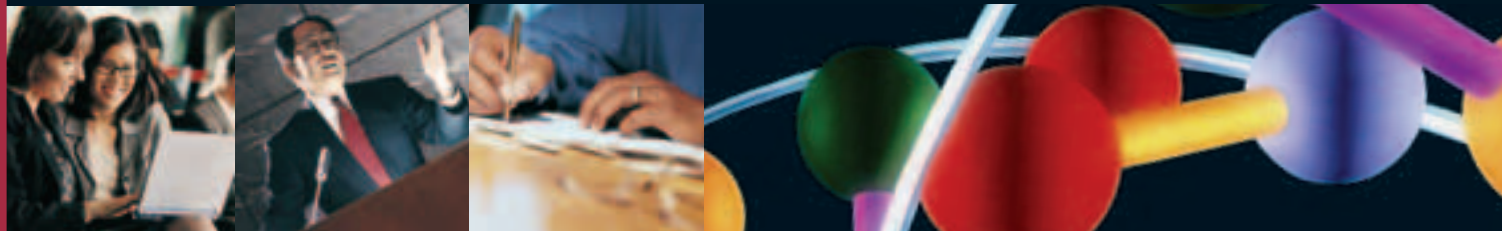


# Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF10/12



## 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.

### Learning Outcomes

- Students will review examples of policies and processes needed to run a Regulatory Affairs department.
- Students will identify and apply recruitment and training objectives in Regulatory Affairs.
- Students will examine tools such as regulatory intelligence and IT that are available to help manage a department.
- Students will categorise the key departments with whom Regulatory Affairs need to work co-operatively.

- Students will establish how they can maximise the contribution they make to product development, maintenance and commercialisation by working in collaboration and negotiating appropriately with other departments.
- Students will evaluate the necessity of project/portfolio management and decision analysis.

### Outline of Module topics:

- 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

## Three-day Course & MSc Regulatory Affairs Module 10

### Date:

7–9 February 2012

### Venue:

Maritim Hotel  
Munchen, Germany

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](http://www.wales.ac.uk/validation) or email: [validation@wales.ac.uk](mailto:validation@wales.ac.uk)



All data correct at time of print.

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### MSc RA M10

15\* hours

Lifelong learning

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**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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