IVDR Technical Documentation Training Course

COURSE DESCRIPTION

The purpose of this course is to familiarise learners with the technical documentation requirements of In Vitro Medical Device Regulation (IVDR) EU 2017/746, understand what notified bodies are looking for and why technical documentation needs 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 what technical documentation is
- Identify the differences in technical documentation between IVDD and IVDR
- Prepare the structure of technical documentation
- Know the critical areas and critical reports in the technical documentation
- Be comfortable with how a Notified Body will assess the technical documentation

AUDIENCE

This course is designed for:

- Medical professionals involved in the development and implementation of IVDR technical documentation
- Product designers for IVDs

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COURSE CONTENT

- Introduction to IVDR technical documentation
- What is technical documentation?
- Critical areas – new requirements
- Structure of technical documentation
- Where to start?
- How notified bodies assess 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
- Regulatory knowledge of the In Vitro Diagnostic Directive (IVDD) current legislation

COURSE CERTIFICATION

On completion of this course:

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

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