

Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF10/09



Optimising the Contribution of Regulatory Affairs to Product Development, Maintenance and Commercialisation

Aim

The aim of this module is to provide students with an understanding of the skills needed to run a successful Regulatory Affairs department in order to optimise the contribution that Regulatory Affairs can make to the development, maintenance and commercialisation of products. In addition, the importance of liaison and collaboration with other key departments will be addressed, together with an introduction to the influencing and negotiation skills needed for effective teamwork.

Course content includes

- Building a Regulatory Department
- Training for a Regulatory Department
- IT support
- Regulatory intelligence
- Collaboration with Pharmacovigilance, Marketing, Quality Control
- Introduction to negotiation skills
- Business planning, budgeting and registration fees
- The politics of regulation (influencing and lobbying)
- Product development plans and Regulatory project planning
- Decision analysis and portfolio management

Learning outcomes

- Students will be able to provide examples of policies and processes needed to run a Regulatory Affairs department.
- Students will understand and be able to outline recruitment and training objectives in Regulatory Affairs.
- Students will examine the tools, such as regulatory intelligence and IT, that are available to help manage a department.
- Students will focus on the key departments with whom Regulatory Affairs need to work co-operatively.
- Students will understand how they can maximise the contribution they can make to product development, maintenance and commercialisation by working in collaboration and negotiating appropriately with other departments.
- Students will appreciate the necessity of project/ portfolio management and decision analysis.

BOOK NOW



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/mscra10 or contact TOPRA via email: mscadmin@topra.org

Three-day Course & MSc Regulatory Affairs Module 10

Date:

8-10 September 2009

Venue:

Bull Hotel,
Gerrards Cross, UK



Lifelong learning

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

email: mscadmin@topra.org tel: +44 (0) 20 7538 9502 fax: +44 (0) 20 7515 7836 web: www.topra.org



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, 7 Heron Quays, Marsh Wall, London E14 4JB, UK

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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

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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.

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