

Three-day short course and module 1 of MSc Medical Technology Regulatory Affairs



Principles of European Medical Technology Regulatory Affairs

Aim

To provide regulatory affairs professionals with a clear understanding of the regulatory path for placing and maintaining medical technology on the market in the European Union (EU) and associated territories.

Course Content

The course addresses European institutions involvement in medical technology regulatory affairs in the EU and the roles they play in relation to current EU legislation, its history and on-going development. The course also outlines the criteria for classifying different types of medical technology and conformity assessment route options for the different classes of technology. It provides an understanding of what is required in a technical file and a design dossier and outlines the detailed activities leading to a CE-Mark.

Lectures

Lectures will be delivered by a number of speakers from industry. Topics covered include:

- Context and structure of directives within the EU legislative framework
- Role of European Commission, competent authorities and notified bodies
- Definitions / classification of technology and devices including drug / device borderline products
- Conformity assessment routes and the role of quality management systems (ISO 13485) in the CE marking process
- Technical documentation – compilation, content and assessment of compliance with requirements of the directives
- Demonstration of conformity through pre-clinical bench testing and clinical evaluation
- Introduction to the central role of risk assessment and management in regulatory affairs
- Introduction to other applicable regulations
- Summary of post-market regulatory activities

Learning outcomes

Upon completion of the course candidates will be able to:

- Demonstrate a thorough understanding of legislation in Europe, its history and on-going development
- Outline the legislation applicable to specific medical technologies to be marketed within the EU and associated territories
- List the European institutions involved in medical technology regulatory affairs in the EU and demonstrate knowledge of the roles they play
- Describe the criteria for classifying different types of medical technology and be able to determine the conformity assessment route options for the different classes of technology
- Describe and understand what is required in a technical file and a design dossier and outline the detailed activities leading to a CE-Mark
- Demonstrate an ability to apply all of the core components of the module within a group setting, where consensus and team leadership skills will be required.

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. 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:

22–24 September 2009

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 1 Date: 22–24 September 2009 Venue: Mitchell Hall, Cranfield University, Cranfield, UK

Principles of European Medical Technology Regulatory Affairs

Ways to book

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

Post: Academic Operations Unit, Cranfield University, Cranfield, Bedfordshire, MK43 0AL, UK

Fax: +44 (0) 1234 751206 **Email:** shortcourse@cranfield.ac.uk

On receipt of your booking form we will confirm your place in writing and an invoice will be sent to you. To ensure admission, payment must be received prior to the course starting.

If you have any queries, contact us on: +44 (0) 1234 754192

or shortcourse@cranfield.ac.uk

Dr Mr Mrs Ms Other

Family name

First name Male Female

Company name

Job title

Telephone

Fax

E-mail

Work Address

City Postcode

Country

Invoice Address
(If different from above address)

City Postcode

Country

Special dietary requirements

Fees and Payment method

£1300.00 (exempt from VAT)

Cheque enclosed Cheque No

Invoice (This will be sent to the supplied address)

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

Cranfield University will seek authorisation from the card-issuing company before confirming any reservation.

By signing below, I confirm that I agree with Cranfield University's Terms & Conditions of Booking.

SIGNATURE	DATE
-----------	------

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

Payment:

- Cheques:** must be made payable to Cranfield University and drawn on a UK bank in £ 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.
- Your place is secured only upon receipt of full payment.

Payment deadline:

Payment is required no later than eight weeks before the course starts. Or immediately for bookings made within eight weeks of the beginning of the course.

Please note:

Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks and buffet lunches. Accommodation is available.

Cancellations:

- A fee is charged when confirmed bookings are cancelled. In the event of a cancellation, you may nominate a substitute but if a suitable substitute cannot be found the following scale of charge will apply:
More than 56 days before the programme starts, the fee is refunded in full. 56 days or less 50% 28 days or less 25% 14 days or less 0%.
- Transfers:** Within the eight week period preceding the start of the course, we are unable to transfer a booking to a later course free of charge. Withdrawal and transfer to a later course at this stage will therefore be subject to the charges as detailed under *Cancellations*.