



A Short Course on Regulatory Affairs with emphasis on the
Background, Content and Detail of Module 3 of the
Common Technical Document (CTD),
the 'Quality Module'

3 - 4 March 2011

Legacy Falcon Hotel, Stratford-upon-Avon, United Kingdom

Our Experts will provide comprehensive and up-to-date training on chemical, pharmaceutical and biological issues in drug regulation. Over two days you will be introduced to or your existing knowledge will be refreshed and updated concerning the important 'Quality Module' of Marketing Authorisation (MA) applications for new and existing Drug Substances/Drug Products.

There will be considerable focus on common deficiencies in submitted applications. Whether you contribute to a new MA dossier as a formulator, analyst, manufacturer, regulatory affairs specialist, scientific/medical writer or manager or in many other ways, this wideranging but detailed and insightful course could suit you. The same could be true if you are involved in the preparation of Active Substance Master Files (ASMFs) or Certificate of Suitability (CEP) applications or if you work on the life-cycle maintenance of MAs, because the majority of Variation applications have important pharmaceutical (chemistry, manufacturing and control or CMC) components.

EXCEPTIONAL VALUE: £995.00 + 17.5% VAT

(VAT rate: 17.5% until 4th Jan, 20% after)

High-quality, carefully-structured training, accommodation for one night (3 March)*, one breakfast, two lunches and a conference dinner (3 March), 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