

SYMPOSIUM: ALTERNATIVES TO ANIMAL TESTING

8-9 September 2011, Strasbourg, France

Duration: 1.5 days; working language: English

PROGRAMME

8 September 2011 OPENING SESSION

8:30-9:00 Registration

9:00-9:10 **Welcome Address and General Introduction**
Dr Susanne Keitel, Director, EDQM, Council of Europe

SESSION 1: Recent Developments in the 3R* Field

Moderator: Mrs Cathie Vielle, Head, European Pharmacopoeia Dept, EDQM, Council of Europe

9:10-9:30 **European Pharmacopoeia Activities - An overview**
Dr Emmanuelle Charton, Deputy Head, European Pharmacopoeia Dept, EDQM, Council of Europe

9:30-9:50 **EU Directive 2010/63/EU**
Ms Susanna Louhimies, Directorate General Environment Chemicals, EU Commission

9:50-10:10 **Serum Institute of India Ltd: Contribution and Achievements towards 3R**
Dr Suresh Jadhav, Serum Institute of India (IN)

10:10-10:40 *Coffee break*

10:40-11:00 **The European Biological Standardisation Programme (BSP)**
Dr Karl-Heinz Buchheit, Deputy Head of the Biological Standardisation, Network of OMCL and HealthCare Department, EDQM, Council of Europe

11:00-11:20 **Commitment of the OCABR network to 3R: Active strategies to reduce, replace and refine**
Dr Dominique Garcia, Afssaps (F)

11:20-11:40 **EPAA and the consistency approach**
Dr Roland Dobbelaer, EPAA (BE)

11:40-12:20 **Discussion**

12:20-14:00 *Lunch break*

SESSION 2: Acellular Pertussis Vaccine

Moderator: Dr Kaare Haslov, Statens Serum Institute (DK)

14:00-14:20 **Collaborative study for the validation of a serological method for the potency testing of acellular pertussis vaccines (BSP083)**
Dr Dorothea Sesardic, NIBSC (UK)

14:20-14:30 **Discussion**

* The 3Rs Principle (Replacing, Reducing and Refining animal testing)

- 14:30-14:50** Implementation of the serological method for the potency testing of acellular pertussis vaccine: users' view
Mr Fabrice Ribaucour, IPH (B)
- 14:50-15:00** Discussion
- 15:00-15:10** Development of xMAP technology for the control of multicomponent vaccines bioactivity
Dr Chantal Mourton-Gilles, Afssaps (F)
- 15:10-15:20** Application of the 3Rs to the histamine sensitivity test (absence of residual toxin) for acellular pertussis vaccine
Ms Angèle Costanzo, Biological Standardisation, Network of OMCL and HealthCare Department, EDQM, Council of Europe
- 15:20-15:30** Discussion
- 15:30 -16:00 Coffee break*

SESSION 3: Tetanus Immunoglobulin

Moderator: Dr Johannes Dodt, Paul-Ehrlich-Institut (D)

- 16:00-16:20** Development of *in vitro* assays for potency determination of human tetanus immunoglobulins. Implementation of the methods at PEI
Dr Steffen Gross, Paul-Ehrlich-Institut (D)
- 16:20-16:30** Discussion
- 16:30-16:50** Collaborative study for the validation of *in vitro* assays for human tetanus immunoglobulin and implementation of the methods in the Ph. Eur.
Dr Berber de Vries, RIVM (NL)
- 16:50-17:00** Discussion
- 17:00-17:20** Manufacturer's experience in implementation of the *in vitro* potency assays for human tetanus immunoglobulin
Dr Ricard Lopez, Instituto Grifols (E)
- 17:20-17:30** Discussion
- 17:30 Cocktail Reception at EDQM premises*

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SESSION 4: Rabies Vaccines for Veterinary and Human Use

Moderator: Dr Gábor Kulcsar, Central Agricultural Office Dir. for Vet Med. Products (HU)

- 08:30-08:50** A BSP collaborative study establishes a serological assay as an alternative to the NIH test for rabies vaccine (inactivated) for veterinary use (BSP105)
Dr Elisabeth Kamphuis, Paul-Ehrlich-Institut (D)
- 08:50-09:00** Discussion

- 09:00-09:20 Reflections on the practical aspects of implementation of the new serological batch potency assay for rabies vaccine (inactivated) for veterinary use**
Dr Fabrizio de Mattia, Intervet (NL)
- 09:20-09:30 Discussion**
- 09:30-09:50 Future perspectives on potency testing in the context of the consistency approach (human and veterinary): Quantitative multi-dilution analysis of serology assay (veterinary) and adaptation of the serology assay to human vaccines**
Dr Elisabeth Kamphuis, Paul-Ehrlich-Institut (D)
- 09:50-10:00 Discussion**
- 10:00-10:20 Exploration of in vitro methods for the assay of rabies vaccine for human use and rabies immunosera**
Dr Sylvie Morgeaux, Afssaps (F)
- 10:20-10:30 Discussion**
- 10:30-11:00 Coffee break*

SESSION 5: Pyrogens Replacement

Moderator: Dr Gerard Lee, MHRA (UK)

- 11:00-11:20 Pyrogen testing in the European Pharmacopoeia and its alternatives**
Dr Emmanuelle Charton, Deputy Head, European Pharmacopoeia Dept, EDQM, Council of Europe
- 11:20-11:30 Discussion**
- 11:30-11:50 Experiences in the field - An Industry Viewpoint**
Dr Peter Bruegger, Novartis Pharma AG (CH)
- 11:50-12:00 Discussion**
- 12:00-12:20 Experiences in the field - An OMCL Viewpoint**
Dr Ingo Spreitzer, Paul-Ehrlich-Institut (D)
- 12:20-13:00 Discussion**
- 13:00-13:20 Use of Toll-Like Receptor Assays to Detect and Identify Microbial Contaminants in Biological Products**
Dr Basil Golding, Food and Drug Administration (USA)
- 13:20-13:30 Discussion**
- 13:30 Close of the meeting*

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