

ISO 13485:2016 - Certified Lead Auditor

Course Outline



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What Modules are covered?

Module 1

Understand the application of Quality Management Principles in the context of ISO 13485:2016.
Relate the quality management system to the organization's medical devices and provision of related services.
Understand the application of the principles, procedures and techniques of management systems auditing.

Module 2

Understand the conduct of an effective audit in the context of the auditee's organizational situation.
Understand the application of the regulations, and other considerations that are relevant to the management system,
Practice personal attributes.

Module 3

Establish, plan and task the activities of an audit team.
Communicate effectively with the auditee and audit client.
Organize and direct audit team members.
Understand conflict management principles.
Prepare and complete the audit report.

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