SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY













Internal Quality Auditing for Manufacturers of Medical Devices

LS019

Internal Quality Auditing for Manufacturers of Medical Devices

Internal auditing is a core requirement of the standards and regulations governing the medical device sector. It plays a critical role in demonstrating compliance internally as well as meeting the expectations of notified bodies and regulatory authorities.

This course is designed to build the practical, handson competencies essential for conducting comprehensive and effective internal audits in the medical device sector.

Over two days, participants adopt an auditor's perspective, giving them deeper insight into compliance expectations, evidence gathering and audit evaluation, through an entirely new lens.

Having well trained, confident internal auditors is fundamental to maintaining a robust and effective quality management system.

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?

This intensive, hands-on two-day programme focuses on applied learning and real-world skills.

Day 1 covers audit principles and the role of internal audits within a QMS, guiding participants through the audit process from preparation to reporting, with interactive exercises on communication and conflict management. Learners then work in teams to prepare for a Day 2 audit, integrating relevant standards and regulatory clauses.

Day 2 consists of three team-based stages: refining preparation, conducting the audit and completing the audit report.

Programme Topics

Day 1

- Understanding the role audits play in maintaining compliance, driving improvement, and supporting organisational performance.
- A clear breakdown of each stage of the audit process: Setting Up, Preparing, Performing & Reporting.
- How to communicate effectively, manage challenging situations, and handle conflict with professionalism and confidence.
- Practical guidance on how to plan and prepare for an audit.

Day 2

A real onsite practical audit takes place on this day

- Audit preparation (building on day 1) - Finalising plans and aligning on the audit approach before commencing the audit.
- Practical on-site audit - Conducting a real, live audit onsite, applying the techniques, behaviours, and processes covered on Day 1.
- Evaluating and reporting the audit - preparing a clear, accurate, and professional audit report.

Class sizes are limited to 12 participants (max 3 audit groups) to support effective supervision during all the practical elements, with tailored training to meet specific organisational needs.

Who should participate?

This course is suitable for anyone working in the medical device industry who wishes to develop new auditing skills or strengthen their existing internal auditing capabilities, regardless of their role or department. This course supports learners at all levels.

A good standard of written and spoken English is important to engage effectively with this course.

What will I learn?

By completing this programme, the learner will be able to:

- Set up, plan, conduct and report internal audits in a structured and professional manner
- Develop confidence in interpreting and applying relevant standards and regulatory requirements
- Strengthen professional conflict management skills, recognising that auditing involves both people as well as processes
- Enhance day-to-day performance through understanding the auditor's mindset and evidence evaluation approach
- Build valuable competencies, including critical thinking, objective evidence gathering and awareness of regulatory expectations
- Build capability, competence, confidence and tangible organisational value
- Drive meaningful quality improvement and compliance beyond procedural box-ticking

These outcomes ensure learners return with practical skills and knowledge necessary to contribute effectively to compliant and value-driven internal audits.

How do we train and support you?

This is an instructor-led highly practical programme, delivered over two days and is offered live virtually or as an in-company programme. The course is busy, interactive, and hands-on, but learners leave with genuine confidence in their ability to carry out internal audits and a much deeper understanding of auditor expectations.

- Pre-training consultation with a highly experienced Tutor to tailor content to organisational needs
- Hands-on experience is provided through conducting real audits within the company environment
- Pre-course work is included to maximise engagement and learning during the training
- The programme goes beyond teaching auditing by influencing how participants think, act and contribute to quality

Class sizes are generally limited to 12 participants to support personalised learning and individual support.

How can you progress?

Learners who complete this programme can progress to further training in auditing, quality management and regulatory compliance to deepen their expertise.

Potential next steps include:

- ISO 13485
- ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)
- Understanding QMSR: Key Updates & Compliance Changes
- MDSAP Internal Quality Auditor

Tutors



Anne Marie Newell
View Profile



Kevina O’Donoghue
View Profile

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.



Click Here

SQT TRAINING THAT DEVELOPS *REAL* CAPABILITY

SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

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

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

QQI AWARD | IEMA APPROVED | CompEx Part of the JTL Group | FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE | CQI IRCA APPROVED TRAINING PARTNER | Chartered Institute of Environmental Health

SQT Training Ltd. | T: +353 61 339040 | E: info@sqt-training.com
W: sqt-training.com

Please follow us on social media for relevant news, events and updates