



Three-day short course and module 4 of MSc Medical Technology Regulatory Affairs



Management of Regulatory Affairs and its Contribution to the Medical Technology Lifecycle

Aim

To provide students with an understanding of the skills required to control regulatory affairs departments and to achieve worldwide compliance and approvals. This will include a clear appreciation of organisational, product and portfolio management and the politics of regulation (influencing and lobbying).

This course is also Module 4 of the MSc in Medical Technology Regulatory Affairs and as such, would count towards the completion of the MSc if you were to successfully complete the assessments and enroll onto the qualification.

Lectures

Topics covered include:

- Roles of the Medical Technology Regulatory Affairs Professional in managing the current regulatory systems and strategies for successful global registration
- Strategic alliances, Mergers and Acquisitions and their impact on the regulatory process including the practice and principles of Due Diligence
- Product acquisition and divestment and the regulatory implications
- Business planning - product and portfolio management including the relationship between regulatory strategy and pricing and reimbursement considerations
- The politics of regulation – building effective problem solving, negotiation and lobbying skills
- The impact of electronic submissions and electronic document management and communication.

Learning outcomes

Upon completion of the course candidates will be able to:

- Advise on Global regulatory strategies and development programmes required to achieve medical device compliance/approval in Europe, North America and Japan

- List and discuss the skills and competencies required of the regulatory affairs professional in managing a department including, communication, training requirements and negotiation skills
- Manage a portfolio of products and describe the process of decision analysis and project planning
- Outline the marketing process and make a contribution to business strategy
- Display an understanding of systems for management of risk
- Demonstrate the confidence and skills required to interact with regulatory agencies and notified bodies.

Teaching and learning methods

Lecturers are drawn from a variety of backgrounds and all are recognised experts currently working in the field of Medical Device Technology related regulatory affairs. There will be a mix of formal lectures, tutorials, discussions and case studies.

Medical Technology Regulatory Affairs MSc

In collaboration with TOPRA, the Cranfield MSc provides for the first time a recognised way for professionals working within healthcare regulatory affairs or related areas to formalise their skills in the field of medical technology. Available on a part-time basis only, the MSc is designed to be flexible to fit around your current job and responsibilities. The course is also available at Diploma and Certificate levels. For even greater flexibility, and for professionals with a specific interest, individual modules can be attended as standalone three-day short courses.

For more information about our MSc please contact our Enquiries Office

Tel: +44 (0) 1234 758008

Email: enquiries.health@cranfield.ac.uk

Date:

11–13 May 2010

Venue:

Mitchell Hall, Cranfield University, Cranfield, UK

Accommodation:

Available

“I chose to study Medical Technology Regulatory Affairs MSc to help broaden and consolidate my knowledge in this area, for practical assistance, for networking and to boost my CV. The length and format is ideal - just enough time to cover the ground at a pace without going into overload. There is a good balance between presentations and practical exercises including case studies. I would strongly recommend the course to colleagues and others, either as stand-alone short courses or as the complete MSc depending on individual needs.”

Dr Sam Martin, Regulatory and Clinical Affairs Manager, Ranier Technology Limited, UK



Lifelong Learning*

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

All data correct at time of print.



Three-day course & module 4 Date: 11-13 May 2010 Venue: Mitchell Hall, Cranfield University, Cranfield, UK

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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: mscadmin@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 mscadmin@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

€750.00 (exempt from VAT)

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

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.

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/mscbookingTandC

SIGNATURE

DATE

Terms and conditions Please note: TOPRA's MSc Terms & Conditions are available on the website at www.topra.org/mscbookingTandC.

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.

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 £150 + GBVAT. Payment can be in Euro or Sterling.

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