

CRED WORKSHOPS

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Ref: CMC 1–2



CMC – Drug Substance and Medicinal Product: The Evolving Pharmaceutical Dossier

14th October 2010: Drug Substance

Programme includes

Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'S'

- Legal framework
- An outline of the different sections within Module 3.2.S and an overview as to content within each section.
- What is a DMF?
- What is the Certificate of Suitability?
- How are these documents incorporated into the CTD Module 3, Part "S"?
- Other sources of information to support 3.2.S.
- ICH Q11 and QBD

Control of Drug Substances

- Sources of drug substances
- The elements of a specification
 - New drug substances
 - Multi-sourced substances (EP and other pharmacopoeial monographs)
- Analytical Methods

Data Requirements and Practical Guidance for Drug Substance Development

- Issues for different phases of development
 - Specifications and analytical methods
 - Production (scale-up, validation, starting materials, application of principles of GMP)
 - Stability programmes and data requirements
- Variations

Regulatory Agency's Perspective on the Drug Substance Section of Marketing Authorisation Applications (MAAs)

- Potential pitfalls and practical issues experienced with the active drug substance section of an MAA
 - An agency perspective on common findings arising during regulatory review
 - Current experience and advice on preparation of the drug substance section of the CTD
 - Quality Overall Summary – what reviewers want to see
- Inspection issues for drug substance manufacturers

Also available as a one-day course. Ref: CMC-1

All data correct at time of print.

For more information or to book your place, please visit www.topra.org/credcmc2010

15th October 2010: Medicinal Product

Programme includes

Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P'

- Legal framework
- An outline of the different sections within Module 3.2.P and an overview as to content within each section.
- Key Sources of reference information concerning the CTD and data requirements for the medicinal product
- ICH Q8 and QBD

Control of Medicinal Product

- Who & what controls medicinal products?
- Overview of various types of medicinal products (new/established actives, different formulations) and aspects of their control.
- Construction, contents and justification of specifications for a range of dosage forms
- Analytical Methods and their validation
- Batch analysis and CoFAs

Data Requirements and Practical Guidance for Medicinal Product Development

- Issues faced at different phases of development
 - The need to agree the specific product type required
 - Medicinal product production, scale up from development to production batches
 - Process validation requirements for different dosage forms
 - Stability programmes and data requirements
- When/how to deal with changes during development to ensure this does not invalidate any of the clinical/other data already generated.
- Specific data requirements for and issues associated with different dosage forms
- Variations

Regulatory Agency's Perspective on the Medicinal Product Section of Marketing Authorisation Applications (MAAs)

- Potential pitfalls and practical issues experienced with the medicinal product section of an MAA
 - An agency perspective on common findings arising during regulatory review for a range of product formulations
 - Current experience and advice on preparation and presentation of the medicinal product section of the CTD
 - Quality Overall Summary – what reviewers want to see

Also available as a one-day course. Ref: CMC-2

One or Two-day
Course

Date:

14–15 October 2010

Venue:

Radisson SAS Portman
Hotel, London



Lifelong Learning (LLL):

The Meeting contributes 6 hours per day of training to your LLL (sometimes known as Continuing Professional Development) and will enhance your Regulatory Skills relevant in the areas of human and veterinary medicines.

For more information please visit
www.topra.org/lifelonglearning

email: meetings@topra.org tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: www.topra.org/credcmc2010

One or Two-day Course Date: 14–15 October 2010 Venue: Radisson SAS Portman Hotel, London Ref: CMC 1–2

CMC – Drug Substance and Medicinal Product: The Evolving Pharmaceutical Dossier

Ways to book

Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

Post: TOPRA, Bellerive House, 3 Muirfield Crescent, London E14 9SZ

Fax: +44 (0) 20 7537 2003 **Email:** meetings@topra.org

On receipt of your booking form we will confirm your provisional place in writing and provide directions to the venue. An invoice will be sent separately. To ensure admission, payment must be received prior to the meeting.

If you have any queries, contact us on: +44 (0) 20 7510 2560 or meetings@topra.org

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Family name

First name Male Female

Company name

VAT reg. no.

Job title

Telephone

Fax

E-mail

Work Address

City Postcode

Country

Invoice Address
(If different from above address)

City Postcode

Country

Special dietary requirements

Experience in the Subject Area

Negligible Average Considerable

Your current role

Generics CRO European role Global role Local affiliate

Other

Experience in Regulatory Affairs Years Months

Fees and Payment method

Two-day Course

Members **£940.00** = £800.00 + £140.00 (17.5% GB VAT)

Non-Members **£1,116.25** = £950.00 + £166.25 (17.5% GB VAT)

One-day Course

Day 1: 14 October **Day 2: 15 October**

Members **£581.63** = £495.00 + £86.63 (17.5% GB VAT)

Non-Members **£699.13** = £595.00 + £104.13 (17.5% GB VAT)

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

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- Bank Transfers:** may be made to Lloyds TSB Bank PLC. Please quote the delegate's name and the course reference in the transmission details. The delegate must pay all bank charges.
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- Your place is secured only upon receipt of full payment.

Please note:

Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks and buffet lunch.

Discounted fees:

Personnel in full-time education, working in academia (full-time) or working for a statutory regulatory body may be entitled to a discount on the above fees. Please contact the TOPRA office for details.

Cancellations:

All cancellations must be received in writing 28 calendar days before the start of the course and will be subject to an administration fee of £100 + GBVAT. Payment can be in Euro or Sterling. Substitutions may be made at any time.

Data Protection:

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