Preliminary Agenda (16 October 2008)

Symposium

Advanced Therapy Medicinal Product Development and Regenerative Medicine

Paul-Ehrlich-Institut

Supported by
Deutsche Gesellschaft für Regulatory Affairs

November 25-26, 2008, Paul-Ehrlich-Institut

Paul-Ehrlich-Strasse 51-59
D-63225 Langen

Chair: Klaus Cichutek

Scientific Committee: Christa Schröder, Bettina Klug, Erhard Schmidt

Organising Committee: Christa Schröder, Bettina Klug, Bettina Vogel, Bettina Ziegele

Speakers and Chairs

Johannes Blümel
(PEI, Germany)

Stephan Brandt
(BMG*, Germany)

Christian Buchholz
(PEI, Germany)

Melanie Carr
(EMEA, United Kingdom)

Patrick Celis
(EMEA, United Kingdom)

Klaus Cichutek
(PEI, Germany)

Gabriele Dallmann
(NDA Consulting, Germany)

Anne Dwenger
(BMG*, Germany)

Andreas Emmendörfer
(Euroderm, Germany)

Egbert Flory
(PEI, Germany)

Ulrich Granzer
(Granzer Consulting, Germany)

Anneliese Hilger
(PEI, Germany)

Heinz Joseph
(TETEC AG, Germany)

Brigitte Keller-Stanislawski
(PEI, Germany)

Bettina Klug
(PEI, Germany)

Sharon Longhurst
(MHRA**, United Kingdom)

Romaldas Mačiulaitis
(State Medicines Control Agency, Lithuania)

Thomas Montag-Lessing
(PEI, Germany)

Gopalan Narayanan
(MHRA**, United Kingdom)

Paula Salmikangas
(Lääkelaitos, Finland)

Peter T. Sawicki (tbc)
(IQWiG*** Germany)

Reiner Seitz
(PEI, Germany)

Jürgen Scherer
(PEI, Germany)

Christian Schneider
(PEI, Germany)

Christa Schröder
(PEI, Germany)

Silke Schüle
(PEI, Germany)

Martina Schüssler-Lenz
(PEI, Germany)

Walter Schwerdtfeger
(BMG*, Germany)

Barbara Sickmüller
(BPI****, Germany)

Martin Terberger (tbc)
(European Commission)

* Federal Ministry of Health
** Medicines and Healthcare products Reg. Agency
*** Institute for Quality and Effiency in Health Care
**** German Pharmaceutical Industry Association

Program:

25 November 2008

10.00 Registration

12.00	**Welcome** K. Cichutek, Vice-President, PEI
12.10	Advanced therapy medicinal products (ATMP) legislation, regulation, certification (M. Terberger – tbc)
12.40	**Session 1: Legislation, incentives and advice** Chair: C. Schröder (PEI)
12.45	Implementation of advanced therapy regulations at EMEA (P. Celis)
13.10	Implementation of ATMP legislation in national law (A. Dwenger)
13.35	Micro, small and medium-sized enterprises (SME) (M. Carr)
14.00-15.00	Coffee break
15.00	**Session 2: Regulatory requirements for marketing authorization, dossier requirements** Chair: U. Granzer (Granzer Consulting), J. Scherer (PEI)
15.05	Requirements Annex I as amended (2003/63/EC) – requirements for MAA (M. Terberger – tbc)

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15.30 Risk management plan and pharmacovigilance
(B. Keller-Stanislawski)

15:55 Enviromental Risk Assessment
(Chr. Buchholz)

16.20-17.00 Coffee break

17.00 Session 3: Impact on stakeholders (with panel discussion)
Chair: W. Schwerdtfeger (German Federal Ministry of Health), K. Cichutek (PEI)

17.05 Advanced Therapies Medicinal Products from the Governmental Point of View
(S. Brandt)

17.20 Comments of industry regarding the regulatory requirements
(H. Joseph)

17.35 Position of industry under the special consideration of SMEs
(B. Sickmüller)

17.50 Reimbursement
(P. T. Sawicki)

18.05 Panel Discussion

19.00 Reception

(20.00 Dinner)

26 November 2008

9:00 Challenges with advanced therapies
(C. Schneider)

9.30 Session 4: Quality aspects of ATMPs
Chair: G. Dallmann (NDA), R. Seitz (PEI)

9.35	Quality requirements for cell-based medicinal products (P. Salmikangas)
9.55	Quality requirements for gene therapy products (S. Schüle)
10.20	International harmonisation for gene therapy medicinal products (S. Longhurst)
10.45	Microbial safety (T. Montag-Lessing)
11.10	Virus safety of advanced therapy medicinal products (J. Blümel)

11.35 – 12.35 Break

12.35	**Session 5: (Non)-Clinical aspects of ATMPs** Chair: A. Hilger (PEI), M. Schüssler-Lenz, (PEI)
12.35	Non-clinical models for cell-based medicinal products (E. Flory)
13.00	Clinical requirements for tissue engineered products. Challenges and possible solutions (R. Mačiulaitis)
13.25	Design of pivotal clinical trials for gene therapy medicinal products (G. Narayanan)
13.50	Clinical follow-up and traceability (B. Klug)
14.15	Comments of industry regarding requirements for (non)-clinical trials under special consideration of ATMPs already legally on the market (A. Emmendörfer)
14:40	Closing remarks (K. Cichutek)

Fees (Conference and Dinner):

For DGRA members: 250 € **For non-members: 350 €**

Registration:

Please contact

Email: info@dgra.de
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Fax: + 49 (0) 228/ 368 26 47

Cancellation terms: see www.dgra.de/fortbildung/veranst_agb.php

Accommodation:

A limited number of rooms are available for participants at special rates in the hotels listed below. Bookings under the special condition are requested until 25 October 2008. .

When making reservations please refer to this event.

ACHAT Hotel Airport-Frankfurt
Achat Hotel
Robert-Bosch-Str. 58
D- 63225 Langen (Germany)
Phone: + 49 (0) 6103 / 7560
Fax: + 49 (0) 6103 / 756999
www.achat hotel.de
langen@achat-hotel.de

Please quote: PEI 22733

Hotel Steigenberger MAXX Langen
SRS Worldhotels
Robert-Bosch-Str. 26
D-63225 Langen (Germany)
Phone: + 49 (0) 6103 / 9720
Fax: + 49 (0) 6103 / 972555
www.srs-worldhotels.com
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