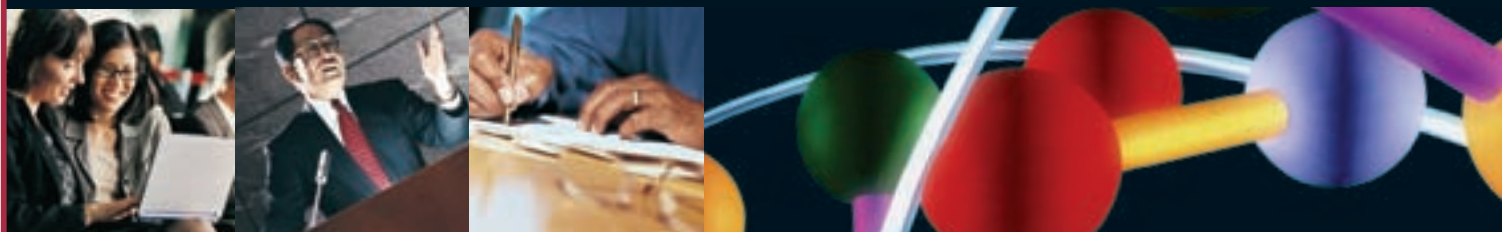


Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF2/10



Regulatory Strategy for a New Active Substance: Preclinical Development

Aim

The purpose of this Module is to provide students with an understanding of the key requirements and submissions strategies associated with the preclinical development process in order to enable them to provide effective advice on the suitability of preclinical programmes from a regulatory perspective.

Learning Outcomes

- Students will gain an insight into the research processes used to identify and select new candidate compounds.
- Students will be able to describe the types and designs of preclinical safety studies generally required to successfully develop a new product. In addition, they will be able to apply this knowledge in assessing the regulatory acceptability of preclinical development programmes. They will be able to advise on the format and content as well as submission strategy for such information.
- Students will gain an understanding of pharmacokinetic principles and how these are applied to link the preclinical and clinical components of pharmaceutical development.
- Students will be able to describe the differing types of preclinical reports and summaries required through development to filing.
- Students will gain an insight into the Regulatory Authorities' views of the preclinical dossier and the influence of ICH.

Course content includes

- The real cost of a new active substance - an insight into trends in the pharmaceutical industry which are causing development costs to rise
- The identification of a candidate product and the planning of its development
- The design of, and data interpretation from, the key safety studies (pharmacology, toxicology, mutagenicity, carcinogenicity and reproduction toxicology) including requirements for Good Laboratory Practice
- An introduction to the key concepts of pharmacokinetics and toxicokinetics and how these are applied during development
- The key regulatory requirements and guidelines covering safety pharmacology, toxicology, mutagenicity, carcinogenicity and reproduction toxicity testing and how to apply these
- The role of the Regulatory Affairs department throughout the preclinical phase to filing
- The Regulatory Authorities' view of the preclinical dossier and the influence of ICH
- The structure, content and focus of key preclinical components of the regulatory submissions including CTX, IND, NDA, MAA and CTD



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

Three-day Course & MSc Regulatory Affairs Module 2

Date:

13–15 April 2010

Venue:

Marriott Hotel, Windsor, UK

All data correct at time of print.

For more information please visit www.topra.org/mscra2 or contact TOPRA via email: mscadmin@topra.org



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Three-day course & MSc Module 2 Date: 13–15 April 2010

Venue: Marriott Hotel, Windsor, UK

Ref: PGF2/10

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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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