



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

1st EGA Workshop on Bioequivalence Study Design, Working to GCP and Interpreting the Guidelines

The Keys to a Successful Generic Application

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

This workshop is open only to pharmaceutical companies operating in the generic medicines sector. Due to a limited number of places, priority will be given to EGA Members.

Hotel Le Meridien Park Atlantic Lisboa
Rua Castilho 149, PT-1099-034 Lisbon, Portugal

23rd - 24th October 2007

TUESDAY 23rd OCTOBER 2007

19:00 - 20.00 REGISTRATION

20:00 - 22:00 WELCOME RECEPTION SPONSORED BY
WITH WELCOMING STATEMENTS BY

Truus Janse-de Hoog, Chairperson: Co-Ordination Group for Mutual Recognition and Decentralised Procedures (Human) CMD(h)
And Susan De Stasio, Chairperson EGA Regulatory & Scientific Affairs Committee - Arrow Generics



WEDNESDAY 24th OCTOBER 2007

08:00 - 09:00 WELCOME COFFEE

09:00 - 10:30 Working to GCP, GCP inspections and their consequences -

Chaired by Susan De Stasio, Chairperson EGA Regulatory & Scientific Affairs Committee - Arrow Generics

Panellists: Olivier Le Blaye (French Agency) Peter Bachmann (German Agency) and Janja Luksa (Sandoz)

10:30 - 11:00 COFFEE BREAK

11:00 - 12.30 Guidance for the development of generic inhaled products -

Chaired by Alicia López de Ocariz, Cinfa

Panellists: Anders Fuglsang (Norwegian Agency), Alfredo Garcia Arieta (Spanish Agency), Mike Wing (G[UK] Ltd.)

12.30 - 13.30 BUFFET LUNCH



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- 13.30 - 15.00 Highly Variable Drugs, Widening of Confidence Intervals**
Chaired by **Susana Almeida**, Co-chair EGA Bioequivalence Working Group - Farnoz-Grupo Tecnimede, Portugal
Panellists: **Tomas Salmonson** (Swedish Agency), **Jan Welink** (Dutch Agency), **Gerald Beuerle** (ratiopharm)
- 15:00 - 15:30 COFFEE BREAK**
- 15:30 - 17:00 Future developments to Regulatory Guidance**
Q & A developments, should Europe publish product-specific guidance?
Chaired by **Mary Smillie**, Senior Advisor Legal and Regulatory Affairs EGA
Panellists: **Professor Morais** (Portuguese Agency), **Ivanka Atanasova** (Bulgarian Agency), **Bruno Flamion** (Belgian Agency)

Organising Programme Committee: **Truus Janse-de Hoog** (Chairperson CMD(h)), **Bruno Flamion** (Chairperson of the Pharmacokinetics subgroup of the EWP), **Tomas Salmonson** (Swedish Agency and Member of the Pharmacokinetics subgroup of the EWP), **Jan Welink** (Dutch Agency and Member of the Pharmacokinetics subgroup of the EWP), **Fergus Sweeney** (Principal Scientific Administrator, Inspections Sector EMEA), **Kevan Cassidy** (G[UK] Ltd., UK), **Susana Almeida** (Farnoz-Grupo Tecnimede, Portugal), **Alicia López de Ocariz** (Cinfa, Spain) and **Mary Smillie** (EGA).

Workshop 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. To ensure this is an interactive workshop, participation will be limited.

REGISTRATIONS

Registration will open on the 16th July 2007 for EGA Members only and on the 1st September 2007 for Non Members and close on the 17th October 2007 on www.egagenerics.com

Due to a limited number of places preference will be given to EGA Members and registrations will be subject to availability.
Cost: €599 per participant for EGA Members & €699 per participant for Non-EGA Members

FURTHER DETAILS

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