

Introduction To Biotech Products For Regulatory Affairs

An introductory course for those with minimal experience in biopharmaceuticals or those coming from a small molecules background who want to get up to speed with biotech products and in particular monoclonal antibodies

What Is The Course About?

Do you have problems finding the right course for staff who are new to regulatory aspects of biotechnology products? The terminology alone is daunting with glycosylation, isoforms, post translational modifications, higher order structures and the list goes on. Also, you don't want new staff to be overwhelmed with information but they need to understand the type of data they will have to handle, what are the key issues to consider and how to present this data in their submissions.

This course is introductory for those with minimal experience in biotech products or new to the discipline. Emphasis is placed on the documentation for monoclonal antibodies in relation to the Clinical Phases and highlighting how quality, safety and efficacy are related.

This course will give delegates the understanding how to achieve good quality IMPD and MAA submissions for biotech products especially monoclonal antibodies.

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 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/Biotech 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: £599 +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

For more information about this or any of our other courses or services, please call us on +44 (0)118 975 4512 or visit our website www.rostrumtrainingsolutions.com

Programme

Introduction To Biotech Products For Regulatory Affairs

Introduction & Objectives

What are the biopharmaceuticals and biologicals?

Terminology and what it means

Protein structure and the differences with small molecules

Expression construct and cell banks

Characterisation and heterogeneity

Manufacturing process - fermentation and purification

Comparability guidelines

Analytical Procedures and Validation

Impurity Profile

Pharmaceutical Formulation, stability and adventitious agents

Preclinical Requirements

Immunogenicity - contributing factors

Clinical Development of biotech products

What level of detail is needed in the IMPD in relation to the Clinical Phases