# Cell & Gene Therapy Bioprocessing & Commercialization



Cell Therapy
Manufacturing &
Gene Therapy Congress

# THE CELL AND GENE THERAPY CONFERENCE FOR GROUND BREAKING BIOPROCESSING, MANUFACTURING & SUPPLY CHAIN STRATEGIES

World renowned leaders share the latest analytical techniques & vector technologies to revolutionize your cell, gene & gene edited ex vivo cell therapy programs

### HEAR FROM THE BRIGHTEST MINDS IN CELL AND GENE THERAPY



Kai Pinkernell
Chief Medical Officer (CMO) and Chief
Development Officer (CDO), Medigene,
Germany

**Jennifer Adrian** 

Operations, bluebird bio, USA



Philippe Parone
Director, Industrialization, Celyad



Mike Fraser
General Manager of EMEA,
AveXis Inc



Kathryn Corzo
Head of Development Oncology Cell
Therapies, Takeda Oncology



**Devyn Smith**COO, Sigilon Therapeutics



**Betsy Rezner**Director, Process & Assay Development at Fate Therapeutics Inc.

Manager, Cellular Therapy Manufacturing



**Dominic Schmidt**Partner, Syncona





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Our networking platform will make it easy to connect with the right people - helping you to have the conversations that matter with the people who matter to you.



"I am glad to see that Informa Connect is paving the way to run Cell Therapy Bioprocessing & Commercialization and Cell & Gene Therapy Manufacturing Europe as a Virtual Conference and Exhibition during the Covid19 pandemic. It is particularly important since cell therapies are in the forefront of Covid19 tested treatments."

Lior Raviv, Vice President Development & Operations, Pluristem Therapeutics



# **Monday 19th October**

		Exhibition Viewing Time	& Live Discussion Groups			
	Cell Therapy	Ex Vivo Cell Therapy	Gene Therapy	Advanced Tools for Cell and Tissue Manufacturing: 20/20 View		
7:30	Data Governance and Data Integrity as a framework during Process Development Sara Levy, CSV & Data integrity Manager, Pluristem Therapeutics Inc., Israel	Senti Bio Case Study – Gene Edited MSc Philip Lee, COO and Co-Founder, Senti Biosciences, USA	Next Generation Cell Line Development & Large-Scale Bioprocessing Technology Sam Wadsworth, Chief Scientific Officer, Ultragenyx Gene Therapy, USA	Scalable, Consistent, Cost-effective Manufacturing for Tissues and Organs Mary Clare McCorry Director, Technology and Process Development, ARMI   BioFabUSA		
7:50	Speaker Q&A - Cell Therapy Process Development  Moderator: Lior Raviv, Vice President Development & Operations, Pluristem Therapeutics Inc., Israel Speakers: Sara Levy, CSV & Data integrity Manager, Pluristem Therapeutics Inc. Mustafa Munye, Lead Scientist, Cell and Gene Therapy Catapult Rachel Yost, Senior Process Engineer, Juno Therapeutics Inc.	Speaker Q&A - Auto vs. Allo Manufacturing & Infrastructure  Moderator: Geoffrey Hodge, formerly, Chief Technical Officer, Unum Therapeutics Inc., USA Speakers: Philip Lee, COO and Co-Founder, Senti Biosciences, USA Gregory Russotti, Chief Technology Officer, Century Therapeutics, LLC, USA	Speaker Q&A Sam Wadsworth, Chief Scientific Officer, Ultragenyx Gene Therapy	The Importance of High Quality Raw Materials for Developing your Cell or Gene-Modified Cell Therapy: A Master Cell Bank Case Study Ben Fryer, Co-Founder, Pluristyx		
8:15	Coffee Break and Exhibition Viewing Time					
	Live Plenary Session					
9:00	Opening Remarks from the Chairperson Miguel Forte, CEO, Bone Therapeutics, Belgium					
10:00	Claudia Berron, Senior Vice President, Business Development and Commercial Operations – Biopharma Production, Avantor, <i>USA</i> Camillo Ricordi, MD, FNAI, Stacy Joy Goodman Professor of Surgery and Chief, Division of Cellular Transplantation, Distinguished Professor of Medicine, Professor of Biomedical Engineering, Microbiology and Immunology, Director, Diabetes Research Institute and Cell Transplant Center, University of Miami, Fellow, National Academy of Inventors, <i>USA</i> , Member, Italian Supreme Council of Health  PANEL: Investment in the CGT space: trends, technologies and early stage success  Jak Knowles, VP Venture Investments, Bayer  Mike Zhao, Senior Vice President, MSQ Ventures, <i>USA</i>					
	Joey Mason, Vice President, M Ventures Dominic Schmidt, Partner, Syncona, <i>UK</i>					
11:00	Sponsor Presentation					
11.00	Exhibition Viewing Time & Live Discussion Groups					
11:30	Risk-Based Approaches for Autologous CAR T-Cell Therapy Comparability Erica Bust, Sr. Process Engineer, Juno Therapeutics, a Bristol Myers Squibb Company, USA	Encapsulation Approaches – A Case study from Sigilon Martha Rook, SVP, Manufacturing, Sigilon Therapeutics Inc., USA	Assessing the Future Prospects of Upstream Bioprocessing Systems for Commercial AAV Production Scott Jeffers, Director, UniQure, USA	Optimization of Cell Culture and Differentiation Jan Jensen, CEO and Founder, Trailhead Biosystems		
11:50	Speaker Q&A - Process Development Considerations & Strategies Moderator: Jon Rowley, Founder & Chief Product Officer, RoosterBio, Inc., USA Speakers: Margarida Serra, Head of Stem Cell Bioengineering Lab, iBET - Instituto de Biologia Experimental e	Speaker Q&A - Auto vs. Allo Manufacturing & Infrastructure  Moderator: Ali Mohamed, VP CMC, Immatics, USA Speakers: Shyam Patel, Director Business Development, California Institute for Regenerative Medicine, USA Martha Rook, SVP, Manufacturing, Sigilon Therapeutics Inc. USA	Speaker Q&A - High Throughput Applications in Production Platforms & Enabling Manufacturing Tech Speakers: Scott Jeffers, Director, UniQure, USA Sha Sha, Postdoc, Massachusetts Institute of Technology, USA	Unique Methods for Cell Harvest Sonia Bulsara, Application Specialist Manager, US & Canada, Cell and Gene Therapy, Cytiva		
	Tecnológica. Erica Bust, Sr. Process Engineer, Juno Therapeutics, a Bristol Myers Squibb Company, <i>USA</i>	Vadim Klyushnichenko, VP Pharmaceutical Development and Quality, Calibr at Scripps Research, <i>USA</i>				

# **Tuesday 20th October**

	Cell Therapy	Ex Vivo Ce	ell Therapy	Gene Therapy	Advanced Tools for Cell and Tissue Manufacturing: 20/20 View
8:00	Exhibition Viewing Time & Networking Breakfast				
	Live Plenary Session				
9:00	Opening Remarks from the Chairperson				
9:10	Fate Therapeutic's Off-the-shelf, iPSC-derived CAR NK Cell Cancer Immunotherapy Programs  Betsy Rezner, Senior Director, Process & Assay Development, Fate Therapeutics Inc., USA				
9:30	Scalable Manufacture Platform of Human iPS-NK Cells for Off-the-Shelf Cell Therapies  Allen Feng, Chief Scientific Officer, HebeCell Corp, USA				
9:50	Non- Gene edited Allogeneic cells Philippe Parone, Director, Industrialization, <i>Celyad, Belgium</i>				
10:10	The Potential of CAR-NK  Kathryn Corzo, Head of Development Oncology Cell Therapies, Takeda Oncology				
10:30	Sponsored Presentation				
11:00	Starting Material Standardiz Christiane Niederlaender, Director, AMBR Consulting			allenges as a Result of Viral Vectors  e Director, External Manufacturing, Kite Pharma, USA	Scaffold Fabrication Michael Francis, Chief Science Officer & Founder, Embody, Faculty at EVMS
11:20	Speaker Q&A - Raw Material, Viral Vector & Supply Chain Considerations  Moderator:  Christopher Bravery, Principal Consultant, Consulting on Advanced Biologicals, UK  Speakers:  Christiane Niederlaender, Director, AMBR Consulting Ltd, formerly MHRA, UK  Scott R. Burger, Principal, Advanced Cell & Gene Therapy, LLC, USA  Tom Walls, Associate Director Supply Chain, bluebird bio, USA			Essential to Biological Relevance and Translational Potential: Standardized, Well-Characterized GMP-grade Tissue-Specific Extracellular Matrix (ECM) Components for Scaffold Fabrication  John O'Neill, Co-Founder & Chief Scientific Officer, Xylyx Bio, Inc.	
11:45	End of Day				

**Wednesday 21st October** 

	Treditionally 2 lot obtained					
	Cell Therapy	Ex Vivo Cell Therapy	Gene Therapy	Advanced Tools for Cell and Tissue Manufacturing: 20/20 View		
7:30	Analytical Method Development and Validati Foundation & Toolkit Lara Ionescu Silverman, Senior Director, Research and		The Case for rAAV Titration by HPLC Franz Schnetzinger, Director Analytical Development, Gyroscope Therapeutics	Developing Your Manufacturing Process from A->Z Priya Baraniak, Vice President, Corporate Development, Organobio		
7:50	Speaker Q&A - Cell Therapy Analytics — Test Moderator: Barrett J. Nehila, Associate Director, Analyt Speakers: Steve Oh, Director of the Stem Cell Bioprocessing, A*S' Lara Ionescu Silverman, Senior Director, Research and	TAR, Bioprocessing Technology Institute, Singapore	Speaker Q&A - Gene Therapy Upstream & Downstream Considerations Thomas R. Kreil, VP, Global Head Pathogen Safety, Takeda Inc., Austria	Speaker Q&A		
8:15		Coffee & Exhibition Viewing Time				
		Live Plena	ry Session			
9:00	Opening Remarks from the Chairperson Anthony Davies, Founder & CEO, Dark Horse Consulting, USA					
9:10	State of the Industry  Janet Lynch Lambert, Chief Executive Office, Alliance for Regenerative Medicine, USA					
9:45	DUAL DIALOGUE: Creating a Partnership in Advanced Therapies to Enable Seamless Transition of a Program  Janelle A. Sabo, PharmD, RPh, MBA, Global Head, Clinical Supplies, Systems and Innovation, Eli Lilly Research and Development Devyn Smith, COO, Sigilon Therapeutics					
10:20	PANEL: Reimbursement Models for Novel Therapies  Moderator: Kevin Mayo, Managing Partner, Venture Genome  Phillip D. Carter, Head, U.S. Market Access, Orchard Therapeutics Mike Fraser, General Manager of EMEA, AveXis Inc., Switzerland					
11:00	Sponsor Presentation					
11:30	Augmenting Automated Analytics for Cell & Gene Therapy Manufacture  Veeren Chauhan, Nottingham Research Fellow, Bioinspired Therapeutics, University of Nottingham, USA	erne Therapy Manufacture eren Chauhan, Nottingham Research Fellow, Bio- eren Chauhan, Nottingham Research Fellow, Bio-		Development of Modular Biofabrication Platforms for Diverse Tissue Engineering Applications George Christ, Professor of Biomedical Engineering and Orthopaedic Surgery, University of Virginia		
11:50	Speaker Q&A - Cell Therapy Analytics – Testing, Characterization & Validation Strategies Speakers: Michael Roberts, Chief Technology Officer (Europe), Asklepios BioPharmaceutical, Inc., UK Qin Zou, Associate Research Fellow, Pfizer Analytics Jennifer L. Dashnau, Head of Analytical Development and Quality Control, Century Therapeutics	Speaker Q&A - Cryopreservation & Vein-to-vein Considerations  Moderator: Donald Singer, Consultant, formerly GSK Senior Fellow, USA  Speakers: Erik J. Woods, Co-Founder, EVP of Technical Operations & Chief Science Officer, Ossium Health, Inc, USA Jason Acker, Professor, Laboratory Medicine and Pathology, University of Alberta, Canada David McKenna, Professor and American Red Cross Chair in Transfusion Medicine, Department of Laboratory Medicine and Pathology, University of Minnesota, USA	Speaker Q&A - Gene Therapy Analytics Moderator: Franz Schnetzinger, Director Quality Control & CMC Analytical Development, Gyroscope Therapeutics Limited, UK Speakers: David Dobnik, Senior Research Associate, National Institute of Biology, Slovenia Michael J. DiBiasio-White, Sr. Scientist: BioProcess Development/Protein Sciences, Ring Therapeutics, USA	Novel Bioreactor System for Fabrication of Musculoskeletal Tissues Lisa Larkin, Ph.D., Professor Molecular & Integrative Physiology Biomedical Engineering, University of Michigan, USA		
12:15	End of Day					
	Life of Day					

# **Thursday 22nd October**

	Cell Therapy	Ex Vivo Cell Therapy	Gene Therapy	Advanced Tools for Cell and Tissue Manufacturing: 20/20 View		
8:00	Process Control strategies for Cell Therapy Rachel Yost, Senior Process Engineer, Juno Therapeutics Inc., USA	Delivering on the Promise of Producing Cost-Effective, High-Quality Allogeneic Immune Cell Therapies Gregory Russotti, Chief Technology Officer, Century Therapeutics, LLC, USA	<b>Optimizing Viral Vector Production</b> Nicole Nunez, Process Development Scientist, Eureka Therapeutics, <i>USA</i>	Microscale Sensors and Systems for Tissue Engineering and Organs on a Chip Applications Mehmet Dokmeci, Adjunct Professor, University of California (UCLA)		
8:20	Sponsor Presentation	Sponsor Presentation	Sponsor Presentation	Robust Preclinical Oxygen Imager JIVA- 25 for Cancer and Regenerative Medicine Therapy Development Mrignayani Kotecha, Co-Founder, CEO, 02M Technologies		
8:50	Coffee & Exhibition Viewing Time					
	Live Plenary Session					
9:20	Opening Remarks from the Chairperson  Nick Timmins, VP of Cell Technologies, Artisan Biotechnologies, Canada					
9:30	PANEL: Strategies and Challenges in Manufacturing and Commercialization					
	Thomas Bollenbach, CTO, Advanced Regenerative Manufacturing Institute					
	Panelists:  Mahendra Rao, CEO, panCELLa Inc					
	Chris Gemmiti, VP Operations, Sentien Biotechnologies, Inc., <i>USA</i>					
	Kai Pinkernell, Chief Medical Officer (CMO) and Chief Development Officer (CDO), Medigene, <i>Germany</i>					
	Ger Brophy, Executive Vice President, Biopharma Production, Avantor, USA					
10:10						
	PANEL: Autologous Manufacturing – What will Autologous Manufacturing of the Future Look Like?  Panelists:					
	Jennifer Adrian, Manager, Cellular Therapy Manufacturing Operations, bluebird bio, USA					
Adam Haskett, Associate Director, External Manufacturing, Kite Pharma, <i>USA</i>						
10:50		Sponsor P	Presentation			
11:20		Sponsor P	resentation			

### **ON-DEMAND PRESENTATIONS**

### These ON-DEMAND presentations will be available to view 24 hours a day starting October 12 for 30 Days

We Encourage You to View as Many of these On-Demand Presentations at Possible Prior to the "Live Event" Dates of October 19 - 22, so that you can fully participate in the live keynote Q&A, speaker panel discussions and other live topic networking activities....see WATCH LIVE schedule showing all the live activities you can participate in on October 19 - 22

### Cell Therapy - Process Development Considerations & Strategies

#### **Adherent Cell Manufacturing & Process Development**

Lior Raviv, Vice President, Pluristem Therapeutics Inc.

#### **Process Development Considerations for Exosomes**

Jon A. Rowley, Ph.D., Founder & Chief Product Officer, RoosterBio Inc.

# Closed, automated and controlled upstream processing for iPSC-derived cell therapies

Mustafa Munye, Lead Scientist, Cell and Gene Therapy Catapult

#### Adherent Cell Manufacturing & Process Development

Margarida Serra, Head of Stem Cell Bioengineering Lab, iBET - Instituto de Biologia Experimental e Tecnológica

#### **Auto vs. Allo Manufacturing & Infrastructure**

# Will Allogeneic Cell Therapies Replace the Current Autologous Models?

Geoffrey Hodge, formerly Chief Technical Officer, Unum Therapeutics

# Implementation of "off the shelf" Closed Systems fit for every purpose

Ali Mohamed, VP, CMC, Immatics

### Development of modern biologics and cell therapy products through global CMOs

Vadim Klyushnichenko, VP Pharmaceutical Development and Quality, Calibr at Scripps Research

## Feedback from the Industry Alliance Partnership (IAP) & CIRM Partnership and Commercialization Opportunities

Shyam Patel, Director Business Development, California Institute for Regenerative Medicine

# High Throughput Applications & Production Platforms & Enabling Manufacturing Tech

### Pathogen Safety Margins for Gene Therapy Manufacturing

Thomas Kreil, Vice President, Global Pathogen Safety, Takeda

### Mechanistic Understanding of Recombinant Adeno – Associated Virus Production

Sha Sha, Postdoc, Massachusetts Institute of Technology

## Exposing the Content of Different AAV Fractions after Ultracentrifugation

David Dobnik, Senior Research Associate, National Institute of Biology, Slovenia

# Cell Therapy Analytics – Testing, Characterization & Validation Strategies

## Quantitative Analytical Technologies for Cell & Gene Therapies

Barrett J. Nehila, Associate Director, Analytical Development, Torque Therapeutics

#### Manufacturing and quality control of cell therapies

Steve Oh, Director Stem Cell Bioprocessing & Institute Professor, Bioprocessing Technology Institute

#### Al in Cell and Gene Therapy Manufacturing

Michael Roberts, Chief Technology Officer (Europe), Asklepios BioPharmaceutical. Inc.

#### Holistic Characterization of AAV Capsid Particle Using Advanced Analytical Tools

Qin Zou, Ph.D., Senior Principal Scientist, Pfizer

# Raw Materials Selection, Supply & Downstream Considerations

# Starting Material Standardization for Auto and Allo Cell Therapies

Scott Burger, Principal, Advanced Cell & Gene Therapy

### Sourcing Appropriate Starting and Ancillary Materials for Manufacturing Cell and Gene Therapy Products

Kathy Williams, VP of Quality and Reg Affairs, RoosterBio, Inc.

#### Raw Materials: BOMs, Risks & Securing Supply

Tom Walls, Associate Director Supply Chain, bluebirdbio

#### Fresh vs. Cryopreserved: Tightening up Supply Chains

Jason Acker, Professor, Laboratory Medicine and Pathology, University of Alberta

### Phase Appropriate Thinking – Microbiology and Contamination Control

Donald Singer, Consultant, formerly, GSK Senior Fellow, Microbiology, Biopharmaceutical GMP Operations, *USA* 

#### **Product Dependent Cryopreservation Protocols**

David McKenna, Professor and American Red Cross Chair in Transfusion Medicine, Department of Laboratory Medicine and Pathology

#### **Cell and Gene Therapy Connect - Partnering Track**

# PANEL DISCUSSION: Partnering and Collaborations among Investors, Incubators and Biotechnology Companies

Jennifer Griffin, VP Industrial Strategy & Investments, Massachusetts Life Science Center

Paul Lammers, President & CEO, Triumvira Immunologics

### PANEL DISCUSSION: Partnering Solutions for Staffing and Recruitment Issues in the CGT Space

Andrew Rigoglioso, Associate Director, Talent Acquisition, Cell Therapy Development & Operations, Bristol Myers Squibb

Alison Quelch, Director, Talent Acquisition, Global Product Development & Supply, Bristol-Myers Squibb

Jennifer Royal-Fitch, Lead Recruiter, Gene Therapy Program & The Orphan Disease Center, Univeristy of Pennsylvania

# PANEL DISCUSSION: Bridging the Gap between Academia and Commercialization: When to Spin Out?

Elizabeth Schwarzbach, CBO, New York Stem Cell Foundation Sofia Braag, Business Development Principal, University of Massachusetts Medical School

Carlton Anderson, COO, Ambulero

# **WATCH ON-DEMAND: SPOTLIGHT PRESENTATIONS**

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### **FUJ!FILM**

Value from Innovation



# Benchtop to Bioreactor: T-cell Culture and Expansion in Chemically Defined Media

Supriya Pokkali, Sr. Scientist II, Research and Development Department, FUJIFULM Irvine Scientific, R&D (Cell & Gene Therapy), USA

# Catalent.



### How to Commercially Scale T-cell Allogeneic Therapies

Jesse Trekker, Business Manager, Catalent Cell and Gene Therapy, *Belgium* 



# Closed Systems — The Solution for the Worlds Increasing Demands on CGT

Jayanthi Grebin, Senior Business Development Manager CGT, CPC - Colder Products Company, USA

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- \*Must select Poster Presentation during registration process, and must submit a poster abstract for approval by Friday, September 4th, 2020.
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