

ISO 13485:2003 Internal Quality Auditor

Course Objectives

As a feedback mechanism in the quality management system, quality audits are of critical importance to maintain the effectiveness of a quality system and its processes in regulated industries such as the medical device industry.

In such an environment, deviations in the quality management system, unless corrected on a timely basis, will eventually lead to violations against regulatory requirements and finally cast significant doubt on the safety and effectiveness of the devices that are manufactured. To this end, a universal expectation of medical device regulators is that manufacturers of medical devices perform quality audits at regular intervals to identify system non conformances and undertake corrective and/or preventive actions to enable affected processes to revert to a compliant level on a timely basis.

This training program is intended to guide internal auditors on the role and functions of an internal audit in assessing compliance to a quality management standard such as ISO 13485:2003. Participants will be introduced to the auditing principles, guidelines and framework set forth in ISO 19011, the international standard for performing audits. This includes a comprehensive discussion on the requirements for establishing and maintaining processes related to how auditors are developed, trained, qualified and evaluated to ensure that they have the necessary background, training and competence to effectively assess a quality system.

Course Outline

- Module 1-0 : ISO 19011 - A Review of Requirements.
- Module 1-1 : Structure and Principles of ISO 19011
- Module 1-2 : Audit Programme Management
- Module 1-3 : The Auditor as A Resource
- Module 1-4 : Planning, Resource and Responsibilities
- Module 1-4 : Reporting of findings and Audit Completion
- Module 1-5 : Effective Follow-up and Close
- Module 2-1 : The Process Approach of ISO 13485 & ISO 9001
- Module 2-2 : ISO 13485 Requirements I: Documentation Requirements
- Module 2-3 : ISO 13485 Requirements II: Management Responsibilities
- Module 2-4 : ISO 13485 Requirements IV: Resource Management
- Module 2-5 : ISO 13485 Requirements V: Product Realization
- Module 2-6 : ISO 13485 Requirements VI: Monitoring and Measurement

Who Should Attend

- Internal auditors
- Quality Assurance Managers
- Laboratory personnel involved in system implementation.

Training Details

Duration	3 Days
Time	9.00 am to 5.00 pm
Fee	\$1,070.00 per participant (<i>Inclusive of GST</i>)

Enquiries

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