

EU: REGULATORY CHALLENGES FOR 2012 AND THEIR IMPACT ON MARKETING AUTHORISATION



*SEMINAR - 23 February 2012 in Ahmedabad
Park Plaza Ahmedabad*

TOPICS:

* REGULATORY CHALLENGES FOR 2012: OVERVIEW OF LATEST CHANGES IN THE EUROPEAN REGULATORY PROCEDURES:

- GCP inspections
- Harmonisation of the Clinical Trial Legislation
- Health Technology Assessment and Registration Approvals: approaches and duplications
- Combination Products: How to manage a medical device and a pharmaceutical product
- Community Referrals: - Now and in the future



* VARIATIONS REGULATION – THE NEW ELEMENTS:

- Variations and line extensions
- What is really new in Regulation 1234/2008

* EUDRAVIGILANCE CHANGES: IMPLEMENTATION OF ELECTRONIC SUBMISSION OF MEDICINAL PRODUCT INFORMATION IN THE EU (ARTICLE 57(2) REQUIREMENTS OF THE NEW PHARMACOVIGILANCE LEGISLATION)

- Requirements for MAH
- Status of implementation by the EMA

* ONGOING IMPLEMENTATION OF THE NEW EU PHARMACOVIGILANCE LEGISLATION BY THE EUROPEAN MEDICINES AGENCY, THE MEMBER STATES AND THE GENERIC PHARMACEUTICAL INDUSTRY.

- Impact on industry processes
- Impact of changes to data submission / study requirements
- The Pharmacovigilance System Master File

**COURSE
OVERVIEW** *(see next page)*

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COURSE OVERVIEW

This training course will provide a limited pool of attendees an excellent overview of latest changes in the European Regulatory procedures.

The course will cover the evolution of the registration systems available for approval of products in the European Union, together with major changes in New Medicines Legislation.

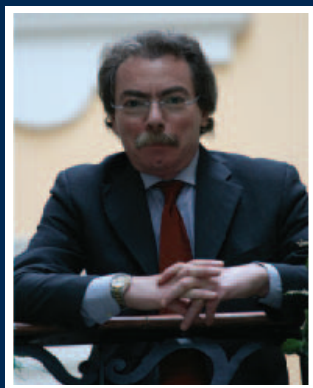
The very important changes in New Medicine Legislation concerning regulatory procedures, access to Centralised and Mutual Recognition Procedures, reduction in Regulatory Data protection will be described in detail.

Detailed review will be offered on the changed Centralised and Mutual Recognition Procedures and New Decentralised Procedure with discussion of practical examples of product types suitable for each procedure.

Regulatory strategy which impacts on commercial, business and licensing arrangements will be of importance to those responsible for business development.

In short, this will be a fantastic opportunity to meet the experts that you need today and to tap into the network of experts that you more than likely will need tomorrow.

ABOUT THE SPEAKER:



Dr. Paolo Biffignandi MD, PhD, QPPV, FTOPRA is a past President of The Organization for Professionals in Regulatory Affairs (TOPRA) and has recently been appointed to the advisory board of the pan-European pharmaceutical regulatory affairs organization, ELC GROUP.

Dr. Biffignandi is a renowned physician, who graduated in Medicine with a PhDs in endocrinology and pharmacology. He started his highly successful career in the pharmaceutical industry after a period at the University of Torino (Italy), and in 1989 he became an independent consultant in medical and regulatory affairs.

He is the author of more than 160 scientific articles and co-author of 3 books on European Regulatory Affairs. He is a member of several scientific societies (such as DIA, RAPS and TOPRA). From 2003 he was a member of the Board of Directors of TOPRA, of which he was President 2009-10. In 2009 he has been appointed Fellow of Royal Society of Medicine (UK).

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Date/Venue: 23 February 2012, 9:00- 16:30 in Park Plaza Ahmedabad, Ellis Bridge
Opposite Gujarat College, Ahmedabad

Fee: 7 000 INR (The fee includes course documentation as well as mid-session refreshments.)

CANCELLATION POLICY:

Our general terms and conditions apply and are available upon request.

We can send them at any time or you can find them on the internet at www.elc-group.com

ANY FURTHER QUESTIONS?

We are gladly at your disposal should you have any further questions about the seminar.