IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Medical Device Single Audit Programme (MDSAP)

The Medical Device Single Audit Program (MDSAP) was developed by the International Medical Device Regulators Forum (IMDRF) to conduct regulatory audits of the quality management systems (QMS) used by manufacturers of medical devices. This course will prepare you to host a MDSAP audit within your organisation, and allow you to determine if your own internal QMS processes are consistent with requirements of the MDSAP for the jurisdictions where your products are marketed, or for those markets which you are planning to access.

Format:
Bespoke training

CPD:
12 hours for your records (depending on your requirements)

Certificate of completion

Overview

The Medical Device Single Audit Program (MDSAP) was developed by the International Medical Device Regulators Forum (IMDRF) to conduct regulatory audits of the quality management systems (QMS) used by manufacturers of medical devices.

The MDSAP audit is based on BS EN ISO 13485:2016 *Medical devices – Quality management systems – Requirements for regulatory purposes* - with the applicable regulatory requirements of the participating jurisdictions – Australia, Brazil, Canada, Japan and the USA – included as areas of focus. Audits conducted in accordance with the MDSAP follow a closely prescribed process of defined tasks. An MDSAP audit uses a process approach, based on a foundation of risk management, to select samples of procedures and records to examine. The audit focuses on how risks are identified and addressed.

This course will prepare you to host a MDSAP audit within your organisation, and allow you to determine if your own internal QMS processes are consistent with requirements of the MDSAP for the jurisdictions where your products are marketed, or for those markets which you are planning to access.

Recommended Reading

It is recommended that delegates have access to the MDSAP Audit Guide and ISO 13485:2016 standard prior to attending the course.

Benefits in Attending

- Gain a comprehensive overview of MDSAP
- Enhance your understanding of the MDSAP audit approach
- Recognize how MDSAP supports the regulations in the participating jurisdictions
- Understand the MDSAP processes and their interrelationships
- Learn how to implement the MDSAP audit model

Who Should Attend

- Quality Management System (QMS) specialists
- Regulatory Compliance specialists
- Internal Auditors
- Regulatory and Quality professionals

Reviews

★★★★★

I was hoping to gain a better understanding of the MDSAP requirements, how they are implemented within an organisation, and how they compare with ISO 13485 and other regulatory requirements. The webinar met my expectations and gave me a solid overview of the MDSAP framework and its practical implementation. Stuart was knowledgeable, engaging, and explained the topics clearly. He used practical examples that made the requirements easier to understand and encouraged interaction throughout the session. The overall experience was excellent.

Jills Mathew
Quality & Regulatory Associate
CamDiab
Jun 25 2026

★★★★☆

I was hoping to achieve a global understanding of the logic followed in MDSAP audits and a more precise understanding of the tasks that concern me (marketing authorizations). I believe I now understand this part quite well. the speaker seemed to be very knowledgeable in this area.

Mehdi BENAMEUR
Regulatory Affairs & Registrations
Laboratoires Théa
Jun 25 2026

★★★★☆

Great training. I am now much more informed and confident. Will keep my eye open for other trainings like this.

Rhys Higginson
Regulatory Affairs Specialist
Spectrum Medical
Jun 25 2026

★★★★★

Objective: to get a better understanding of MDSAP requirements was well met by training. Very well put together and delivered. The presenters came across very knowledgeable and experienced, and valuable insight was shared through group discussions. I really liked the structure and pace of the course, and it was suited to my needs.

Sukhjit Sidhu
Quality Assurance and Compliance Specialist
Sterimedix Ltd
Jul 10 2025

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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