

CHANCES AND LIMITATIONS WITH RESPECT TO REPLACEMENT OF ANIMAL EXPERIMENTATION IN THE DEVELOPMENT OF NEW PHARMACEUTICALS

Workshop organized by *ecopa* and the national platforms *hucopa* and *set*
October 2/3, 2009, Budapest

Friday October 2nd, 2009

12:00 – 13:00 Registration and Lunch Buffet

13:00 – 13:35 Welcome and Introduction

Chairs: Lajos Balogh, Gisbert Sponer

13:00 – 13:10	Welcome address	Lajos Balogh, hucopa (HU)
13:10 – 13:25	ecopa and status of START-UP	Vera Rogiers, Chair of ecopa (BE)
13:25 – 13:35	Introduction, objective of the workshop	Gisbert Sponer, set (DE)

13:35 – 15:20 Session I: Replacement in the development of new chemical entities

Chairs: ECOPA I, Hucopa I

13:35 – 14:00	Keynote I	Friedlieb Pfannkuch, Roche (CH)
14:00 – 14:40	Preclinical Pharmacology Healthcare (DE)	Klaus-Dieter Bremm, Bayer Jan-Willem van der Laan, (NL)
14:40 – 15:20	Toxicology including Safety Pharmacology (UK)	Tim G. Hammond, Astra – Zeneca David Jones, EMEA (UK)

15:20 – 15:40 Coffee Break

15:40 – 17:40 Session II: Replacement in the development of new chemical entities (cont)

Chair: ECOPA II, HUCOPA II

15:40 – 16:20	Mutagenicity and Cancerogenicity (NL) EMEA (DE))	Philippe Vanparys, Altovicon (BE) Jan-Willem van der Laan, EMEA (replacing Doris Höschele, Michael Schwarz, University of Tübingen (DE) Klaus Olejniczak, EMEA (DE) Mario Monshouwer, JNJ (BE) Sonja Beken, EMEA (BE)
16:20 – 17:00	Reprotoxicology Tübingen (DE)	
17:00 – 17:40	Pharmacokinetics	

17:40 – 18:10 Free communications

Chair: ECOPA II, HUCOPA II

17:40 – 17:55	<i>In vitro – in vivo</i> : alternative or complementary approaches? (HU)	István Gyertyán, Gedeon Richter
17:55 – 18:10	Katy Taylor	
18:10 – 18:20	Conclusions of the day	Gisbert Sponer, set (DE)

20:00 Dinner

Saturday, October 3rd, 2009

Session III: Replacement in the development of new biological entities

Chair: ECOPA III, HUCOPA III

- 09:00 – 09:25 Keynote II Levente Pencz, Animal Welfare Organization (HU)
- 09:25 – 10:05 Biologics I (sera, vaccines) Coenraad Hendriksen, Netherland Vaccine Institute (NL)
- (DE) Steffen Gross, Paul-Ehrlich-Institute
- 10:05 – 10:45 Biologics II (peptides, humanized antibodies etc.) Bernd Mueller-Beckmann, Roche (DE)
- Beatriz Lima, EMEA (PT)

10.45 - 11.05 Coffee Break

Session IV: Replacement in quality control

Chair: ECOPA IV, HUCOPA IV

- 11:05 – 11:45 Aspects of quality control, requirements of the pharmacopoeia Jean-Michel Chapsal, Sanofipasteur (FR)
- Karl-Heinz Buchheit, EDQM (FR)

11:45 – 12:15 Free communications

12:15 – 13:00 Round table discussion

Moderator: Bernward Garthoff, ecopa

- 13:00 – 13:10 Concluding remarks Gisbert Sponer
Thanks, Fair well hucopa, set

13.10 - 14.00 Lunch buffet

After the end of the START-UP workshop there will be a press conference and a local conference of the Hungarian platform hucopa in **Hungarian language**.

MAGYARORSZÁGI KONSZENZUS PLATFORM AZ ALTERNATÍV MÓDSZEREKÉRT EGYESÜLET

(Hungarian Consensus Platform on Alternatives – hucopa), www.hucopa.hu

14.00 – 16.00 Session V: The 3R actualities in Hungary

Chair: Lajos Balogh

- 14.00 – 14.10 Basic information on hucopa history, activities Lajos Balogh, hucopa (HU)
- 14.10 – 14.30 The 3Rs actualities from the Authorities point of view Laszlo Pallos, hucopa (HU)
- 14.30 – 14.50 The 3Rs actualities from the Industry's point of view Zsuzsa Somfai, hucopa (HU)
- 14.50 – 15.10 The 3R actualities from the Academy/Education's point of view Tibor Bartha, hucopa (HU)
- 15.10 – 15.40 The 3Rs actualities from the Animal Welfare's point of view Eva Hercsuth, hucopa (HU)
- 15.40 – 16.00 Round table discussion
- Moderator: Lajos Balogh, hucopa (HU)*

Evaluation, summary of the 2 days conference. How to continue our work, how to improve our efficiency.