

CRED WORKSHOPS

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Ref: CRED-ERP 1 & 2



European Regulatory Procedures: Strategic and Practical Considerations

Aim

This course is intended for all those working within European regulatory affairs.

Day 1 will cover the strategic considerations

- Devising a company strategy for effectively working with the regulators including how to ensure a win-win outcome; the role of the European Medicines Agency, CHMP, CMD(h), EU Commission and national authorities in the procedures
- Integrating scientific advice into your strategic decision including how and where to obtain it
- How to decide which procedure and which Regulatory agency to increase your chance of success including an overview of current procedures and accompanying legislation
- Planning for the application filing including what you should avoid in order to achieve a successful result; how to manage your company's expectations.

Day 2 will cover Practical Considerations

- An overview and comparison of the Centralised and Mutual Recognition/ Decentralised procedures and accompanying legislation
- How to plan, compile and manage the applications including what the guidelines don't tell you; pitfalls to avoid to achieve a successful result
- How to work with the regulators to maximise your chance of a positive outcome including the role of the European Medicines Agency, CHMP, EU Commission and national authorities in the procedures
- Appeals and hearings including the articles and what they mean in practice.

Who should attend

- The less experienced Regulatory Professional who requires comprehensive information on a subject
- The experienced professional who is a newcomer to a particular regulatory aspect
- Anyone who wishes to update their knowledge in a particular subject area

Topics include

Day 1

- Overview of European Regulations
- Developing your Global Filing Strategy
- Developing Strategy for Non-NCEs
- Finalising your European Regulatory Strategy
- Working Effectively with Regulators – Regulators Perspective
- Working Effectively with Regulators – Regulators Perspective

Day 2

- Key EU Region Considerations
- Decentralised and Mutual Recognition Procedures
- Centralised Procedure – The Details
- Health Technology Assessment
- Working together with the Regulators to ensure Success

Speakers include

Marie-Hélène Pinheiro, Regulatory Affairs Adviser, European Medicines Agency (EMA)

Bob Clay, Vice President, Oncology and Infection, Astra Zeneca, UK

Mike Bateman, Director – European Regulatory Consulting and Submissions, Kendle International Ltd, UK

Jackie Mitchell, Director Regulatory Affairs, Archimedes Pharma Ltd, UK

Mira Pavlovic, Head of Unit for National Scientific advice, AFSSAPS and vice chair EMA SAWP, France

Kim Wharton, Managing Director, Regulis Consulting Ltd., UK

Dave Gilbert, Vice President, NDA Regulatory Science, UK

Anna Somuyiwa, Director, Segulah Consulting Ltd, UK

One-day
Course

Date:

7–8 September 2010

Venue:

Hilton Paris La Defense,
Paris, France



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

All data correct at time of print.

For more information please contact TOPRA via email: meetings@topra.org tel: +44 (0) 20 7510 2560 or web: www.topra.org/crederp

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

One-day Course Date: 7–8 September 2010 Venue: Hilton Paris La Defense, Paris, France Ref: CRED-ERP 1 & 2

European Regulatory Procedures: Strategic and Practical Considerations

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

Dr Mr Mrs Ms Other

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

Members **€1,315.60** = €1,100.00 + €215.60 (FR VAT 19.6%)

Non-Members **€1,554.80** = €1,300.00 + €254.80 (FR VAT 19.6%)

CREDit Voucher Number

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

Cheque enclosed Cheque No

Bank transfer Date of transfer / /

Please charge my debit/credit card Purchase Order No.

Debit/Credit card details

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Security code Visa, MasterCard, Debit cards: the last 3 digits AFTER the card number in the signature area of the card.

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Payment:

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- Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. All cards will be charged in Sterling.
- 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.
- Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC LOYDGB21013
- Euro Transfers:** Account No: 86330987, Sort Code: 30-00-09, IBAN: GB19 LOYD 3000 0986 3309 87, BIC LOYDGB21013
- 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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