Agenda

The 2016 Cell Therapy conference will identify the key issues to be addressed for the manufacture of cell therapies and provide scientific consensus on selected aspects to inform the drafting of future guidance. The meeting will bring together representatives from industry, academia, health services and regulatory bodies. It is intended that the conference output should provide core elements that will be useful in establishing international consensus on the requirements for manufacture of cell based medicines and enable progress towards a potential future WHO endorsed guidance.

Scientific Committee

Prof. Glyn Stacey
Chair; National Institute for Biological Standards and Control, MHRA, United Kingdom

Dr. Anthony Lubiniecki
Pharmaceutical Development & Manufacturing Sciences, Janssen R&D, LLC, U.S.A.

Dr. Steven Bauer
Office of Gene and Cell Therapy Products, FDA-CBER

Dr. Karin Hoogendoorn
Quality RA B.V., The Netherlands

Dr. Maura Kibbey
US Pharmacopeia, USA

Dr. Ivana Knezevic
World Health Organisation, Switzerland

Prof. Nick Metcalf
University of Loughborough-EPSRC, United Kingdom

Dr. Yoji Sato
National Institute of Health Sciences, Japan

Prof. Dr. Gerald Schumann
Paul-Ehrlich-Institut, Langen, Germany

Prof. Jean-Hugues Trouvin
University Paris Descartes, France

Dr. Bao-Zhu Yuan
National Institutes for Food and Drug Control, China

Day 1 – Wednesday, November 2, 2016

08:00 - 08:30 **Registration & Welcome Coffee**

Session 1
Regulatory developments
Chair: Dr. John Petricciani and Dr. Ivana Knezevic

1.1 Keynote Notes: Perspectives on the development of cell derived medicines

08:30 – 08:35 Introductory overview of IABS strategy on cell therapy
Dr. John Petricciani, IABS

08:35 – 08:50 Cell substrates – historical overview
Dr. John Petricciani, IABS

1.2 Current approaches to regulation of cell therapies

08:50 – 09:05 NIBSC experiences with the standardisation of complex biological materials
Dr. Paul Stickings, NIBSC-MHRA**,** United Kingdom

09:05 – 09:20 Recent developments in regulation for cell therapy in Japan
Dr. Yoji Sato, National Institute of Health Sciences (NIHS), Tokyo, Japan

09:20 – 09:35 Health Canada experiences in regulating the manufacture of cell therapy products
Dr. Francisca Agbanyo, Blood, Cells, Tissues and Organs Division, Health Products and Food Branch, Health Canada, Ottawa, Ontario, Canada

09:35 – 09:50 A global perspective on developing regulation for cell therapy
Dr. Ivana Knezevic, WHO, Geneva, Switzerland

09:50 – 10:10 **Coffee Break**

1.3 Registries and banking

10:10 – 10:20 Assessment and monitoring of cell lines for clinical application in the hPSCreg database for stem cell lines
Prof. Andreas Kurtz, Charite Hospital Berlin, Germany

10:20 – 10:40 Development of the Global Alliance for iPSC Therapies
Dr. Jacqueline Barry, Cell and Gene Therapy Catapult, London, United Kingdom

10:40 – 11:00 **Discussion**

Session 2
Raw materials and Starting materials
Chair: Prof. Glyn Stacey and Dr. Bao Zhu Yuan

11:00 - 11:15 Viral safety of raw materials for cell-based medicinal products
Dr. Johannes Blümel, Paul-Ehrlich-Institut, Langen, Germany

11:15 – 11:30 Japanese guidance documents on the quality and risk assessment of raw materials for cell-based therapeutic products
Dr. Yoji Sato, National Institute of Health Sciences (NIHS), Tokyo, Japan

11:30 – 11:45 Suitability of Donor Tissues for Development of Cell Therapies
Prof. Marc Turner, Scottish National Blood Transfusion Service (SNBTS) Head Quarters, Scotland

11:45 – 12:30 **Discussion**

12:30 – 13:30 **Lunch**

Session 3
Experiences with autologous and allogenic cell therapies
Chair: Prof. Jean-Hugues Trouvin and Dr Yoji Sato

13:30 – 13:45 Late-stage development and commercial manufacturing of cell therapy products: key lessons learned from ChondroCelect and Cx601
Dr. Pilar Redondo, TiGenix NV, Leuven, Belgium

13:45 - 14:00 Industrialisation and scale-up of allogeneic ATMP, and new specificities
Dr. Charlotte Lequeux, Cell*for*Cure, France

14:00 – 14:15 Manufacture of limbal stem cell therapy
Prof. Julie Daniels, University College London, United Kingdom

14:15– 14:30 The challenge of manufacturing safe and reliable CAR T cell therapy
Dr. David Gilham, Celyad, Belgium

14:30 – 14:45 MSC products and their control
Dr. Bao-Zhu Yuan, National Institutes for Food and Drug Control (NIFDC), Beijing, China

14:45 – 15:15 **Coffee Break**

15:15-15:30 Recent developments in the scientific and industrial community in standards coordination: The Standards Coordination Body
Dr. Michael Mendicino*,* Hybrid Concepts International, LLC, U.S.A.

15:30 – 16:15 **Discussion**

Day 2 – Thursday, November 3, 2016

08:30 – 09:00 **Registration**

Session 4
Manufacture
Chair: Prof. Nick Medcalf and Dr. Karin Hoogendoorn

09:00 – 09:15 A re-distributed manufacturing feasibility study on MSCs and the implications for automation
Prof. Nick Medcalf, University of Loughborough, United Kingdom

09:15 – 09:30 Practical Approach for Process Characterization
Dr. Francis Meacle, Janssen L.P., New Jersey, U.S.A.

09:30 – 09:45 Cell banking strategies for cell banking and manufacturing for cell therapies in Korea
Dr. Jung-Hyun Kim, Korean National Institute of Health, Osong, South Korea

09:45 – 10:30 **Discussion**

10:30 – 11:00 **Coffee break**

Session 5
Standardisation and testing for final product
Chair: Dr. Gerald Schumann and Prof. Nick Medcalf

11:00 – 11:15 Development of analytical assays for cell therapies: strategy development
Dr. Damian Marshall, Cell Therapy Catapult, United Kingdom

11:15 – 11:30 Design of tumorigenicity test for pluripotent stem cell-derived cell product
Dr. Shin Kawamata, Foundation for Biomedical Research and Innovation (FBRI), Kobe, Japan

11:30 – 11:45 Acquired genetic variation in human pluripotent stem cells: significance for clinical applications in regenerative medicine
Prof. Peter Andrews Centre for Stem Cell Biology, University of Sheffield, United Kingdom

11:45 – 12:00 Approaches to standardization assisting cell therapy manufacturing
Tatsuo Heki, Forum for Innovative Regenerative Medicine (FIRM), Japan

12:00 – 12:15 Standardisation of viability/cell measurements
Dr. Sheng Lin-Gibson, National Institute of Standards and Technology (NIST), Gaithersburg, Maryland, U.S.A

12:15 – 12:30 Mesenchymal stromal cell characterisation: a comparative analysis of product specification in European transplant centres
Dr. Cristina Trento, University College London on behalf of EBMT, United Kingdom

12:30 – 13:00 **Discussion**

13:00 – 13:50 **Lunch**

14:00 – 14:15 The MSC consortium and FDA regulatory science
Dr. Steven Bauer, Division of Cellular and Gene Therapies, Food and Drug Administration, U.S.A.

Session 6
Chair: Dr. Karin Hoogendoorn and Glyn Stacey

Preservation and shipment
14:15 – 14:30 Cryopreservation of Mesenchymal Stem Cells
Dr. Alexandra Stolzing, Loughborough University, United Kingdom

14:30 – 14:45 Key issues in the development of improved preservation and storage
Dr. Peter Kilbride, Asymptote, Cambridge, United Kingdom

14:45 – 15:00 Cryostorage stability and vitrification approaches for industrial scale
Prof. Heiko Zimmermann, IBMT/Fraunhofer, Sulzbach, Germany

15:00 - 15.30 **Discussion**

Session 7
Conclusions

15:30 – 16:15 Key areas of consensus on best practice and areas in need of special attention
Prof. Glyn Stacey, Chair; National Institute for Biological Standards and Control, MHRA, United Kingdom

16:45 Closing message