

# Career development opportunities in Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: PGF9/12



## Registration of Biological, Biotechnology and Advanced Therapy Products

### Aim

The purpose of this Module is to enable students to study and understand the scientific principles underpinning development of biological/biotechnology products and how the inherent complexities impact on regulation.

### Learning outcomes

Students will discriminate between a biological and a chemical entity and will recognise and interpret the complex nature of biological/biotechnology products.

Students will appraise the quality issues specific to biologicals, for example potential virus contamination, assay by bioassay.

Students will analyse the implications of change in production process on product and the concept of comparability.

Students will differentiate between classes of biological products such as vaccines, monoclonal antibodies and gene therapy and the data requirements specific to these products.

### Course Content includes

- What is a biological? How are they regulated?
- Characterisation and quality control

- Implications for change in process on product development
- Preclinical requirements
- Clinical development of biotech products
- New technologies, for example gene therapy, and how they are regulated
- Biosimilar products

### Speakers

**Alison Porter**, *Fujifilm DioSynth Biotech*

**Richard Keane**, *Biogen Idec*

**Mairead Duke**, *Biogen Idec*

**Paul Chamberlain**, *bioLOGICA Consulting & NDA*

**Nicolas Dumey**, *Texcell SA*

**Dr Elizabeth Pollitt**, *MHRA*

**Jane Robinson**, *National Institute of Biological Standards and Control*

**Jason Hampson**, *Amgen*

**Frank Brennan**, *Novartis*

**Fabio Magrini**, *Medimmune*

**Robin Thorpe**, *National Institute of Biological Standards and Control*

**Sergio Fracchia**, *MolMed*

**Cecil Nick**, *Parexel*

**Dr Michael Pfeleiderer**, *PEI*

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/mscra9](http://www.topra.org/mscra9) or contact TOPRA via email: [mscadmin@topra.org](mailto:mscadmin@topra.org)

Three-day  
Course &  
MSc Regulatory  
Affairs  
Module 9

### Date:

17–19 April 2012

### Venue:

The University  
Arms Hotel,  
Cambridge, UK



**MSc RA M9**

**15\* hours**

Lifelong learning

\*For more information  
please visit [www.topra.org/  
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 or [mscadmin@topra.org](mailto:mscadmin@topra.org)

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Job title

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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

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