ISO 13485:2016 Medical Device Quality Management Systems (MD QMS) Lead Auditor Training Course

COURSE DESCRIPTION

The objective of this course is to equip learners with the knowledge and skills required to perform audits of MD QMS against ISO 13485:2016 in accordance with ISO 19011 and ISO 17021, as applicable.

DURATION:	5 Day 40 hours	ACCREDITATION:	CQI / IRCA
DELIVERY:	Face to Face VILT	LANGUAGE:	English

"DESIGNED FOR MEDICAL DEVICE AUDITORS"

LEARNING OBJECTIVES

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

- Explain the purpose of a Medical Device Quality Management System (MD QMS), interaction with appropriate medical device regulatory authority requirements, quality management systems standards, third-party certification, and the business benefits of the quality management system.
- Explain the role and responsibilities of an Auditor to plan, conduct, report and follow-up a quality management system audit in accordance with ISO 19011 and ISO 17021, where appropriate.
- Plan, conduct, report, and follow-up an audit of a medical device quality management system to establish conformity (or otherwise) with ISO 13485 and applicable medical device regulatory requirement documents in accordance with ISO 19011, ISO/IEC 17021.

AUDIENCE

This course is designed for:

- Professionals looking to audit organisations against ISO 13485:2016
- Medical Device Quality management representatives

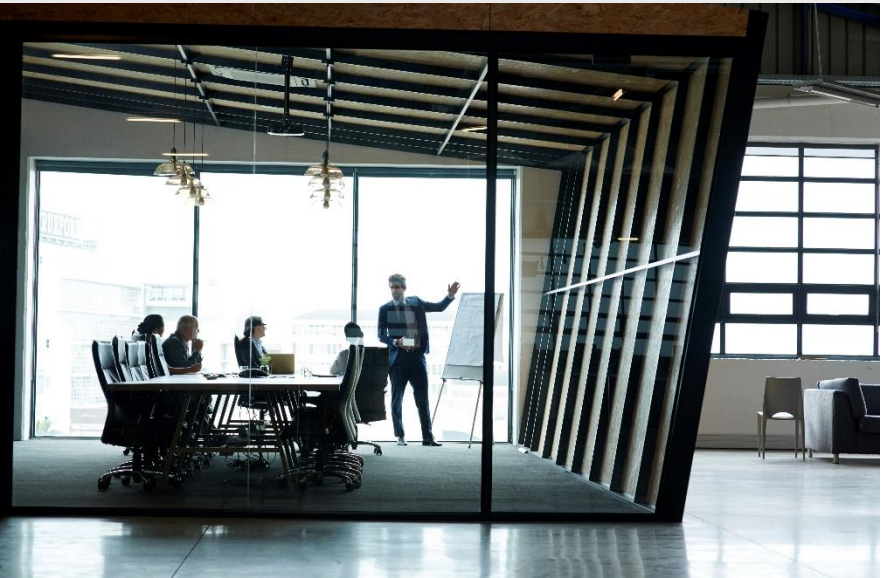
SGS A GLOBAL MEDICAL DEVICE TRAINING ORGANISATION

SGS is a Global Training Organisation with extensive testing capabilities across all Medical Device categories. We are a designated UKCA Approved Body, a CE Notified Body and a recognised MDSAP Auditing Organisation.

ISO 13485:2016 Medical Device Quality Management Systems (MD QMS) Lead Auditor Training Course

COURSE AIM

- The aim of this course is to equip learners with the knowledge and skills required to perform audits of MD QMS against ISO 13485:2016 in accordance with ISO 19011 and ISO 17021, as applicable.



PRIOR KNOWLEDGE

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

- ISO 13485
  - Knowledge of the requirements of ISO 13485, which may be gained by completing a CQI and IRCA Certified MD QMS ISO 13485:2016 Foundation (FD132) course or equivalent.
- Medical Device Management System Audit
  - The Plan, Do, Check, Act (PDCA) cycle.
  - The relationship between ISO 13485 and applicable international regulatory requirements for medical devices.
  - Commonly used quality management terms and definitions within ISO 13485 and ISO 9000.
  - The process approach used in MD QMS.
  - A working knowledge of medical device regulatory process applicable to countries the course is designed to cover, including device regulations, regulatory auditing standards and their relationship with ISO 13485. This knowledge may be gained by successfully completing a CQI and IRCA course relating to individual regulatory authority standards, which will be available subject to demand (e.g. MD QMS Comprehensive EU Medical Device Regulation 2017/745 (EU MDR) Practitioner – PT219).
  - A working knowledge of risk-management principles related to the design of a medical device, for example ISO 14971, the purpose and benefits of a business impact analysis.

ISO 13485:2016 Medical Device Quality Management Systems (MD QMS) Lead Auditor Training Course

COURSE CONTENT

- Introduction to MD QM
- Process-based MD QMS
- Accreditation, Certification and Auditor Competence
- Audits: Definitions, Principles and Types
- The Audit Process
- Preparing for the On-site Audit (Audit Stage 1)
- Developing the Checklist
- Conducting the On-site Audit (Audit Stage 2)
- Audit Review, Report and Follow-up

COURSE CERTIFICATION

On completion of this course, learners who have been in attendance for the full duration of the course will be issued with a "Certificate of Attendance".