ESS01 Essentials of EU and US Regulatory Affairs for Human Medicinal Products

Approximate study time: 3 hours

Level: Foundation

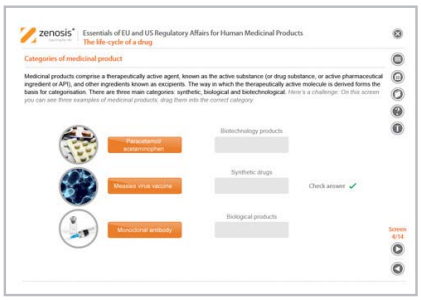
Audience: Regulatory

Category: Preclinical, Clinical, Pharmacovigilance, Manufacturing and QC, IT, Regulatory Submissions, Commercial, Chemistry and Pharmacy

Region: USA, Europe

CPD Points: 3

Module outline
- Regulatory affairs primer
- The life-cycle of a drug
- Registering a drug
- After marketing approval
- Assessment



This foundation-level module is the ideal introduction for new entrants to the field of pharmaceutical regulatory affairs and compliance. It describes the principal requirements that must be satisfied to gain and maintain approval to market medicinal products in the USA and Europe. The legal framework and the roles of major players in regulation are presented. The life-cycle of a drug is outlined. The various procedures available for assessment and approval of products are described and their requirements outlined. Obligations to be fulfilled after marketing approval are discussed.

Who will benefit from this module?

All staff in the pharmaceutical and biotechnology industries who are inexperienced in regulatory affairs and compliance will find the module an invaluable introductory training course. More experienced personnel will find it a useful reference tool. It will also be of benefit to healthcare professionals who contribute to the development of medicinal products.

Learning objectives

- Describe the role and responsibilities of regulatory affairs within the pharmaceutical industry in both the EU and the USA.
- Identify the main legislative instruments relating to medicinal products in both the EU and USA.
- Understand the main phases of the drug development process and be aware of the regulatory requirements that apply.
- Describe the requirements for applications for marketing approval and the procedures to be followed in both the EU and USA.
- Identify post-marketing regulatory activities in both the EU and USA.

Module outline

Regulatory affairs primer
This session gives a definition of regulatory affairs and outlines the function and evolution of regulation in the pharmaceutical industry as well as providing a source of key legislation and guidelines. National and international regulatory authorities are introduced including the legal frameworks in the USA and EU.

The life-cycle of a drug
This session looks at the main differences between types of medicinal products, outlines the discovery phase and nonclinical studies and gives a basic introduction to Good Laboratory Practice. It also identifies the four phases of clinical development and introduces some of the special difficulties associated with paediatric trials.

Registering a drug
This session looks at the regulatory requirements during the nonclinical studies phase as well as the salient points of Good Clinical Practice. It also introduces the regulatory processes involved in gaining marketing authorisation in the EU and the USA. The session also introduces the learner to orphan drugs, line extensions, generics, naming conventions and compassionate use.

After marketing approval
This session explores post-marketing approval activities, including variations and supplements, line extensions and pharmacovigilance, GMP, basic patent law in the EU and USA, marketing issues, advertising and generics.

Assessment
Multiple-choice mastery assessment.