



First Workshop on Advanced Therapy Medicinal Products (ATMPs)

AGENDA

Friday 3rd April 2009, 09:00hrs-16:00hrs

*EMEA, 7, Westferry Circus, Canary Wharf,
London E14 4HB
2nd floor, Conference Room 2A*

Chairperson: Patrick Celis (EMEA)

Registration and Coffee 08:00hrs – 09:00hrs

Welcome by EMEA

09:00hrs – 09:10hrs

1. Introductory Session

09:10hrs – 10:30hrs

- The ATMP Regulation and Implementation at EMEA 20 min P. Celis (EMEA)
- The new Committee on Advanced Therapies (CAT) 15 min L. D'Apote (EMEA)
- Challenges with Advanced Therapy Medicinal Products 20 min C. Schneider (PEI)
- Innovation section: Experience in the area of ATMP 15 min M. Boucaumont (EMEA)
- Business Pipeline project 10 min E. Tognana (EMEA)

2. Evaluation of ATMPs

10:30hrs – 11:00hrs

- Overview of the procedure and interactions between CAT and CHMP M.-H. Pinheiro (EMEA)

Coffee 11:00hrs– 11:20hrs

3. New procedures

11:20hrs – 12:05hrs

- Certification procedure 25 min E. Pedone (EMEA)
- Scientific Recommendation on the classification of ATMP 20 min M.-H. Pinheiro (EMEA)

4. Question and Answer session

12:05hrs – 12:30hrs

Networking Lunch 12:30hrs – 13:30hrs

5. Dossier Requirements for ATMPs

13.30hrs – 15.35hrs

- Technical requirements in Annex I 25 min P. Celis (EMA)
- Scientific requirements for cell therapy and tissue engineered products
 - Quality aspects 20 min P. Salmikangas
 - Non clinical and clinical aspects 20 min G. Migliaccio
- Scientific requirements for gene therapy products
 - Quality aspects 20 min S. Ruiz
 - Non clinical and clinical aspects 20 min G. Narayanan
- Post-authorisation follow-up and traceability for ATMPs 20 min J. Petracek (EMA)

6. Question and Answer session

15:35 hrs– 15:55hrs

~ Closing Remarks by Chairperson ~

15:55hrs – 16:00hrs

Coffee