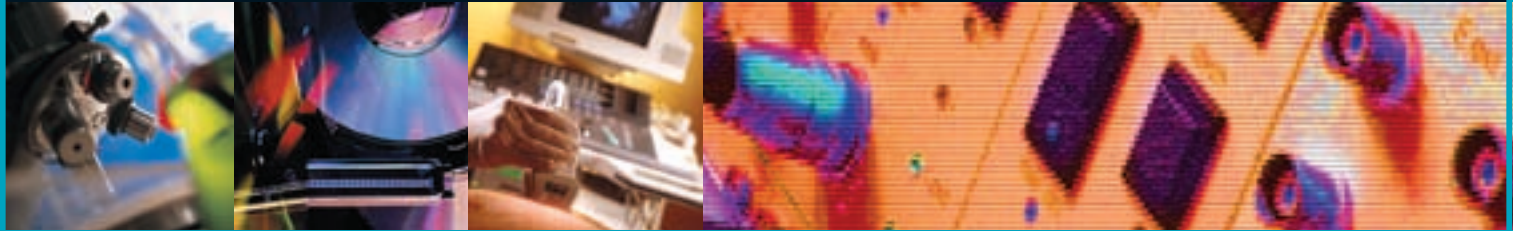




Three-day short course and module 5 of MSc Medical Technology Regulatory Affairs



Medical Technology Vigilance, Post-Market Surveillance and Risk Management

Aim

The course will define the terminology and explain the concepts of vigilance, post-market surveillance and risk management, their practical applications and integration into the lifecycle of a medical device.

This course is also Module 5 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:

- European Regulatory requirements for PMS, including recalls and vigilance
- Responsibility for Post-Market Surveillance (PMS) - Competent Authorities, Notified Bodies and manufacturers
- Other Regulatory requirements – e.g. US MDRs
- Guidance documents for PMS, including Commission, Notified Body and Competent Authority documents
- Key elements of PMS – reactive and pro-active
- Tailoring PMS systems to specific products, including IVDs
- Principles of ISO 14971 “Application of risk management to medical devices”
- Requirements of ISO 13485, Quality Management Systems standard
- Feedback of PMS data into the risk management process
- Exchange of information: PMS databases e.g. MAUDE and EUDAMED
- GHFTF Study Group II.

Learning outcomes

Upon completion of the course candidates will be able to:

- Define the requirements and describe the guidance notes for PMS sufficiently well to critically design a PMS system appropriate to defined products.
- Describe the requirements and guidance notes for vigilance sufficient to write and operate a vigilance procedure which would meet regulatory requirements.
- Describe the principles and practice of risk management as set out in the ISO 14971 to a level where they can be applied to a complex medical device within the range of the candidate's technical competence.

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:

21–23 September 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 short course and module 5 Date: 21–23 Sept 2010 Venue: Mitchell Hall, Cranfield University, Cranfield, UK

Medical Technology Vigilance, Post-Market Surveillance and Risk Management

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

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

£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
<input type="text"/>	<input type="text"/>

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*.