SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

MDSAP: The Medical Device Single Audit Programme

LS005

MDSAP: The Medical Device Single Audit Programme

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

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, the EU MDR and the US Quality System Regulation (QSR). The course also deals with the MDSAP audit process and how to prepare for the MDSAP audit.

Note: All manufacturers who sell Medical Devices (class 2 or higher) into Canada from 1st January 2019 onwards must have their Quality Management Systems 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.

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?

Day 1

- Introduction to MDSAP
- Auditing Organizations (AOs) authorised to conduct MDSAP audits
- MDSAP Audit Process:
  - How to apply for MDSAP
  - The Three- Step Audit Approval System
  - Introduction to the Audit Companion Document
  - The New Non-conformance Rating System
  - Audit Approval and Re-certification Timelines
- Advantages and Disadvantages of adopting the MDSAP approach
- Overview of the Requirements for Medical Device Registration and Labelling in Brazil, Australia, Canada and Japan and how these compare to with EU and US medical device regulations:
  - Specific requirements of the Brazilian ANVISA Regulation of Medical Products RDC 185/2001 where these differ from US and European Requirements
  - Specific requirements of the Australian Therapeutic Goods (Medical Devices) Regulations SR 2002 No. 236 where these differ from US and European Requirements
  - Specific requirements of the Canadian Medical Devices Regulation (CMDR) SOR/98/28, where these differ from US and European Requirements.
  - Specific requirements of the Japanese PMD Act 2014 (formerly JPAL) where these differ from US and European Requirements

Day 2

- The similarities and differences between the requirements for Quality Management System Requirements in the various regions:
  - Brazil; ANVISA RDC 16/2013 GMP for Medical Devices and IVDs
  - Australia; Therapeutic Goods (Medical Devices) Regulations SR 2002 No. 236
  - Canada; Canadian Medical Devices Regulation SOR/98/28
  - Japan; PMD Act 2014

How the above relate to ISO 13485 and the US QSR 21 CFR Part 820

- Participation in Mock Audit Scenarios against the Requirements of MDSAP Participant Countries
- How to Prepare for the MDSAP audit

Delegates must attend both days to receive a Certificate of Attendance

Who should participate?

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

What will I learn?

Participants achieve the following learning outcomes from the programme;

- State the key points of the MDSAP approach
- Identify key differences between the regulations from the various jurisdictions involved in MDSAP
- Identify the key Quality Systems requirements necessary for success in the MDSAP audit
- Determine the steps necessary to prepare for the MDSAP audit

Determine key elements to include in an audit programme designed to maintain compliance with the regulations of MDSAP countries

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

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