Medical Device Regulation Technical Documentation Transition (MDD – MDR)

COURSE DESCRIPTION

The purpose of this course is to familiarise learners with the technical documentation requirements of Medical Device Regulation (MDR) 2017/745, understand what notified bodies are looking for and why technical documentation need to be 'live' documents which cover the full product life cycle.

DURATION: 1 Day 8 hours	ACCREDITATION: SGS
DELIVERY: Face to Face VILT	LANGUAGE: English

"FOR MEDICAL DEVICE PROFESSIONALS"

LEARNING OBJECTIVES

Upon completion of this course, learners will be able to:

- Understand the technical documentation requirements of the Medical Device Regulation (MDR) 2017/745
- Understand what Notified Bodies are looking for, when Technical Documentations are assessed
- Understand why Technical Documentations need to be "live" documents and cover full product life cycle
- Updating your MDD technical documentation to an MDR compliant one
- Appreciate the role of guidance documents

AUDIENCE

This course is designed for:

- Medical device professionals with knowledge of MDD, involved in the development and implementation of the Medical Device Regulation (MDR) 2017/745

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COURSE CONTENT

- Introduction to technical documentation
- Technical documentation content Annex II
- Technical documentation content Annex III
- Where to start
- How the notified body assesses technical documentation

PRIOR KNOWLEDGE

It will benefit learners if they have a knowledge of the following principles and concepts:

- Working knowledge of ISO 13485:2016 Quality Management principles and some regulatory knowledge of the MDD Directive (current legislation) but no prior knowledge of new MDR Technical Documentation requirements

COURSE CERTIFICATION

On completion of this course:

- Learners will be issued with a "Certificate of Attendance"

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SGS FACEBOOK
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TRAINING@SGS.COM

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