ISO 13485:2016 Medical Device Quality Management Systems (MD QMS) Internal Auditor

COURSE DESCRIPTION

The course provide you with the knowledge and skills required to perform an internal audit, based on the Management Development Quality Management System (MD QMS) requirements of ISO 13485:2016.

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

"DESIGNED FOR MEDICAL DEVICE AUDITORS"

LEARNING OBJECTIVES

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

- Explain the purpose of a Medical Device Quality Management System (MD QMS) and the business benefits of improving MS performance.
- Understand the basic requirements of ISO 13485:2016.
- Explain the audit definitions, principles of auditing and types of audits.
- Explain the role and responsibilities of an Auditor to plan, conduct, report and follow-up an internal MD QMS, in accordance with ISO 13485:2016.
- Prepare documentation and understand how to establish conformity (or otherwise) against ISO 13485:2016 and local regulations, as applicable.

AUDIENCE

This course is designed for:

- Medical professionals who have a knowledge/experience of performing ISO 13485:2016 audits.
- Medical Device Quality Management Auditors.

SGS is a designated UKCA Approved Body, a CE Notified Body and a recognised MDSAP Auditing Organisation providing accredited training courses and extensive testing capabilities across all Medical Device categories.

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COURSE CONTENT

- Introduction to Medical Device QMS and ISO 13485:2016; Clause 4 (Quality Management System), Clause 5 (Management Responsibility), Clause 6 (Resource Management), Clause 7 (Product Realization) and Clause 8 (Measurement Analysis and Improvement)
- Audit: Definition, Principles and Types
- Roles and Responsibilities of Auditors
- Planning and Preparation for the Audit, including On-site Activities
- Audit Reporting and Follow-up

PRIOR KNOWLEDGE

Before starting the course, you are expected to have knowledge of the following principles and concepts:

- The requirements of ISO 13485:2016, which may be gained by completing the ISO 13485:2016 Introduction training course.
- Medical Device management systems audit, including the Plan, Do, Check, Act (PDCA) cycle, the relationship between ISO 13485:2016 and applicable international regulatory requirements for medical devices, commonly used quality management terms and definitions within ISO 13485:2016 and ISO 9000 series.
- MD QMS process approach.
- Basic knowledge of the concepts of quality management and the relationship between quality management and customer satisfaction, including knowledge/experience of performing ISO 13485:2016 audits.
- 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.

COURSE CERTIFICATION

On completion of this course you will be issued with a “Certificate of Attendance.”