MD01 An Introduction to the Regulation of Medical Devices

Approximate study time: 1 hour

Level: Introductory

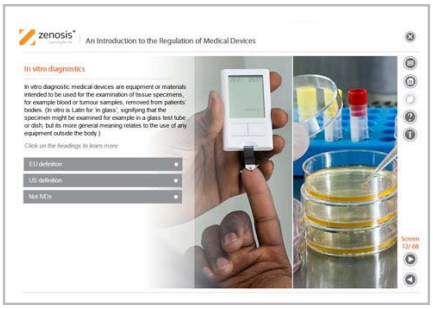
Audience: Research, Regulatory, Manager, Other

Category: Medical devices

Region: Europe, USA

CPD Points: 1

Module outline
- Module overview
- Medical devices and their regulation
- Regulation of medical devices in the USA
- Regulation of medical devices in Europe



This module provides an introduction to the basics of medical device regulation, especially the requirements that manufacturers must meet in order to market devices in Europe and the USA.

We explain what medical devices are and give examples of the various types. We outline the principles of their regulation and the criteria for placing them on the market. We identify major players in regulation worldwide.

We then outline prominent characteristics of the regulation of medical devices in the USA and in Europe. The module is up to date with the current upheaval in European Union legislation on medical devices.

Who will benefit from this module?

This module provides essential training for all personnel concerned with the development, regulatory compliance, or marketing of medical devices. It is especially suitable for induction training of entry-level staff.

Learning objectives

- Define and give examples of the various categories of medical device
- Outline the principles of medical device regulation and the criteria for placing devices on the market
- Identify major players in the regulation of medical devices worldwide
- Identify legal statutes and sources of regulatory guidance on medical devices in the European Union and the USA
- Outline prominent characteristics of the regulation of medical devices in the USA
- Outline prominent characteristics of the regulation of medical devices in the European Economic Area

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Medical devices and their regulation
In this session we explain what medical devices are and how they differ from medicinal products. We define various special categories of such devices. We identify basic principles of their regulation, including risk classification. We outline requirements for technical documentation, clinical data, and post-market surveillance and vigilance. Finally, we identify the major players in regulation.

Regulation of medical devices in the USA
In this session we outline prominent characteristics of the regulation of medical devices in the USA.

Regulation of medical devices in Europe
In this session we outline prominent characteristics of the regulation of medical devices in the European Economic Area.

Assessment
Multiple-choice mastery assessment.