



BSI Training Academy

Medical Device Single Audit Program (MDSAP) Fundamentals and Readiness training course

Essential information about the course

The Medical Device Single Audit Program (MDSAP) is an international initiative led by Regulatory Authorities (RA) to implement a program where Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that would be accepted by multiple regulators to address QMS/GMP requirements. Participating RAs include Australia, Brazil, Canada, Japan and the USA.

Our Medical Device Single Audit Program (MDSAP) two day training course is relevant for any size organisation selling medical devices into the participating territories. It will prepare you to host a MDSAP audit and allow you to determine if your own internal Quality Management System

(QMS) processes are consistent with the requirements of the MDSAP audit model for the jurisdictions where your products are marketed.

Our expert tutors will make sure you complete the course feeling confident that you can apply the knowledge as soon as you step back inside your organization.

The course is structured to optimize your learning using our unique approach to accelerated learning, and it will consist of a blend of practical activities, group discussions and classroom learning.

Our course agenda

Day 1

- Benefits to you, welcome and introductions
- Course aim, learning objectives and course structure
- Fundamentals of MDSAP
- Structure and scope of the MDSAP audit program
- MDSAP and other QMS audits
- MDSAP documents
- Management process
- Measurement, analysis and improvement process

Day 2

- Design and development process
- Production and service controls process
- Purchasing process
- Device marketing authorization and facility registration process
- Medical device adverse events and advisory notices process
- Course review and final questions

Book today by visiting bsigroup.com.my/our-services/Training

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We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire skills that will continue to be of use beyond the course.

Make sure this is the right course for you.

This is the course for you if:

- You are a Quality Assurance and Regulatory Affairs professional within a medical device organization currently active in participating territories
- Your organization is expanding their market reach to jurisdictions participating in MDSAP.
- Delegates will benefit from reviewing the MDSAP Companion Document

What is the course like?

- Two days long
- Led by a BSI expert tutor
- Relaxed and comfortable learning environment
- You'll receive detailed course notes to take away

How will I benefit?

- Improve auditing skills focused on regulatory auditing
- Improve competence for MDSAP internal auditors and the support needed to host a MDSAP audit
- Assess your own audit models and suggest improvement
- Be prepared to support an efficient MDSAP audit by your selected Auditing Organization

Why invest in training from BSI?

BSI training courses are delivered by experts with experience in the subject. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples.



Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

Training delivered at your site



This could be a convenient and cost effective option, especially if you have multiple delegates.

Talk to one of our experts to find out more.

Next steps with the BSI Academy



Want to learn more? You may be interested in:

ISO 13485: 2016 Transition and Auditor

Refresher

ISO 13485:2016 Clause by Clause

bsi.

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