



Making Medicines Affordable



2nd EGA-CMD(h) SYMPOSIUM ON BIOEQUIVALENCE

“Bioequivalence guideline revision, regulatory procedures and Good Practices: Paving the way towards an even more efficient regulatory framework”

A joint workshop with members of CMD(h), European Assessors (Members of the EWP), members of the European Inspectorate and of the European Generics medicines Association

Hotel Marriott Rive Gauche
17, Boulevard St Jacques - 75014 Paris, France

7 - 8 October 2008

The revised Bioequivalence guideline is available on the EMEA website and is open for consultation until 31 January 2009:
<http://www.emea.europa.eu/pdfs/human/gwp/140198enrev1.pdf>

Organising Programme Committee

Truus Janse-de Hoog (Chairperson CMD(h)), **Tomas Salmonson** (Swedish Agency and Member of the Pharmacokinetics subgroup of the EWP), **Jan Welink** (Dutch Agency, Member of the Pharmacokinetics subgroup of the EWP), **Kevan Cassidy** (Mylan, UK), **Susana Almeida** (Grupo Tecnimede, Portugal), **Janja Luksa** (Sandoz, Slovenia), **Yu Chung Tsang** (Apotex, Canada) and **Julie Maréchal** (EGA)

Symposium Format

Each topic will be introduced and discussion led by panel of invited speakers from Regulatory Authorities, and from the European generic medicines Industry. Full participation from all attendees will be encouraged in a round-table discussion format.

This is a unique opportunity to discuss in-depth, topics, which affect bioequivalence in Europe

TUESDAY 7 OCTOBER 2008

EGA-CMD(h) Symposium on Bioequivalence

18:30 - 19:00 REGISTRATIONS

19:00 - 19:30 WELCOME ADDRESS: Susan De Stasio, Chairperson EGA Regulatory and Scientific Affairs Committee
OPENING SPEECH: Truus Janse-de Hoog, Chairperson Co-Ordination Group for Mutual Recognition and Decentralised Procedures (Human) CMD(h)

And

KEYNOTE SPEAKER: Fabienne Bartoli, Deputy Director General, French Agency

19:30 - 21:30 WELCOME COCKTAIL & LIGHT BUFFET RECEPTION



Making Medicines Affordable

WEDNESDAY 8 OCTOBER 2008

EGA-CMD(h) Symposium on Bioequivalence

08:00 - 09:00 WELCOME COFFEE

09:00 - 10:30 SESSION 1: DATA INTEGRITY, GCP AND GLP INSPECTIONS

Chaired by Janja Luksa (Sandoz)

Panellists: Olivier Le Blaye (French Agency) - Louise Mawer (UK Agency) - Janja Luksa (Sandoz)

Questions and Answers

10:30 - 11:00 COFFEE BREAK

11:00 - 12:15 SESSION 2: EARLY AND LATE DIALOGUE WITH AUTHORITIES, FROM SCIENTIFIC ADVICE TO REFERRALS

Co-Chaired by Truus Janse-de-Hoog (Chair of the CMD(h)) and Susan De Stasio (Chair of the EGA Regulatory & Scientific Affairs Committee, Arrow Generics)

Panellists: John Warren (UK Agency) - Tania Meier (German Agency) - Ulrike Poller (German Agency) - Julie Maréchal (EGA)

Questions and Answers

12:15 - 13:15 BUFFET LUNCH

13:15 - 14:30 SESSION 3: OUTCOME OF THE REVISION OF THE BIOEQUIVALENCE GUIDELINE

Co-Chaired by Tomas Salmonson (Swedish Agency) and Susana Almeida (Co-Chair of the EGA Bioequivalence Working Group, Grupo Tecnimede)

Panellists: Jan Welink (Dutch Agency) - Jose Morais (Portuguese Agency) - Gerald Beuerle (ratiopharm)

14:30 - 15:30 Questions and Answers on the NEWLY RELEASED BIOEQUIVALENCE GUIDELINE

15:30 - 16:00 COFFEE BREAK

16:00 - 17:15 SESSION 4: GUIDANCE FOR THE DEVELOPMENT OF LOCALLY ACTING PRODUCTS (DERMATOLOGICAL AND OPHTHALMIC MEDICINAL PREPARATIONS, GI TRACT MEDICINES)

Chaired by Kevan Cassidy (Co-Chair of the EGA Bioequivalence Working Group, Mylan)

Panellists: Andrea Laslop (Austrian Agency) - Ridha Belaiba (French Agency) - Vit Perlik (Zentiva)

Questions and Answers

17:15 - 17:30 CLOSING REMARK BY Truus Janse-de Hoog, Chairperson: Co-Ordination Group for Mutual Recognition and Decentralised Procedures (Human) CMD(h)

REGISTRATIONS

Registrations are opened until the 1 October 2008 on www.gpaconferences.com/ega.htm

Due to a limited number of places preference will be given to EGA Members and registrations will be subject to availability.

FEES: €390 + 19.6% VAT per participant for Academic representatives

€690 + 19.6% VAT per participant for EGA Members - €910 + 19.6%VAT per participant for Non-EGA Members

FURTHER DETAILS

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