MEDICAL DEVICE REGULATION (EU) 2017/745 IMPLEMENTATION TRAINING COURSE

COURSE DESCRIPTION

The objective of this course is to provide leaners with knowledge and understanding of the additional requirements within the Medical Device Regulation (MDR) as well as of the current directives (MDD 93/42/EE) and ISO 13485:2016, including the terminology used and the certification requirements.

COURSE CRITERIA

UPON COMPLETION OF THIS COURSE, LEARNERS WILL BE ABLE TO:

- Identify the links between EN ISO 13485:2016 (QMS) and MDR EU/2017/745
- Explain how terminology has changed and where gaps require additional work for clients to meet the new requirements
- Define new requirements for proactive post-market surveillance
- Outline the stages of the transition from MDD to MDR so that clients can create individual transition plans
- Define the key deliverables for all economic operators

Learners will need to demonstrate acceptable performance in these areas to complete the course successfully.

PRIOR KNOWLEDGE

Before starting this course, learners must have a good understanding of the:

- Current Medical Directives
- EN ISO 13485:2016
- Terminology used; and
- Requirements to achieve certification

COURSE CONTENT

SESSION 1: SCOPE, DEFINITIONS AND CLASSIFICATIONS

- Scope of the MDR
- Relevant MDR definitions

SESSION 2: CONFORMITY ASSESSMENT PROCEDURES

- Conformity assessment procedures
- Certification process requirements within MDR
- Additional requirements under MDR Annex XII
- EU declaration of conformity
- Criteria for notified bodies and how this is achieved

SGS ACADEMY

www.sgs.com/en/training-services
www.facebook.com/sgsglobalacademy
www.linkedin.com/showcase/sgsacademy
training@sgs.com

COURSE DURATION: 2 days
DELIVERY METHODOLOGY: Face to Face
COURSE LANGUAGE: English
ACCREDITATION: SGS

COURSE CERTIFICATION

On completion of this course, learners will be issued with a "Certificate of Attendance".

SGS

SESSION 3: QMS REQUIREMENTS

- QMS and regulations

SESSION 4: GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

- GSPR matrix
- GS&PRs vs MDD ERs

SESSION 5: TECHNICAL FILE REQUIREMENTS

- Technical file requirements
- Conformity assessment

SESSION 6: CLINICAL EVIDENCE REQUIREMENTS

- Clinical evaluation
- Clinical investigations
- Post-market clinical follow-up
- Clinical evaluation plan

SESSION 7: POST-MARKET SURVEILLANCE AND VIGILANCE

- Post-market surveillance lifecycle
- Guidance documents
- Post-market surveillance plan
- PMCF
- PMCF study

SESSION 8: RISK MANAGEMENT REQUIREMENTS

- General safety and performance requirements
- Usability review
- Design life cycle

SESSION 9: IDENTIFICATION AND TRACEABILITY

- Traceability of devices
- Identification in supply chain
- Unique device identifiers and the UDI system

SESSION 10: SUPPLY CHAIN REQUIREMENTS

- Economic operators and their general obligations
- Other economic operators
- Systems and procedure packs

SESSION 11: TRANSITION AND NEXT STEPS

- Transition requirements
- Transition plan

SESSION 12: BUSINESS IMPACT, TIMELINE AND PORTFOLIO PLANNING

- Step 1: Understand the detail of the MDR
- Step 2: Project Planning
- Step 3: Product Portfolio
- Step 4: Organisational changes