



A Short Course on Regulatory Affairs with emphasis on
UNDERSTANDING 'SMALL MOLECULE' GENERIC MEDICINES

12-13 October 2011
Legacy Falcon Hotel, Stratford-upon-Avon, United Kingdom

A Short Course on Regulatory Affairs with emphasis on
BIOPHARMACEUTICAL DRUG SUBSTANCES AND PRODUCTS,
INCLUDING BIOSIMILARS

17-18 November 2011
Legacy Falcon Hotel, Stratford-upon-Avon, United Kingdom

COURSE OBJECTIVES, STRATEGY & TARGET AUDIENCE:

GENERIC:

Our Experts will provide comprehensive and up-to-date training on EU pharmaceutical legislation, legal base and other official requirements and guidelines concerning appropriately-focused elements of pharmaceutical science and clinical investigation that are important to the development and licensing of generic medicines in the Europe.

This course is suitable for people (likely to be from analytical, formulation, pharmaceutical development, manufacturing and regulatory/registration departments) needing to understand how to prepare Abridged Marketing Authorisation Applications for generic medicines. It will also be useful to people wanting better to understand regulatory science and scientific writing and other skills needed for the creation of successful licensing dossiers.

All details on www.PharmaQMtraining.eu

BIOPHARMACEUTICALS:

In this course our Expert Speakers will be examining the legal, nonclinical, clinical and quality issues concerning the successful development of biopharmaceutical medicines. Because there are growing opportunities for introducing biosimilar medicines to the medical marketplace, the course will also address the challenges facing the biogeneric companies.

Delegates are likely to be from the pharmaceutical and biotechnology industries and have an interest in product development and regulatory affairs associated with biopharmaceuticals.

All details on www.PharmaQMtraining.eu

EXCEPTIONAL VALUE: £995.00 + VAT

Includes high-quality, carefully-structured training, **accommodation for one night** (1st day) one breakfast, two lunches and a conference dinner (1st day), daytime in-course refreshments, a substantial delegates manual to reinforce the learning experience and a certificate of attendance

[14h Continuing Professional Development (CPD)]

* extra night(s) bookable if required, subject to availability