



## New Pharmaceutical Regulatory Conferences in the UK

**NEWS FLASH: ONLY A FEW PLACES LEFT ON OUR VARIATIONS COURSE (10-11 September 2009)**

Please phone +44 (0) 20 8429 1105 or email [admin@pharmaQMtraining.eu](mailto:admin@pharmaQMtraining.eu) to check availability, before booking

### OCTOBER COURSE

Course packages of exceptional value

CTD MODULE 3 ... AND MORE

BOOK SOON TO ENSURE YOUR PLACE

Internationally recognised speakers

Group interactive training

Attractive, accessible location: Stratford-Upon-Avon

Chemistry & Pharmacy regulatory training

To better understand CTD required content

For better scientific / medical writing

Extend your CPD, on building the CTD

### A Short Course on Regulatory Affairs with emphasis on...

**BACKGROUND, CONTENT AND DETAIL OF MODULE 3 OF THE COMMON TECHNICAL DOCUMENT (CTD), THE 'QUALITY MODULE'**

1-2 October 2009

ARE YOU LOOKING FOR A TRAINING COURSE GIVING

- Wide Coverage of EU Regulatory Procedures for the Quality [Chemistry, Manufacturing & Control (CMC)] Part of Marketing Authorisation Applications?
- Insight into the Content of the Pharmaceutical Dossier - CTD Module 3?
- Expert Explanations of Legislation, Global, EU and Other Guidelines and Requirements concerning Chemistry and Pharmacy Topics?
- Advice on the Quality Overall Summary - CTD Module 2.3?
- Advice on pharmaceutical contributions to the Summary of Product Characteristics, Labelling and Package Leaflet - Module 1?

DO YOU UNDERSTAND

- How to write an excellent CTD section 3.2.P.2 on Pharmaceutical Development and why it can be especially important to the success of your application?
- ICH and European Guidelines on classification and control of impurities?
- The extensive impact of the General Monograph "Substances for Pharmaceutical Use"?

### Learn first-hand about the answers by attending our conference

Over two days we will introduce you to (or refresh and update your existing knowledge about) the important 'Quality Module' of Marketing Authorisation (MA) applications for new and existing Drug Substances/Drug Products. Pharmaceutical regulatory understanding is also essential to those working on maintenance of MAs, as the majority of Variation applications have pharmaceutical components.

### FURTHER DETAILS:

**BACKGROUND, CONTENT AND DETAIL OF MODULE 3 OF THE COMMON TECHNICAL DOCUMENT (CTD), THE 'QUALITY MODULE'**

1-2 October 2009

#### The Legacy Falcon Hotel,

Chapel Street, Stratford-upon-Avon, CV37 6HA, United Kingdom

Good road access from junction 15 of the M40; 5 minutes walk from Stratford-Upon-Avon station; 25 minutes drive from Birmingham airport

#### Speakers: Professor Derek Calam & Dr Mike Robertson

The two-day course **offers exceptional value at £995 + 15% VAT** and includes high-quality, carefully-structured training, accommodation for one night\*, one breakfast, two lunches and a conference dinner, daytime in-course refreshments and a substantial delegate's manual to reinforce the learning experience

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

Bookings for this course will close on 23 September 2009 or sooner if oversubscribed

For further information about the Variations Course or any of PharmaQMtraining.eu conferences go to [www.PharmaQMtraining.eu](http://www.PharmaQMtraining.eu) or alternatively email your enquiry to [admin@PharmaQMtraining.eu](mailto:admin@PharmaQMtraining.eu)

**To book one or more places on the course go to [www.PharmaQMtraining.eu/booking\\_form.html](http://www.PharmaQMtraining.eu/booking_form.html)**