

# CRED WORKSHOPS

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: ERP-1-2



## European Regulatory Procedures Strategic and Practical Considerations

### Aims of the course

This CRED Workshop is designed to provide information on European Regulatory procedures from a strategic and a practical point of view. If you are about to plan a marketing application in Europe then this course will provide you with practical advice on how to work with the regulators, how to plan scientific advice, which procedures can be used, planning your filing, negotiations during review and the appeals process and how to manage your company's expectations. There will also be workshop sessions to help reinforce the theoretical presentations.

### Who should attend

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

### Speakers include

- Hilde Boone, EMEA
- Bob Clay, Pfizer, USA
- Dave Gilbert, NDA Regulatory Science, UK
- Debbie Haynes, Genentech, UK
- Patrick Salmon, Irish Medicines Board, Ireland
- Philip Senior, GlaxoSmithKline, UK
- Sharon Standerwick, Allergan, UK
- Kim Wharton, Regulis Consulting Ltd, UK

### Two-day Course

#### Dates:

Wednesday 12th –  
Thursday 13th  
November 2008

#### Venue:

Sheraton Brussels  
Airport Hotel, Belgium

### Course content

#### Day 1: 12th November

##### Strategic considerations

- Overview of European Regulations including role of regulatory bodies, orphan drugs, paediatrics and SME's
- Developing your Global Filing Strategy
- Developing Strategy for Non – NCEs
- Finalising your European Regulatory Strategy including trade names and pre-submission meetings
- Working Effectively with Regulators – Regulators Perspective
- Case Study Session and Feedback
- Question & Answer Session

#### Day 2: 13th November

##### Practical considerations

- Key EU Region Considerations including CTD/ eCTD, "user testing", translations, risk management and PIPs
- Decentralised Procedure – The Details
- Mutual Recognition Procedure
- Centralised Procedure – The Details
- Case Study
- Working together with the Regulators to Ensure Success including managing internal and external communications



### Lifelong Learning (LLL):

The workshop 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 or to obtain a booking form, please contact TOPRA via email: [meetings@topra.org](mailto:meetings@topra.org) or tel: +44 (0) 207 538 9502 or go to the website: [www.topra.org](http://www.topra.org)

email: [meetings@topra.org](mailto:meetings@topra.org) tel: +44 (0) 20 7538 9502 fax: +44 (0) 20 7515 7836 web: [www.topra.org](http://www.topra.org)

Date: **Tuesday 12th - 13th Nov 2008** Venue: **Brussels, Belgium**

Reference: **ERP 1-2**

## Two-day Course

### 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, 7 Heron Quays, Marsh Wall, London E14 4JB, UK

**Fax:** +44 (0) 20 7515 7836

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 7538 9502** or [meetings@topra.org](mailto: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

Please indicate if in your regulatory experience you have worked in one or more of the following areas:

1) CMC  2) EU clinical trials  3) Variations  4) Medical Technologies

### Discounted fees

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

### Fees and Payment method

Members  €1,331.00 = €1,100.00 + €231.00 (21% BEVAT)

Non-Members  €1,573.00 = €1,300.00 + €273.00 (21% BEVAT)

(NB: Bookings cannot be accepted without payment)

Cheque enclosed  Cheque No.

Bank transfer  Date of transfer  /  /

Please charge my debit/credit card  Purchase Order No.

### Debit/Credit card details

(For cards accepted, see payment section below)

Debit Card  Visa  MasterCard  American Express

Card No

Expiry date  /

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

Card holder name (as given on card)

Billing address for card (must be provided if different from the Work Address)

City  Postcode

Country

TOPRA will seek authorisation from the card-issuing company before confirming any reservation (BE VAT dispensation number will be shown on invoice/receipt).

SIGNATURE	DATE
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### Terms and conditions *(Please note: new TOPRA bank details)*

**Payment:** may be made in Euro or Sterling by cheque or bank transfer.

Debit/Credit cards will be charged in Sterling.

- Cheques:** must be made payable to TOPRA and drawn on a UK bank.
- Debit/Credit cards:** 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 on receipt of full payment.

**Please note:** Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks and buffet lunches. Unless stated otherwise the official language of all our meetings is English. It may be necessary for reasons beyond the control of the organisers to alter the dates, venue, timing and content of the programme (including speakers) without prior notice; TOPRA regrets that it cannot accept liability for losses incurred by delegates in these circumstances. Meals requiring special preparation (such as Kosher) may incur additional costs.

**Cancellations:** All cancellations must be received in writing 21 calendar days before the start of the course and will be subject to an administration fee of €150. Payment can be in Euro or Sterling. For cancellations after this time, or if the delegate fails to attend the course, no refund of fees will be given. Substitutions may be made at any time. TOPRA reserves the right to cancel the course at any time without liability. In these circumstances, delegates will be offered an alternative date, a credit note or a full refund.

**Additional support:** Please advise TOPRA, at least one month before the meeting, if you have any disability that may require additional support. TOPRA makes no distinction in its admission policy with regards to disability. TOPRA will make every reasonable effort to supply delegates with services that meet their needs.

**Liability:** TOPRA regrets that it cannot accept liability for losses incurred by delegates in the event of postponement or other alterations to the meeting, i.e. timing, venue, etc. Normal TOPRA terms and conditions apply; please contact the TOPRA office for further details.

**Data protection:** TOPRA is registered under the Data Protection Act 1998. Your details will not be passed to other companies. If you would like us to change any details or if you do not wish to be sent marketing communications about our meetings please write to TOPRA e-mail address: [membership@topra.org](mailto:membership@topra.org)

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- We may occasionally send you promotional or product information from organisations and companies other than TOPRA. If you do not wish to receive this information, you can opt out by ticking this box