International Society for Cellular Therapy
ISCT®

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

NOT TO BE MISSED

A UNIQUE REGULATORY EDUCATIONAL PARTNERSHIP BETWEEN ISCT AND CAT-EMA

CAT-ISCT Joint Workshop: Challenges and Opportunities for the Successful Development and Approval of Advanced Therapy Medicinal Products

Friday September 25, 2015 • 14:15 – 18:45

ISCT REGIONAL MEETING
SEVILLE • SPAIN • 2015

International Society for Cellular Therapy
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CAT-ISCT Joint Workshop Program

14:15 WELCOME FROM WORKSHOP CHAIRS

- Paula Salmikangas, Finnish Medicines Agency (FIMEA) – CAT Chair, Finland
- Natividad Cuende, Executive Director, Andalusian Initiative for Advanced Therapies, Spain

14:20 INTRODUCTION

Moderator: Natividad Cuende, Executive Director, Andalusian Initiative for Advanced Therapies, Spain

- **Intelligent ATMP Development: Flexibilities and Pitfalls**
  Speaker: Paula Salmikangas, Finnish Medicines Agency (FIMEA) – CAT Chair, Finland

14:40 QUALITY DEVELOPMENT/MANUFACTURING ISSUES AND NON-CLINICAL TESTING

Moderator: Dariusz Śladowski, Medical University of Warsaw – CAT member, Poland

- **Experience from CAT on Quality Development/Manufacturing/GMP**
  Speaker: Margarida Menezes Ferreira, Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.(INFARMED) – Alternate CAT member, Portugal
- **Experience from CAT on Non-Clinical Development**
  Speaker: Tiina Palomäki, Finnish Medicines Agency (FIMEA) – CAT member, Finland
- **Views from ATMP developer from academia on quality/manufacturing issues encountered during the manufacture of ATMPs for clinical trials**
  Speaker: Laura Leyva, Technical Director of the Cell Therapy GMP facility, University Regional Hospital in Málaga, Spain
- **Q&A**

16:10 CLINICAL DEVELOPMENT

Moderator: Edwin Wagena, ISCT Europe Regional Vice President, Netherlands

- **Clinical Trials with ATMPs: Experience from CAT**
  Speaker: Tomáš Boráň , Státní ústav pro kontrolu léčiv – CAT member, Czech Republic
- **Specificities of Clinical Development of ATMPs: Considerations regarding exploratory and confirmatory trials**
  Speaker: Martina Schüßler-Lenz, Paul-Ehrlich-Institute, Germany – CAT member and Vice-Chair, Germany
- **Use of Retrospective Studies for Marketing Authorization**
  Speaker: Giovanni Milazzo, Chiesi Farmaceutici, Head Regulatory Affairs Advanced Medicines, Italy
- **The New Clinical Trial Regulation: What will change for ATMP developers**
  Speaker: Simona Badoi, Agentia Națională a Medicamentului şi a Dispozitivelor Medicale – CAT member, Romania
- **Q&A**

17:50 SUPPORT FROM EMA/CAT TO ATMP DEVELOPERS

Moderator: Paula Salmikangas, Finnish Medicines Agency (FIMEA) – CAT Chair, Finland

- **Presentation on support available to ATMP developers and approval mechanism (adaptive pathways, conditional approval, approval under exceptional circumstances)**
  Speaker: Patrick Celis, European Medicines Agency, CAT Scientific Secretariat, UK

18:15 OPEN FORUM/PANEL DISCUSSION

18:45 CLOSING REMARKS

Visit www.isct-eu2015.com to register