from those Already Manufacturing at Commercial Scale** • What is the next big thing beyond CD19? • How do manufacturing strategies differ for solid tumours, NK cells, TCR's as opposed to CAR-T • Is investment in the market too focussed on CAR-T? Is it neglecting other therapies?		
	Spotlight Presentation		
9:25	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: **Jennifer Wickett, Tel: +1 857 504 6694; Email: jennifer.wickett@knect365.com**		
9:45	*Networking Refreshment Break in the Biotech Week Boston Poster & Exhibit Hall*		
	Bioprocessing	**Commercialization**	**Pre-clinical and Clinical Development**
10:10	**Chairperson's Remarks**	**Chairperson's Remarks**	**Chairperson's Remarks** **Ken LeClair,** VP, Technical Development and Manufacturing, **Editad Medicine,** *USA*
	Monitoring Quality Across the Process – Process and Automated Analytics for Cell Therapies	**Strategies and Facility Design for Commercial Stage Manufacturing – End-to-End Solutions**	**Current Pipeline Updates**
10:15	**The Evolution of Analytics in CAR-T Cell Therapy** CAR-T cell therapy is quickly emerging as an approach that has the potential to be a curative treatment for myriad oncology indications. As this immunotherapy advances in the industry, the analytical tools that exist to determine and track critical quality attributes (CQA) must evolve alongside the treatment. Recent advances in the manufacturing processes have led to improved analytical methods that can measure and track CQA with higher accuracy and reliability. Amgen is positioning itself to be a leader in cell and gene therapy, and as part of this effort we will discuss the next generation of analytical approaches that need to evolve to supplement a better understanding of products. **Tariq Warsi,** Senior Scientist, Process Development, **Amgen,** *USA*	**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? **Donna Rill,** Vice President of Manufacturing, **Cell Medica Inc**	**CASE STUDY: Nohla Therapeutics** **Colleen Delaney,** Founder and Chief Medical Officer, **Nohla Therapeutics,** *USA*

	Bioprocessing	Commercialization	Pre-clinical and Clinical Development for Cell and Gene Therapies
	Monitoring Quality Across the Process – Process and Automated Analytics for Cell Therapies	**Strategies and Facility Design for Commercial Stage Manufacturing – End-to-End Solutions**	**Current Pipeline Updates**
10:35	**Analytical Method Establishment and Qualification** • What type of qualification activities are appropriate • What will this look like when the method is validated further along in the process? • Specific case studies **Ruti Goldberg,** QC Validation Manager, **Pluristem,** *Israel*	**Implementation of an Affordable and Scalable Manufacturing Strategy** • Case study **Jon Gunther,** Associate Director Technology Strategy and Innovation, **Juno Therapeutics,** *USA*	**T Lymphocyte Targeting Strategies: CAR-T and TCR-T Success Challenges and Path Forward** • Status to the current field of T lymphocyte adoptive cell therapy • Current opportunities and challenges • Comparison of CAR-T vs TCR-T • Future perspectives **Miguel Forte,** CEO, **Zelluna Immunotherapy,** *Norway*
10:55	**New Analytical Technologies for Facilitating Qbd in Process Analytics** • Product profiling • A look a product potency and functionality **Junxia Wang,** Director, Analytical Development, **Mustang Bio Inc.,** *USA*	**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 **Trent Munro,** Executive Director, Process Development, **Amgen Inc.,** *USA* **Lan Cao,** Senior Director, Cell Therapy Head of Product Development and Clinical Manufacturing, **Takeda Pharmaceuticals International Co.,** *USA*	**Pre-clinical and Clinical Development of a Next Generation Stromal Cell Therapy** **Larry Couture,** CEO, **Orbsen Therapeutics,** *USA*
11:15	**Improving Confidence in Cell Therapy Analytical Methods: When Cell Counts Count** Analytical methods are essential for establishing quality attributes of cell-based products and for monitoring key steps in the manufacturing process. Measurement assurance strategies and standards for cell therapy product characterization have been increasingly recognized for their critical roles in streamlining efforts in R&D, translation, manufacturing and regulatory submissions. Discussions are underway within various standards development organizations to develop standards to ensure quality, consistency and measurement confidence for cell-based products. Cell count is a fundamental measurement for cell therapy products, underpinning quality attributes (e.g. identity, purity, potency) used in characterization. Although performed routinely in laboratories for over a century, this measurement now requires greater confidence and specification to support the development of cell-based products. NIST, in collaboration with other government agencies and industry stakeholders is developing approaches to provide fit-for-purpose measurement assurance strategies, in the form of documentary standards, experimental designs, and control materials to improve cell counting measurements. These strategies can be further extended to other aspects of cell characterization that face similar measurement challenges. **Sumona Sarkar,** Biomedical Engineer, **NIST,** *USA*		
	Technology Workshops		
11:45	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: **Jennifer Wickett, Tel: +1 857 504 6694; Email: jennifer.wickett@knect365.com**		
12:45	*Networking Luncheon in the Biotech Week Boston Poster & Exhibit Hall*		

	Bioprocessing	Commercialization	Pre-clinical and Clinical Development for Cell and Gene Therapies
	Analytics Associated with Cell and Gene Therapy Bioprocessing – Process Modelling and Design Space		**Current Pipeline Updates**
1:25	**Combination of Analytical Methods for Characterization of Viral Vectors** • New combinations of analytical methods used in development and production of Lentiviral vectors for gene therapy • Performance of Lentiviral quantification with molecular methods **Gillian Payne,** Director, Vector Analytics, **bluebird bio,** *USA*		**Marrow Infiltrating Lymphocytes (MILs): Adoptive T Cell Therapy from a Road Less Travelled By** We have developed a method to isolate, activate and expand bone marrow T cells, the product of which we call MILs. While having some similarities to other types of adoptive T cell therapy we believe our product is unique relative to other products currently being developed by virtue of the fact that MILs are the only adoptive T cell therapy where the cells are both inherently tumor-specific and of a central memory phenotype. Herein we will describe the distinctive properties of MILs, how we have used them in multiple myeloma and other hematologic malignancies, how we plan to use them for solid cancer indications and finally how they may serve as a platform cell for genetic modification. **Kimberly A. Noonan, Ph.D., MPH,** Co-Founder and CSO, **WindMIL Therapeutics, Inc.,** *USA*
	Spotlight Presentation		
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2:25	*Networking Refreshment Break in the Biotech Week Boston Poster & Exhibit Hall*		
	BWB KEYNOTE SESSION		
2:45	 **High-Impact Ideas and Use-Inspired Research….a chat with MIT's Bob Langer on How to Create Innovations That Matter** **Dr. Robert Langer, Sc.D.,** David H. Koch Institute Professor, Koch Institute of Integrative Cancer Research, **Massachusetts Institute of Technology**		
3:30	 **Bioprocessing 4.0 – Digital Technologies are Transforming Biologics Manufacturing** **Thomas Seewoester, Ph.D.,** Executive Director, Plant Manager, **Amgen**		
4:15	 **The Complex World of Biosimilar Process Development** **Elsie DeBella,** Vice President, Biologics Process and CMC Development, **Momenta Pharmaceuticals**		
4:45	*Grand Opening of the Poster & Exhibit Hall and Cocktail Reception*		
6:30	*End of Day One*		

7:00 *Registration and Coffee*

PLENARY SESSION

8:00 **Chairperson's Remarks**

Regulatory Updates and Recent Progress: US, Japan and EU

8:05 **It Depends: Understanding the Science and History behind the Regulations**

Nancy Markovitz, Assoc. Director, Regulatory Affairs CMC, **Nantkwest,** *USA*

8:35 **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:

• IND's and BLA's – expectations • Raw materials and viral safety considerations

• Autologous therapies – who should take the burden? The manufacturer or the supplier? • CE marking

• Process development and new process implementation – what do the regulators think? • Analytics and CMC – Potency assays, comparability etc.

Spotlight Presentation

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9:45 *Networking Refreshment Break in the Biotech Week Boston Poster & Exhibit Hall*

	Bioprocessing	Commercialization	Pre-clinical and Clinical Development
10:10	**Chairperson's Remarks** **Jon A. Rowley,** Founder & Chief Technology Officer, **RoosterBio, Inc.,** *USA*	**Chairperson's Remarks**	**Chairperson's Remarks**
	Process Automation and Closed Systems – Applications and Case Studies	**Internal Vs. External Manufacturing and CMO/CDMO Management throughout Development Lifecycle**	**Process Validation and Supply Chain Strategies in the Clinic**
10:30	**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 • 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 **Ali Mohamed,** VP, CMC, **Immatics,** *USA*	**DUAL DIALOGUE: When to Make the Decision to Either Insource or Outsource** **Talk One: Becoming Cell Therapy Makers - Opportunities And Challenges In "In House" Manufacturing of Cell Therapy Products** **Lior Raviv,** Vice President Development, **Pluristem,** *Israel*	**The Balancing Act: Engineering vs. Tinkering Platform Processes with GMP Manufacturing in Mind** At Adverum, our focus is on bringing innovation to patients in need. With that mindset, we are leveraging our next-generation adeno-associated virus (AAV)-based directed evolution platform to identify and develop new therapies. Within Process Development, we have built an adaptable platform process that works across multiple therapeutic constructs, at varying scales. As we continue to develop new products, we are assessing new technologies to refine and improve our platform, while preserving aspects that enable versatility. In this talk, we will review aspects of our platform process and provide insight into potential changes that are under consideration, based on our scale-up experiences. **Pratik Jaluria,** Executive Director, Process Development and Manufacturing, **Adverum,** *USA*

	Bioprocessing	Commercialization	Pre-clinical and Clinical Development for Cell and Gene Therapies
	Monitoring Quality Across the Process – Process and Automated Analytics for Cell Therapies	**Internal Vs. External Manufacturing and CMO/CDMO Management throughout Development Lifecycle**	**Process Validation and Supply Chain Strategies in the Clinic**
11:00	**The Economics of Closed Systems – Ensuring Reproducibility** • How can showing reproducibility then lead to a more economical scale up or out process? • Using closed systems to make facilities more economical • How does having a closed system impact autologous manufacturing and how does this affect the design of the plant? **Ohad Karnieli,** CEO & Co-Founder, **ATVIO Biotech,** *Israel*	**DUAL DIALOGUE** *(continued)*: **When to Make the Decision to Either Insource or Outsource** **Talk Two: Phase-Appropriate Manufacturing - Finding the Right Balance Between Internal and External Manufacturing as a Cell Therapy Company Grows** **Chris Gemmiti,** VP Operations, **Sentien Biotechnologies, Inc.,** *USA*	**Developing a Scaled Process for Manufacturing Stem Cell Derived Islets** • ESCs as starting material, allogeneic approach, selection of clinical line • Differentiation optimization Scale-up to bioreactors • Raw materials for cGMP manufacturing (evaluation, cost, supply chain) • Path to commercialization **Austin Thiel,** Senior Principal Scientist, **Semma Therapeutics,** *USA*
11:30	**AUTOMATION EXPERT PANEL** Knect365 is looking for 5 speakers to join our expert led discussion panel to talk on the below topics: • Case studies/feedback on closed systems in general • Is there a need to have closed systems in clean rooms? • Process automated sampling • What can we learn from automation for MAbs? • How do you make thinks connectable between different devices? • Automation linked to cost of goods **Ohad Karnieli,** CEO & Co-Founder, **ATVIO Biotech**, *Israel* **Ali Mohamed,** VP, CMC, **Immatics,** *USA* **Lior Raviv,** Vice President Development, **Pluristem,** *Israel*	**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? **Wouter Van t'Hof,** Cord Blood Bank Director, **Cleveland Cord Blood Centre,** *USA*	**Ensuring Enough Supply and Magnitude in Terms of Patient and Dose Increases** **Someet Narang,** Senior Scientist, **MedImmune,** *USA*
	Spotlight Presentation		
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12:35	*Networking Luncheon in the Biotech Week Boston Poster & Exhibit Hall*		

	Bioprocessing	Commercialization	Pre-clinical and Clinical Development for Cell and Gene Therapies
	Reducing the Cost of Manufacturing – Costs of Goods Calculations and Considerations	**Internal Vs. External Manufacturing and CMO/CDMO Management throughout Development Lifecycle**	**Collaboration for End-to- End Solutions in Preclinical and Clinical Research**
1:40	**Dual Dialogue: Cost of Goods Calculations for Cell Therapy Products** Knect365 is looking for 2 speakers to present back to back on carrying out cost of goods calculations when manufacturing cell therapy products • Case studies **Talk One: Better Processes with "Better" Cells – Engineering Cells for Enhanced Manufacturability.** While much of the focus of gene engineering in the CGT field is on therapeutic activities, synthetic biology presents a significant opportunity to augment our approaches to cell manufacturing. How might we employ cell engineering strategies to improve product quality, reduce COGs, or better understand and control our manufacturing processes? **Nick Timmins,** VP Process Sciences, **BlueRock Therapeutics,** *Canada* **Talk Two: TBA** **Boaz Leshem,** Vice President, Operations and Manufacturing, **Pluristem,** *Israel*	**CDMO Expert Led Panel: How Do You Choose Your Development Partner?** • How do you choose your CDMO • What capabilities should they have? • Centralised manufacturing • Regional manufacturing • Local manufacturing • Considerations for autologous, allogeneic and gene therapy products • Tech transfer of processes to new facilities *Confirmed speakers:* **Chris Gemmiti,** VP Operations, **Sentien Biotechnologies, Inc.,** *USA* **Lior Raviv,** Vice President Development, **Pluristem,** *Israel* **David Peritt,** Chief Technology Officer, **Sigilon Therapeutics,** *USA* **Wouter Van t'Hof,** Cord Blood Bank Director, **Cleveland Cord Blood Centre,** *USA*	**CASE STUDIES: Low Cost Automation to Drive Efficiency and Reproducibility** In basic and preclinical research associated with cell therapy, most cell processing is performed manually, straining resources as well as posing challenges in reproducibility and consistency. With dendritic cell based therapies as the context, several case studies will be presented to illustrate how simple automation solutions can overcome these constraints as well as help optimize future larger scale process development. **Shashi Murthy,** Professor of Chemical Engineering, **Northeastern University,** *USA*
		Facility Design and Flexibility for Efficient Cell Therapy Manufacturing	
2:10		**CASE STUDY: Key Success Factors for Planning and Building a Facility for Cell Therapies** **Knut Niss,** Chief Technology Officer, **Mustang Bio,** *USA*	**Leveraging Academic and Commercial Contract Manufacturing Organizations to Facilitate Accelerated FDA Approvals** The 21st Century Cures Act and the FDA mandate for accelerating the approval process for cellular therapies has impact on the approach to GMP manufacturing for early phase clinical trials. We have embraced an academic and industry partnership to facilitate multicenter clinical trials using Tumor Infiltrating Lymphocytes (TIL) and CAR-T cells for liquid and solid tumors. Through a combination of process improvements intended to shorten product manufacturing time, as well as innovative implementation of GMP practices, we have maximized the contribution of academic and contract manufacturing organizations to support multiple on-going trials intended to receive accelerated FDA approval for a new cellular therapy. **Linda Kelley,** Senior Member, Director Cell Therapy Facility, **Moffitt Cancer Center,** *USA*
	Technology Workshops		
2:40	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: **Jennifer Wickett, Tel: +1 857 504 6694; Email: jennifer.wickett@knect365.com**		
3:10	*Networking Refreshment Break in the Biotech Week Boston Poster & Exhibit Hall*		

	Bioprocessing	Commercialization	Pre-clinical and Clinical Development for Cell and Gene Therapies
	Manufacturing and Process Development Strategies – Solutions for Efficient Scale Up and Scale Out	**Viral Vector Manufacturing Strategies for Commercialization**	**Cell Therapy Clinical Progression and Key Business Deals and Partnership Milestones**
4:00	**Meeting the Challenge of Delivering Autologous Therapies in the Commercial Sector** • Case study • What is the future for autologous therapies? • Are they commercially viable • What are the strategies for ensuring that they are?	**Developing a Commercially-Ready Process for Viral Vector Manufacturing** ·What can we apply from the 30+ years of biologics manufacturing? ·Strategies for developing a validation plan ·Leveraging platforms to provide manufacturing efficiencies ·Supply of raw materials and viral banks for low cadence products **John Kerwin,** Manufacturing Scientist, Gene Therapy, **Biogen,** *USA*	**Current State of Play for the Cell Therapy Industry in the Clinic – Stats and Facts** **Patricia Reilly,** Head of Intelligence Alliances and Unification, Pharma Intelligence, **Informa,** *USA*
4:30	**Delivering New Investigational Medicinal Products to the Clinic Through Next-Generation Allogeneic Cell Therapies** **Bryan D. Utter,** Procurement Manager, GMP Solutions, **Cellectis Inc.,** *USA*	**Strategies to Deliver Scalable and Reliable Lentiviral Vector Biomanufacturing** Large-scale clinical production of lentiviral vectors (LV) using current good manufacturing practice (cGMP) methods comes with significant challenges. We have established the CytegrityTM stable cell line system for LV bioproduction and have defined key process, quality and regulatory parameters needed to achieve desired productivity and quality across multiples scales and different bioproduction systems. This approach has allowed scalable bioproduction of LV required for Phase I and II clinical trials, while paving the way for future commercialization. **Jeffrey S. Bartlett,** Chief Scientific Officer, Senior Vice President, Research and Development, **Calimmune, Inc.,** *USA*	**What Academia are Looking for in a Development Partner** • Case study • What are academia doing the research looking for in a business partner? • How can these partnerships work to drive success? **Olive J Sturtevant,** Administrative Director of Connell & O'Reilly Families, Cell Manipulation Core Facility, **Dana Farber Cancer Institute**
5:00	**The Next Wave of Cell Therapy Product – Allogeneic Manufacturing Solutions** • Strategies for manufacturing an 'off the shelf' product • Regulatory perspectives on this • How can you ensure large batch sizes • Scaling out solutions **Yajin (Jenny) Ni,** Associate Research Fellow, Director Manufacturing Process Development Lead, **Allogene Therapeutics, Inc., USA**	**Solving Challenges in Lentiviral Vector Manufacturing** For a long time commercial scale viral vector manufacturing was a bottleneck in the field. Biggest challenges were related to those vectors, such as lentiviral vectors, requiring plasmid transfection of adherent cells in big volumes. We have developed a commercial scale lentiviral vector manufacturing process utilizing PEIpro® based four plasmid transfection and the iCELLis® fixed-bed bioreactor for adherent 293T cells. iCELLis Nano (2.67-4 m2) was used for optimizing several production parameters for scale-up. For scalable LV production, perfusion rate control by measuring cell metabolite concentrations in the bioreactor leads to higher productivity and reduced costs. Optimization of transfection conditions, cell seeding density for targeted cell concentration during transfection, use of low compaction fixed-bed and lowering the culture pH have a positive effect on LV productivity. Developed process was scaled up into iCELLis500 and were able to show the real commercial scale lentiviral vector manufacturing in commercial scale yielding >10^16 viral particles. Commercial scale upstream process development was followed by development of scalable downstream process. Virus containing medium was harvested by perfusion, concentrated and diafiltrated by tangential flow filtration and virus was purified using anion exchange chromatography. These results show for the first time that plasmid transfection of adherent cells in iCELLis bioreactor is scalable from bench level to clinical scale LV production. **Hanna Leinonen,** Senior Scientist, **Kuopio Center for Gene and Cell Therapy,** *Finland*	**DISCUSSION PANEL: Driving Collaboration for Development In Cell and Gene Therapy** **Linda Kelley,** Senior Member, Director Cell Therapy Facility, **Moffitt Cancer Center, USA** **Olive J Sturtevant,** Administrative Director of Connell & O'Reilly Families, Cell Manipulation Core Facility, **Dana Farber Cancer Institute**
5:30	*Cocktail Reception in the Poster & Exhibition Hall*		
6:30	*End of Day Two*		

7:00	*Registration and Coffee*
	CELL THERAPY BIOPROCESSING AND COMMERCIALIZATION
7:55	**Chairperson's Remarks** **Erik J. Woods,** Co-Founder and Chief Science Officer, **Ossium Health, Inc.,** *USA*
	Logistics, Supply Chain, and Cryopreservation Techniques
8:00	**Cryobiology – Effects of Freezing and Thawing on Cell Viability** • Case study on the effect freezing and thawing has on cell viability • How can manufacturers ensure optimum viability?
8:30	**Importance of a Temperature Controlled Supply Chain for Therapeutic Cells Prior to their Cryopreservation** • Case study
9:00	**Cryopreservation: A Critical Tool for MSC Translation** **James Ankrum,** Assistant Professor, Biomedical Engineering, **The University of Iowa,** *USA*
9:30	*Networking Refreshment Break in the Biotech Week Boston Poster & Exhibit Hall*
	Vein-to Vein Supply Chain and Transportation Considerations
10:15	**Transportation Strategies from Manufacture to the Patient: Elevating Bottle Necks** • Logistics of the transfer from manufacture to patient • Current systems used for transport/cryogenically freezing • Preparing samples for use • Systems used to track shipments • What improvements can be made • Storage and packaging
10:45	**Understanding the Regulatory Requirements of Sample Handling** • What are the specific handling requirements from regulators? • How do you meet the documentation and regulatory compliance for storage?
11:15	**LOGISTICS ROUND-TABLES: Analyzing where the Gaps Lie** Knect365 is looking for 4 round-table leaders to host round-tables 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
	Technology Workshops
11:45	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: **Jennifer Wickett, Tel: +1 857 504 6694; Email: jennifer.wickett@knect365.com**
12:15	*Networking Luncheon in the Biotech Week Boston Poster & Exhibit Hall*

	LOGISTICS, SUPPLY CHAIN, AND CRYOPRESERVATION TECHNIQUES
1:30	**CASE STUDY: Best Practice for Managing Particulates and Visible Inspections** **Erik J. Woods,** Co-Founder and Chief Science Officer, **Ossium Health, Inc.,** *USA*
2:00	**Leachable Profiles of Final Product Containers** • 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
	Managing the Chain of Identity in Cell Therapeutics Manufacturing – Supply Chain Security
2:30	**Implementation of Technologies and Workflows to Achieve High Quality Patient Specific Batches** • Improving chain of identity • Reduction of errors caused by manual procedures **Jian Irish,** Senior Vice President, Supply Chain, **Kite Pharma,** *USA*
3:00	**Chairpersons Closing Remarks**
3:10	*End of Conference*

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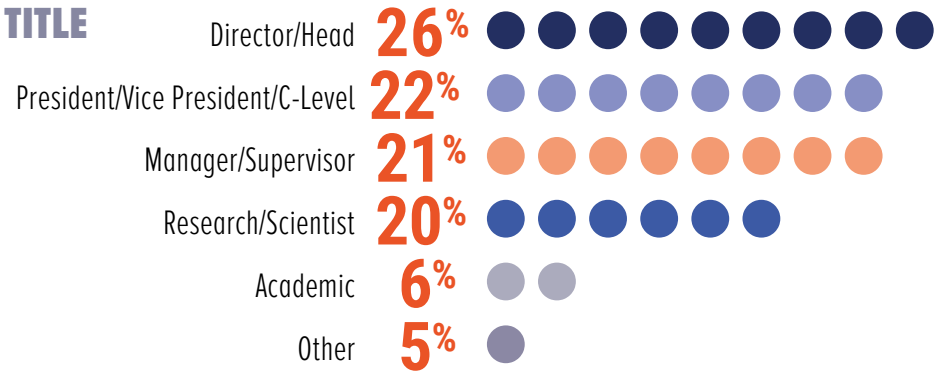
ATTENDEES BY TITLE



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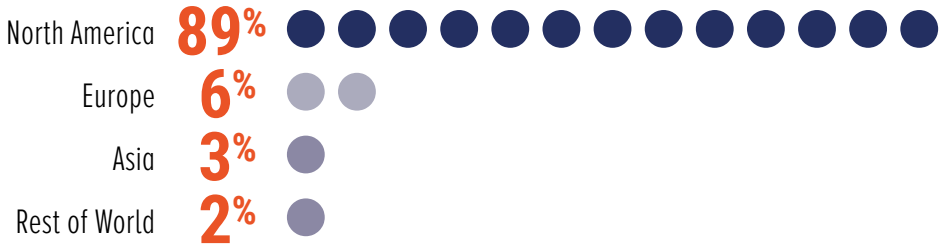

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