



Making Medicines Affordable

3rd EGA SYMPOSIUM ON BIOEQUIVALENCE

Training for Industry on the Revised Bioequivalence Guideline with Pharmacokinetic Assessors

1 June 2010

De Vere Venue
1 Westferry Circus, Canary Wharf, London E14 4HA, UK

A joint workshop with European PK Assessors, members of CMD(h) and bioequivalence experts from the European Generic medicines Association (EGA)

This year's edition will be **exclusively dedicated to the revised EMA Bioequivalence guideline** <http://www.ema.europa.eu/pdfs/human/qwp/140198enrev1fin.pdf>
It will offer a unique discussion platform for industry and regulators to gain essential updates and clarification on the new concepts and approaches now part of the bioequivalence guideline.

Each topic will be introduced and the discussion led by a panel of invited speakers from Regulatory Authorities and from the European generic medicines industry followed by a panel discussion.

Speakers and Panellists*:

Tomas Salmonson (Swedish Medicines Agency MPA, Deputy Chair of CHMP) - **Jan Welink** (Dutch Medicines Agency, MEB) - **Henrike Potthast** (German Medicines Agency, BfArM) - **Kersti Oselin** (UK Medicines Agency, MHRA) - **David Brown** (UK Medicines Agency, MHRA) - **Jose Morais** (Portuguese Medicines Agency, INFARMED) - **Alfredo García-Arieta** (Spanish Medicines Agency, AEMPS) - **Jayne Crowe** (Irish Member of the CMD(h)) - **Jitka Vokrouhlická** (Czech Member of the CMD(h))

Susana Almeida (Grupo Tecnimede, PT) - **Kevan Cassidy** (Consilient, UK) - **Gerald Beuerle** (ratiopharm, DE) - **Andrzej Dzierbicki** (Polpharma, PL), **Suzette Kox** (EGA)

*The final decision on the panellists nominated for each session will be made from the confirmed speaker list.

For further information and to register on-line, please visit:

www.gpaconferences.com or www.egagenerics.com

Cristina Romagnoli - T: +377-93-501348 - F: +44-208-0825368 - E: info@gpaconferences.com

Registrations close officially on 14 May 2010 & are subject to availability.

EUROPEAN GENERIC MEDICINES ASSOCIATION

Rue d'Arlon 50, B-1000 Brussels, Belgium

T: +32-(0)2-736 8411 F: +32-(0)2-736 7438

E: info@egagenerics.com www.egagenerics.com

VAT: BE 0449 332 209



TUESDAY 1 JUNE 2010

3rd EGA Symposium on Bioequivalence

09:00 **Welcome address** | *Suzette Kox, Senior Director Scientific Affairs, EGA*
Opening speech | *Tomas Salmonson, Deputy Chair of CHMP, MPA (SE)*

09:30 **Session 1 - In Vitro Testing and Biowaiver**

Chairs | *Henrike Potthast (BfArM) and Andrzej Dzierbicki (Polpharma)*

- **Authorities perspective** | *Henrike Potthast (BfArM, Germany)*
- **Industry perspective** | *Andrzej Dzierbicki (Polpharma, Poland)*

Panel Discussion composed of session speakers and other representatives of the EU Authorities

11:00 Networking Coffee Break

11:30 **Session 2 - Study Design**

Chairs | *Jan Welink (MEB) and Susana Almeida (Grupo Tecnimede)*

- **Authorities perspective** | *Jan Welink (MEB, Netherlands)*
- **Industry perspective** | *Susana Almeida (Tecnimede, Portugal)*

Panel Discussion composed of session speakers and other representatives of the EU Authorities

13:00 Networking Buffet Lunch

14:00 **Session 3 - Exclusion of Data, Evaluation of Results and Acceptance Criteria of Studies**

Chairs | *Kersti Oselin (MHRA) and Gerald Beuerle (ratiopharm)*

- **Authorities perspective** | *David Brown (MHRA, UK) and Kersti Oselin (MHRA, UK)*
- **Industry perspective** | *Gerald Beuerle (ratiopharm, Germany)*

Panel Discussion composed of session speakers and other representatives of the EU Authorities

15:30 Networking Coffee Break

16:00 **Session 4 - Ask your questions to the regulators**

Chairs | *Tomas Salmonson (MPA) and Kevan Cassidy, Consilient (UK)*

Questions should be formulated generally without reference to a given product/procedure and should be sent 2 weeks in advance to beata@egagenerics.com

Panel Discussion composed of session speakers and other representatives of the EU Authorities.

17:00 **Closing Remarks** - *Susana Almeida, Grupo Tecnimede (PT) and Kevan Cassidy, Consilient (UK) - Co-Chairs of EGA Bioequivalence Working Group*

ORGANISING PROGRAMME COMMITTEE

Tomas Salmonson (Swedish Medicines Agency MPA, Deputy Chair of CHMP) - **Truus Janse de Hoog** (Dutch Medicines Agency MEB, Chair of the CMD(h)) - **Jan Welink** (Dutch Medicines Agency, MEB) - **Monica Edholm** (Swedish Medicines Agency, MPA) - **Jayne Crowe** (Irish Member of the CMD(h)) - **Jitka Vokrouhlická** (Czech Member of the CMD(h)) - **Henrike Potthast** (German Medicines Agency, BfArM) - **Kersti Oselin** (UK Medicines Agency, MHRA) - **Susana Almeida** (Grupo Tecnimede, PT) - **Kevan Cassidy** (Consilient, UK) - **Gerald Beuerle** (ratiopharm, DE) - **Andrzej Dzierbicki** (Polpharma, PL) - **Beata Stepniewska** (EGA)

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