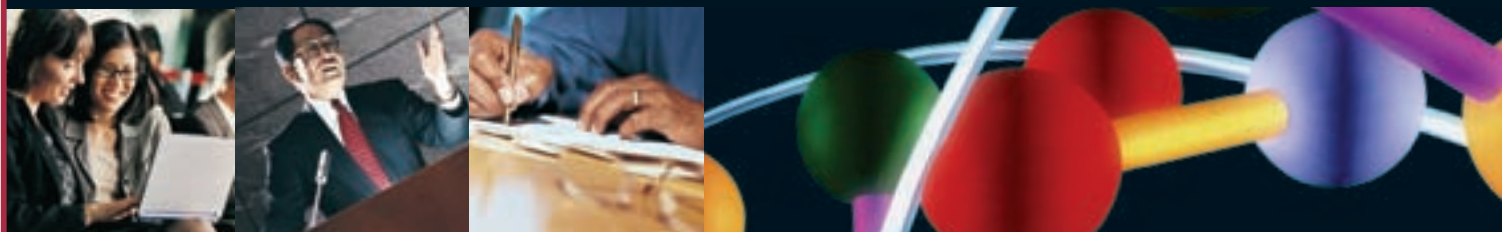


# Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF4/10



## Regulatory Strategy for a New Active Substance: Global Clinical Development

### Aim

The purpose of this module is to provide students with an understanding of the needs of global clinical development to enable them to provide effective advice on the suitability of clinical programmes from a regulatory perspective.

### Learning Outcomes

- Students will be able to describe the different types of clinical study design and identify the pros and cons of each within the context of global regulatory requirements.
- Students will understand the statistical principles underpinning trial design.
- Students will be able to identify the activities required in setting up and monitoring studies and managing data.
- Students will be able to describe the differing types of reports, summaries etc. required and understand how to produce such documents in a timely effective manner.
- Students will gain an insight into the Regulatory Authorities' views of the clinical dossier.

### Course content includes

- Designing the clinical programme: strategy for global development; the clinical trial programme; core protocol, pivotal studies, dose-finding, special studies, trial designs, patient numbers; statistical input (intention to treat, efficacy populations); pharmacoeconomics.
- Setting up the trial: Clinical Trial Application strategy, GCP, ADRs, trial supplies, monitoring
- Managing the data: creation of a protocol and CRF, data capture (databases, data entry and validation, documentation and audit trails), analysis techniques, presentation of data (data listings, tabulations and summaries), meta-analyses
- Reporting the data: the clinical report, the ICH guideline, use of the clinical report in international dossiers
- Summarising the data: minimising duplication, clinical overview, NDA Summary of Safety and Effectiveness compared with European and other summaries, global SmPC, European Public Assessment Report
- Evaluating the data: Regulatory Authorities: philosophies and assessment techniques, common faults in clinical registration packages, a Global Clinical Programme and dossier – is it achievable?

Three-day  
Course &  
MSc Regulatory  
Affairs  
Module 4

### Date:

7–9 September 2010

### Venue:

The Thon Hotel City  
Centre, Brussels,  
Belgium

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)

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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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