In Association With:
International Society for Cellular Therapy
ISCT

Cell Therapy Manufacturing & Gene Therapy

CONGRESS

Wednesday 2 - Thursday 3 December 2015 - Sheraton Airport Hotel, Brussels, Belgium

Discover the Latest Technical, Manufacturing and Commercial Strategies Driving the Cell and Gene Therapy Revolution

200+ Industry Leaders

Jonathan Appleby
MDL and CSO, Rare Diseases Gene Therapy,
GSK
UK

Lothar Germeroth
SVP, Managing Director
Juno Therapeutics
Germany

Bernadette Keane
VP, QA/QP
Bluebird
USA

Christian-Homsy
CEO
Celyad
Belgium

Harald Petry
CSO
Uniqure
The Netherlands

Maria Cristina Galli
EATRIS
Italy

1 Conference **Cell Therapy Manufacturing**

2 Conference **Gene Therapy**

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Day One

Wednesday 2 December 2015

Joint PLENARY SESSION: Regulatory Updates and Recent Progress

Session Supported by International Society for Cellular Therapy ISCT

07.30 Registration and Morning Coffee

08:20 Chairperson's Opening Remarks
Christopher Bravery, Director, Consulting on Advanced Biologicals Ltd., Member, **ISCT EU Legal and Regulatory Affairs Committee,** UK

Taking an ATMP to Market

08.30 **The challenges of developing GSK2696273, GSK's first ex vivo, autologous gene therapy**

- Safety assessment
- Clinical
- Regulatory
- Manufacturing

Jonathan Appleby, MDL and Chief Scientific Officer, Rare Diseases Gene Therapy, **GSK,** UK

The First Stem-Cell Based ATMP in the EU – CMC and Post-Approval Considerations

09.00 **Holoclar®, the first Stem Cell-based ATMP Approved in the EU: how an academic research became a pharmaceutical product.**

Part 1: Regulatory hurdles and key considerations during development

- From Advanced Therapy to ATMP
- Development and implementation of regulatory strategy
- Key CMC, pre-clinical and clinical challenges

Alex Bloom, Senior Manager, Global Regulatory Affairs, Biologics and Advanced Therapies, **Chiesi,** UK

Part 2: From clinical development to commercialization

- Use of retrospective clinical data from health records to generate regulatory-valuable evidence: issues and challenges
- Review and contextualization of Holoclar clinical data package within marketing authorization procedures and clinical practice
- Transition from a single-country clinical experience to EU-wide distribution and commercialization
- Facing post-approval commitments and patient's access

Diego Ardigo, Project Leader, Cell and Gene Therapy Products, **Chiesi,** Italy

09.30 **Discussion Panel - Regulatory Strategies for Cell and Gene Therapies**

Jonathan Appleby, MDL and Chief Scientific Officer, Rare Diseases Gene Therapy, **GSK,** UK

Harald Petry, Chief Scientific Office, **Uniqure,** The Netherlands

Maria Cristina Galli, ATMP platform co-chair, **EATRIS,** Italy

Margarida Menezes-Ferreira, Infarmed,Portugal, Member, **Committee of Advanced Therapies** (invited)

Jurjen Velthuis, Vice President, CMC, **Kiadis Pharma,** The Netherlands

Diego Ardigo, Project Leader, Cell and Gene Therapy Products, **Chiesi**

10.15 **Morning Coffee**

1 Cell Therapy Manufacturing

10.55 Chairperson's Opening Remarks

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

Manufacturing Strategies for Cell Therapies

Session Supported by ISCT

11.00 **How manufacturing models will define the success of cell therapies**

Christian-Homsy, CEO, **Celyad,** Belgium

11.20 **Building a large-scale GMP manufacturing facility for cellular therapy in Europe**

Miguel Forte, Chair, **ISCT Commercialization Committee,** Chief Operating Officer, **Txcell,** France

2 Gene Therapy

10.55 Chairperson's Opening Remarks

Alan Boyd, MD, **Boyd Consultants,** UK

Commercialisation and Pricing Strategies

11.00 **Scientific and regulatory challenges for developing gene therapy medicinal products**

Maria Cristina Galli, ATMP platform co-chair, **EATRIS,** Italy

11.30 **EU Gene and Cell Therapy support in Horizon 2020**

David Gancberg, Scientific and Project Officer, DG Research & Innovation, **European Commission**, Belgium

To **register** or for the **latest information,** please visit: **www.cellgenecongress.com**

11.40 **Discussion Panel: Manufacturing strategies for clinical and commercial launch**
Panelists:
Miguel Forte, Chief Operating Officer, **Txcell,** France
Christian-Homsy, CEO, **Celyad,** Belgium
Knut Niss, Member, ISCT Commercialization Committee, CMC Team Director, **Biogen Idec,** USA

Raw Materials & Media Development

12.10 
Customer / regulatory requirements on raw material
Bernd Schröder, Global Head Regulatory Affairs, **Miltenyi,** Germany

12.20 
Raw materials in the manufacture of ATMPs: Quality attributes and quality assurance
Bernd Leistler, Director Development & Production, **CellGenix,** Germany

12.30 
Leveraging expertise in raw material science to address regulatory and supply challenges in stem cell therapy
Antoine Heron, Head of Market & Portfolio Development, Stem Cell Bioprocessing Group **Merck Millipore,** Germany

12.40 **Presentation TBC**
Representative, **Cook Regentec**

12.50 **DISCUSSION PANEL:**
Part 1: Raw materials quality and traceability
Part 2: Serum-free
- Control and risk assessment of raw materials – what systems do companies have to protect themselves?
- Serum free media development
- Ensuring the long-term supply of raw materials
- Qualifying raw materials to ensure optimal quality – sources of good raw material
- How should companies work with suppliers?


Anthony Davies,President, **Dark Horse Consulting,** USA
Bernd Leistler, Director Development & Production, **CellGenix**, Germany
Bernd Schröder, Global Head Regulatory Affairs, **Miltenyi,** Germany
Antoine Heron, Merck, Germany

11.50 **Pricing and re-imbursement - what is the payers' perspective?**
Deborah Morrison, Senior Scientific Adviser, **NICE Scientific Advice Centre for Health Technology Evaluation, UK**

Commercialising Gene Therapies

12.10 
Bringing orphan drugs and gene therapies to market: Maximising ROI through an effective communication plan
Howard Sinclair, Strategic Director – Rare Diseases and Gene Therapy, **The Prime Medical Group,** UK
Andrew Jobson, PhD, Senior Editorial Manager – Rare Diseases and Gene Therapy, **The Prime Medical Group,** UK

12.30 **DISCUSSION PANEL**
Pricing and reimbursement strategies for gene therapies
- Pricing structures for gene therapies
- Preparing for commercialisation
- "Pay for play" payment options


Harald Petry, Chief Scientific Office, **Uniqure,** The Netherlands


Diego Ardigo, Project Leader, Cell and Gene Therapy Products, **Chiesi,** Italy


Maria Cristina Galli, IATRIS, Italy

Deborah Morrison, Senior Scientific Adviser, **NICE Scientific Advice Centre for Health Technology Evaluation,** UK

13.15 **Lunch and Live Labs Exhibition Tour**

Characterisation - From TTP to Product Release

14.30 
Manufacturing development guided by Quality-by-Design principles
Wouter Harink, Head of Manufacturing, **Kiadis,** The Netherlands

14.50 
Searching for the best cells for TCR engineered T-cell therapy
Gwendolyn Binder-Scholl, Executive VP, **AdaptImmune,** USA

15.10 **Extractables and leachables Testing**
Li Ren, Associate Director, Manufacturing Sciences, **Celgene,** USA

Gene Therapy Clinical Updates

14.30 **Latest updates from RegenxBio**
Stephen Yoo, Chief Medical Officer, **REGENXBIO Inc,** USA

15.00 **Challenges when deigning gene therapy trials**
- How to design a clinical trial
- Setting end-points
- Biomarkers

Panelists:
Alan Boyd, MD, **Boyd Consultants,** UK
Stephen Yoo, Chief Medical Officer, **REGENXBIO Inc,** USA
Abraham Scaria, Senior Scientific Director, Gene Therapy/ Ophthalmology, **Sanofi-Genzyme R&D Center,** USA

15.30 **Afternoon Break**

Characterisation - From TTP to Product Release

16.10 
QA/QC considerations for cell therapies
Bernadette Keane, VP, QA/QP, **Bluebird,** USA

16.30 
Setting specifications
Dr Christopher Bravery, Director, Consulting on Advanced Biologicals Ltd., Member, **ISCT EU Legal and Regulatory Affairs Committee,** UK

Delivery of Gene Therapies

16.10 
Delivery strategies to the eye
Abraham Scaria, Senior Scientific Director, Gene Therapy/ Ophthalmology, **Sanofi-Genzyme R&D Center,** USA

16.30 
The role of mRNA when delivering to the patient
Harald Petry, Chief Scientific Office, part of the management team, **Uniqure,** The Netherlands

16.50 
Joint Closing Plenary: 3D BioPrinting for Regenerative Medicine

Professor Lorenzo Moroni, Maastricht University, The Netherlands

17.30 **Drinks and Networking Reception**

To **register** or for the **latest information,**
please visit: **www.cellgenecongress.com**

Day Two

Thursday 3
December 2015

Manufacturing Genetically Modified T-Cells

08.55 **Anthony Davies,** President, **Dark Horse Consulting,** USA

09.00 **The ExCELLence cell handling platform for efficient production of gene-modified T-cells**
Lothar Germeroth, SVP, Managing Director, **Juno Therapeutics GmbH,** Germany

09.20 **Manufacturing strategies for CAR-T therapies –Cellectis case study**
Sylvain Arnould, Head, Manufacturing, **Cellectis,** France

09.40 **Simplify, optimise and control – The Autolus approach to CAR-T manufacturing**
Jim Faulkner, Head, Manufacturing, **Autolus,** UK

10.00 **DISCUSSION PANEL: The realities of manufacturing CAR-T Cells**

DISCUSSION PANEL

- What are the unique manufacturing strategies for CAR-T cells?
- In-house vs. external manufacturing of CAR-T cells
- Centralised vs. de-centralised models
- Vector development issues
- Supply chain management of CAR-T cells
- Workflow optimisation in a commercial phase overlaps between process development and quality
- Software support for CAR-T cells

Panelists:

Lothar Germeroth, SVP, Managing Director, **Juno Therapeutics GmbH,** Germany

Bernadette Keane, VP, QA/QP, **Bluebird,** USA

Gwendolyn Binder-Scholl, Executive VP, **AdaptImmune,** USA

Sylvain Arnould, Head, Manufacturing, **Cellectis,** France

Jim Faulkner, Head, Manufacturing, **Autolus,** UK

10.30 **Morning Coffee and Networking**

1 Cell Therapy Manufacturing

Scale-Up, Bioreactors and Process Development

11.15 

Making the largest therapeutic cell bank in the world
Mark W Lowdell, Member, ISCT Advisory Board, Director of Cellular Therapy & Biobanking / Senior Lecturer, **UCL,** UK

11.30 **Spotlight Presentation**

11.45 

Matching manufacturing of cell therapies to the commercial market
Knut Niss, Member, ISCT Commercialization Committee, CMC Team Director, **Biogen Idec,** USA

12.15 

Advancing towards next generation allogeneic stem cell production
Bart Vaes, Group Leader, **Regenesys,** Belgium

12.45 **Spotlight Presentation**
please contact
luke.pickering@informa.com for more information

13.15 **Lunch**

14.30 

Cell Therapy Production Surgery
Chairs: **Ohad Karnieli,** Chair, **Process and Product Development committee,** (ISCT), and VP, Technology and Manufacturing, **Pluristem,** Israel
Hot topics to discuss:

- Bioreactors • Scale-up
- Working towards closed systems • Serum-free media development • Freeze, thaw
- Working with DSMO free formulations

Panelist:
Lothar Germeroth, SVP, Managing Director, **Juno Therapeutics GmbH,** Germany
Knut Niss, CMC Team Director, **Biogen Idec,** USA

2 Gene Therapy

Manufacturing Strategies: Vector Selection, Scale-Up and GMP

11.15 

Transition from large-scale research grade vector production to industrial strength process
Robert Kotin, Vice President, Production, **Voyager Therapeutics,** USA

11.45 

Develpment of fully scalable rAAV manufacture process
Guang Qu, head of process development
Spark Therapeutics, USA

12.15 

Lentivirus based manufacturing strategies for gene and cell therapies
James Miskin, Chief Scientific Officer,
Oxford Biomedica, UK

12.45 

Possibilities of iCELLis® fixed-bed bioreactor for viral vector manufacturing
Hanna P. Lesch, R&D Director, **FinVector,** Finland

14.30 

Lentivirus vectors manufacturing
Matthias Hebben, Head, Bioprocess, **Genenthon,** France

15.00 

Regulatory requirements on lentiviral vector = Starting material or API
Bernd Schröder, Global Head Regulatory Affairs, **Miltenyi,** Germany

15.30 **Afternoon Break**

Storage, Logistics and Supply

16.00 

Cryopreservation strategies for cell therapies

Jeppe Skytte, International Sales and Business Director, **Pharmacosmos,** Denmark

16.20 

Sourcing strategies for CAR-T and gene therapy projects

Bernard Huyghe, Senior Director, **Pfizer,** USA

16.40 

Supply chain and logistics challenges for an autologous cell & gene therapy

Sadia L'Baouch, Operations & Supply Director, ATD, ATMP UK, RD Biopharm R&D, **GSK,** UK

17.00 DISCUSSION PANEL

Discussion Panel: Needle-to-needle

*What is the best level of freezing? 48hrs or 24hrs?

- Ensuring supply chain custody through end to end supply chain tracking
- Problems when moving between borders
- Process validation
- Shipping stability studies
- Barcoding
- Onsite training for Drs and nurses

Sadia L'Baouch, Operations & Supply Director, ATD, ATMP UK, RD Biopharm R&D, **GSK,** UK

Bernard Huyghe, Senior Director, **Pfizer,** USA

16.00 

Manufacturing and CMC challenges when moving into phase III

Julian Hanak, VP Manufacturing and CMC, **NightstaRx,** UK

16.30 

Assessing and modulating immune responses in gene therapy

Federico Mingozzi, Team Leader - Immunology and Liver Gene Transfer, **Genethon,** France

17.00 

Latest developments in Duchenne muscular dystrophy

Prof George Dickson, Professor or Molecular Cell Biology, **Royal Holloway University,** UK

Co-located With

Genome Editing Applications – Therapeutic and Biomedical Applications of CRISPRs, ZFNs, TALENs and other Genome Engineering Technologies

2-3Dec 2015 * Sheraton Brussels Airport, Belgium From improving lead discovery, validation of targeted cell lines and development of transgenic animal models to therapeutic uses in cell therapy, gene therapy and immunotherapy, this event will highlight the advances and latest applications of genome editing technologies.

Confirmed Speakers to Date:

- **TJ Cradick,** Head of Genome Editing, **CRISPR Therapeutics,** USA
- **Philippe Duchateau,** Chief Scientific Officer, **Cellectis,** France
- **Lorenz Mayr,** Vice President, Reagents & Assay Development, **AstraZeneca,** UK
- **Ines Royaux,** Senior Scientist, Janssen R&D, a division of **Janssen Pharmaceutica NV,** Belgium
- **Myung Shin,** Senior Principal Scientist, **Merck & Co., Inc.** USA

17.30 **End of Cell Therapy Manufacturing and Gene Therapy Congress**

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Evening Seminar: Wednesday 2 December 2015

Qualification and Validation of Analytical Methods for Cell and Gene Therapies

Register: 18:15 • Start: 18.30 Finish: No later than 20:00 – Networking Dinner to follow

- What is the difference between qualification, validation and verification?
- How much should I do at each stage of development?
- What am I trying to achieve?
- Common mistakes, pitfalls and issues.

Workshop Leader:

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

Post-Conference Workshop: Friday 4 December 2015

Characterising ATMPs: Developing Potency Assays & Performing Comparability Studies for Cell and Gene Therapies

Registration 08:30 • Start: 09:00 • End: 15:00 • Networking Lunch, and Refreshments will be included

Potency testing is often the most difficult aspect of ATMP characterisation, involving measurement of the product's biological function in a scientifically valid, controlled, timely manner. Tests of product function, arguably the most critical characteristic of all, can also provide valuable comparability data.

This workshop will discuss regulatory requirements and practical strategies for identifying suitable functional assays, potency assay qualification, potency testing in lot release, and the role of functional assays in comparability studies.

Aims of the Workshop

- Review regulatory requirements for ATMP potency testing
- Strategies for potency assay selection and qualification, and use in lot release
- Effective use of functional assays in comparability studies

Workshop Leader:

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

Pre-Conference Workshops and Exclusive Site Visit to Brussels Biopark

Tuesday
1 December 2015

Limited Spaces available

Meet at 9am * 10.00am Start followed by Site Visit at Biopark and Networking function * Ends approximately 16.30

PART ONE: WORKSHOPS
10.30 UNTIL 14.30

Option 1

Scale-up Considerations for Cell Therapies

Updated for 2015

As cell therapies begin to enter commercialisation stages, bottlenecks in production and processing must be addressed

Agenda:

- Autologous vs allogenic products: scale-out vs. scale up
- Technology strategies and their timing: when do I need which quantity of product
- Early-stage considerations to help late-stage development – a roadmap to large scale production
- Autologous products
- Scale out – automation – segregation of patient samples/ products, down-stream technologies
- Allogenic products
- Adapting bioproduction tools to cell manufacture
- Cell factories vs bioreactors: moving from planar culture-expansion systems to 3D systems. Rationale, key considerations, industry experience –
- Large-scale downstream technologies
- Implementing change: streamling legacy processes, identity of APIs, regulatory feeback, bridging studies
- Strategies to reduce cost of goods
- Avoiding aggregation
- Available technologies to support scale-up. Plug and play?
- Procurement strategies
- Setting specifications – what do you measure?

Workshop Leader

Christian van de Bos,
Independent Consultant to the ATMP market, **Mares,** Germany

Option 2

From Academia to Commercial:

The Challenges of Technology Transfer in ATMP Trials and Development

Advanced therapy medicinal products (ATMPs) typically derive from academic investigator-led research and thus early clinical trials are in single centres with local GMP production in small, academic GMP facilities. Few academic GMP units are focussed on the horizon beyond proof-of-concept clinical trials and are neither skilled nor resourced to design the product specification and manufacturing process so that it is suitable for supplying the ultimate patient population if the preliminary trials are successful.

This workshop will highlight the technical issues, regulatory challenges and responsibilities during technology transfer from site to site and propose some solutions from real case examples.

The presentations should provoke lively debate regarding early stage process development and validation with a view to the horizon of large scale delivery.

Agenda:

- Different technical abilities between academic and commercial GMP units,
- Demonstration of product comparability
- Documentation, – Change Control – GCP responsibilities – Validation/verification
- Quality Control, reverse technology transfer from industry to academia

Workshop Leaders

Professor Martin Hildebrandt,
Executive Director, **TUM Cells TU,**
München, Germany

Professor Mark Lowdell, Professor of Cell & Tissue Therapy Centre for Cell, Gene & Tissue Therapy, **Royal Free London NHS FT & UCL**, UK

PART TWO: SITE VISIT TO BIOPARK AND NETWORKING FUNCTION

14.30 UNTIL 16.30

About the BioPark

The Biopark of Charleroi is a good example of what can be achieved when a university, the ULB, public authorities, the Walloon government, and companies are partnering.

Today, the Biopark is an ecosystem with high-level researches, a training centre and an incubator that contributes to create and attract companies. It has around 1000 scientists working in 3 research institutes from the ULB and 32 companies that have been created or attracted on the campus.

The Biopark is home to companies working to develop products (Bone Therapeutics, Promethera, Orgenesis, Pluriomics), companies providing services for the cell therapy sector (SISE, Ovizio, Univercells) and research centres.

With the recently inaugurated "Walloon Cell Therapy Platform" SISE, Wallonia is one of the strongest places in Europe for the development of cell therapy products. This site visit will comprise a detailed tour of the Biopark facilities and our partners'.

In collaboration with:

BIOPARK
CHARLEROI BRUSSELS SOUTH

16.30 **RETURN BACK TO THE HOTEL**

To **register** or for the **latest information,**
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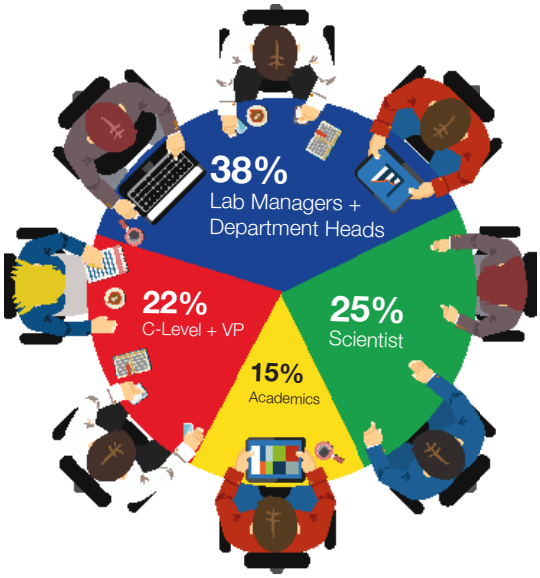
Cell Therapy Manufacturing & Gene Therapy

CONGRESS

2 - 3 December 2015 - Sheraton Airport Hotel, Belgium

Primary Audience Breakdown



Vital Statistics from 2014

280+ Attendees

170+ Companies represented

25% increase in attendee numbers vs 2013

62:38 buyer vs seller attendee ratio

Attendee Job Title Breakdown

Production Manager • Managing Director • COO • Head of Production • Process Development Director • Head of Manufacturing • CSO • Scientific Director • VP Global Operations • CEO • R&D Director • Systems Engineer • Operations Manager • Head of Bioprocess Development • Associate Scientist • VP of CMC • CTO • Logistics Manager • Seniour Scientist • Quality and GMP Manager • VP Supply Chain

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☐ Evening Seminar: Qualification and Validation of Analytical Methods

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