

Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF8/09



Data Requirements for Abridged Applications and Specialised Products

Aim

The purpose of this module is to provide an understanding of the diversity of abridged applications, and to outline the data requirements for a variety of different new dosage forms and new indications. The module also covers consideration of the data requirements for certain specialised products.

Learning outcomes

- Students will be able to identify the chemical/ pharmaceutical, preclinical and clinical data required for line extensions taking into account the interaction between the various parts of a dossier.
- Students will gain an understanding of the requirements for bridging data in various situations.
- Students will gain an understanding of the data requirements for generic applications and for a number of specialised products.
- Students will gain an understanding of the data requirements for Supplemental applications in the USA.

BOOK NOW

Course content includes

- Discussion of various types of line extension including new routes of administration, new dosage forms and new indications
- Chemical and pharmaceutical requirements for line extensions including Drug Master Files
- Bioequivalence
- Preclinical requirements for abridged applications
- Clinical data requirements for line extensions
- Discussion of particular product categories such as novel delivery systems, sustained release products, combination products and inhalation products
- Requirements for drug/device combinations
- Radiopharmaceuticals
- Blood products
- Herbal medicines



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/mscra8 or contact TOPRA via email: mscadmin@topra.org

Three-day Course & MSc Regulatory Affairs Module 8

Date:

16–18 June 2009

Venue:

Apex International, Edinburgh, Scotland



Lifelong learning

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

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Three-day course & MSc Module Date: 16-18 June 2009 Venue: Apex International, Edinburgh, Scotland Ref: PGF8/09

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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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 degree is validated and awarded by the federal 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



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