5th Annual Commercial Translation for Regenerative Medicine
Translating research into commercially successful products

LONDON
15th and 16th of November 2007

The Hype has Gone – Tissue and Cell Based Therapies are Real

Addressing the leading strategies and in-depth analysis to allow for successful commercialisation of cell and tissue based products, services and devices.

Attending this premier marcus evans conference will enable you to:

Learn from the new legislation and how it will assist in getting regenerative medicine products to the market

Gain insight into the complexities of manufacturing regenerative medicine products and the role of automation in realising the commercial dream

Understand the challenging path ahead for all tissue and cell-based organisations and the lessons learnt by the current leading companies

Examine how to structure your reimbursement strategy to guarantee a market for your product

Learn from the leaders in regenerative medicine on how to successfully structure a commercial path

Maximise collaborative opportunities with biotech, pharma, hospitals and CMO’s

Explore the latest case studies and critical strategies from some of the leaders in regenerative medicine:

ACT evaluating the role of process development in optimising manufacturing

Athersys examining production scale-up in the path to commercialisation

Geron exploring licensing, collaboration and IP issues

Genzyme considering the regulatory advancements and how they will affect the regenerative medicine industry

Intercytex examining strategies for successfully getting a product to market

Johnson & Johnson discussing the role of big pharma in the regenerative medicine arena

Novocell considering the role of clinical evolution in acquiring market success

Organogenesis assessing commercial opportunities under the new ATMP regulations

TiGenix detailing how a European based company successfully markets in the US

In the Chair:

Chris Mason Professor
Regenerative Medicine Bioprocessing Group
Department of Biochemical Engineering
University College London

Leading Industry Experts:

Michael West
President and CSO
Advanced Cell Technology

Robert Deans
Senior Vice President Regenerative Medicine
Athersys

Ducan MacKay
Head of Regulatory Affairs
Genzyme

David Earp
Chief Patent Counsel
SVP Business Development
Geron

Paul Kemp
CSO
Intercytex

Susan Pond
Managing Director
Johnson & Johnson Research Pty Limited Australia

Melissa Carpenter
Vice President Research and Development
Novocell

Geoff Mackay
CEO
Organogenesis

Greg Bonfiglio
Managing Director
Proteus Venture Partners

Tim Bertram
Senior Vice President Science and Technology
Tengion

Gil Beyen
CEO
TiGenix

For further information, please contact:
Julia Murphrey, Conference Producer, marcus evans Prague
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Experts from Regulatory and Associations:

David Williams  Professor of Healthcare Engineering
Wolfson School of Mechanical and Manufacturing Engineering
Director Research School Health Sciences
Loughborough University

Chris Mason  Professor
Regenerative Medicine Bioprocessing Group
Department of Biochemical Engineering
University College London

Awaiting Final Confirmation

Michael Lysaght  Professor and Director
Centre for Biomedical Engineering
Brown University

Steve Bauer  Chief Tissue and Cell Therapy Branch
FDA

KEYNOTE ADDRESS
09:50  Understanding the Road to Approval in the USA
- Assessing the approval criteria and understanding what the authorities need to see
- Exploring product classifications complexities
- Clarification of the criteria for combination products
- Analysing manufacturing processes requirements and controls
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Awaiting Confirmation:
Steve Bauer  Chief Tissue and Cell Therapies
FDA

10:30  Morning Coffee and Networking

PANAL DISCUSSION
This session invites delegates to raise practical issues to a selection of panel members
10:50  Understanding Differences Between US, Europe and Asia Regulations
- Assessing US the regulatory process as a benchmark?
- A rocky road ahead for the Asian regulatory framework
- Looking outside the EU and the US – the possibilities in international markets

Any delegates wishing to pre-submit questions to be addressed during this session can do so by contacting: Julia Murphrey, Conference Producer, 00420 234 702 320, Juliam@marcusevanscz.com

Panel Members Include:

Steve Bauer  Chief Tissue and Cell Therapies
FDA

Duncan MacKay  Head of Regulatory Affairs
Genzyme

Susan Pond  Managing Director
Johnson & Johnson Research Pty Limited Australia

11:30  Analysing how the Advanced Therapies Legislation has Impacted Early and Late Stage Funding
- Examining the SMEs struggle with mid-stage funding
- Assessing funding opportunities under the new regulations
- Understanding the economies of production – making sure you have a commercial product
- Benefiting from new successes in the industry, increased regulatory clarity and increased investment

Greg Bonfiglio  Managing Director
Proteus Venture Partners
CLINICAL EVOLUTION

12:10 Developing Clinical Trial Standardisation as a Process
- Establishing when is the appropriate time to start clinical testing
- Evaluating the safety/risk threshold and determining what is deemed as acceptable risk
- Defining the control group
- Understanding the documentation requirements of clinical research
- Analysing the lab production requirements to support your clinical trial

Melissa Carpenter
SVP Research and Development
Novocell

12:50 Luncheon

13:50 Coffee and Networking

MANUFACTURE

15:30 Developing a Standardisation of Procedures when Scaling-Up Manufacture
- Evaluating needs and requirements on a large scale
- Determining the role of process automation when scaling-up your manufacture
- Evaluating the use of non-discovery focused automation
- Developing manufacturing standardisation
- Tackling regulatory requirements for manufacture
- Understanding GMP requirements
- Considering cost effective manufacturing possibilities
- Exploring best practices in logistics management

David J Williams
Professor of Healthcare Engineering
Wolfson School of Mechanical and Manufacturing Engineering
Director, Research School of Health and Life Sciences
Loughborough University

16:10 Afternoon Tea and Networking

CASE STUDY

16:30 Developing Novel Technologies From Academic Laboratories onto Commercial Utility
- Integrating transformational technologies into medicine – educating thought leaders
- Technology transfer – academic to commercial and bed to bench
- Development speed – parallel development of multiple novel platforms
- Meeting production challenges – experimental to clinical to commercial

Tim Bertram
SVP Science and Technology
Tengion

CASE STUDY

17:10 Examining the Role of Process Development in Optimizing Manufacturing
- Accelerating the isolation of novel cell types
- Establishing strategies to database markers
- Utilizing multiplex propagation assays
- Exploring high throughput functional assays

Michael West
President and CSO
Advanced Cell Therapy

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17:50  Exploring Contract Manufacture as Key to the Future Success of Regenerative Medicine
- Determining if the necessary technology is available
- Considering the CMO’s understanding of regenerative medicine products
- Evaluating current limitations and future cell handling capabilities
- Establishing if the CMO can deal with alternative product types – developing a flexible approach to manufacturing
- Assessing the regulatory requirements from a CMO
- Achieving effective communication in your contract agreement
- Who defines safety data?
- Addressing short shelf life – looking into the need of supply of materials/products
- Investigating process oriented contracting – outsource various processes, not whole manufacturing

18:30  Closing Remarks from the Chair
18:40  Close of Day 1

DAY 2
08:00  Coffee and Registration
08:20  Opening Remarks from the Chair

Chris Mason
Stem Cell & Regenerative Medicine Bioprocessing Unit
Advanced Centre for Biochemical Engineering
University College London

KEY NOTE
08:30  Tissue Engineering: The Eight Day – Industry Survey Results
  • Awaiting Bullet Points

Awaiting Confirmation:
Michael Lysaght
Professor and Director
Centre for Biomedical Engineering
Brown University

COMMERCIAL TRANSLATION

CASE STUDY
09:10  Assessing the Commercial Opportunities and Developing a Business Model Under the New ATMP Regulations
  • Understanding new and existing regulations – what is going to change
  • Companies perspective on what this means to future funding opportunities
  • Commercial path of getting marketing authorisation in European markets
  • Assessing production capabilities and future growth
  • Scrutinising the reimbursement process under the new regulations

Geoff MacKay
CEO
Organogenesis

CASE STUDY
09:50  Examining Successful Paths and Considerations When Getting a Product to Market
  • Determining product specifications and market size
  • Deciding which registration classification to use
  • Integrating manufacturing, regulatory and clinical groups to maximise product development
  • Identifying cost of goods and economies of scale
  • Establishing process development... when and how

Paul Kemp
CSO
Intercytex

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**CASE STUDY**

**11:10** How to Successfully Break into the US Market as a European Based Company
- Investigating which regulatory path to follow
- Considering to outsource or manufacture in-house
- Identifying the commercial strategy

**Gil Beyen**  
CEO  
Tigenix

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**COLLABORATION AND PARTNERSHIPS**

**KEY NOTE**

**11:50** The Role of Big Pharma in Regenerative Medicine
- Investment drivers for big pharma
- Identifying innovation and technology needs
- Choice of direction, collaborations and partnerships
- Creating and developing business models
- Strategies for commercialisation

**Susan Pond**  
Managing Director  
Johnson & Johnson Research Pty Limited Australia

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**12:30** Coffee and Networking

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**12:50** Luncheon

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**14:00** Investigating Licensing, Collaborations and Intellectual Property Considerations
- Examining legal implications of licence purchase
- Evaluating advancements in patent law
- Addressing cross licensing and IP difficulties
- Establishing the way forward – partnering your IP
- Optimising licensing with major players as a key to the future

**David Earp**  
Chief Patent Counsel & SVP Business Development  
Geron

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**PRICING AND REIMBURSEMENT**

**PANEL DISCUSSION**

This session invites delegates to raise practical issues to a selection of panel members

**14:40** Convincing Health Authorities: Communicating Product Classification and Price
- What are the new requirements from the health authorities under the new ATMP regulation
- Addressing classification of products
- Analysing pricing methods in line with costs of development
- Addressing health economics concerns
- Exploring the time perspective
- Understanding the reimbursement process

Any delegates wishing to pre-submit questions to be addressed during this session can do so by contacting: Julia Murphrey, Conference Producer, 00420 234 702 320, juliam@marcusevanscz.com

**Panel Members Include:**

**Robert Deans**  
SVP Regenerative Medicine  
Athersys

**Paul Kemp**  
CSO  
Intercytex

**Geoff MacKay**  
CEO  
Organogenesis

**Gil Beyen**  
CEO  
Tigenix

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**15:20** Closing Remarks from the Chair

**15:30** Close of Conference

**15:40** Afternoon Tea and Networking

This marcus evans event brings together key industry, academic and regulatory experts to capitalise on the fact that the regenerative medicine industry is in the process of a step change. The field has grown from its old research orientated, cottage-industry past to a shining example of a 21st century, translation focused, healthcare enterprise. This new perspective, along with strong public and political support, has allowed regenerative medicine to enter the second era.

Now is the time to focus on the pragmatic translation of great science into routine clinical practice. This unique event gives the opportunity to gain insight into how to successfully translate the science into social benefits. The forum will discuss the challenging path ahead for the regenerative medicine industry to produce clinical therapies that either perform significantly better than their earlier counterparts or produce real cost benefit.
Who should attend:

Marcus evans invites CEO’S, CSO’S, Presidents and Directors dealing with the commercial applications of cell and tissue based products from the leading Biotechnology organisations.

Also, Heads, Directors and Senior Decision Makers of:
- Bioengineering
- Cell based Manufacture
- Production
- Business Development
- Regulatory Affairs

As well as experts from the following institutions:
- Leading Academic Research
- Regulatory Authorities
- Automation Specialists
- Venture Capital
- Research Foundations

Producer info
I would like to thank everyone who has assisted with the research and organisation of the event, particularly the speakers for their support and commitment.

Julia Murphrey, Conference Producer
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Marketing info
If you would like further information about the event or information about how to book, please contact:
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