

## Introduction To CMC Regulatory Affairs

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An introductory course for those with minimal experience in CMC or new to the discipline.

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### What Is The Course About?

Do you have problems finding the right course for staff who are new to the discipline of Chemistry and Pharmacy Regulatory Affairs? 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 look out for and how to present this data in their submissions.

This course is introductory for those with minimal experience in CMC or new to the discipline. Emphasis is placed on the CMC documentation in relation to the Clinical Phases and highlights how quality is relevant to safety and efficacy.

This course will give delegates the understanding how to achieve good quality IMPD and MAA submissions.

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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 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: £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

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# Programme

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### **Introduction & Objectives**

CMC in the drug development programme

Drug substance - characterisation and synthesis related issues

Drug master files and Certificates of Suitability

Drug product and formulation considerations

Control of Drug Substance and Drug Product

Setting specifications - drug substance and drug product

Stability - drug substance and drug product

The Quality Overall Summary

What level of CMC detail is needed in the IMPD in relation to clinical phases