



TOPRA Annual MEDICAL DEVICES Symposium 2009



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: SYM/09



Understanding Medical Device Regulatory Hurdles – Now and in the Future

Organised in conjunction with Medical Devices Medical Products Agency, Sweden

This Symposium will discuss practical issues of relevance to Medical Device Manufacturers, large and small. Combination products are an increasing regulatory challenge to industry and regulators. Medical devices and drugs are regulated differently and depending on classification of a combination product the process for market access will be different.

2009 will see TOPRA's 4th Medical Devices Symposium. Previous Symposia were held in Amsterdam, Copenhagen and Budapest. Building relationships is an important part of the TOPRA Symposium and this year we welcome the Medicines Product Agency, Sweden, who will be assisting with the organisation of the programme. This meeting will be an ideal opportunity to get to know this important agency better, as well as to network with key regulatory professionals in the Medical Devices field.

Programme includes

Combination Products (drug-device)

This session is common to the main Symposium and Medical Devices Symposium

- Combination products in Europe
- Notified Body
- Combination products in US

Borderline and Classification Issues

- Borderline and Classification Work Group – European Commission
- Borderline and Classification Work Group – National Competent Authority
- Borderline and Classification Work Group – Industry Perspective

Implementation of Directive 2007/47/EC

- The 2007/47/EC Implementation: Key Practical Issues and Timetable
- Clinical Data Requirements under 2007/47/EC
- Technical File Sampling and Review Depth Requirements for Class IIa and IIb Devices

What Does The Future Hold?

- Progress on European Commission 2009 Work Plan
- The Recast: Views of the Medical Device Industry
- Recast of the legal framework for medical devices: Notified Body ideas to improve and strengthen the regulatory system and offer a uniform level of protection to public health.

Confirmed Speakers include:

- Neil Adams, BSI, UK
- Gert Bos, BSI, UK
- Gert W. Bruse, MPA, Sweden
- Malcolm Carlisle, ABHI, UK
- Sébastien Hardy, LNE/G-MED, France
- Suzanne Halliday, BSI, UK
- Margareth Jorvid, LSM Group, Sweden
- Matthias Neumann, Bundesministerium für Gesundheit, Germany
- Ann O'Connor, Human Products Licensing and Registration Manager, Irish Medicines Board (IMB), Ireland
- Lennart Philipson, Scientific Director Medical Devices Medical Products Agency, Sweden
- Mika Reinikainen, Abnovo Ltd
- Janice Soreth, US FDA
- Valérie Viejo, KEMA, The Netherlands

Other speakers invited.

One-day Symposium

Date:

Thursday 8th
October 2009

Venue:

Clarion Hotel,
Ringvägen, Stockholm,
Sweden

For more information or to register your interest, please contact TOPRA (see below).



Lifelong learning

*For more information please visit
www.topra.org/lifelonglearning

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The 4th Medical Devices Symposium 2009



Date: 8 October 2009 Venue: Clarion Hotel Stockholm, Sweden

Reference: SYM/09

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

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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.

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Experience in Regulatory Affairs Years Months

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Fees

Medical Devices Symposium

Member: €343.75 = €275.00 (normal price* €575.00) + €68.75 (SE VAT 25%)

Non Member: €406.25 = €325.00 (normal price* €625.00) + €81.25 (SE VAT 25%)

*As charged in 2008. The VAT rate will be the prevailing rate at the time of invoicing.

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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 8th October 2009.

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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