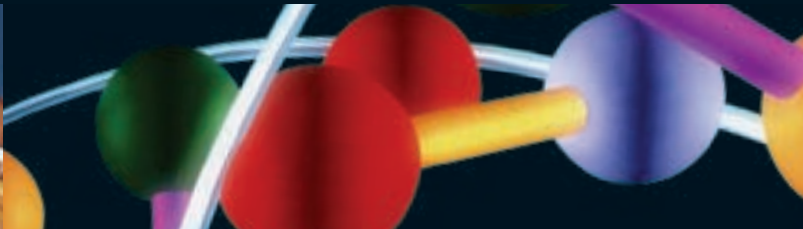


# Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF12/11



## Medical Device Regulatory Affairs

### Aim

To provide students with a good appreciation of the regulatory control of medical devices particularly within the European Union. After participation in the Module, students should be able to provide strategic advice on the application of the medical device directives to enable products to be CE-Marked and on key international legislation.

### Learning Outcomes

- Students will distinguish the routes to Conformity Assessment in the EU.
- Students will assess the role of the Competent Authorities and the Notified Bodies.
- Students will define the requirements of post-market surveillance and vigilance, and the role that risk management plays throughout the lifecycle of a device.
- Students will identify the documentation requirements for CE-Marking and the application of Harmonised Standards.
- Students will compare how medical devices are regulated in other markets and examine related international activities such as the Global Harmonisation Task Force.

- Students will interpret the requirements of clinical evaluation, how to initiate a clinical study and the ever increasing impact of Health Technology Assessment.

### Course content includes

- The New Approach legislative environment in the European Union and the medical devices directives
- Conformity Assessment procedures
- Clinical evaluation
- Essential Requirements and Standards
- Risk-based classification system
- Post-market surveillance including vigilance
- Risk analysis and risk management
- The role of the Competent Authority and the Notified Body
- Medical device legislation in other markets and the Global Harmonisation Task Force
- Labelling for medical devices
- Devices containing drugs and borderline products
- In-vitro diagnostics

## Three-day Course & MSc Regulatory Affairs Module 12

### Date:

5–7 April 2011

### Venue:

De Vere, Denham  
Grove, Denham, UK

This module is part of the MSc Regulatory Affairs, a degree validated and awarded by the University of Wales, UK. For further details regarding the University and its validation services, please log on to [www.wales.ac.uk/validation](http://www.wales.ac.uk/validation) or email: [validation@wales.ac.uk](mailto:validation@wales.ac.uk)



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For more information please visit [www.topra.org/mscra12](http://www.topra.org/mscra12) or contact TOPRA via email: [mscadmin@topra.org](mailto:mscadmin@topra.org)



MSc RA M12

15\* hours

Lifelong learning

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Three-day course &amp; MSc Module 12 Date: 5-7 April 2011 Venue: De Vere, Denham Grove, Denham, UK

Ref: PGF12/11

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Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

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**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

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**Student**  **£1,800.00** = £1,500.00 + £300.00 (20% GB VAT)

**Non-Student**  **£2,040.00** = £1,700.00 + £340.00 (20% GB VAT)

The VAT rate charged will be the prevailing rate at the time of invoicing.

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### 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.

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