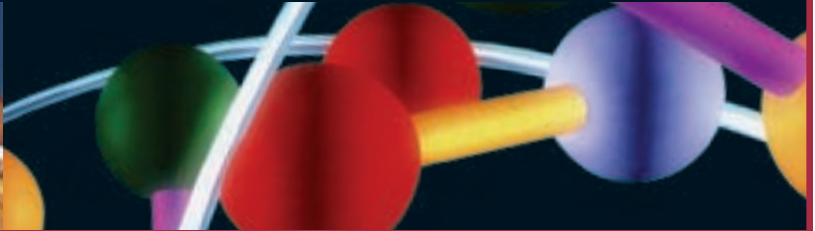


Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF5/10



Regulatory Control of Clinical Operations

Aim

The purpose of this module is to provide students with an understanding of the practical regulatory aspects of global clinical research, to enable them to provide effective advice on the regulatory issues likely to arise during clinical programmes.

Learning Outcomes

- Students will understand the practical aspects of Good Clinical Practice and how it supports clinical research.
- Students will be able to identify the regulatory requirements for clinical research in major markets, understand the importance of the EU Clinical Trial Directive and the requirements and practicalities of preparing the required clinical trial applications and associated documentation.
- Students will gain an insight into the complexities and requirements of pharmacovigilance in clinical research.
- Students will be able to understand the management of clinical trial supplies.
- Students will be able to understand the requirements of Good Manufacturing Practice, authorisation and importation of investigational medicinal products.

- Students will be able to understand clinical trial reporting, the management of the data, data auditing and the practicalities of Good Clinical Practice inspections.
- Students will gain an appreciation of the legal and ethical aspects of clinical research, including insurance, indemnity and the role of the ethics committees and safety boards.

Course content includes

- Investigational Medicinal Product Dossier (IMPD), Investigational New Drug (IND) and other clinical dossier requirements including the progression of clinical trials in relation to the toxicity programme.
- Ethics Committees and Safety Boards.
- Clinical trial labelling, supplies management and Good Manufacturing Practice requirements
- Pharmacovigilance of clinical trials.
- Clinical trial reports.
- Data management.
- Good Clinical Practice - Inspections, data auditing and compliance with the Declaration of Helsinki.
- Compassionate use/extended access.
- The legal aspects of clinical trials.

Three-day
Course &
MSc Regulatory
Affairs
Module 5

Date:

23–25 November 2010

Venue:

The Bull Hotel,
Gerrards Cross, 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 or email: validation@wales.ac.uk



Lifelong learning

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

email: mscadmin@topra.org tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: www.topra.org



Three-day course & MSc Module 5 Date: 23–25 November 2010 Venue: The Bull Hotel, Gerrards Cross, UK

Ref: PGF5/10

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.

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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

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 or email: validation@wales.ac.uk



Fees and Payment method (Accommodation included)

Student **£1,703.75** = £1,450.00 + £253.75 (17.5% GB VAT)

Non-Student **£1,938.75** = £1,650.00 + £288.75 (17.5% GB VAT)

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

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
(preferred)

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.*

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SIGNATURE	DATE
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- **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.
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- Your place is secured only upon receipt of full payment.

Discounted fees:

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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 + GB VAT. Payment can be in Euro or Sterling.

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