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Internal Auditor ISO 13485
Medical Device Quality

Course Description	This course is intended for medical device quality professionals aiming to build on their current knowledge of ISO 13485 and evaluate the effectiveness of the quality management system in their organization.
	This intensive two-day course teaches the principles and practices of effective quality management systems process audits in accordance with the ISO 13485 and ISO 19011. An experienced instructor guides students through the internal audit process, from planning an audit to reporting on audit results and following up on corrective actions. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, and group workshops.
Course Benefits	• Be better able to continue compliance with ISO 13485 • Maintain and improve a global benchmark in quality standards • Be confident that your organization can rely on ISO certified internal auditors • Motivate colleagues through CPD and build customer confidence.
Learning Objectives	Upon completion of this training, delegates will be able to: • Explain the structure and scope of ISO 13485 management system standard and how it applies to the organization aiming for regulatory compliance worldwide. • Identify the principles of auditing and auditor responsibilities. • Plan an internal audit. • Conduct informal opening and closing meetings. • Conduct an audit based on process identification, sampling and questioning. • Provide verbal and written feedback. • Document concise nonconformities. • Effectively report on an audit. • Follow-up on corrective actions
Intended Audience	• Medical Device Quality professionals with knowledge of quality management systems and ISO 13485 • Individuals interested in conducting first-party or second-party audits • Management representatives • Internal auditors • Managers • Consultants

Course Duration	2 Days
Prerequisites	This course does not detail the requirements of ISO 13485. Prior knowledge of the ISO 13485 standard is strongly recommended as a prerequisite for this course.