

The Annual European Medicines Agency Review of the Year and Outlook for 2012

TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: CA5



A joint TOPRA/European Medicines Agency meeting



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Two-day Conference

Date:

24–25 November 2011

Venue:

European Medicines
Agency, 7 Westferry
Circus, Canary Wharf,
London, UK

Programme includes

- The EMA Road Map - from Vision to Reality in 2012 and beyond
- CHMP: Work Programme and Current Issues
- Past experience and future trends for development of medicines in paediatrics and the elderly
- The work of the EMA: Hear how the EMA works at a practical level
- Benefit/Risk: what are the outcomes of the 3 year project on risk benefit decision making?
- Health Technology Assessment: the work of the Tapestry network, industry and can the Darwinian divide be overcome to generate multi-purpose data?
- Risk Benefit in Action: How are the Centralised Procedure and Community Referrals changing
- Impact of Pharmacovigilance legislation for patients, industry and member states

Have you ever wondered exactly who to contact at EMA on a particular subject? Have you ever spoken to someone and not known exactly what their role is?

The 4th session on Thursday 24 November will introduce the new EMA structure and its governance. This will be followed by short presentations from some of the key units of the EMA. After this formal session there will be a networking drinks reception at the EMA.

Speakers include

From the EMA: Noel Wathion, Emer Cooke, Isabelle Moulin, Marie-Helene Pinheiro, Agnes Saint Raymond, Francesca Cerreta, Xavier Luria Oller, Spiros Vamvakas, Michael Berntgen, Anthony Humphreys, Peter Arlett and others to be announced.

From the national agencies we have Eric Abadie of Afssaps, Jens Heisterberg of Danish Medicines Agency, Bert Leufkens of the Dutch MEB, Ian Hudson of the MHRA and others to be confirmed.

From the European Commission we have Maria Iglesia and Florian Schmidt of unit D3 Pharmaceuticals.

Additional speakers from national agencies; European Commission; EMA and other leading pioneers and practitioners from within industry and academia and patient groups have been invited.

Working party

Peter Bachmann, member of CMD(h), BfArM, Germany
Liz Gifford, NDA, UK

Ian Hudson, member of CHMP, MHRA, UK

Anthony Humphreys, European Medicines Agency

Brenton E James, Consultant in Strategic Regulatory Affairs in European Union (working party Chair)

Angelika Joos, Merck Sharp & Dohme (Europe) Inc, Belgium

Angela Miller, Eisai, UK

Marie-Helene Pinheiro, EMA

Agnes Saint Raymond, EMA

Emer Cooke, EMA

Xavier Luria Oller, EMA

Nuno Simoes, Infarmed, Portugal

Fiona Reekie, Janssen Pharmaceutical Companies of Johnson & Johnson, UK

Sandy Eisen, Frontline Pharma Consulting Ltd

Ian Laws, GlaxoSmithKline

Tomas Salmonson, MPA, Sweden

Isabella Sanderfelt, Pfizer, Sweden

Judith Creba, Novartis, Switzerland

Gabriela Conti, AIFA, Italy



TOPRA/EMA

12* hours

Lifelong learning

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please visit www.topra.org/lifelonglearning

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BOOKING FORM 2011

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Fees and Payment method

Members ☐ €1650 = €1375 + €275 (GB VAT 20%)

Non-Members ☐ €2130 = €1775 + €355 (GB VAT 20%)

The VAT rate charged will be the prevailing rate at the time of invoicing.

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