edqm European Directorate for the Quality of Medicines & HealthCare
COUNCIL OF EUROPE CONSEIL DE L'EUROPE

SYMPOSIUM: ALTERNATIVES TO ANIMAL TESTING
8-9 September 2011, Strasbourg, France

Duration: 1.5 days; working language: English

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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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9 September 2011

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**

12:0012:20 **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

For further information, please contact the EDQM Public Relations Division & Documentation:
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