

# CRED WORKSHOPS

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: LCM-Var



## Life Cycle Management Variations

### Aims and Course Content

The new Commission Regulation (EC) No 1234/2008 issued on 24th November 2008 for variations applies from 1st January 2010 to products approved via the Mutual recognition, Decentralised and Centralized procedures.

The scope is further broadened to include nationally registered products via Directive 2009/53/EC issued on 18th June 2009 such that they comply from 20th January 2011.

This revised practical CRED workshop will look into the principles of the new Regulation for variations and the new types of variation (IA<sub>IN</sub>, IA, IB and II). The workshop will cover the new procedures on grouping, worksharing and the guidelines on categorisation. The use of Type IA<sub>IN</sub> 'annual reports' and the involvement of CMD(h) will also be covered. The impact of changes relating to the quality dossier will be evaluated, and similarly the safety/efficacy and changes to Pharmacovigilance system to be introduced will be reviewed. The potential impact on regulatory strategy and implementation will be considered.

The day will include a practical workshop based around a case study where attendees will be split into small groups to work upon possible real life examples of how to use and interpret the new variation regulation and guidelines.

This is an essential workshop for all companies operating within the European Union with marketing authorizations for human and veterinary products.

One-day  
Course

### Date:

Thursday  
25 February 2010

### Venue:

Radisson SAS  
Portman Hotel  
London, UK

**BOOK  
NOW**



### Lifelong Learning (LLL):

The Meeting contributes 7 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](http://www.topra.org/lifelonglearning)

### 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.

### Speakers

Speakers include  
**Sonia Ribeiro** of the EMEA,  
**Merete Schmiegelow**,  
Novonordisk, Denmark,  
**Krystyna Fielden**, Senior  
Pharmaceutical Assessor,  
MHRA, UK.

*All data correct at time of print.*

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) 20 7510 2560** or go to the website: [www.topra.org](http://www.topra.org)

email: [meetings@topra.org](mailto:meetings@topra.org) tel: **+44 (0) 20 7510 2560** fax: **+44 (0) 20 7537 2003** web: [www.topra.org/credlcm](http://www.topra.org/credlcm)

## Life Cycle Management – Variations

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

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

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

(For cards accepted, see payment section below)

Debit Card  Visa  MasterCard  American Express   
(preferred)

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 (VAT Registration No.: GB 342 7398 40).

By signing below, I confirm that I agree with TOPRA's Terms & Conditions of Booking. These are available from the office or on the TOPRA website at: [www.topra.org/bookingTandC](http://www.topra.org/bookingTandC)

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### Terms and conditions

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## Payment:

- Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Euro or Sterling.
- 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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