SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY











MDSAP: The Medical Device Single Audit Programme

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MDSAP: The Medical Device Single Audit Programme

The Medical Device Single Audit Programme (MDSAP) represents a major step towards the harmonisation of international medical device regulations. This highly interactive two-day training course provides a detailed understanding of the requirements from Brazil, Australia, Canada and Japan and how they align with ISO 13485, the EU MDR and the US Quality Management System Regulation (QMSR). The course is delivered by highly experienced tutors and provides an in-depth examination of the MDSAP audit process, including comprehensive guidance on effective preparation.

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
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?

The programme introduces the principles of MDSAP and provides learners with the tools to prepare for and succeed, in the audit process.

Day 1

- Introduction to MDSAP
- Role of Auditing Organisations (AOs)
- MDSAP Audit Process including:
- Application process
- Three-Step Audit Approval System
- Audit Companion Document
- Non-conformance Rating System
- Audit approval and re-certification timelines
- Advantages and disadvantages of MDSAP adoption
- Regulatory requirements for registration and labelling in Brazil, Australia, Canada and Japan compared to EU and US regulations

Day 2

- Quality Management System requirements by region:
- Brazil (ANVISA RDC 16/2013)
- Australia (Therapeutic Goods Regulations SR 2002 No. 236)
- Canada (CMDR SOR/98/28)
- Japan (PMD Act 2014)
- How these relate to ISO 13485 and US QMSR 21 CFR Part 820
- Participation in mock audit scenarios
- Practical guidance on preparing for an MDSAP audit

The training involves practical exercises covering all relevant topics, with learners encouraged to work on examples from their own workplace as part of these practical exercises. If required, content may be tailored to reflect your organisation’s specific processes, risk profile and regulatory setting.

Who should participate?

This course is designed for professionals working in quality, compliance and auditing roles in the medical device sector.

The training is particularly beneficial for:

- Quality Managers and Quality Engineers
- Staff responsible for designing and implementing Quality Systems
- Internal Auditors
- Personnel responsible for supplier or external audits
- Departmental Managers and supervisory staff

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 core principles of the MDSAP framework.
- Compare regulatory requirements across Brazil, Australia, Canada, Japan, the EU and the US.
- Identify Quality Management System requirements critical for MDSAP compliance.
- Implement key steps to prepare for an MDSAP audit.
- Analyse audit findings and integrate them into a compliance programme.
- Develop an approach for maintaining ongoing compliance across MDSAP participant countries.

These outcomes ensure that learners return with the practical skills and knowledge necessary to prepare effectively for audits and maintain global regulatory compliance.

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 12-15 participants to support personalised learning and individual support.

How can you progress?

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

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

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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

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