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In Vitro Diagnostic Medical Devices Regulation (IVDR)

Your Training at TÜV SÜD Akademie

Course description
This is a foundation level course on In Vitro Diagnostic Medical Devices Regulation (IVDR). It covers basic information about the new regulation, classification of rules and procedure to carry out the assessment. The course is divided into three modules that provide details on technical documentation requirements under IVDR: Quality Management System requirements under IVDR, understanding of traceability requirements and post-market surveillance under IVDR.

The Technical Documentation requirements under the IVDR module are created for building an understanding of regulations and technical documentation that play an important role in IVDR. Further the requirements of Quality Management System, which are emphasized in Article 10 (8) of EU MDR 2017/746, under the general obligation of manufacturers, states that manufacturers must demonstrate performance, safety, and possible risks/controls of products prior to availability within the European Union marketplace

Who should attend
This e-learning course is specially designed for manufacturers of medical devices, Regulatory Affairs, Design and Development, Quality Management, and Quality Assurance personnel, clinical affairs specialists, students and professors.

Course objectives
After completing the e-learning you will be able to...

- explain In Vitro Diagnostic Medical Devices Regulation
- discuss the impact of the IDVR on quality management systems and requirements under Article 10 (8)
- describe some of the important terms such as market surveillance, unique device identification, and their traceability

Course content
There are three modules to this e-learning course:

- Technical Documentation requirements
- Quality Management System requirements
- Understanding of traceability requirements and post-market surveillance under IVDR

Methodology
The e-learning course employs a variety of training tools to enhance the learning experience such as content-embedded assessment, and other interactive exercises. Easily accessible via your preferred choice of device, the course allows you to log in and learn whenever, wherever.

Certificate
The cumulative duration of the program is 105 minutes. You will be required to pass a final assessment to receive your internationally recognized e-certificate.

Sale Modes: Single License, Group License, SCORM Sale

Duration: 105 minutes

Number of Modules: 3

Number of Quizzes: 9 (including final assessment)

Learning Mode: Self-Paced (LMS)

Interactivity Level (1-4): 2-complex

Language: English