

CRED WORKSHOPS

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Ref: CRED-SPC 2



Summary of Product Characteristics, Patient Information Leaflets and Labelling: The SmPC and Promotion – Strategic Issues and Planning

Aim

This one day workshop from regulators and industry experts will provide an insight on European SmPC preparation and subsequent promotional materials, from both a strategic and practical point of view. A case study will be used to reinforce learnings of the day.

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 include

Paul Woods, Global Compliance Policy Director, AstraZeneca, UK

Beryl Keeley, Unit Manager for Product Information and Advertising, MHRA, UK

Paul N McCleverty, Senior Director, Regulatory Affairs Speciality Business Unit, Pfizer, UK

Melanie Eatough, Associate Director, Regulatory Labelling, Stiefel, UK

Rob Cassells, Director Global Regulatory Affairs (Infectious Diseases), GSK, UK

Course content includes

Overview of the Directives and Guidelines Relating to Labelling and Promotion

- The role of the SmPC
- Overview of SmPC legislation/guidelines and template
- Current SmPC issues and developments
- The role of promotional material
- Overview of promotional legislation/guidelines
- Current advertising issues and developments

Strategy for the Development of the Optimal SmPC

- Definition of an optimal SmPC
- Contributing factors to an optimal SmPC
- Key Stakeholders in an optimal SmPC
- Common Pitfalls in the development of an optimal SmPC
- Influence of the optimal SmPC on the development programme
- Competitor analysis

Overview of the Constraints on Product Labelling, and their Effect on Strategic Planning

- Overview of constraints on product labelling, including the effects of the international community & globalisation
- The preparation and importance of Core Company Safety Information
- Global differences (EU vs. US and other regions)
- Discussion whether EU labelling affects US and Rest of World labelling/decisions & vice versa

EU Regulatory Procedures: SmPC maintenance

- Exploring the impact of the choice of application procedure
- Product lifecycle (line extensions, variations, referrals)
- Post-licensing SmPC changes – their impact on promotional material within EU, US and Rest of World as appropriate

Regulatory Affairs and Promotional Materials.

- What is promotional material?
- When it can be used?
- Who uses it?
- What it cannot be used for
- Who polices the control of promotional material?
- Key contributors to promotional material
- Developments in promotional material and their control
- Affect of globalisation and the internet – their influence on promotional material

One-day workshop

Date:

Wednesday
14th July 2010

Venue:

Radisson SAS Portman
Hotel, London, UK



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/credsmpc

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Summary of Product Characteristics, Patient Information Leaflets and Labelling

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 (17.5% GBVAT)

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

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

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<input type="text"/>	<input type="text"/>

Terms and conditions (Please note: TOPRA's full standard Terms & Conditions are available on the website at www.topra.org/bookingTandC).

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:

- We may occasionally send you promotional or other information about TOPRA's products and services. If you do not wish to receive this information, you can opt out of future communications by ticking this box
- 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 of future communications by ticking this box