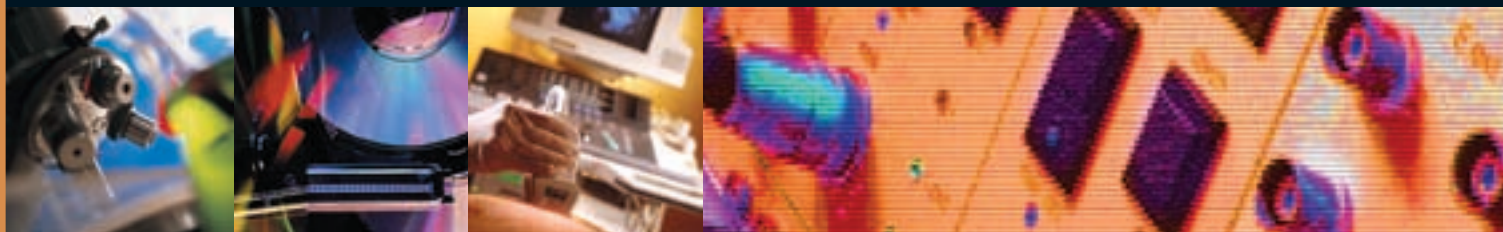




Three-day short course and module 3 of MSc Medical Technology Regulatory Affairs



Clinical Evaluation of Medical Technology

Aim

To understand when a clinical investigation is necessary and the regulatory processes involved in clinical evaluation and the alternative routes to demonstrate compliance.

Lectures

Topics covered include:

- Types and designs of clinical studies
- Preclinical requirements
- Clinical evaluation and when to do a study
- Good clinical practice (ISO 14155)
- Clinical trial supplies and labelling
- Post market surveillance studies
- Health economics and device trials

Learning outcomes

Upon completing the course, it is expected that students will be able to:

- Understand and assess the need for clinical evaluation, including the need to critically evaluate existing literature
- Understand the methodology and conduct of clinical research
- Understand the factors that influence the quality of clinical evaluation

Teaching and learning methods

Lecturers are drawn from a variety of backgrounds but all are recognised experts currently working in Clinical Research & regulatory affairs relating to medical technology. There will be a mix of formal lectures, case studies and a dynamic Clinical Trial Simulation Exercise.

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:

23–25 February 2010

Venue:

The Vincent Building
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



Three-day short course & module 3 Date: 23–25 February 2010 Venue: The Vincent Building, Cranfield University, Cranfield, UK

Clinical Evaluation of Medical Technology

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
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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*.