Medical Device Single Audit Program (MDSAP) Training Course

Learn how to save time and audit costs by conducting a single audit of your medical device quality management system that satisfies the requirements of multiple regulatory jurisdictions.

Through the Medical Device Single Audit Program (MDSAP), medical device manufacturers can perform just one audit of their quality management system to satisfy the standard and regulatory requirements of Australia, Brazil, Canada, Japan and United States.

This 2-day interactive course provides step-by-step guidance to the MDSAP audit approach, noting the specific requirements of participating countries at each stage. It includes a comprehensive and detailed look at tasks throughout the process, and offers delegates an opportunity to test their learning with group exercises. The course is led by a tutor who is both an industry expert and a practised teacher.

COURSE DURATION
2 days

CPD
Equivalent to 14 hours

COURSE PRICE
From £1195 + VAT

DATES & VENUES
View dates & venues

CERTIFICATES
All delegates will receive a certificate on completion.

Course details >

Who should attend?

Those who would benefit from attending an MDSAP training course include:

- quality managers
- quality engineers
- regulatory affairs professionals
- auditors
- anyone responsible for ensuring compliance with medical device regulations and standards, such as: FDA QSR, ISO 13485, and ISO 9001.

Additionally, those who work in quality control, production, design and development, and sterilisation may also benefit from this training.

We recommend that those wishing to attend have some basic knowledge of quality systems and auditing principles, such as ISO 9001 or FDA regulations. However, participants without prior experience can also benefit from the training, as the course will cover the basics of auditing quality management systems for medical devices.

Key topics

Topics covered on the course include:

- history and overview of MDSAP
- audit model
- audit concept
- audit sequence
- audit NC grading
- the companion document
- FDA website
- management process
- device marketing authorisation and facility registration process
- measurement analysis and improvement process
- design and development process
- production and service control
- purchasing
- technical documentation
- audit times considerations
- audit reports, review and assessment

Skills gained

MDSAP training enables attendees to develop essential skills to navigate the complex regulatory requirements of medical device manufacturing.

Skills gained can include:

- regulatory and compliance knowledge
- understanding of MDSAP requirements
- identifying, managing and mitigating risks
- audit preparation and management
- continuous process improvement
- audit data analysis to improve the QMS
- communication and collaboration with stakeholders and across functions
- problem-solving and decision-making

By completing this MDSAP training course, attendees will be well-prepared to support their organisation in achieving and maintaining MDSAP certification, ensuring compliance with international regulatory standards, and driving continuous improvement initiatives.

Course agenda >

Course agenda

Our training courses are designed to optimise the learning experience for delegates both in face-to-face settings and in our Virtual Classroom.

Under the guidance of our expert tutors, attendees will follow an agenda which is briefly outlined below:

- Welcome and Introductions
- Session 1 Overview
- Session 2 Audit Model
- Group Exercises
- Session 3 Management
- Group Exercise
- Session 4 Device Marketing Authorisation and Facility Registration Process
- Session 5 Measurement, Analysis and Improvement
- Group Exercise
- Session 6 Medical Device Adverse Events and Advisory Notices Reporting
- Group Exercise
- Day 1 Review
- Day 1 Summary
- Session 7 Design and Development
- Group Exercise
- Session 8 Production and Service Control
- Group Exercises
- Session 9 Purchasing
- Group Exercise
- Session 10 Technical Documentation
- Session 11 Audit Time Considerations
- Session 12 Audit Reports
- Review and Assessment

In-company training

Ideal for groups, you can receive this course exclusively for your organisation at your premises or online in our user-friendly Virtual Classroom.

Enjoy cost-effective flexibility and personalised learning with tailored messaging designed to address your unique business challenges. Contact us for a quote.

Delegates who complete all elements of the course will receive a certificate of completion.

Thorough explanation of all modules involved whilst keeping it engaging through the use of discussion and workshops.

Endomagnetics Ltd

The tutor was very patient and engaging and made you feel really comfortable learning something completely new.

Vision Rt Ltd

The tutor was excellent at breaking down and explaining a complex subject for all candidates to understand.

2gether Support Solutions

Read our Medical Devices course reviews

Why train with Bywater?

Bywater is the leading independent provider of professional management systems training in the UK.

Our expert training offers practical understanding of how to realise the benefits and assess the success of implementing and operating successful management systems.

Bywater delegates know they can rely on proven training delivered by experts at times and locations to suit their needs.

40 years established

100+ course titles

15 UK locations

1000+ courses annually

Global Virtual Classroom

CQI & IRCA, ISEP, RSS and IOSH approved training provider.

VIEW DATES & VENUES

Booking is easy

Simply select a course date and venue and fill in the online form. View our full range of courses at **www.bywater.co.uk**

If you have any questions please call us on 0333 123 9001, use our online chat or email **contact@bywater.co.uk**

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