CELL 2024

BY OXFORD GLOBAL

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06 – 08 November 2024 | London, UK

Now In Its 13th Year!

Connecting Leaders From Every Stage of the Value Chain to Drive Advanced Therapy Development & Novel Biologics Processing

13 Content Tracks

230+ Hours of 1:1 Meetings

25+ Partners

600+ Attendees

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100+ Industry-Leading Speakers Including...

DOLORES SCHENDEL, Chief Scientific Officer, **Medigene AG**

RUBEN RIZZI, Senior Vice President Global Regulatory Affairs, **BioNTech SE**

JOHN GILL, Senior Director Cell Line Development, **Gilead Sciences**

ELI GILSOHN, Vice President Intellectual Property, **Resolution Therapeutics**

MARIA LUISA GIORELLO, Global Gene Therapy Platform Enablement Director, **Pfizer**

MANA YEN, Global Head Franchise Policy and Health Systems, **Novartis Gene Therapies**

CHARLOTTE MAISONNEUVE-SERRA, Vice President Quality Assurance, **Galapagos**

MATTHEW GARNER, Head of Intellectual Property, **Cell and Gene Catapult**

ANNA NOWOCIN, Head of Flow Cytometry Standardisation, **MHRA**

WELCOME TO

Cell 2024

Welcome to **Cell 2024**, Oxford Global's flagship event connecting leaders from pharma, biotech, academia & regulatory institutions working across the entire CGT value chain. The 3-day programme features the **Cell Culture Congress**, **Advanced Therapy Development Congress** and **Cell & Gene Therapy Manufacturing Congress**.

Join our cutting-edge programme, which includes our brand new Innovation & Collaboration track, as well as exclusive closed-door C- & Executive panel discussions. Don't miss this opportunity to immerse yourself in the CGT landscape, with unparalleled presentations, interactive sessions, and networking opportunities!

Eszter Sutowski Nagy
Director of Editorial & Event Content,
Oxford Global

3 High-Level Events in 1

Cell 2024 features three co-located programmes:

- Cell Culture & Bioprocessing
- Advanced Therapy Development
- Cell & Gene Therapy Manufacturing

You'll benefit from specialised programmes for each topic, as well as combined networking opportunities across the entire audience. In particular, reflecting the challenges of manufacturing complex cell & gene therapies, the shared programme allows for knowledge-sharing between process development experts working on a wide variety of biologic drugs to remove bottlenecks & integrate new technologies into workflows.

Unlock The Latest News & Insights

Sign up for our monthly newsletter to keep up with all things Cell & Gene

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WHAT'S NEW

Benefits Of Attending

Why Attend?

- **Take a deep dive into the latest advancements for cell line development** & cell line engineering, with focused presentations and panels exploring CRISPR engineering and gene delivery methods.
- **Explore case studies form gene therapy discovery & development** – from gene target validation and vector engineering through to next-gen strategies such as gene editing technologies and preclinical validation methods including off-target effects.
- **Discuss iPSCs and stem cell therapy development** with key opinion leaders. Topic areas include delivering stem cell therapies from discovery to the clinic, bioprinting & biomaterials within stem cell therapy and strategies to control and optimise stem cell bioprocessing
- **Gain invaluable insights into best practice strategies for CGT manufacturing,** production, supply chain & logistics. Explore real-world case studies of successful R&D to GMP transitions, regulatory insights and compliance considerations and cryopreservation & collaboration and partnerships across the supply chain
- **Tap into CGT manufacturing technologies:** automation, digitalization & scale up – from implementing continuous manufacturing processes through to leveraging bioinformatics and digital twin technologies

What's New?

Expanded 3-Day Programme: New for 2024, Cell has expanded into a three-day conference – meaning there's more networking, more impactful content and more business opportunities than ever before. Reflecting the most pertinent areas at the forefront of scientists' minds currently, we've updated our agenda to feature sessions on preclinical assessments, iPSCs, commercialization, market access, supply chain and collaboration

Innovation & Collaboration Track: Featuring a series of short, impactful presentations from emerging biotechs & academic spin-outs, our new track provides a vital platform for the most innovative companies to share their latest data and showcase how their approach is poised to transform the advanced therapies market

More Stakeholders Than Ever Before: This year's event will be the biggest yet, bringing together over 600 experts from across the industry. Alongside our established community of biopharma and academic leaders, expect to connect with regulators, investors, patient advocates and government organisations.

C-Level Panel Discussions: Alongside the scientific insights you've learnt to expect from an Oxford Global event, our day 1 sessions are your chance to deep-dive into the key strategic challenges facing the industry with our panel of biotech c-suite leaders – from navigating the evolving regulatory landscape and exploring patent challenges through to ensuring supply chain success and mapping the future of CGT investment

WHY PARTNER WITH
OXFORD GLOBAL?

At Oxford Global, our mission is to curate personalized experiences that foster community and inspire innovation.

We believe in the power of networking, connection, and knowledge to deliver quality products and services that exceed expectations. Partnering with Oxford Global means having a dedicated team committed to helping you achieve your goals and navigating the industry's ever-changing landscape.

- **Arrange 1-2-1 Meetings**

Benefit from guaranteed one-to-one face time with your key prospects, with detailed pre-meeting information provided to enable effective and productive conversations.

- **Speaking Opportunities**

Showcase your company's recent work to a relevant and highly engaged audience.

- **Host Panel & Roundtable Discussions**

Feature alongside key opinion leaders to discuss current hot topics and highlight your company's expertise.

- **Organise Workshops**

Demonstrate best practice within the industry in front of your peers with case studies from your clients.

- **Exhibit your Products & Solutions**

Promote your offerings and ensure delegates know where to find you with a prominent brand presence in the exhibition hall.

- **Digital Marketing & Lead Generation**

Accessing the Oxford Global database, amplify your thought leadership and branding messaging through a post-event case study e-Book.

LEARN MORE

DRIVE INNOVATION & ACCELERATE RESEARCH
Who Is Partnering?

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Network & Programme Sponsors

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NETWORK & KNOWLEDGE-SHARE

Attendees

600+ VPs, Directors & Senior Managers will be attending on-site and online, coming from leading healthcare, biotech, pharma & research institutions in the following fields & more

- Cell Line Engineering
- Cell Culture
- Upstream Processing
- Downstream Processing
- Organoid Development
- Cell Line Development
- Cell Therapy
- Gene Therapy
- CAR T Development
- Clinical Sciences
- Regulatory Affairs
- Characterisation

Formal & informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers. Formal 1-2-1 meetings will be available to arrange prior to the event which take place during the dedicated networking breaks covering:

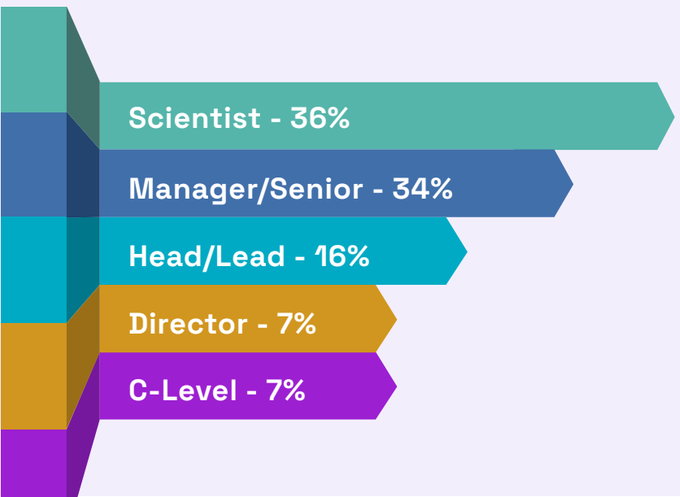
- Bioprocessing Solutions
- Cell Line Development
- Cell Culture Media
- Genomic Technologies
- Downstream Processing
- Off-the-shelf Therapies
- Safety Profiling
- CAR-T Development
- Clinical Development
- Market & Patient Access
- Gene Therapy Discovery
- Characterisation
- Process Improvement
- Automation
- Technology

Attended by these companies & many more:

MUVON THERAPEUTICS · AstraZeneca · Boehringer Ingelheim · Bayer · King's College London · UCB · Orchard therapeutics · Novartis · GSK GlaxoSmithKline · Bloomsbury Genetic Therapies · NHS England · Medicines & Healthcare products Regulatory Agency

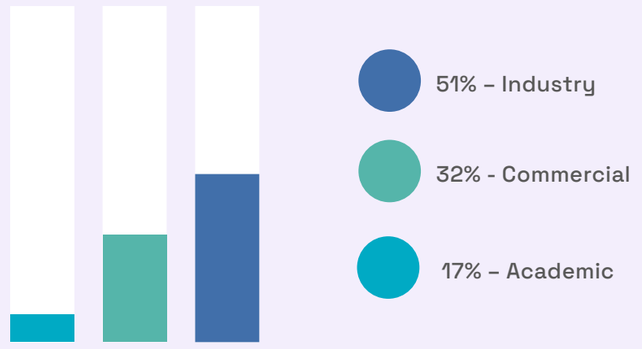
Previous Attendee Profile:

Function



Geography

Sector



GAIN EXPERTISE FROM THOUGHT LEADERS

Confirmed Speakers

KEY SPEAKERS

Day One | 17:00

MARIA LUISA GIORELLO, Global Gene Therapy Platform Enablement Director, Pfizer

Day Two | 09:35

KYLE ZINGARO, Head of Gene Therapy Process Sciences, UCB

Day Two | 09:35

MANUEL CARRONDO, Vice-President, iBET

Day Two | 09:35

RUBEN RIZZI, Senior Vice President Global Regulatory Affairs, BioNTech SE

Day Three | 09:30

CATIA ANDREASSI, Director, Discovery, AviadoBio

Day Three | 09:30

CHARLOTTE MAISONNEUVE-SERRA, Vice President, Head of Quality Assurance, Cellular Therapy Galapagos

DAY ONE

CHRISTOPHER MIDDENDORF
Senior Director Pharma and Biotech GMP Compliance, HoganLovells, LLP

KIRSTY CRAME
Vice President Clinical Strategy and Development, Medigene

VICKI COUTINHO
Managing Director & Consultant, Geni Consulting

STEPHEN SULLIVAN
Chief Operating Officer & Board Member, iPSirius

MARINA TARUNINA
Research Director, Plasticell

MARIA LUISA GIORELLO
Global Gene Therapy Platform Enablement Director, Pfizer

MARCEL VAN HOUTEN
Director-Distribution, Logistics & Site Qualification, Orchard Therapeutics

LINDSAY DAVIES
European Regional Secretary, ISCT & Chief Scientific Officer, NextCell Pharma AB

DJORDJE DJORDJEVIC
Co-Founder and Chief Executive Officer, Plurify

MANA YEN
Global Head Franchise Policy and Health Systems, Novartis Gene Therapies

SIMON CHANDLER
Chief Executive Officer, Rinri Therapeutics

MARTIN DASS
Senior Scientist, Boehringer Ingelheim

AKI KO
Co-Founder & Chief Executive Officer, Elixirgen Therapeutics

BENEDIKT BERNINGER
Professor, King's College London

PAOLO MORGESE
Vice President Public Affairs Europe, Alliance for Regenerative Medicine

ELI GILSOHN
Vice President Intellectual Property, Resolution Therapeutics

MATTHEW GARNER
Head of Intellectual Property, Cell and Gene Catapult

TIM ALLSOPP
Chief Technology Officer, Lacerock Therapeutics

NIRAJMATHI GOVINDASAMY
Senior Scientist, Bluu Seafood

SAM GOLDSMITH
Head of Commercialisation of Research & Investments, Cell and Gene Therapy Catapult

RAHUL KHETAN
Venture Capital Associate, UCB Ventures

LUCY WILLIAMS
Partner, European and UK Patent Attorney, J A Kemp

AJAN REGINALD
Chief Executive Officer, Roquefort Therapeutics

DAY TWO

MANUEL CARRONDO
Vice-President, iBET

RUBEN RIZZI
Senior Vice President Global Regulatory Affairs, BioNTech SE

KYLE ZINGARO
Head of Gene Therapy Process Sciences, UCB

ROLF KOEHLER
Associate Director/Group Head Cell Line Development, Novartis

UWE BUECHELER
Senior Advisor Biopharmaceuticals, Former Bio Business Unit Head, Boehringer Ingelheim

SAKIS MANTALARIS
Don Panoz Chair of Pharmaceutical Biology & Principal Investigator, Trinity College Dublin & NIBRT

MENASHEH FOGEL
IT Head Cell and Gene Therapy, Bayer

SUJITH SEBASTIAN
Viral Vector Hub Manager, Clinical Biotechnology Centre NHSBT

CHRYSANTHI SITMALIDOU
Scientist II, Orchard Therapeutics

WONJONG SI
Associate Director Cell Therapy Platform Process, Bayer

JAMES CARLSON
Principal Safety Director ATMP Enablement, Roche

HIMANSU PATEL
Head Of Quality Innovation, Cell And Gene Therapy Catapult

ELEONORA ZUCCHELLI
Associate Lead Scientist, Cell and Gene Therapy Catapult

GAIN EXPERTISE FROM THOUGHT LEADERS

Confirmed Speakers

LUIS AYALA
Scientist Perfusion Systems, Merck KGaA

ANNA NOWOCIN
Head Of Flow Cytometry Standardisation, MHRA

DOLORES SCHENDEL
Chief Scientific Officer, Medigene AG

JOSE BONAFONT
Principal Scientist, Research and Process Development, DanausGT

LUZ ALONSO-CRISOSTOMO
Senior Scientist, AstraZeneca

SERGEY PILETSKY
Professor & Head of Research, University of Leicester

NICOLAS WEBER
Quality Team Leader QC, Novartis

MONICA RAIMO
Director of Product And Process Development, Glycostem Therapeutics

ULRICH RÜMENAPP
Senior Biotech Program Lead, Bayer

GABRIEL KENT
Senior Analytical Development Scientist, Resolution Therapeutics

AISLING MCMAHON
Professor of Law, Maynooth University

MILLIE FOX
Senior Scientist, AstraZeneca

EMMA CHAN
Director of Process Development, Orchard Therapeutics

DARREN NESBETH
Associate Professor of Synthetic Biology, University College London

NITIN GARG
Director, CMC Product Lead, Adaptimmune

HARRIS MAKATSORIS
Professor of Sustainable Manufacturing Systems, King's College London

ANTON HUTTER
Partner, Patent Attorney, Venner Shipley

CHARLOTTE WILDING
Associate Patent Attorney, Venner Shipley

JAS UPPAL
Founder & Chief Executive Officer, BQP Consultancy

KATE ROCHLIN
Chief Operating Officer, IN8bio

SALLY GU
Senior Associate Global Regulatory, HoganLovells, LLP

FARHAD PAYLAKHI
Co-Founder & Vice President of R&D, 64x Bio

MOLLY STEVENS
Professor, Oxford University

DAY THREE

ADAM SIDAWAY
Lead Scientist - Molecular Biology, Uncommon

CATIA ANDREASSI
Director, Discovery, AviadoBio

CHARLOTTE MAISONNEUVE-SERRA
Vice President, Head of Quality Assurance, Cell Therapy, Galapagos

SARAH HOWLETT
Associate Director UK Cell Culture & Banking, AstraZeneca

RAIKO STEPHAN
Gene & Cell Therapy Lead Biomarker, Novartis

KELLY EVANS
Senior Scientist, AstraZeneca

ROSHNI DESAI
Nonclinical Assessor, MHRA

IBON GARITAONANDIA
Chief Scientific Officer, CellProthera

TERRI GASKELL
Chief Technology Officer, Rinri Therapeutics

DARIUS WIDERA
Professor of Stem Cell Biology and Regenerative Medicine, University Of Reading

ELENA PILETSKA
Professor, University Of Leicester

MARC SCHNEIDER
Director Product Supply Cell & Gene, BioNTech SE

KLARA KULENKAMPFF
Project Manager, Bayer

MATTHEW GIBSON
Chair (Professor) of Sustainable Biomaterials, University Of Manchester

EMILIE GAUTHY
Head Of CMC, Zelluna Immunotherapy

ALINE MILLER
Principal Investigator, Professor of Biomolecular Engineering and Associate Dean for Business Engagement and Innovation, The University of Manchester

JOHN WOLFE
Stokes Investigator, Children's Hospital of Philadelphia & Professor of Pathology, University of Pennsylvania

XAVIER FONTANA
Principal Scientist Allogenic Process Development, Adaptimmune

PHILIPPE HENON
Founder & Chairman of The Board, CellProthera

JOHN GARCIA
Head of New Manufacturing Technologies, UCL

ATHANASIOS DIDANGELOS
Director of Pharmacology, Complement Tx

PATRICIA MENDOZA
Senior Scientist, AstraZeneca

ROELOF RONGEN
Chief Executive Officer, Adolore BioTherapeutics

BEN TAYLOR
Senior Director, AstraZeneca

NABIHA SAKLAYEN
Co-Founder & Chief Executive Officer, Cellino Biotech

ESTHER KITTO
Vice President Clinical Operations, Resolution Therapeutics

PATRIZIA FERRETTI
Professor, University College London

ALEX SMITH
Director Regulatory Science, Hogan Lovells

DAY ONE OVERVIEW

Wednesday 06 November 2024

Day One offers a diverse range of discussions: from strategies to enhance efficiency and establish monoclonality in cell line engineering, to novel approaches in cell culture process control and vector engineering for gene therapy. Delve into commercialisation strategies, regulatory compliance in supply chain management, and executive-level panels on navigating evolving landscapes in advanced therapies.

EXPLORE CURATED & INSIGHTFUL CONTENT

Agenda At A Glance

Track 1: Cell Line Engineering & Development

- Improving efficiency & removing bottlenecks
- Clone selection strategies and establishing monoclonality
- Screening clones

Track 2: Cell Culture & Cell Therapies Quality Control & Analysis

- Characterizing cell-based therapies
- Novel approaches to cell culture process control
- Quality Control

Track 3: Gene Therapy Discovery & Development

- Vector engineering: designing and optimizing viral and non-viral vectors
- Gene therapy platform development

Track 4: CGT Commercialisation

- Strategies for commercialisation & navigating competetive market landscapes
- Patient-centred product launch & access challenges

Track 5: Supply Chain & Logistics

- Regulatory compliance and cold chain management
- Optimizing transportation routes and inventory management

Track 6: CLOSED DOOR C- & Executive Level Panels + Innovation Track

- Strategies for Navigating Evolving Regulatory Landscapes
- Navigating the Advanced Therapy Landscape & Emerging Modalities

DAY TWO OVERVIEW

Thursday 07 November 2024

Day Two offers in-depth discussions on essential topics such as CRISPR applications for bolstering cell line stability, advancements in continuous bioprocessing, novel approaches to NK and TCR cell therapies in cancer treatment, and critical strategies for scaling up gene therapy production while ensuring quality through digital twin technology.

EXPLORE CURATED & INSIGHTFUL CONTENT

Agenda At A Glance

Track 1: Cell Line Engineering & Development

- Strategies for single-cell isolation
- Enhancing stability via gene editing and delivery e.g., CRISPR

Track 2: Upstream & Downstream Bioprocessing: Novel Technologies & Continuous Processing

- USP, DSP & continous processing
- PAT tools for predictivity, facilitating technology transfer

Track 3: Cell Culture & Cell Therapies Quality Control & Analysis

- Analytical strategies, potency assays & development
- Raw material management

Track 4: CGT Development

- NK, TCR, Innate Killer CelL Therapies
- Combination therapies for immunothereapeutic responses
- Cell therapies for solid tumours & blood-based cancers
- Regulatory, ethical, and safety considerations

Track 5: Strategies for Gene Therapy Manufacturing & Production

- Scale-up challenges and strategies
- Quality by Design approaches
- Leveraging bioinformatics and digital twin technology
- Scalable platforms for vector production; optimizing quality and yield

DAY THREE OVERVIEW

Friday 08 November 2024

Day Three offers innovative discussions on optimizing cell culture media for greater productivity, preclinical assessments focusing on toxicology and biomarker discovery, patient-centred clinical trial design, stem cell therapy development for regenerative medicine, and insights into transitioning to cGMP manufacturing and the role of automation in ensuring regulatory compliance in cell therapy production.

EXPLORE CURATED & INSIGHTFUL CONTENT

Agenda At A Glance

Track 1: Optimising Cell Culture Media & Models

- Cell culture media analysis, development & optimization
- 2D Vs. 3D Cell Culture Models
- Cell banking and strategies for greater productivity

Track 2: Preclinical CGT Assessments: Research & Development

- Toxicology and pharmacology for cell and gene therapies
- Biomarker discovery and development
- In vivo research e.g., animal models

Track 3: CGT Clinical Development & Clinical Trial

- Patient engagement and patient-centred clinical trial design
- From bench to bedside-translational case studies

Track 4: iPSCs and Stem Cell Therapy Development

- Stem cell therapy: discovery to clinic
- Use of stem cells in regenerative medicine & tissue engineering
- Derivation, manipulation, and characterization of iPSCs

Track 5: Strategies for Cell Therapy Manufacturing & Production

- Autologous vs. allogenic products
- Transitioning to cGMP Manufacturing
- Regulatory insights and compliance considerations
- Automation and digitalization in cell therapy manufacturing
- Analytical techniques: quality control and assurance

DAY ONE: 06 NOVEMBER 2024

08:40 **Oxford Global's Welcome Address**

09:00 **Keynote Address: Novel Cell Therapy Approaches In Solid Tumors: A Regulatory Perspective**

- Novel approaches to overcome some of the limitations of cell therapy in solid tumors
- ATMP combinations and their potential in areas of unmet need
- The regulatory framework for advanced therapies: staying ahead of the curve of innovation?

RUBEN RIZZI, Senior Vice President Global Regulatory Affairs,
BioNTech SE

Q&A Session & Transition Time Between Conference Rooms

CELL CULTURE & BIOPROCESSING CONGRESS

Track Chair

MANUEL CARRONDO, Vice-President,
iBET

09:25 **Programme Keynote Address:**
Cell And Gene Therapy Regulatory Overview

- FDA's framework for regulating Cell and Gene therapies from clinical development to commercialisation
- The impact of proposed legislation on biotech manufacturers, harmonization, new guidance, and FDA Cell and Gene Therapy initiatives

CHRISTOPHER MIDDENDORF, Senior Director Pharma and Biotech GMP Complicance,
HoganLovells, LLP

Q&A Session & Transition Time Between Conference Rooms

09:50 **Biological Standardisation And Development Of Potency Reference Reagents For EV**

- Bioactivity and potency testing considerations for Biotherapeutics and ATMPs
- Development and establishment of International Reference Reagents
- Process optimisation for manufacturing of MSC-EVs bioactivity standards

ANNA NOWOCIN, Head Of Flow Cytometry Standardisation,
MHRA

10:15 MORNING BREAK | 1-2-1 Meetings x4 | Poster Displays

ADVANCED THERAPY DEVELOPMENT CONGRESS

Track Chair

MENASHEH FOGEL, IT Head Cell and Gene Therapy,
Bayer

Programme Keynote Address:
Reimagining The Power of RNA: Utilising Bobcat mRNA Technology

- Elixirgen Therapeutics has developed a suite of technologies to enable mRNA therapeutics
- Bobcat mRNA can deliver large genes that other therapeutic modalities cannot, unlocking brand-new targets
- The lead program is EXG-7001, a full-length dystrophin mRNA therapeutic for Duchenne muscular dystrophy

AKI KO, Co-Founder & Chief Executive Officer,
Elixirgen Therapeutics

Q&A Session & Transition Time Between Conference Rooms

Development Of First-In-Class Advanced Therapies For Immunology And Oncology

- STAT6 siRNA showed efficacy in validated model of inflammation
- MK cell therapy demonstrates natural killer cell engagement and activation

AJAN REGINALD, Chief Executive Officer,
Roquefort Therapeutics

GENE THERAPY MANUFACTURING CONGRESS

Track Chair

KLARA KULENKAMPFF, Project Manager,
Bayer

Program Keynote Address:
Global Site Qualification & Impact On Supply Chain Logistics

- Geographical Importance of site selection
- Limitations of shelf life to logistics
- Choosing the right logistics partner

MARCEL VAN HOUTEN, Director-Distribution, Logistics & Site Qualification,
Orchard Therapeutics

Q&A Session & Transition Time Between Conference Rooms

Development And Manufacturing Of An Oncolytic Virus For Clinical Trials

- Oncolytic Viruses (OV) and Advanced Therapy Medical Products (ATMPs) are new modalities in cancer treatment and entered the development and manufacturing in pharmaceutical industry
- At Boehringer Ingelheim, we have successfully developed a genetically modified oncolytic virus using vesicular stomatitis virus (VSV) which is currently tested in clinical trials
- The general production process and development steps including the associated challenges are summarized in the presentation

MARTIN DASS, Senior Scientist,
Boehringer Ingelheim

DAY ONE: 06 NOVEMBER 2024

	ROOM 1: CELL CULTURE & BIOPROCESSING CONGRESS	ROOM 2: GENE THERAPY MANUFACTURING CONGRESS
11:35	**ACRO Biosystems Solution Provider Workshop** BIOSYSTEMS Acro	**Accelerating Product Development By Using Advanced Analytical Solutions** **Introduction & Welcome** (5 minutes) • Brief introduction to the workshop and its objectives • Overview of the importance of advanced analytical tools in cell and gene therapy • Introduction of the speakers and their expertise **Session 1: The Need For Advanced Analytical Tools In Cell & Gene Therapy** (20 minutes) • Current challenges in cell and gene therapy analytics • Placement of analytical platforms for process development of AAV/pDNA/mRNA/LNP • Overview of the chromatographic analytical system and its unique features **Session 2: Real-World Applications & Case Studies** (25 minutes) • Detailed case studies demonstrating the system's application in cell and gene therapy • Data and results showcasing the system's performance and benefits **Break & Networking** (10 minutes) • Opportunity for attendees to network and discuss the content presented • Light refreshments provided **Session 3: PATfix LNP Switcher | Live Demonstration & Hands-On Experience** (30 minutes) • Live demonstration of the LNP Switcher analytical system • Step-by-step walkthrough of the system's operation • Interactive Q&A session with the audience **Session 4: Panel Discussion & Q&A** (25 minutes) • Open floor for questions from the audience • Panel discussion on the future of analytical systems in cell and gene therapy • Insights on upcoming trends and innovations in the field **Closing Remarks & Call to Action** (5 minutes) • Summary of key takeaways from the workshop • Information on how attendees can learn more or get involved • Invitation to visit the company's booth or schedule a one-on-one meeting for further discussion ANDREJA GRAMC LIVK, Head of Process Analytics, NEJC PAVLIN, Process Analytics Development Manager, **Sartorius BIA Separations** SARTORIUS
13:35	LUNCH BREAK | 1-2-1 Meetings x3 | Poster Displays	

DAY ONE: 06 NOVEMBER 2024

CELL CULTURE & BIOPROCESSING CONGRESS

Track Chair

MANUEL CARRONDO, Vice-President,
iBET

14:35

Solution Provider Presentation

Senior Representative,
Sphere Fluidics

ADVANCED THERAPY DEVELOPMENT CONGRESS

Track Chair

MENASHEH FOGEL, IT Head Cell and Gene Therapy,
Bayer

1-HOUR Mycoplasma Release Test: Novel CAGT Low Volume Protocol & Rapid Implementation Strategy

CAROLINE KASSIM HOUSSENALY, R&D Manager, BioMérieux & Laurens Raes, Project Manager,
Anabiotec

GENE THERAPY MANUFACTURING CONGRESS

Track Chair

KLARA KULENKAMPFF, Project Manager,
Bayer

Solution Provider Presentation

Senior Representative,
Sartorius

Q&A Session & Transition Time Between Conference Rooms

CELL CULTURE & BIOPROCESSING CONGRESS

Track Chair

MANUEL CARRONDO, Vice-President,
iBET

15:00

Closed-Door C- & Executive-Level Panel Discussion: Strategies For Navigating Evolving Regulatory Landscapes

- EU HTA Regulation
- Regulatory harmonization
- Inter-country communication
- Real-world evidence

Moderator: RUBEN RIZZI, Senior Vice President Global Regulatory Affairs, **BioNTech SE**

Panellists:

CHRISTOPHER MIDDENDORF, Senior Director Pharma and Biotech GMP Complicance, **HoganLovells, LLP**

CHARLOTTE MAISONNEUVE-SERRA, Vice President, Head of Quality Assurance, Cell Therapy, **Galapagos**

SALLY GU, Senior Associate, Global Regulatory, **HoganLovells, LLP**

ADVANCED THERAPY DEVELOPMENT CONGRESS

Track Chair

MENASHEH FOGEL, IT Head Cell and Gene Therapy,
Bayer

Closed-Door C- & Executive-Level Panel Discussion: Navigating The Advanced Therapy Landscape & Emerging Modalities

- Exploring cutting-edge methods, such as synthetic biology, gene editing, and more
- Next generation cell therapies
- Interdisciplinary collaboration

Moderator: TIM ALLSOPP, Chief Technology Officer, **Laverock Therapeutics**

Panellists:

STEPHEN SULLIVAN, Chief Operating Officer & Board Member, **iPSirius**

DJORDJE DJORDJEVIC, Co-Founder and Chief Executive Officer, **Plurify**

AMIR HEFNI, Chief Executive Officer, Resolution Therapeutics

GENE THERAPY MANUFACTURING CONGRESS

Track Chair

KLARA KULENKAMPFF, Project Manager,
Bayer

Closed-Door C- & Executive-Level Panel Discussion: Exploring Autologous Vs. Allogenic Therapies

- Clinical insights & patient considerations
- Immunological considerations
- Manufacturing challenges
- Market access

Moderator: MARC SCHNEIDER, Director Product Supply Cell & Gene, **BioNTech SE**

Panellists:

IBON GARITAONANDIA, Chief Scientific Officer, **CellProthera**

KIRSTY CRAME, Vice President Clinical Strategy and Development, **Medigene**

KATE ROCHLIN, Chief Operating Officer, **IN8bio**

VOLKER HUPPERT, Chief Development Officer, **Glycostem**

INNOVATION & COLLABORATION

Track Chair

LUCY BARNES, Partner, Patent Attorney,
J A Kemp LLP

EXCLUSIVE Investor-Focused Panel Session: Mapping The Future of CGT Investment: Strategies For Funding & Reimbursement

- Investor perspectives
- Navigating funding uncertainty: funding freeze, mergers, acquisitions
- Patient Access and equity

Moderator: SAM GOLDSMITH, Head of Commercialisation of Research & Investments, **Cell and Gene Therapy Catapult**

Panellists:

RAHUL KHETAN, Venture Capital Associate, **UCB Ventures**

PAOLO MORGESE, Vice President Public Affairs Europe, **Alliance for Regenerative Medicine**

SIMON CHANDLER, Chief Executive Officer, **Rinri Therapeutics**

Q&A Session & Transition Time Between Conference Rooms

DAY ONE: 06 NOVEMBER 2024

CELL CULTURE & BIOPROCESSING CONGRESS

Engineering Neurons From Glial Cells By In Vivo Lineage Reprogramming

- Concept of lineage reprogramming for brain repair
- Experimental strategies of (re)generating neurons in vivo from local glia
- Molecular underpinnings of glia-to-neuron fate conversion

BENEDIKT BERNINGER, Professor,
King's College London

ADVANCED THERAPY DEVELOPMENT CONGRESS

Treating Global Brain Lesions In Monogenic Diseases

- 60 lysosomal storage diseases, ~1/5,000 live births aggregate
- 90% due to specific enzyme deficiency - common mechanism to amplify treatment
- Global brain lesions require widespread distribution of therapeutic enzyme

JOHN WOLFE, Stokes Investigator, Children's Hospital of Philadelphia & Professor of Pathology,
University of Pennsylvania

GENE THERAPY MANUFACTURING CONGRESS

Navigating Challenges In Gene Therapy Commercialisation: Hospital And Network Operational Readiness

- Hurdles of Infusion centers and network operational readiness in the commercial settings
- High level overview of the pain points related to Infusion centers and referring centers
- Readiness & potential role of the industry to support the overcoming of those issues

MARIA LUISA GIORELLO, Global Gene Therapy Platform Enablement Director,
Pfizer Ltd

INNOVATION & COLLABORATION

10min Presentation 1: Mesenchymal Stromal Cells - An Interventive Approach To The Treatment Of Type 1 Diabetes

- Umbilical cord mesenchymal stromal cells possess inherent immunomodulatory properties that can be exploited for the treatment of autoimmune and inflammatory diseases
- NextCell Pharma has developed an allogeneic, off-the-shelf mesenchymal stromal cell drug product, ProTrans, that can be thawed at bedside and infused peripherally for the treatment of type 1 diabetes
- A single infusion of ProTrans and delay the progression of type 1 diabetes development for 5 years

LINDSAY DAVIES, European Regional Secretary, ISCT & Chief Scientific Officer,
NextCell Pharma AB

10min Presentation 2: A Broadly Applicable And Scalable Cell Purification Platform

- Removing unwanted residual cells during allogeneic cell therapy manufacture is a major bottleneck with safety implications
- At Plurify we apply molecular logic to tackle this problem in a new way
- We will present our very early proof-of-concept data

DJORDJE DJORDJEVIC, Co-Founder and Chief Executive Officer,
Plurify

15:50

Q&A Session & Transition Time Between Conference Rooms

16:15

Attendees Are Welcome To Attend The Co-Located Sessions

Industry Presentation

HARRIS MAKATSORIS, Professor of Sustainable Manufacturing Systems,
King's College London

Challenges In The Adoption & Utilization Of Gene Therapies Within Health Systems

MANA YEN, Global Head Franchise Policy and Health Systems,
Novartis Gene Therapies

10min Presentation 1: Revolutionising Hearing Loss With Regenerative Cell Therapy

- Rinri Therapeutics is pioneering Rincell-1, a first-of-its-kind, off-the-shelf allogenic cell therapy designed to regenerate cochlear innervation and restore hearing
- Preclinical models show Rincell-1 delivers significant hearing restoration with an outstanding safety profile
- Nearing clinical stage, Rinri will launch first-in-human trials in 2025, aiming for rapid clinical proof of concept

SIMON CHANDLER, Chief Executive Officer,
Rinri Therapeutics

10min Presentation 2: Targeting Cancer With A New Comprehensive Stem Cell-Based Immunotherapy, IPVAC

- Introducing IPVAC, a stem cell-based immunotherapy developed by iPSirius to target cancer
- Highlighting preclinical development and therapeutic potential for multiple cancer types, including upcoming first-in-human clinical trials.
- Exploiting similarities between iPSCs and cancer cells to enhance immune system recognition and response.

STEPHEN SULLIVAN, Chief Operating Officer & Board Member,
iPSirius

16:40

AFTERNOON BREAK | 1-2-1 Meetings x3 | Poster Displays

DAY ONE: 06 NOVEMBER 2024

CELL LINE ENGINEERING & DEVELOPMENT

Track Chair

LEILA ABBAS, Preclinical Lead,
Rinri Therapeutics

Panel Discussion:
Cryopreservation Techniques & Transportation: Safeguarding Cell Viability In ATMP Development

- Process characterization
- Scalability
- Optimizing protocols
- Transportation logistics

Moderator: LINDSAY DAVIES, European Regional Secretary, ISCT & Chief Scientific Officer, **NextCell Pharma AB**

Panellists:
MONICA RAIMO, Director of Product and Process Development, **Glycostem Therapeutics**

CHARLOTTE MAISONNEUVE-SERRA, Vice President, Head of Quality Assurance, Cell Therapy**, Galapagos**

MAHDIEH HASSANJANI, Innovation Project Manager, **Catapult**

VOLKER HUPPERT, Chief Development Officer, **Glycostem**

ADVANCED THERAPY DEVELOPMENT

Track Chair

MENASHEH FOGEL, IT Head Cell and Gene Therapy,
Bayer

Panel Discussion:
Cell Therapy Manufacturing & Process Development

- Advancements and challenges
- Scalability
- Supply and cost
- Raw materials: compliance & regulatory considerations
- Quality of materials

Moderator: TERRI GASKELL, Chief Technology Officer, **Rinri Therapeutics**

Panellists:
JOHN GARCIA, Head of New Manufacturing Technologies, **UCL**

JOSE BONAFONT, Principal Scientist - Research and Prcoess Development, **DanausGT**

EMMA CHAN, Director of Process Development, **Orchard Therapeutics**

ROELOF RONGEN, Chief Executive Officer, **Adolore BioTherapeutics**

CELL CULTURE & CELL THERAPIES QUALITY CONTROL & ANALYSIS

Track Chair

MANUEL CARRONDO, Vice-President,
iBET

Panel Discussion:
CGT IP Challenges

- Developing strategic patent portfolios
- In house versus private challenges & opportunities
- Lessons from past and looking to emerging CGT trends

Moderator: ELI GILSOHN, Vice President Intellectual Property, **Resolution Therapeutics**

Panellists:
ANTON HUTTER, Partner, Patent Attorney, **Venner Shipley**

LUCY WILLIAMS, Partner, European and UK Patent Attorney, **J A Kemp**

AISLING MCMAHON, Professor of Law, **Maynooth University**

MATTHEW GARNER, Head of Intellectual Property, **Cell and Gene Catapult**

INNOVATION & COLLABORATION

Track Chair

LUCY BARNES, Partner, Patent Attorney,
J A Kemp LLP

10min Presentation 1: Leveraging A Cell's miRNA Network For Conditional, Tunable, Target Gene Silencing

- Novel approaches for functionalizing immune effector cells
- Innovating the next generation of cell programmable, advanced therapies
- Delivering safer more effective therapies, resolving patients' unmet medical needs

TIM ALLSOPP, Chief Technology Officer,
Laverock Therapeutics

10-min Presentation 2: Developing Optimal Stem Cell Expansion And Differentiation Protocols For Advanced Cell Therapies

- iPSC-derived immunotherapies represent the next-generation of cell therapies
- Plasticell employed CombiCult®, to develop robust, feeder-free, serum-free, GMP-compliant protocols for production of functional Natural Killer (NK) cells from human iPSCs
- Collaboration between Cell and Gene Therapy Catapult and Plasticell led to development of closed and seamless scaled-up process for manufacturing iPSC-derived NK cells in GMP-ready setting

MARINA TARUNINA, Research Director,
Plasticell

10min Presentation 3: Cell Culture Media Development For Cultivated Meat

- Bluu Seafood is addressing the rising global protein demand by producing cultivated fish meat
- Bluu Seafood has developed a specialized cell culture medium for rainbow trout cells. However, challenges remain in achieving a fully serum-free medium that is both efficient for large-scale production and meets food regulatory requirements
- The future focus is on overcoming these hurdles to ensure cultivated fish meat can be produced in a sustainable, cost-effective, and regulatory-compliant manner

NIRAIMATHI GOVINDASAMY, Senior Scientist,
Bluu Seafood

17:40

18:30 **End of Day One & Drinks Reception**

DAY TWO: 07 NOVEMBER 2024

Roundtable Discussion 1: Innovating Advanced Therapeutics And Nanomedicine
- Recent breakthroughs in nano medicine
- Personalized nano medicine
- Future tends and emerging technologies

Moderator:
MOLLY STEVENS, Professor, **Oxford University**

Roundtable Discussion 2: How Do We Deal With Particulates In CGT Drug Formulations?
- Impact on safety and efficacy
- Characterization and detection methods
- Risk assessment and control strategies

Moderator:
LINDSAY DAVIS, European Regional Secretary, ISCT & Chief Scientific Officer, **NextCell Pharma AB**

Roundtable Discussion 3: Exploring Challenges & Strategies For CGT Patent Landscaping
- Challenges in patenting CGT and the current landscape
- Patent enforcement
- Licensing and collaboration

Moderator:
CHARLOTTE WILDING, Associate Patent Attorney, **Venner Shipley**

Roundtable Discussion 4: Strategies For First-In-Human / Phase I Studies
- Where to start your First-In-Human (FIH) Study?
- Fast study start-up countries based on regulatory ease or are they really?
- Alternate pathways to generate clinical data

Moderator:
VICKI COUTINHO, Managing Director & Consultant, **Geni Consulting Limitied**

	TRACK 1: CELL LINE ENGINEERING & DEVELOPMENT	TRACK 2: UPSTREAM & DOWNSTREAM BIOPROCESSING: NOVEL TECHNOLOGIES & CONTINUOUS PROCESSING	TRACK 3: CELL CULTURE & CELL THERAPIES QUALITY CONTROL & ANALYSIS	TRACK 4: CGT DEVELOPMENT	TRACK 5: STRATEGIES FOR GENE THERAPY MANUFACTURING & PRODUCTION
	Track Chair CHRYSANTHI SITMALIDOU, Scientist II, **Orchard Therapeutics**	**Track Chair** MANUEL CARRONDO, Vice-President, **iBET**	**Track Chair** PATRICIA MENDOZA, Senior Scientist, **AstraZeneca**	**Track Chair** TERRI GASKELL, Chief Technology Officer, **Rinri Therapeutics**	**Track Chair** HARRIS MAKATSORIS, Professor of Sustainable Manufacturing Systems, **King's College London**
09:30	**Keynote Address: Advancing ATMPs And Biopharmaceutical Production: Trends & Challenges** • Improving product yield • Enhancing product quality • Minimizing foot print • Reducing cost of production • Facilitating sterile operation MANUEL CARRONDO, Vice-President, **iBET**			**Keynote Address: Making The Ordinary Extraordinary: MDG1015 A Clinic Ready 3rd Generation TCR-T Therapy** • Extraordinary natural 3S TCR • Armouring & enhancement through the PD1-41BB CSP • Optimal drug product composition • Evaluation in orphan and non-orphan indications KIRSTY CRAME, Vice President Clinical Strategy & Development, **Medigene**	**Keynote Address: Perspectives On Transitioning Clinical Production To Commercial Demand In AAV Gene Therapies** • The dynamics between cost of development & cost of goods • Evolution of CMC technologies during development • Strategies to consider in process validation & clinical exposure KYLE ZINGARO, Head of Gene Therapy Process Sciences, **UCB**
	Q&A Session & Transition Time Between Conference Rooms				
09:55	**CHO Cell Lines: Going Fast But Not Furious!** • Considering the growing complexity of biological modalities expressed in CHO, we generated new parental cell lines with improved features, conferring higher productivity and stability, and having less protease activity making the derived cell lines most suitable for expression of complex Biologics • Furthermore, combining the improved host cell lines with our FACS based selection method to enrich for high producing clones shortens cell line development timelines substantially, making fast-track cloning (FTC) a new standard at Novartis for bringing drug candidates most rapidly into clinics (FiH) ROLF KOEHLER, Associate Director/Group Head Cell Line Development, **Novartis**	**Current Trends And Approaches In Life Science & Biopharma Industry-Towards Biologics Modality Manufacturing** • Paradigm shift in Biologics Manufacturing • The role of Life Science suppliers and CDMOs in a changing environment • Approaches for Bio-Pharmaceutical companies to New Biologics Modalities • Evolution of Biomanufacturing and future perspective of New Biologic Modalities • How to achieve convergence of diverse manufacturing techniques • Potential role of Biopharma Clusters in Translation of Innovation and Technology UWE BUECHELER, Senior Advisor Biopharmaceuticals, Former Bio Business Unit Head **Boehringer Ingelheim**	**Bridging The Academic To Industry Gap: Overview Of NIBRT's Cell Therapy Capabilities** • NIBRT's mission is to help the growth and development of the biopharma manufacturing industry by providing cutting edge training and research solutions • NIBRT completed construction of its €21M (an investment from IDA Ireland and the Government of Ireland) facility dedicated to advancing research and training in Advanced Therapy Medicinal Products SAKIS MANTALARIS, Don Panoz Chair of Pharmaceutical Biology & Principal Investigator, **Trinity College Dublin & NIBRT**	**CGTs Are Revolutionary, So CGT Digital Means AI Right?** • Revolutionary medicine does not necessarily translate to adopting the most innovative digital technologies – at least not as the first step • We as an industry have some basic nuts and bolts to solve first. While many existing technologies like ERP or MES can be re-applied for CGTs, we need new capabilities in areas like patient engagement and treatment center interactions • In this talk, we will explore how Bayer is approaching the digital transformation for CGT, rooted in key commercial business model changes which extend beyond our experience in small molecule and biotech MENASHEH FOGEL, IT Head Cell and Gene Therapy, **Bayer**	**Transitioning From R&D To Clinical Manufacturing - Navigating The Path To Commerical** • Outlining the critical steps in transitioning gene therapy products from R&D to clinical manufacturing and commercialisation • Explore key strategies such as early planning, Quality by Design (QbD), and technology transfer • Emphasis will be placed on the importance of collaboration with CDMOs and academic partners, with real-worldcase study form commercial products • Attendees will gain actionable takeaways to streamline the transition from R&D to commercial success NITIN GARG, Director CMC Product Lead, **Adaptimmune**
	Q&A Session & Transition Time Between Conference Rooms				

DAY TWO: 07 NOVEMBER 2024

	TRACK 1: CELL LINE ENGINEERING & DEVELOPMENT	TRACK 2: UPSTREAM & DOWNSTREAM BIOPROCESSING: NOVEL TECHNOLOGIES & CONTINUOUS PROCESSING	TRACK 3: CELL CULTURE & CELL THERAPIES QUALITY CONTROL & ANALYSIS	TRACK 4: CGT DEVELOPMENT	TRACK 5: STRATEGIES FOR GENE THERAPY MANUFACTURING & PRODUCTION
10:20	**Solution Provider Presentation** Senior Representative, **Asimov**	**Solution Provider Presentation** Senior Representative, **Novo Nordisk**	**Innovative Contamination Control In Cell Therapy: Enabling Integrity And Efficiency** • We will discuss the use of upstream solutions such as automated closed systems for isolation and activation, and larger bioprocess containers • Also, the application of analytical assays for sterility testing, mycoplasma detection, and environmental monitoring. These measures aim to reduce contamination and improve overall operational effectiveness • An integrated approach combining these solutions can enhance contamination control, boost process efficiency, and ensure the production of high-quality cell therapy products SUZY BROWN, Senior Field Application Specialist & GEORGE PROUT, Senior Field Application Specialist **Thermo Fisher Scientific**	**Gold and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*	**Gold and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*
10:45	MORNING COFFEE & REFRESHMENTS	1-2-1 Meetings x4	Poster Displays	Company Spotlights x6	
12:05	**Generation Of Disease-Relevant Cell Models To Support Drug Discovery** • AstraZeneca relies on cell models to support different stages of drug development • Gene editing techniques such as CRISPR/Cas9, base editing, and overexpression systems are utilized to create cell models that address key questions • We will showcase examples of successful delivery and the impact of cell models, underscoring the advancements and future potential of 2D model generation in delivering drugs to patients LUZ ALONSO-CRISOSTOMO, Senior Scientist, **AstraZeneca**	**Antibody-Drug Conjugates: Antibodies Meeting Highly Potent APIs For Specific & Efficient Bio-Pharmaceutical Drugs** • ADCs – conjugation of antibodies with small molecule toxins • The development and manufacture of ADCs - challenges and solutions • The make-or-buy question – what to outsource and what to do in-house • Bayer's ADC production concept • Best practices for CMO selection and outsourcing ULRICH RÜMENAPP, Senior Biotech Program Lead, **Bayer**	**Use Of Bact/Alert 3D Instrument For Release Testing Of C&GT Product** • Presentation of BacT/ALERT® 3D system • Usage of BacT/ALERT® 3D system for release testing of C&GT product NICOLAS WEBER, Quality Team Leader QC, **Novartis**	**Enhancing Pharmacovigilance For ATMPs: Strategic Design & Development Of Safety Capabilities** • Impact of ATMPs on the PV system - Internal vs External factors • Adopting the PV system for ATMPs • Evolution vs Revolution JAMES CARLSON, Principal Safety Director ATMP Enablement, **Roche**	**Manufacturing Multiple ATMP Modalities In The Same Facility** • Addressing the needs of the ATMP industry • Facility design • Managing a compliant PQS HIMANSU PATEL, Head Of Quality Innovation, **Cell And Gene Therapy Catapult**
	Q&A Session & Transition Time Between Conference Rooms				
12:30	**Cell Line Development Inefficiencies And Streamlining The Clone Selection Process For Protein Biologic Production With The Solentim Ecosystem** • Adaptable Automation solutions: Discover the Cell Metric X portfolio's range, offering versatile levels of automation for every CLD need • AI-Powered Data Analysis: Discover the role of AI in automating the digital aspects of CLD, including sophisticated image analysis for accurate cell line evaluation and optimal clone selection • Application in Complex Cell Lines: Learn about the application of CMX in analyzing some of the most challenging cell lines ensuring detailed and reliable results SIVANE KOSKAS, Global Product Manager Cell Metric Protfolio, **Advanced Instruments**	**Solution Provider Presentation** Senior Representative **Waters S.A.S.**	**Silver and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*	**Solution Provider Presentation** Senior Representative, **Qiagen**	**Silver and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*
	Q&A Session & Transition Time Between Conference Rooms				

DAY TWO: 07 NOVEMBER 2024

	TRACK 1: CELL LINE ENGINEERING & DEVELOPMENT	TRACK 2: UPSTREAM & DOWNSTREAM BIOPROCESSING: NOVEL TECHNOLOGIES & CONTINUOUS PROCESSING	TRACK 3: CELL CULTURE & CELL THERAPIES QUALITY CONTROL & ANALYSIS	TRACK 4: CGT DEVELOPMENT	TRACK 5: STRATEGIES FOR GENE THERAPY MANUFACTURING & PRODUCTION
12:55	**Unravelling HEK293 Cell Biology To Improve Adeno-Associated Viral Vector (AAV) Manufacturing Bottleneck** • Challenges in AAV manufacturing • Building knowledge on HEK293 cell biology during AAV production: from clone selection to establishing a batch-mode production process and a multi-omics analytical characterisation • Target validation strategies with cell engineering technologies ELEONORA ZUCCHELLI, Associate Lead Scientist, **Cell and Gene Therapy Catapult**	**Challenges Faced With Analytical Strategies & Potency Assay Matrices** • Challenges of developing an analytical strategy for the characterization of a macrophage cells and gene therapy • RTX001 product background • Impact of complex MoA on AD strategy • Benefits of a potency matrix approach to support early clinical development GABRIEL KENT, Senior Analytical Development Scientist, **Resolution Therapeutics**	**Clinical Scale Production & Characterisation Of Novel Gamma-Delta T Cell Therapies** • Clinical applications, leveraging the power of gamma-delta T cells in Oncology • Clinical scale manufacturing and drug product analysis, how to understand the impact of your process on your product • An analysis of gene expression changes, reproducibility and robustness of clinical scale gamma-delta T cell manufacturing • Do donors matter, how donor selection and manufacturing process may impact your outcomes KATE ROCHLIN, Chief Opperating Officer, **IN8bio**	**Natural Killer Cell Product Development As Non-Engineered, Engineered, And Combination Therapy** • Allogeneic, off-the-shelf cryopreserved NK cells are a safe, scalable and cost-effective solution for the treatment of cancer and other diseases • Glycostem has developed an in-house platform for the manufacturing of NK cell therapeutics from cord blood stem cells • Glycostem's NK cells exert their functions as non-engineered, genetically engineered and combination therapies MONICA RAIMO, Director of Product & Process Development, **Glycostem Therapeutics**	**Innovation Hubs for Gene Therapies: Viral Vector Platform Development And Scale-Up At The Clinical Biotechnology Centre** • Gene Therapy clinical translational support to UK academic developers through Innovation Hubs for Gene Therapies • Updates on viral vector manufacturing platforms, focusing on development, scale-up processes, and production efficiency • Key challenges facing manufacturers and gene therapy developers, including scalability, regulatory hurdles, and production of adequate vector quantities SUJITH SEBASTIAN, Viral Vector Hub Manager, **Clinical Biotechnology Centre NHSBT**
13:20	LUNCH BREAK	1-2-1 Meetings x4	Poster Displays	Company Spotlights x6	
	Track Chair HIMANSU PATEL, Head Of Quality Innovation, **Cell And Gene Therapy Catapult**	**Track Chair** NIRAIMATHI GOVINDASAMY, Senior Scientist, **Bluu Seafood**	**Track Chair** PATRICIA MENDOZA, Senior Scientist, **AstraZeneca**	**Track Chair** TERRI GASKELL, Chief Technology Officer, **Rinri Therapeutics**	**Track Chair** HARRIS MAKATSORIS, Professor of Sustainable Manufacturing Systems, **King's College London**
14:20	**Stable Cell Lines In Cell And Gene Therapeies - Development Of A Stable Cell Line For An LVV Suspension Process** • Development of a CLD workflow: Key steps and technologies • Automation in CLD platforms • Introduction of Stable lines to an LVV suspension process CHRYSANTHI SITMALIDOU, Scientist II, **Orchard Therapeutics**	**Strategies To Reduce Media Demands In Perfusion Processes** • Media demand & logistics are considered roadblocks for adoption of perfusion processes • During this presentation three different strategies (perfusion supplement, cell density dependent automation of perfusion rate and fit for purpose tools to accelerate process development) are presented to tackle reduction of media demand in perfusion LUIS AYALA, Scientist Perfusion Systems, **Merck KGaA**	**Autonucleolytic Host Cells To Reduce DNA Impurity Levels In Gene Therapy Process Streams** • Mammalian cells were engineered with a transgene encoding secretion of a bacterial nuclease, into serum-free media • Yields of adenovirus, adeno-associated virus (AAV) and lentivirus from the resulting autonucleolytic cell lines were largely unaffected. For AAV and lentivirus, autonucleolytic cell lines effected a reduction DNA impurity level in process streams DARREN NESBETH, Associate Professor of Synthetic Biology, **University College London**	**New Materials For Therapeutics And Cell Delivery** • Design of new polymeric and LNP-based nanomedicines • New equiptment for nanomedicine analysis and quality control MOLLY STEVENS, Professor, **Oxford University**	**Process Development For Gene Therapy Products** • A knock-in gene editing-based strategy combining CRISPR/Cas9 system and adeno-associated viral vector (rAAV6) donor delivery showed promising results for the treatment of Pyruvate Kinase Deficiency (PKD), an inherited rare blood disorder • Now, we have developed and optimised a clinically relevant manufacturing protocol in CD34+ cells from four different healthy donors JOSE BONAFONT, Principal Scientist - Research and Prcoess Development, **DanausGT**
	Q&A Session & Transition Time Between Conference Rooms				
14:45	**Solution Provider Presentation** JONATHAN WHITCHURCH, Senior Field Application Scientist, **Iota Sciences**	**Isolator For Aseptic Manufacturing Of ATMPs** • Aseptic manufacturing of ATMPs requires a robust strategy, based on process knowledge, streamlined protocols and proper controls • What is the GMP state of mind, how does it apply to tech transfer from open, BSC based processes to full closure of an isolator? MICHELA CASTELLANI-KLEINSCHROTH, Head of MS&T, SKAN. Koji Ushioda, President, SKAN Japan **Aseptic Technologies**	**Smart PAT: Enhanced Process Control To Accelerate Time To Market In Cell Culture Bioprocesses** • Smart PAT's two pillars enable real-time monitoring and control to prevent bioprocess deviations • Pillar 1: New in-situ measurement technologies address durability, specificity, and faster time to market • Pillar 2: Digitalization enhances process analytics, digital twins, and asset management GIOVANNI CAMPOLONGO, Senior Market Segment Manager, **Hamilton**	**Solution Provider Presentation** Senior Representative, **Genscript**	**XOFLX™ Stable Cell Lines - A Flexible Platform For Lentiviral Vector Production** • We developed stable LVV packaging and producer cell lines that yield titres equivalent to the 4-plasmid process • Consistent LVV production with various cargo genes and promoters shows the robustness and the flexibility of the XOFLX™ platform MARIA PATRICIO, Group Leader, Cell Line Development, **OXGENE**
	Q&A Session & Transition Time Between Conference Rooms				

DAY TWO: 07 NOVEMBER 2024

	TRACK 1: CELL LINE ENGINEERING & DEVELOPMENT	TRACK 2: UPSTREAM & DOWNSTREAM BIOPROCESSING: NOVEL TECHNOLOGIES & CONTINUOUS PROCESSING	TRACK 3: CELL CULTURE & CELL THERAPIES QUALITY CONTROL & ANALYSIS	TRACK 4: CGT DEVELOPMENT	TRACK 5: STRATEGIES FOR GENE THERAPY MANUFACTURING & PRODUCTION
15:10	**Solution Provider Presentation** Senior Representative, **Beckman Coulter**	**Solution Provider Presentation** Senior Representative, **Eppendorf**	**Solution Provider Presentation** Senior Representative, **Oxford Biomedica**	**Nio | Elevating the Gold Standard In dPCR: Viral Vectors, BioPharma Assays, And Biologics Manufacture** • Stilla have demonstrated that increasing plex levels maintains sensitivity, accuracy, and precision, significantly enhancing multiplexing capabilities for robust quantification • In collaboration with Niba labs, our first Niba-plex assays will be presented, which will effectively address the rigorous demands of modern production • The 7-plex Kanamycin resistance assay, alongside outlining future assays assessing critical parameters such as payload integrity, capsid classification (empty, partial, or full), and both residual and host-cell DNA contamination ALEXANDER WIDGER, Country and Business Development Manager (UK/IRL), **Stilla Technologies**	**Next Generation AAV Manufacturing Process** • Replacing affinity capture with a strong anion exchanger offers a 30% higher recovery, resulting in a 30% increase in doses available for clinical use • The new process also improves the removal of empty and partial AAV capsids, as well as infectious viruses and endotoxins • Additionally, the PATfix Switcher provides insight into the upstream processing (USP) black box, enabling the optimization of full capsid production ALES STRANCAR, Managing Director, **Sartorius BIA Searations**
15:35	AFTERNOON BREAK	1-2-1 Meetings x3	Poster Displays	Company Spotlights x6	
16:35	**Panel Discussion: How To Troubleshoot Cell Line Engineering & Development Bottlenecks** • Strategies for optimizing transfection methods • Impact of emerging technologies **Moderator:** LUZ ALONSO-CRISOSTOMO, Senior Scientist, **AstraZeneca** **Panellists:** DARREN NESBETH, Associate Professor of Synthetic Biology, **University College London** FARHAD PAYLAKHI, Co-Founder & Vice President of R&D, **64x Bio** PATRICIA MENDOZA, Senior Scientist, **AstraZeneca** KIRTHIKA SREENIVAS, Senior Scientist, **Polpharma Biologics**	**Improving Instrumentation For Biopharmaceutical Drug Production** • How can chemical sensing support the development of cell therapy? • What are the barriers for the development of robust sensors and how can we resolve existing issues? SERGEY PILETSKY, Professor & Head of Research, **University of Leicester** *Q&A Session & Transition Time Between Conference Rooms* **Linking Phenotype To Genotype: Semi-Automated, Multiplexed CRISPR Screening For Target Discovery** • Why? Rapid target validation (TV) following whole-genome pooled screens • How? A Semi-automated, multiplexed arrayed CRISPR screening workflow maximises information obtained in one screen • So What? Validated targets may provide novel drug targets, combination strategies or new patient populations MILLIE FOX, Senior Scientist, **AstraZeneca**	**Panel Discussion: Advancing Cell Therapies: Exploring Quality Control & Personalised Medicine Integration** • Patient-centered approaches • Data management • Emerging technologies • Assay development **Moderator:** PHILIPPE HENON, Founder & Chariman of The Board, **CellProther** **Panellists:** ZHONG YU, Scientific Liaisons Manager**, Axion BioSystems** MONICA RAIMO, Director of Product And Process Development, **Glycostem Therapeutics** NICOLAS WEBER, Quality Team Leader QC, **Novartis** NABIHA SAKLAYEN, Co-Founder & Chief Executive Officer, **Cellino Bio**	**Panel Discussion: Ensuring Early Success And Accelerating The Development Of CGT Products** • Early-stage characterisation and optimisation • Challenges and opportunities facing CGT commercialization and digitalisation • Regulatory strategies to facilitate development acceleration • Collaborative partnerships and resource sharing **Moderator:** ROELOF RONGEN, Chief Executive Officer, **Adolore BioTherapeutics** **Panellists:** AKI KO, Co-Founder & Chief Executive Officer, **Elixirgen Therapeutics** JAS UPPAL, Founder & Chief Executive Officer, **BQP Consultancy** MENASHEH FOGEL, IT Head Cell & Gene Therapy, **Bayer**	**Panel Discussion: Strategies For Gene Therapy Manufacturing Success & Commercialization** • Central versus bed side manufacturing • Optimization of vene to vene processing/release time • Challenges of end to end aseptic processing • Attempts for convergence of manufacturing processes • Economy of Scale: Scale up versus Scale out • Automation of manufacturing processes • Autologous versus allogenic approaches **Moderator:** UWE BUECHELER, Senior Advisor Biopharmaceuticals, Former Bio Business Unit Head, **Boehringer Ingelheim** **Panellists:** KYLE ZINGARO, Head of Gene Therapy Process Sciences, **UCB** SUJITH SEBASTIAN, Viral Vector Hub Manager, **Clinical Biotechnology Centre NHSBT** MARIA LUISA GIORELLO, Global Gene Therapy Platform Enablement Director, **Pfizer** NITIN GARG, Director CMC Product Lead, **Adaptimmune**
17:00					
17:25	**End of Day Two & Drinks Reception**				

DAY THREE: 08 NOVEMBER 2024

MORNING ROUNDTABLE DISCUSSIONS

09:00

Roundtable Discussion 1: Insights From Emerging Cell Technologies
- Latest technologies including CRISPR
- Novel technological applications for Cell & Gene Therapies

Moderator: ADAM SIDAWAY, Lead Scientist - Molecular Biology, **Uncommon**

Roundtable Discussion 2: Advancing Cell Culture Through Harnessing Biometric Systems
- Integration of biometric systems in cell culture
- Enhancing cell culture efficiency
- Improving accuracy and precision

Moderator: SAKIS MANTALARIS, Don Panoz Chair of Pharmaceutical Biology & Principal Investigator, **Trinity College Dublin & National Institute for Bioprocessing Research & Training**

Roundtable Discussion 3: Advancing Biotechnology Innovation & Collaboration
- Facilitating cross disciplinary collaboration
- Accelerating innovation through creation and growth of startups, spinouts and cross academia-industry collaboration
- Building knowledge-based ecosystems for delivering innovation

Moderator: ALINE MILLER, Principal Investigator, Professor of Biomolecular Engineering and Associate Dean for Business Engagement and Innovation, **The University of Manchester**

TRACK 1: OPTIMISING CELL CULTURE MEDIA & MODELS	TRACK 2: PRECLINICAL CGT ASSESSMENTS: RESEARCH & DEVELOPMENT	TRACK 3: CGT CLINICAL DEVELOPMENT & CLINICAL TRIALS	TRACK 4: IPSCS AND STEM CELL THERAPY DEVELOPMENT	TRACK 5: STRATEGIES FOR CELL THERAPY MANUFACTURING & PRODUCTION
Track Chair NIRAIMATHI GOVINDASAMY, Senior Scientist, **Bluu Seafood**	**Track Chair** HIMANSU PATEL, Head Of Quality Innovation, **Cell And Gene Therapy Catapult**	**Track Chair** JOSE BONAFONT, Principal Scientist - Research and Prcoess Development, **DanausGT**	**Track Chair** LUCY WILLIAMS, Partner, European and UK Patent Attorney, **J A Kemp LLP**	**Track Chair** SAKIS MANTALARIS, Don Panoz Chair of Pharmaceutical Biology & Principal Investigator, **Trinity College Dublin & NIBRT**
09:30 **Track Keynote Address: Global Cell Bank Management: Generating, Ensuring Quality, And Promoting Sustainability In AstraZeneca** • Cell bank generation, operating models, importance of QC analysis as well as incorporating sustainable endeavours into the cell banking workflow SARAH HOWLETT, Associate Director UK Cell Culture & Banking, **AstraZeneca**	**Track Keynote Address: Guide Me: AviadoBio Path To Precise Gene Silencing Therapies** • Overview of NGS thechnologies & application sin preclinical studies • Gene silencing as therapeutic approach in neurode-generative diseases • Development of vMiX™ , a versatile, robust and ready-to-use miRNA-based gene therapy platform CATIA ANDREASSI, Director Discovery, **AviadoBio**	**Track Keynote Address: Clinical Development Of Autologous Cell Based Therapy For The Treatment Of Post-Acute Myocardial Infarction (AMI)** • AMI background and mechanism of action CD34+ cells • Technology for automated manufacturing of autolo-gous CD34+ cell based therapy • Preliminary preclinical and clinical results IBON GARITAONANDIA, Chief Scientific Officer, **CellProthera**	**Track Keynote Address: Bioengineered CD34+ Cells (ProtheraCytes) Regenerate The Heart After Myocardial Infarction** • Severe acute myocardial infarction (AMI) generally causes secondary chronic heart failure (CHF) with short or middle-term bad prognosis • Direct intra- cardiac injection of GMP-expanded autologous CD34+ stem cells (ProtheraCytes®) after such severe AMI could sufficiently regenerate the heart to avoid the occurrence of secondary CHF, thus favorably modifying the patient's prognosis • Results of a phase II clinical trial point in this direction PHILIPPE HENON, Founder & Chairman of The Board, **CellProthera**	**Track Keynote Address: Quality And Manufacturing Lessons Learned From Decentralised Manufacturing CT Model** CHARLOTTE MAISONNEUVE-SERRA, Vice President, Head of Quality Assurance, Cell Therapy, **Galapagos**

Q&A Session & Transition Time Between Conference Rooms

09:55 **Orbitally Shaken Bioreactors (OSB)** DR DAVID FLITSCH, Head of Application Support, **Kuhner Shaker**	**Solution Provider Presentation** Senior Representative, **GemPharmatech**	**Gold and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*	**Gold and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*	**Solution Provider Presentation** Senior Representative **Thermo Fisher Scientific**

10:20 **MORNING COFFEE & REFRESHMENTS** | 1-2-1 Meetings x4 | Poster Displays | Company Spotlights x6

DAY THREE: 08 NOVEMBER 2024

	TRACK 1: OPTIMISING CELL CULTURE MEDIA & MODELS	TRACK 2: PRECLINICAL CGT ASSESSMENTS: RESEARCH & DEVELOPMENT	TRACK 3: CGT CLINICAL DEVELOPMENT & CLINICAL TRIALS	TRACK 4: IPSCS AND STEM CELL THERAPY DEVELOPMENT	TRACK 5: STRATEGIES FOR CELL THERAPY MANUFACTURING & PRODUCTION
11:40	**Solution Provider Presentation** Senior Representative, **Cancer Tools**	**Building Better CARs For The Treatment Of Solid Tumours** • Whilst CAR T-cells have achieved revolutionary outcomes against haematological malignancies, success has been more limited in solid tumours • Here, we demonstrate how rational CAR design and appropriate armouring can be combined to achieve a step-change in function against solid tumours MARC DAVIES, Vice President R&D, Leucid Bio **Axion Biosystems**	**Silver and Above Solution Provider Presentation** *For sponsorship opportunities, please contact sponsorship@oxfordglobal.com*	**Solution Provider Presentation** **RESERVED**	**Solution Provider Presentation** **RESERVED**
	Q&A Session & Transition Time Between Conference Rooms				
12:05	**How Cultivated Meat Technologies Can Push Boundaries To Enable iPSCs For Therapeutics - The Synergy Between Two Seemingly Disparate Fields** • We will highlight how the two spaces (Cultivated Meat and Therapeutics) are not as disparate as they may seem, as well as highlight how different industries can learn from each other to advance different areas, such as efficiency, scale, and cell line production • Finally, we will discuss how Uncommon are now working with other industries to break new ground with our technologies ADAM SIDAWAY, Lead Scientist - Molecular Biology, **Uncommon**	**Gene Therapy For Chronic Pain** • Transcriptomics revealed novel intracellular proteins that can downregulate pain signal: Carbonic Anhydrase-8 (CA8) emerged as superior • rdHSV emerged as superior method for intracellular delivery of CA8 for treatmen of chronic pain, administered locally at site of pain • Advanced preclinical development has demonstrated long-acting and potent analgesia and a superb safety profile with benign immunogenicity and biodistribution limited to adminstration site • rdHSV manufacturing technologies have proven to be cost efficient and suitable for mass-market applications ROELOF RONGEN, Chief Executive Officer, **Adolore BioTherapeutics**	**Cell Therapy Liver: Clinical Development Of Engineered Macrophage Cell Therapy RTX001 As A Potentially Transformative Treatment For End Stage Liver Disease** • Previous research highlighted the beneficial role of macrophages in the resolution of chronic inflammation and liver fibrosis • Human monocyte-derived macrophages with no genetic modifications were tested in an academic study (MATCH) involving subjects with compensated liver cirrhosis. This data supports rationale to develop RTX001 as a treatment for liver cirrhosis ESTHER KITTO, Vice President Clinical Operations, **Resolution Therapeutics**	**Featured Panel Discussion: Exploring The Potential Of Stem Cell Therapy: Advantages, Challenges, & Clinical Applications** • Navigating regulatory roadblocks • Therapeutic potential • Enhancing durability **Moderator:** BEN TAYLOR, Senior Director, **AstraZeneca** **Panellists:** TERRI GASKELL, Chief Technology Officer, **Rinri Therapeutics** KLARA KULENKAMPFF, Project Manager, **Bayer** PATRIZIA FERRETTI, Professor, **University College London**	**Featured Panel Discussion: Technologies For Cell Therapy Scale Up & Commercialisation** • Current challenges of autologous & allogeneic cell therapies • Early process and analytical considerations for a successful commercial product • State of the art & innovations in cell therapy manufacturing **Moderator:** MARC SCHNEIDER, Director Product Supply Cell & Gene, **BioNTech SE** **Panellists:** XAVIER FONTANA, Principal Scientist Allogenic Process Development, **Adaptimmune** WONJONG SI, Associate Director Cell Therapy Platform Process, **Bayer** EMILIE GAUTHY, Head Of CMC, **Zelluna Immunotherapy**
	Q&A Session & Transition Time Between Conference Rooms				
12:30	**Optimisation Of Cell Culture To Increase The Regenerative Potential Of Stem Cells** DARIUS WIDERA, Professor of Stem Cell Biology and Regenerative Medicine, **University Of Reading**	**Nonclinical Evaluation Of CTx001, A Gene Therapy For The Treatment Of Geographic Atrophy In Age-Related Macular Degeneration** • Complement Therapeutics is developing CTx001, an AAV gene therapy expressing a soluble, truncated form of the complement regulatory protein complement receptor 1 (mini-CR1) for the treatment of geographic atrophy (GA). • In this study we tested Mini-CR1 [CTx001] AAV2 gene therapy for GA using a cohort of in-vitro, in-cellulo and in-vivo systems. Our aim was to establish the potent bioactivity of CTx001 on the proteolytic inhibition of pathological complement substrates C3b & C4b ATHANASIOS DIDANGELOS, Director of Pharmacology, **Complement Tx**	**Roundtable Discussion: CGT Biomarker Strategies: Navigating Challenges & Opportunities** • Current challenges and limitations • Clinical applications • Long-term monitoring • Integration of biomarkers into clinical trial design **Moderator:** RAIKO STEPHAN, Gene & Cell Therapy Lead, **Novartis**		
12:55	LUNCH BREAK	1-2-1 Meetings x3	Poster Displays	Company Spotlights x6	Live Q&A With Regulatory Speakers Charlotte Maisonneuve, Galapagos

DAY THREE: 08 NOVEMBER 2024

TRACK 1: OPTIMISING CELL CULTURE MEDIA & MODELS

Track Chair

NIRAIMATHI GOVINDASAMY, Senior Scientist,
Bluu Seafood

Cell Model Selection: The Model Match Approach In Drug Discovery

- Comprehensive OMICs characterization of preclinical cell models to underpin project strategies
- Cross-functional framework to address disease translatability of cell models and accelerate drug discovery

PATRICIA MENDOZA, Senior Scientist,
AstraZeneca

**Panel Discussion:
The Impact & Future Of 3D Cell Culture**

- 2D vs. 3D cell culture
- Challenges and opportunities in translation to clinical practice

Moderator:

DARIUS WIDERA, Professor Of Stem Cell Biology and Regenerative Medicine, **University Of Reading**

Panellists:

KELLY EVANS, Senior Scientist, **AstraZeneca**

ALINE MILLER, Principal Investigator, Professor of Biomolecular Engineering and Associate Dean for Business Engagement and Innovation, **The University of Manchester**

TRACK 2: PRECLINICAL CGT ASSESSMENTS: RESEARCH & DEVELOPMENT

Track Chair

MARTIN DASS, Senior Scientist,
Boehringer Ingelheim

Exploratory Safety Concerns In Gene Therapy Preclinical Assessment

- Clinical translation
- Rare disease
- Translational biomarkers
- Disease biology
- AAV gene therapy development

RAIKO STEPHAN, Gene & Cell Therapy Lead,
Novartis

Safety Considerations In ATMP Preclinical Assessment

- Current landscape of ATMP trials in the UK
- Potential safety concerns for ATMPs
- Pre-clinical requirements for early phase trials

ROSHNI DESAI, Nonclinical Assessor,
MHRA

Biomarker Discovery & Validation In Preclinical Models

- This presentation is an overview of the novel "snapshot" imprinting method developed by Leicester Biotechnology Group
- The method allows identifying the linear surface epitopes of the individual proteins, whole cells and viruses using molecularly imprinted polymers (MIPs)
- The specific epitopes are biological markers for particular cellular conditions
- The MIP nanoparticles specific for these epitopes could be labelled and used for imaging and diagnostics

ELENA PILETSKA, Professor,
University Of Leicester

TRACK 4: IPSCS AND STEM CELL THERAPY DEVELOPMENT

Track Chair

LUCY WILLIAMS, Partner, European and UK Patent Attorney,
J A Kemp LLP

TCR-T Platform For Solid Tumours

- Medigene's End-to-End Platform provides cutting-edge technologies for the development of TCR-T therapies for solid cancer
- High precision technologies to select 3S TCRs that display extraordinary attributes of specificity, sensitivity and safety to guide precise and sensitive tumor cell recognition
- Armoring and enhancement technologies that enable TCR-T cells to function effectively in the hostile microenvironments created by solid tumors
- Innovative tools to tag and trace 3S TCRs and TCR-T cells through all stages of research and clinical development

DOLORES SCHENDEL, Chief Scientific Officer,
Medigene AG

AI-Driven Biomanufacturing Of Cell And Tissue Replacements

- Itroduction to Cellino's optical bioprocess that combines optics and image-guidied machine learning for iPSC management
- Optical cassette-based manufacturing for scalable production of cells and tissues

NABIHA SAKLAYEN, Co-Founder & Chief Executive Officer,
Cellino Bio

Delivering Sustainable Pathways For The Provision Of CAR-T Therapies To Patients: Legal, Ethical, And Regulatory Challenges And Opportunities

- Focusing on the legal, ethical, and regulatory challenges in delivering sustainable pathways for the provision of CAR-T therapies
- Drawing on research developing as part of a recent Irish study on 'Access and Provision of CAR-T therapies' it will identify key aresa which need to be considered in such contexts to deliver patient centred pathways for provision of such therapies

AISLING MCMAHON, Professor of Law,
Maynooth University

TRACK 5: STRATEGIES FOR CELL THERAPY MANUFACTURING & PRODUCTION

Track Chair

SAKIS MANTALARIS, Don Panoz Chair of Pharmaceutical Biology & Principal Investigator,
Trinity College Dublin & NIBRT

Autologous Manufacturing - What Is Next?

- What are the main challenges of autologous cell therapy manufacturing?
- What manufacturing platforms are available?
- What could bedside approaches look like?

MARC SCHNEIDER, Director Product Supply Cell & Gene,
BioNTech SE

Bringing A MAGE-A4 Targeting, "Off The Shelf", Allogeneic TCR-NK Cells Into The Clinic: Learnings Through Scale Up Manufacturing & Regulatory Interactions

- Key decisions to make from the early process development onwards
- Common pitfalls while scaling-up and how to avoid them
- Pre-IND meeting interactions: polishing the regulatory path

EMILIE GAUTHY, Head Of CMC,
Zelluna Immunotherapy

Translating Allogeneic Research To Cell Therapy Manufacturing For Efficacy & Quality

- This talk will provide you with a framework for success in early cell therapy process development whilst laying out a strategy to avoid pitfalls in scaling up cell manufacture
- Main challenges to bring Allogeneic T-Cell therapies to the clinic
- Key Process and Analytical Development principles to guide you early on during the research stage
- Lessons for transitioning from lab scale to developing a large scale manufacturing process

XAVIER FONTANA, Principal Scientist Allogenic Process Development,
Adaptimmune

14:20

Q&A Session & Transition Time Between Conference Rooms

14:45

15:10

Q&A Session & Transition Time Between Conference Rooms

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DAY THREE: 08 NOVEMBER 2024

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15:35	**Moving Towards Animal Free 3D Cell Culture For Drug Discovery & Disease Modelling** • 3D cell culture is an increasingly reliable method to mimic the in vivo environment in vitro; however, some widely used biomaterial scaffolds have limitations as they are animal derived and lack tuneability and reproducibility • Recent advancements in synthetic tuneable peptide hydrogels have shown potential to overcome these limitations by better simulating tissue microenvironments, allowing the generation of more physiologically and clinically relevant data ALINE MILLER, Principal Investigator, Professor of Biomolecular Engineering and Associate Dean for Business Engagement and Innovation, **The University of Manchester**	**Human Relevant Cell Models And Their Use In Preclinical Safety Assessments** • Preclinical safety assessments are essential in the drug development pipeline, but animal models are not always predictive • Optimisation and utilisation of 2D human immune co-culture models to assess potential adverse immune risks of therapeutics, including cell and gene therapies • Establishment of 3D human lung organoids for assessment of lung toxicity in vitro • Limitations, challenges, and future directions KELLY EVANS, Senior Scientist, **AstraZeneca**	**Human In Vitro Models Of Birth Defects To Investigate Disease Mechanisms And Therapies** • Value of different sources of patient-derived cells for therapeutic development • Use of iPSCs-derived patient cells can allow the study of different aspects of birth defects as they often affect several organs that may require different therapeutic solutions • Examples will include diseases such as Duchenne muscular dystrophy, acrodysostosis and microtia with a focus on cartilage and neural tissues PATRIZIA FERRETTI, Professor, **University College London**	**CAR-T Manufacturing: Successes, Challenges & Future Implications** • A history of CAR T cell manufacturing • An overview of the challenges manufacturers face in producing autologous and allogenic CAR T products • An understanding of the paradigm shifts that will be needed for the future of CAR T cell manufacturing JOHN GARCIA, Head of New Manufacturing Technologies, **UCL**
	Q&A Session & Transition Time Between Conference Rooms			
16:00	**Cryopreservation Of Complex Cell Models Using Macromolecular Cryoprotectants** • To widen the use of complex cell models, new cryopreservation tools are essential to allow sharing, banking and wider uptake • Standard DMSO cryopreservation is not sufficient for cells in monolayers or 3D • We have developed new macromolecular cryoprotectants which allow near quantitative recovery of cells in complex 2 and 3D formats such as monolayers, spheroids or on transwells MATTHEW GIBSON, Chair (Professor) of Sustainable Biomaterials, **University Of Manchester**	*Attendees Are Welcome To Attend The Co-Located Sessions*	*Attendees Are Welcome To Attend The Co-Located Sessions*	**Automation & AI In Cell & Gene Therapy Manufacturing** ALEX SMITH, Director Regulatory Science, **HoganLovells, LLP**
16:25	**End of Congress**			

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