



# **ALTERNATIVES TO ANIMAL TESTING: NEW APPROACHES IN THE DEVELOPMENT AND CONTROL OF BIOLOGICALS**

International Symposium organised by the  
European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe  
in close co-operation with the Ministry of Health and Social Welfare of Croatia

**23-24 April 2008, Dubrovnik, Croatia**

Duration: 2 days, Working language: English

## **PROGRAMME**

A **Posters Session** is open to all participants for the entire duration of the symposium.

Registration: 7h00 onwards

**Wednesday 23<sup>rd</sup> April 2008**

9h00 - 9h10 **Welcome Address**  
9h10 - 9h20 **General introduction**

### **SESSION 1**

#### **Current regulations on alternatives and review of progress**

**Moderator:** Mr Jean-Marc Spieser, Head of Department of Biological Standardisation,  
OMCL Network & HealthCare, EDQM, Council of Europe

- 9h20 - 9h40 **European Pharmacopoeia activities – an overview**  
Dr Emmanuelle Charton, Deputy Head of the European Pharmacopoeia Dept.,  
EDQM, Council of Europe
- 9h40 - 10h00 **The achievements of the European Biological Standardisation Programme**  
Dr Karl-Heinz Buchheit, Deputy Head of Department of Biological Standardisation,  
OMCL Network & HealthCare, EDQM, Council of Europe
- 10h00 - 10h20 **The World Health Organisation (WHO)**  
Dr David Wood, WHO Family and Community Health
- 10h20 - 10h50 **Coffee Break**
- 10h50 - 11h10 **European Centre for the Validation of Alternative Methods (ECVAM): its role  
and contribution**  
Dr Marlies Halder, Representative of ECVAM/JRC-EU
- 11h10 - 11h30 **The European Union**  
Dr Antonio Lacerda de Queiroz, EU Commission
- 11h30 - 11h50 **What are the priorities for the future?**  
Dr Roland Dobbelaer, Former Chair of Steering Committee BSP (B)
- 11h50 - 12h20 **Discussion with the panel of speakers**
- 12h20 - 14h00 **Lunch**

## **SESSION 2: Human Vaccines – Safety and Potency Which possible alternatives?**

**Moderator:** Dr David Wood, WHO Family and Community Health

- 14h00 - 14h20 Review of the need for safety tests and the progress made**  
Dr Michel Duchêne, GSK Biologicals (B)
- 14h20 - 14h40 Review of the need for potency tests and the progress made**  
Dr Roland Dobbelaer, Former Chair of Steering Committee BSP (B)
- 14h40 - 15h00 Technical up-dates on progress in *in vitro* tests for vaccines**  
Dr Florence Fuchs/Dr Sonia Prieur, Afssaps DLC/OMCL Lyon (F)
- 15h00 - 15h50 Discussion with the panel of speakers with special emphasis to the following issue “Could batch-to-batch consistency be demonstrated without using animals”**
- 15h50 - 16h20 Coffee Break**

## **SESSION 3: Veterinary Vaccines**

**Moderator:** Dr Lukas Bruckner, Member of the Ph. Eur. and  
Chair of Group of Experts 15V on Veterinary sera and vaccines

- 16h20 - 16h40 PCR for extraneous agents**  
Dr Hans Peter Ottiger, Institute of Virology and Immunoprophylaxis (CH)
- 16h40 - 17h00 Role of OIE in animal welfare standards**  
Dr Sarah Kahn, International Trade Department, OIE
- 17h00 - 17h20 Perspectives from industry: development of alternative testing**  
Dr Imke Kross/Dr Keith Redhead, IFAH-Europe
- 17h20 - 17h50 Discussion with the panel of speakers with special emphasis to the following issue “Could batch-to-batch consistency be demonstrated without using animals”**

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**Thursday 24<sup>th</sup> April 2008**

**SESSION 4: Biotherapeutics**

**Moderator:** Dr Florence Fuchs, Afssaps (F)

- 8h30 - 8h50 Potency and safety testing for toxins and anti-toxins – an overview**  
Dr Dorothea Sesardic, NIBSC (UK)
- 8h50 - 9h10 Therapeutic toxins – the road to replace LD50 in mice**  
Dr Ester Fernandez-Salas, Allergan Inc (USA)
- 9h10 - 9h30 Possible approaches for replacement of erythropoietin *in vivo* potency assay**  
Dr Adrian Bristow, NIBSC (UK)
- 9h30 - 9h50 The role of animal models and cell cultures in advanced therapies**  
Prof. Klaus Cichutek, Paul-Ehrlich Institute (D)
- 9h50 - 10h20 Discussion with the panel of speakers**
- 10h20 - 10h50 Coffee Break**

**SESSION 5: New Technologies**

**Moderator:** Dr Roland Dobbelaer, Former Chair of Steering Committee BSP (B)

- 10h50 - 11h10 Proteome and transcriptome analysis of a human cell line to identify markers for a novel *in vitro* assay for anthrax toxin**  
Dr Sjoerd Rijpkema, NIBSC (UK)
- 11h10 - 11h30 Dendritic cells as *in vitro* indicators of adjuvant and vaccine efficacy**  
Dr Kenneth McCullough, Institute of Virology and Immunoprophylaxis (CH)
- 11h30 - 11h50 Multiplex systems for serology**  
Dr Sylvie Uhlrich, Sanofi Pasteur (F)
- 11h50 - 12h10 Glycan mapping**  
Dr Joerg Hoernschemeyer, F. Hoffmann La Roche AG (CH)
- 12h10 - 12h40 Discussion with the panel of speakers**
- 12h40 - 14h00 Lunch**

## SESSION 6: Case studies and validation studies

**Moderator:** Dr Karl-Heinz Buchheit, Deputy Head of Department of Biological Standardisation, OMCL Network & HealthCare, EDQM, Council of Europe

- 14h00 - 14h20* **Replacement of tetanus immunoglobulin *in vivo* potency assay**  
Dr Steffen Gross, Paul-Ehrlich Institute (D)
- 14h20 - 14h40* **Alternative to Kendrick test (whole cell pertussis vaccines)**  
Dr Christina Von Hunolstein, Istituto Superiore di Sanità - ISS (I)
- 14h40 - 15h00* **Combined vaccines – single animal approach for several antigens**  
Dr Randi Winsnes, Norwegian Medicines Agency (N)
- 15h00 - 15h20* **Novel methods for long-nosed viper venom**  
Dr Lidija Habjanec, Institute of Immunology (CR)
- 15h20 - 15h50* **Discussion with the panel of speakers**

## CLOSING SESSION: Final Roundtable Discussion

**What have we achieved, what have we learned, what remains to be done – the lessons, experiences and future strategy**

**Moderator:** Mr Jean-Marc Spieser, Head of Department of Biological Standardisation, OMCL Network & HealthCare, EDQM, Council of Europe

*15h50 - 16h50* **Final Roundtable Discussion**, with the participation of: **Prof. Klaus Cichutek**, Paul-Ehrlich Institute (D); **Dr Michel Duchêne**, EFPIA/EVM; **Dr Marlies Halder**, ECVAM/JRC-EU; **Dr Sarah Kahn**, International Trade Department, OIE; **Dr Imke Kross**, IFAH-Europe; **Dr Antonio Lacerda de Queiroz**, EU Commission; **Dr David Wood**, WHO Family and Community Health.

*16h50 - 17h10* **Closing remarks**

*17h10 - 17h40* **Coffee Break**

### Scientific Programme Committee

**Dr A. Bristow**, National Institute for Biological Standards and Control (UK)  
**Dr L. Bruckner**, Institute of Virology and Immunoprophylaxis (CH)  
**Dr K. H. Buchheit**, European Directorate for the Quality of Medicines & HealthCare  
**Mr P. Castle**, European Directorate for the Quality of Medicines & HealthCare  
**Dr R. Dobbelaer**, Scientific Institute of Public Health (B)  
**Dr M. Duchene/Dr A. Sabouraud**, EFPIA/EVM Representative  
**Dr F. Fuchs**, Agence Française de Sécurité Sanitaire des Produits de Santé (F)  
**Dr T. Hartung**, European Centre for the Validation of Alternative Methods  
**Prof. P. P. Pastoret**, World Organisation for Animal Health  
**Mr R. Santos Ivo**, DG Enterprise and Industry, E.U.  
**Dr D. Sesardic**, National Institute for Biological Standards and Control (UK)  
**Mr J. M. Spieser**, European Directorate for the Quality of Medicines & HealthCare  
**Dr K. Sewerin**, EuropaBio Healthcare Council  
**Dr D. Wood**, World Health Organisation

### Further Information

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