

PharmaQMtraining.eu

A Short Course on Regulatory Affairs with emphasis on the
Biological/Biotechnological Drug Substances
and Products
Early 2011

A Short Course on Regulatory Affairs with emphasis on the
Licensing Process and Marketing Authorisation Application (MAA)
Content for Generic Medicines
Early 2011

A Short Course on Regulatory Affairs with emphasis on the
Background, Content and Detail of Module 3 of the Common Technical Document (CTD), the
'Quality Module'
Early 2011

All the courses above are held in Legacy Falcon Hotel,
Stratford-upon-Avon, United Kingdom

COURSE OBJECTIVES, STRATEGY & TARGET AUDIENCE:

BIOLOGICALS:

The programme offers scientific information with a regulatory focus on the many different classes of 'biologicals' including some hormones, blood products and factors, 'immunologicals' (e.g. vaccines, antibodies) made using sophisticated (recombinant) biological culture or cloning systems.

The subjects of comparability and biogenerics will be addressed as will special and varied issues concerning possible contamination and necessary purification activities.

Regulatory insight will be provided about documentation supporting EU applications at IMP (investigational medicinal product) and MA (Marketing Authorisation) stages in the life of biopharmaceuticals.

Common deficiencies in companies' applications will be identified.

GENERIC:

Building from first principles in several disciplines, delegates will learn about many important aspects of pharmaceutical development, manufacturing and control of the dosage forms, what comparator products are acceptable and the importance of comparative impurity profiles and of key pharmacokinetic parameters. Submissions (MAAs) for generic medicines must have a substantial Common Technical Document (CTD) Module 3 and much attention in the course will be given to the Chemistry & Pharmacy components. However, some Module 4 and 5 issues will also be addressed, with emphasis on the importance of bioequivalence study report which has to be lodged in CTD Module 5.

CTD MODULE 3:

This Course will be a comprehensive and group interactive course that builds from first principles and explores numerous pharmaceutical topics that have to be addressed in supporting documentation for Marketing Authorisation Applications (MAAs)