

CRED DEVICES

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: DEV-1



Technical Documentation requirements of the Medical Devices Directive

Aim

This new one day CRED course on Medical Devices is intended to provide regulatory professionals with a thorough grounding in the requirements of the European Medical Devices Directives for "Technical Documentation". Each presentation will include an interactive "mini-tutorial" where delegates are invited to provide opinions on the answers to questions on the topic and where guidance to possible answers will be given.

Who should attend

This course is primarily intended for regulatory professionals working with Medical Devices - whatever their experience in this area. It will also be of interest to regulatory professionals working with other products and who wish to learn more about medical device requirements, as well as other professionals (e.g. in Clinical, R&D, Manufacturing, and QA) working with devices and who are involved in compiling "Technical Documentation".

Course content

Legal Background

- Legal purpose of technical documentation (including declaration of conformity); legal view on what is necessary / wise for technical documentation.
- Latest requirements from the medical device directives.
- CEC guidance to requirements (the blue book) and its legal status.
- Other guidance to requirements (standards and others) and its legal status.
- Other applicable legal requirements (e.g. product liability).
- Legal powers of regulators (and notified bodies) to review / inspect technical documentation.
- Legal view on what is 'good' and 'bad' technical documentation.
- Legal consequences when technical documentation is incomplete or inaccurate-role of the courts.

Compliance-Notified Body Perspective

- Notified Body expectations on the content / format of technical documentation.
- Notified Body review of technical documentation (when and how this happens and the consequences).
- What manufacturers should do to ensure the adequacy of their technical documentation

Compliance-Competent Authority Perspective

- MHRA expectations regarding the content / format of technical documentation.
- MHRA role in reviewing technical documentation (when, how this might happen and the consequences).
- How best to handle an MHRA inspection or request for technical documentation.

Content of technical documentation for investigational devices

- Requirements of technical documentation for standard devices (MDD) intended for clinical investigation including:
 - Design and development information
 - Demonstration of ER compliance
 - Declarations of Conformity
- Applications to MHRA for approval of clinical investigations.
- MHRA process for reviewing applications for clinical investigations

Content of technical documentation for medical devices

- Technical requirements and format of technical documentation for 'standard' devices falling under the MDD.
- The 'documentation' to be addressed includes:
 - Quality System documentation relating to a product
 - Design and development Information
 - Demonstration of ER compliance
 - Certificates /Declarations of Compliance
 - Post-market product experience
- Other documentation issues to be addressed include:
 - Centralised documentation systems
 - Decentralised documentation systems
 - Guidance from Notified Bodies
 - Design Dossiers
 - Maintaining technical documentation
 - Results of internal audits

Content of technical documentation for IVDs

- Technical requirements and format of technical documentation for IVDs.
- The 'documentation' to be addressed includes:
 - Performance evaluation procedures
 - Standards and Common Technical Specifications (CTSs), including EDMA's Involvement in CTS
 - Labelling and Instructions for Use

One-day Course

Date:

Wednesday
17 March 2010

Venue:

TOPRA Office,
London, UK

Speakers:

Grant Castle, Partner,
Covington & Burlington, UK

Neil Adams, Director,
Operations and Delivery,
BSI, UK

Bruce Petrie, MHRA, UK

Daniella Smolenska,
MHRA, UK

Jane Hare, Wound
Management Division,
Smith & Nephew Medical
Ltd, UK

Ben Jacoby, Manager,
European Regulatory
Affairs, Global Regulatory
Systems, Ortho-Clinical
Diagnostics, UK

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

All data correct at time of print.

For more information or to obtain a booking form, please contact TOPRA via email: meetings@topra.org or tel: +44 (0) 20 7510 2560 or go to the website: www.topra.org

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

One-day Course Date: **Wed 17 March 2010** Venue: **TOPRA Office, London, UK**

Ref:

Technical Documentation requirements of the Medical Devices Directive

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

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

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- **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.

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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

SIGNATURE	DATE
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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