SQT

TRAINING THAT DEVELOPS
REAL CAPABILITY

MDSAP Internal Quality Auditor

LS004

MDSAP Internal Quality Auditor

The Medical Device Single Audit Programme (MDSAP) is the single biggest step towards global harmonisation of medical device regulation seen to date. This course details the main requirements of the regulations from Brazil, Australia, Canada and Japan and shows how these relate to ISO 13485: 2016 and the US QSR and how to audit against them.

All manufacturers who sell Medical Devices (class 2 or higher) into Canada from 1st January 2019 onwards must have their Quality Management Systems (QMS) approved under the MDSAP programme. In order to meet this deadline, manufacturers will have to apply for MDSAP and successfully complete the audit programme in 2018. The Auditing Organizations that approve Medical Device manufacturers under MDSAP will expect to see evidence that the QMS has been audited, by trained auditors, against the MDSAP requirements.

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

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	
29 - 30 Apr 2025	Virtual	Book Date
08 - 09 Oct 2025	Virtual	Book Date

In-Company Training

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

What's covered?

Day 1:

- Introduction to MDSAP
- Specific QMS Requirements of MDSAP
- The similarities and differences between the requirements for Quality Management System Requirements in the various regions: o Australia; Therapeutic Goods (Medical Devices) Regulations SR 2002 No. 236
  o Brazil; ANVISA RDC 16/2013 GMP for Medical Devices and IVDs
  o Canada; Canadian Medical Devices Regulation SOR/98/28
  o Japan; PMD Act 2014
  o USA; QSR 21 CFR Part 820
- How the above relate to ISO 13485 and the US QSR 21 CFR Part 820
- 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
- MDSAP Internal Audit Preparation

Day 2:

- MDSAP Internal Audit Preparation (follow on from day 1)
- Practical on site MDSAP Internal Audit
- Evaluating and Reporting the Audit

Please Note: For in-house courses a practical audit within the company forms the basis of Day 2 of this course. 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 necessary to ensure that they become effective Auditors. For this reason, also it is essential that all participants and auditees who participate in the course must each have use of an individual laptop. For public courses the audit conducted on Day 2 of the course will be performed on the basis of a case study.

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 to MDSAP requirements
- Departmental managers and supervisory staff new to MDSAP
- Quality Managers, Quality Engineers and supervisory staff new to MDSAP
- Staff with responsibility for designing and implementing quality systems
- Personnel responsible for supplier / external audits
- It is desirable, but not essential that personnel attending this course have a basic knowledge of ISO 13485: 2016
- It is not necessary for attendees to have any prior knowledge of experience of internal auditing to get the best out of this course.

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:
  - o the Canadian Medical Devices Regulation SOR/98/28
  - o the Japanese PMD Act 2014
  - o the Brazilian ANVISA RDC 16/2013 GMP for Medical Devices and IVDs
  - o the Australian Therapeutic Goods (Med. Dev.) Regulations SR 2002 No. 236
  - o the US QSR 21 CFR part 820
- Collect and analyse evidence objectively
- Evaluate and report the results of a MDSAP internal audit

How do we train and support you?

In-House Courses

For In-House courses, the Tutor will contact the Course Organiser in advance to discuss the programme in more detail in order to tailor it specifically to the organisation.

Course Manual

Delegates will receive a very comprehensive course manual.

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

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