

# Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF7/11



## Regulatory Strategy for Established Active Substances

### Aim

The purpose of this Module is to enable students to study and understand the strategic issues to be considered in relation to medicines containing established active substances, including line extensions, generics and OTC products.

### Learning Outcomes

- Students will distinguish between the differing types of abridged applications possible in the EU and identify situations when the use of each of these is appropriate.
- Students will design and evaluate strategies for submissions in EU markets for products containing established active substances.
- Students will compare the routes to approval in the USA for products containing established active substances, sufficient to provide regulatory leadership to colleagues in this market.

### Outline of Module topics

- The commercial importance of abridged applications
- The type and range of abridged applications in Europe
- The legal background to abridged applications including data protection, marketing exclusivity and patent protection
- Options for abridged applications, and use of the different regulatory procedures
- Strategy for abridged applications including implications for harmonisation of the SmPC
- Processing of abridged applications by the Regulatory Authorities
- Particular issues for products containing well-established active ingredients, generic and over-the-counter (OTC) products
- Routes to approval of products containing established active ingredients in the USA

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.*

For more information please visit [www.topra.org/mscra7](http://www.topra.org/mscra7) or contact TOPRA via email: [mscadmin@topra.org](mailto:mscadmin@topra.org)

Three-day  
Course &  
MSc Regulatory  
Affairs  
Module 7

### Date:

21–23 June 2011

### Venue:

NH Tropen Hotel,  
Amsterdam, the  
Netherlands



**MSc RA M7**

**15\* hours**

Lifelong learning

\*For more information  
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Three-day course & MSc Module 7 Date: 21–23 June 2011 Venue: NH Tropen Hotel, Amsterdam, The Netherlands Ref: PGF7/11

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Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

**Post:** TOPRA, Bellerive House, 3 Muirfield Crescent, London E14 9SZ

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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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