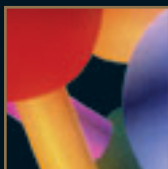


Module 11



Aim:

The USA is the largest single country market for pharmaceutical products in the world. As such, the regulatory requirements of the US Food and Drug Administration have a major influence on the design of pharmaceutical development programmes aimed at achieving successful registration in both the USA and globally. This influence impacts to some extent on all Regulatory Affairs Professionals, whether directly involved with the USA or not. The purpose of this module is to provide students with an understanding of the regulatory environment in the USA in order to place these global influences in perspective.

The US Regulatory Environment

Learning outcomes

- Students will be able to describe the legal basis of pharmaceutical Regulatory Affairs in the USA and how the FDA operates within the legal framework.
- Students will acquire knowledge of the format and content of IND, NDA, BLA, ANDA and SNDA submissions, and will understand the differences between them and the practical issues associated with these applications.
- Students will gain an understanding of FDA approaches to specific product types such as OTC products and orphan drugs.
- Students will gain an understanding of the impact of US Regulatory Affairs on the global development and regulatory strategy for pharmaceuticals.

The module will cover the following topics

- History of drug regulation in the USA
- The basis of Regulatory Affairs in the USA
- FDAMA and PDUFA
- The IND
- The NDA and BLA
- The ANDA
- The SNDA and manufacturing strategies
- OTC products
- Orphan drugs
- Fast track approvals
- Adverse event reporting
- Labelling and advertising controls
- Communicating with FDA
- Making maximum use of the NDA

Links with other modules

- Module 1 covers global regulatory strategy.
- Module 4 and 5 cover the global clinical development programme.
- Module 7 and 8 cover regulatory strategies and data requirements for abridged applications.
- Module 9 covers global strategies for biotechnology products.