

Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF6/11



Regulatory Strategy: The Market Place

Aim

The purpose of this Module is to provide students with an understanding of the strategic issues related to protecting and maintaining brand awareness throughout the product life.

Learning Outcomes

- Students will recognise the needs of marketing colleagues in commercializing products and maintaining brand awareness through the development of new dosage forms, indications and switching of legal status.
- Students will demonstrate how the marketing life of a product can be optimised by use of patents and supplementary protection certificates and their role as regulatory professionals in maintaining the edge that such protection might offer.
- Students will evaluate the role of the Regulatory Affairs group in optimising the regulatory strategy in a manner which is sympathetic to the needs of pricing and reimbursement committees, such that any commercial advantages may be gained.
- Students will illustrate the importance of the SmPC as a means of communication with prescribers and as the basis for advertising and patient information.
- Students will identify the international constraints on the promotion of pharmaceutical products and OTC medicines.

- Students will define the responsibilities and requirements for keeping the licence current with respect to the reporting of adverse drug reactions.
- Students will differentiate the internal and external activities and interactions associated with issues management.

Course content includes

- The Needs of the Market: what is the market place, what does marketing want from regulatory, maintaining/extending brand awareness
- Intellectual Property, patents, trademarks, product naming, copyrights, supplementary protection certificates
- Demonstrating Value: pricing and reimbursement policies, pharmacoconomics, formularies, NICE
- Getting the Foundations Right: the importance of SmPC statements, links to advertising, patient information, public assessment reports, Freedom of Information/Transparency
- Advertising and Controls of POMs and OTCs: EU, USA, Direct to Consumer (DTC) advertising
- Life Cycle Management: data and marketing exclusivity, line extensions, new indications and dosage forms, influence of generics
- Issues Management
- OTC Switching

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



All data correct at time of print.

For more information please visit www.topra.org/mscra6 or contact TOPRA via email: mscadmin@topra.org

Three-day Course & MSc Regulatory Affairs Module 6

Date:

8–10 February 2011

Venue:

Macdonald Holyrood
Hotel, Edinburgh,
Scotland



Lifelong learning

*For more information
please visit [www.topra.org/
lifelonglearning](http://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 6 Date: 8–10 February 2011 Venue: Macdonald Holyrood Hotel, Edinburgh, Scotland

Ref: PGF6/11

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

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 **£1,800.00** = £1,500.00 + £300.00 (20% GB VAT)

Non-Student **£2,040.00** = £1,700.00 + £340.00 (20% 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.*

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 (VAT Registration No: GB 342 7398 40).

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 + GB VAT. 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