



6th EGA Regulatory and Scientific Affairs Conference

13th and 14th February 2007
Hotel Sheraton | Brussels

MAIN TOPICS

- European Commission's priorities for the pharmaceutical sector
- European Medicines Regulatory Network
- Decentralised Procedure for Generics: Has the new procedure satisfied expectations?
- Interpretation of the "Potential Serious Risk to Public Health" in the context of the referral procedure
- Centralised Procedure for Generics: Is the framework complete? What are the advantages and disadvantages?
- Can competitors influence your approval process?
- Final outcome of the Paediatrics Regulation
- Status of the SmPC harmonisation process
- PIL User Testing: Has the objective been achieved?
- Development of monographs in today's Bolar environment
- Revision of the Variations Regulation
- What is new in the bioequivalence field?
- Guidelines on Pharmacovigilance: New Volume 9
- PSUR work sharing and Harmonised Birth Dates initiative
- Pharmacovigilance Inspection: How to be prepared

Speakers include the European Commission, the National Agencies, the EMEA and industry experts

REGISTER NOW



ON WWW.EGAGENERICS.COM

Brussels Event
organised by



Cristina Romagnoli
E: cristina@gpaconferences.com
T: + 377-93-501348
F: + 377 93 501 348