SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

MDSAP Internal Quality Auditor

LS004

MDSAP Internal Quality Auditor

The Medical Device Single Audit Programme (MDSAP) is a significant step towards harmonising medical device regulation across multiple global markets. This highly interactive training course provides a clear understanding of MDSAP requirements, demonstrates how they align with ISO 13485:2016 and US QMSR 21 CFR Part 820 and equips attendees with the auditing skills necessary to perform and MDSAP internal audit.

This two-day course, delivered by expert tutors combines practical auditing exercises with detailed guidance. The trainee auditors receive detailed feedback from both the tutor and their peers giving them the clarity and skills required to confidently undertake MDSAP audits once they return to the workplace.

We can tailor the training to meet your specific training needs and incorporate examples from your processes and procedures into the training programme as required.

Duration & Price

Duration: 2 days
Public Virtual Training: 795
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
28 - 29 Apr 2026	Virtual	Book Date

In-Company Training

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

What's covered?

This practical two-day course develops both understanding and capability in internal auditing under the MDSAP framework. Topics include:

- Introduction to MDSAP and its global scope
- Regional regulatory requirements: Australia, Brazil, Canada, Japan, USA
- Relationship of MDSAP to ISO 13485:2016 and US QMSR
- Internal audit purpose, process and preparation
- Selecting audit teams and effective auditor behaviours
- Tools and techniques available to auditors
- Internal quality audit procedure review
- Practical audit exercises (case study or in-company audit)
- Evaluating evidence and reporting audit results

On Day 2, learners participate in a practical internal audit exercise, which may take the form of a live in-company audit or a structured case study (for Public courses), providing valuable experience in preparing for, conducting and reporting on an MDSAP internal audit.

Content can be tailored to reflect your organisation’s specific processes, risk profile and regulatory setting.

Who should participate?

This programme is designed for individuals responsible for conducting internal audits against MDSAP requirements.

The training is particularly beneficial for:

- Quality Managers, Quality Engineers and Supervisors new to MDSAP
- Departmental Managers and staff with audit responsibilities
- Personnel responsible for supplier or external audits
- Staff involved in designing or implementing quality systems

A basic knowledge of ISO 13485:2016 is helpful but not essential. No prior internal auditing experience is required. A good standard of written and spoken English is important to engage effectively with this programme.

What will I learn?

On successful completion of this course, learners will be able to:

- Explain the purpose and importance of internal auditing in a Quality Management System.
- Identify and interpret the MDSAP requirements of Australia, Brazil, Canada, Japan and the USA.
- Map regulatory requirements to ISO 13485:2016 and US QMSR 21 CFR Part 820.
- Plan and prepare for an internal audit against MDSAP requirements.
- Apply effective audit techniques, including evidence collection, analysis and reporting.
- Demonstrate professional auditor behaviours, such as active listening and constructive communication.
- Evaluate audit findings and prepare clear, structured reports.

These outcomes ensure that learners return with the practical skills and knowledge necessary to perform effective internal audits against global MDSAP requirements.

How do we train and support you?

Our training approach is practical, highly interactive and discussion-based, with flexibility to meet organisational needs

- Pre-training consultation for in-company courses to tailor content to organisational needs
- Emphasis on industry specific application through practical exercises, case studies and group activities that reinforce key concepts and encourage active participation.
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Live training is available virtually or delivered onsite to suit the needs of the team
- Real-time support from expert tutors

Class sizes are generally limited to 10-12 participants to support personalized learning and individual support.

How can you progress?

Learners who complete this course often continue to deepen their skills in:

- ISO 13485:2016 & The Medical Devices Regulation (CE Marking Process)
- Internal Auditing for Manufacturers of Medical Devices
- Medical Device Risk Management and ISO 14971:2019
- Technical Writing Skills

Tutors

Gerry Burke
View Profile

John Lafferty
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

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