SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

Internal Quality Auditing for Manufacturers of Medical Devices

LS019

Internal Quality Auditing for Manufacturers of Medical Devices

This programme is available In-House and currently delivered through virtual classroom training.

Internal auditing is fundamental to any quality improvement initiative. In particular, ISO 13485 and the FDA Quality System Regulation for Medical Devices require that an organisation conducts internal quality audits to determine the effectiveness of its quality system. Trained auditors must carry out these audits.

Thousands of internal audits are performed each year providing little internal business benefit. This course focuses on auditing ISO 13485 or the FDA QSR for real quality improvement rather than just compliance.

This two day course provides detailed training in developing the skills necessary to be an effective internal auditor.

Duration & Price

Duration: 2 days
Delivery mode: This programme is available In-Company

Dates & Locations

In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

Please Note: A practical audit within the company forms the basis of day 2. Audit areas within the company must be organised prior to the training so that effective preparation can commence on day 1. For this reason the numbers on this course are restricted to max 12 (4 audit groups of 3) to ensure all delegates get the attention needed to ensure they become effective Auditors.

Day 1:

- Introduction to Quality Systems
- Purpose of Internal Audits
- The Audit Process
- Selecting the Audit Team & Audit Behaviour (Assumptions, Effective Listening, Dealing with Conflict)
- Tools available to Auditors
- Review of Internal Quality Audit Procedure
- Audit Preparation

Day 2:

- Audit Preparation (follow on from day 1)
- Practical on site audit
- Evaluating & Reporting the Audit

Delegates must attend both days to receive a Certificate of Attendance

Who should participate?

- Any person in the organisation with responsibility for conducting internal audits
- Departmental managers and supervisory staff
- Quality Managers, quality engineers and supervisory staff
- Staff with responsibility for designing and implementing quality systems
- Personnel responsible for supplier / external audits

What will I learn?

Participants achieve the following learning outcomes from the programme;

- Understand the importance of internal auditing within a quality management system
- Understand the responsibilities of Internal Auditors
- Conduct an effective internal audit e.g. plan and prepare for an internal audit against the organisation’s documented procedures and specific sections of ISO 13485 or the FDA Quality System Regulation for Medical Devices
- Collect and analyse evidence objectively
- Evaluate and report the results of an internal audit

Tutors

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What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.

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- Lean Six Sigma
- Join our Lean Six Sigma Network
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- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

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- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

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