



The 5th TOPRA Annual MEDICAL DEVICES Symposium 2010



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: SYM/10



Compliance for today and planning for tomorrow

MHRA Organised in conjunction with the UK MHRA

This important annual Medical Device Symposium is now recognised as a key event in the European calendar of all those working in the medical device arena.

Aim

This annual Symposium is for all those involved with medical devices and brings together representatives of industry, notified bodies and regulatory authorities to discuss and understand today's compliance requirements, and debate the future plans for medical device regulation. This is the key annual European regulatory forum for all those involved in the medical devices sector and aims to bring you all the latest information and importantly what is coming over the horizon. There will also be ample time to network in the breaks and view services from exhibitors in the industry and the regulatory bodies.

Who should attend

All those working in the devices industry, notified bodies and regulatory authorities and those in the pharmaceutical industry who have medical devices or use devices in combination with their medical products.

Programme includes

Keeping Compliant – Everyday issues to focus on covering:

- Clinical Data and Clinical Trails: A Case Study
- Vigilance, Device Bulletins and Post Market Surveillance
- Counterfeiting: A constant problem for industry, regulators and the patient

The First Six Months of Directive 2007/47/EC covering:

- The Impact of 2007/47/EC – A Competent Authority View
- Practical Implementation of 2007/47/EC by the Medical Device Industry

- Working with Manufacturers and Competent Authorities: The Notified Body experience with 2007/47/EC

Planned Directive 2007/47/EC Initiatives covering:

- Impact of EUDAMED on all Parties in the Regulatory Cycle
- e-Labeling

The Future Plans for Medical Device Regulation covering:

- EU Re-cast MDD, IVD and AIMD from viewpoint of EU Commission, member state and industry

There will also be ample time for questions during the panel discussions throughout the day.

Speakers include

- **Richard Gutowski**, *European & Compliance - Head, MHRA, UK*
- **Neil Adams**, *Director of Healthcare Operations, BSI, UK*
- **Sue Ludgate**, *Director of Devices Clinical, MHRA, UK*
- **Tony Sant**, *Group Manager, Device Technology & Safety, MHRA, UK*
- **Bruce Petrie**, *Compliance Unit Manager (Medical Devices), MHRA, UK*
- **David Pulis**, *Assistant Head, Regulatory Affairs Directorate, Malta Standards Authority, Malta*
- **Hilde Viroux**, *Asst. Director EU Medical Device RA, Alcon Laboratories, Belgium*
- **Suzanne Halliday**, *Orthopaedic & Dental Team Leader, BSI, UK*
- **Dario Piravano**, *Consultant Regulatory Affairs, Eucomed, Belgium*
- **Malcolm Carlisle OBE**, *Chairman Technical and Regulatory Policy Group, ABHI, UK*

Plus other speakers invited

One-day Symposium

Date:

5 October 2010

Venue:

Hilton Park Lane,
London, UK



Lifelong learning

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www.topra.org/lifelonglearning

For more information please contact TOPRA via email: meetings@topra.org or
tel: +44 (0) 207 510 2560 or go to the website: www.topra.org/medicaldevsym2010

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



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

Form fields for personal and work details: Dr, Mr, Mrs, Ms, Other, Family name, First name, Company name, VAT reg. no., Job title, Telephone, Fax, E-mail, Work Address, City, Postcode, Country, Invoice Address, Special dietary requirements.

Payment method

Cheque enclosed [] Cheque No []

Bank transfer [] Date of transfer [] / [] / []

Please charge my debit/credit card [] Purchase Order No. []

Fees

Medical Devices Symposium

Member: [] £293.75 = £250 + £43.75 (GB VAT 17.5%)

Non Member: [] £340.75 = £290 + £50.75 (GB VAT 17.5%)

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(For cards accepted, see payment section below)

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DATE []

Experience in the Subject Area

Negligible [] Average [] Considerable [] Your current role Generics [] CRO [] European [] Global [] Local affiliate [] Other [] Experience in Regulatory Affairs Years [] Months []

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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
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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 on 5th October 2010 but not the drinks reception and the Gala Dinner.'

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 + GB VAT. Payment can be in Euro or Sterling.

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