



Strasbourg, 24-25 February 2003

*Standardisation and  
Quality Control  
Cell and Gene Therapy  
Products*

**International symposium organised  
by the EDQM, European Pharmacopoeia**

**Scientific Programme**

**Working language: English**



# STANDARDISATION AND QUALITY CONTROL

**Monday, 24 February 2003**

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## *Opening Session*

- **Welcome address**

9:30 Prof. Dr H. G. Kristensen, Chair of the European Pharmacopoeia Commission.

### *Session I: Latest Scientific Developments in Cell and Gene Therapy Products: Where are we*

*Chair: Dr S. Braun, Transgene (F)*

- **Gene and cell therapies: perspectives and problems**

9:40 Dr O. Danos, Genethon (F)

- **Latest trends and developments:**

#### **For Gene Therapy**

Development of gene transfer medicinal products

10:00 Prof. Dr K. Cichutek, PEI (D)

Quality control of plasmid DNA

10:30 Dr D. Faucher, Gencell, Aventis Pharma (F)

10:50 Discussion

11:00 Coffee Break

#### **For Cell Therapy**

Including Autologous, Allogeneic and Xenogeneic cell therapy products, Stem cells, Human somatic cell therapy medicinal products and Genetically modified cells

11:20 Dr J. Sinden, ReNeuron (UK)

11:45 Dr E. Balbirnie, IDM (F/USA)

12:10 Discussion

12:20 Lunch

### *Session II: New Quality Challenges for Cell Therapy Products*

*Chair: Dr R. Dobbelaer, Scientific Institute of Public Health, SIPH (B)*

- **Manufacturing overview:**

QC of cell banks, starting materials, final product and state of the art testing methods

#### **For Cell Therapy:**

13:45 Dr M. Wisher, BioReliance (UK)

14:05 Discussion

#### **For Gene Therapy:**

14:05 Prof. O. Merten, Genethon (F)

14:25 Discussion

# CELL AND GENE THERAPY PRODUCTS

- **Development issues:**

**Virological and microbiological safety aspects of novel cell therapies and tissue engineered products**

14:30 Dr D. Galbraith, Q-One Biotech (UK)

14:50 Discussion

**Strategy for QC and release for individual cell therapy products**

15:00 Dr Ch. Bogedain, MediGene AG (D)

15:20 Discussion

**Formulation, Potency testing, Stability indicators and storage**

15:30 Dr G. C. Du Moulin, Genzyme Biosurgery (B/USA)

15:50 Discussion

16:00 Coffee Break

- **Manufacturing overview:**

**Gene therapy of SCID-X1: practical experience in the product elaboration**

16:30 Dr M. Cavazzana Calvo, Hopital Necker (F)

16:50 Discussion

**Manufacture and characterisation of adenoviral vectors for gene therapy clinical trials**

17:00 Dr G. Sharpe, Cobra Therapeutics Ltd (UK)

17:20 Discussion

17:30 Closure

## Tuesday, 25 February 2003

*Session III: New Quality Challenges for Gene Therapy Products*

*Chair: Prof. Dr K. Cichutek*

- **Development issues:**

**Stability of viral vectors for gene therapy**

8:50 Dr D. Malarme, Transgene (F)

**Stability of Plasmid DNA vectors in gene therapy**

9:10 Dr D. Thatcher, Cobra Therapeutics Ltd (UK)

9:30 Discussion

**Improvements in GMP plasmid DNA production: Vector topology and product safety**

9:40 Dr M. Schleef, PlasmidFactory (D)

10:00 Discussion

10:10 Coffee Break

**Characterization and use of an Adenovirus reference material**

10:40 Dr B. Hutchins, Canji (USA)

11:10 Discussion

**Need of reference materials for retroviruses & lentiviruses**

11:20 Dr K. Mitrophanous, Oxford BioMedica (UK)

11:40 Discussion

*Session IV: The regulatory issues*  
*Chair: Prof. J. H. Trouvin, AFSSAPS (F)*

• **Present and Future Regulatory Challenges for Gene and Cell Therapy Products**

11:50 Dr L. Tsang, Arnold & Porter (UK)

12:10 Discussion

• **Needs for the Industry in Standardisation and Quality Control**

12:20 Dr E. Tambuyser, EUROPABIO-Chair Health Care Board (B)  
representatives from EFPIA/ACTIP (speakers invited)

12:50 Discussion

13:00 Lunch Break

• **Needs for the Regulatory authorities**

- Regulatory developments at E.U. level

14:15 Mr M. Robert, DG Enterprise (B)

- Experience at national level

14:30 Mrs P. Zorzi Morre, AFSSAPS (F)

• **Needs for the Control laboratories (OMCLs)**

14:55 Dr M. H. Tissier, AFSSAPS (F)

15:15 Discussion

15:50 Coffee Break

*Session V: The future*

16:20 **Final round table discussion and action plan**

to 17:30 Round table discussion with the participation of representatives from the Manufacturers, Regulatory Authorities, Professional Associations in BioIndustry, the European Commission, the EMEA and the EDQM.

## Programme Committee

A. Artiges, EDQM, Council of Europe;  
P. Castle, EDQM, Council of Europe;  
K. Cichutek, Paul-Ehrlich-Institut, D;  
O. Danos, Genethon, F;  
R. Dobbelaer, Scientific Institut of Public Health – Louis Pasteur, B;  
C.-L. Julou, EFPIA, B;  
H. G. Kristensen, Chair of the European Pharmacopoeia Commission;  
D. Malarme, Transgène, F;  
H. Schepens, EuropaBio, B;  
J. M. Spieser, EDQM, Council of Europe;  
D. Thatcher, Cobra Therapeutics Ltd., GB;  
J.-H. Trouvin, AFSSAPS, F;  
L. Tsang, Arnold & Porter, GB.



## Organisation

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