

## Regulatory Affairs For Clinical Trials Professionals

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This course covers a wide range of regulatory issues and procedures, explaining how these can affect strategies for obtaining marketing authorisations.

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### What Is The Course About?

This course is for regulatory professionals with less than one year of practical experience as well as those who regularly liaise with regulatory departments. It also reveals the stages after marketing approval by explaining the concepts behind pharmacovigilance, licence maintenance and POM to P switching.

By the end of this course, you will be able to:

- Understand the need for regulatory controls in clinical trials.
  - Understand how data is collected, reviewed and reported to the relevant regulatory authorities
  - Understand the importance of marketing authorisations
  - Understand the importance of regulatory affairs within the drug development and maintenance processes
  - Have a good knowledge of the key regulatory authorities around the world
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### The Trainer

Paul Jeffreys

Paul is an incredibly knowledgeable trainer who never fails to impress people with his deep understanding of many drug development topics. His anecdotal experiences enable him to bring situations to life so that key points are clearly explained and are given meaning through contexts that are at the heart of how this industry works.

Paul's varied qualifications include a first degree in chemistry, a Masters degree in industrial chemistry and a Diploma in Marketing, and he has used this academic knowledge to build successful careers in Technical Development, Product Development and Regulatory Affairs.

Paul currently works for a global Pharma Company as a Regulatory Manager, and his expertise includes product registrations and their documentation, writing and reviewing expert reports, and advising on the current status of regulatory directives and guidelines.

#### **Course Fee: £1,095 +vat**

If you book on the course more than 9 weeks in advance, a 10% discount will be applied.

Location: The Regency Hotel, 100 Queens Gate, South Kensington, London, SW7 5AG

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# Programme

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### **Introduction & Objectives**

#### **History of Regulatory Affairs**

- Regulatory Affairs Explained and It's Necessity
- The Regulatory Authorities and Their Function

#### **ICH and Other Guidance and Locations**

- What is ICH?
- How does it impact on Regulatory Affairs?

#### **Good Practices**

##### Data requirements

- Data required by the company
- Time factors
- Common pitfalls and deficiencies
- Labelling & Patient Information
- Patient Information Leaflets

#### **Clinical Trials Control**

- What are the main systems in place in the EU and the USA?
- What data is required before trials can start?
- Ethics, informed consent and ethics committees

#### **GCP Directive**

##### **Data Presentation & Review - USA**

- IND Submissions
- What data is needed for a US submission?
- How does the FDA function?
- Regulatory review of submissions made in the US
- EU vs USA

##### **EU Submissions**

- Data requirements for EU submissions
- What does an EU dossier look like?
- Preparing an EU dossier
- The EU regulatory procedures
- Common Technical Document

##### **The EU Expert Report/Overview**

- What is an expert report?
- What does it contain?
- Why is a good expert report so critical?
- Who are "experts"?

##### **Pharmacovigilance**

- Collecting adverse event data
- Why is it necessary and what actions should be taken?

##### **Licence Maintenance**

- Variations
- Keeping licences up to dates and renewals

##### **Licence Extensions & Generics**

- Abridged licences
- New formulations

##### **POM to P Conversions**

##### **Parallel Imports**

##### **The Future**