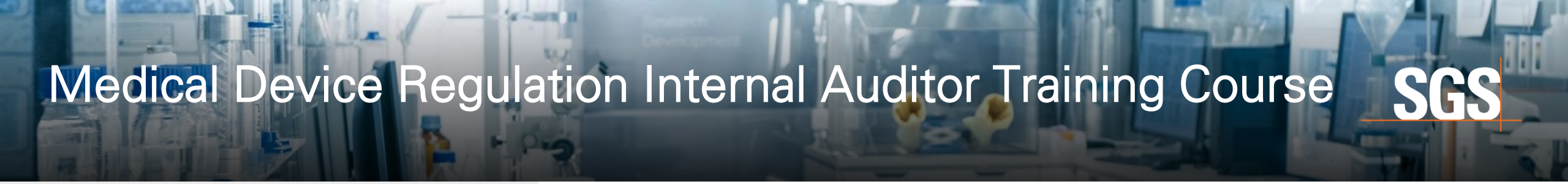

Medical Device Regulation Internal Auditor Training Course

COURSE DESCRIPTION

This course has been developed by SGS for the benefit of clients wishing to understand Medical Device Regulation (EU) 2017 – 745 and how to conduct an internal audit against its requirements.

The course refers to the Medical Device Regulation that provides the context for internal audit. However, this course does not address Medical Device Regulation in detail.

DURATION: 2 Days 16 hours	ACCREDITATION: SGS
DELIVERY: Face to Face VILT	LANGUAGE: English

"FOR MEDICAL DEVICE AUDITORS"

LEARNING OBJECTIVES

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

- Plan, conduct, report and follow-up on an internal audit of their companies management system and technical documentation based on Medical Device Regulation (EU) 2017 / 745 requirements

AUDIENCE

This course is designed for:

- Medical professionals involved in the internal audit of Medical Device Regulation(EU) 2017 / 745 requirements

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Medical Device Regulation Internal Auditor Training Course

COURSE CONTENT

- Overview of the Changes in MDR from MDD
- Auditing for Continual Improvement
- Audit Definition, Types and Principles
- Roles and Responsibilities of Auditors
- The Audit Process
- Preparing for the Internal Audit
- Conducting the Audit
- Audit Review

PRIOR KNOWLEDGE

It will benefit learners if they have knowledge of the Medical Device Regulation (MDR) and an understanding of:

- The requirements of MDR
- Commonly used terms and definitions, as provided in the MDR

COURSE CERTIFICATION

On completion of this course:

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

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