IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Medical Device Single Audit Programme (MDSAP)

10-11 July 2025
+ 26-27 November 2025

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:
Live online

CPD:
12 hours for your records

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

Programme

Day 1

Overview of MDSAP

- Background to MDSAP
- Benefits for regulators and manufacturers
- Participating jurisdictions
- Auditing organizations
- Interaction with EU regulations for medical devices

MDSAP audit approach

- MDSAP process sequence
- MDSAP audit planning
- Grading of nonconformities
- Post audit activities
- MDSAP documents

Management process

- Audit tasks
- QMS planning
- Policy and objectives
- Management review

Device marketing authorisation and facilty registration

- Audit tasks
- Marketing authorization
- Facility registration
- Change notification

Syndicate exercise - Management process

- Feedback and discussion

Measurement, analysis and improvement

- Audit tasks
- Data sources
- Investigations
- Nonconforming product
- Post-production information

Adverse events and advisory notice reporting

- Methodologies
- Introduction to threat modeling
- Relation to safety risk management

Syndicate exercise - Measurement, analysis and improvement

- Feedback and discussion

Q & A

Day 2

Introduction and recap of Day one

Design and development

- Audit tasks
- Regulatory requirements for design and development
- Design and development planning
- Risk management
- Design and development processes
- Design and development transfer

Syndicate exercise - Design and development

- Feedback and discussion

Production and service controls

- Audit tasks
- Planning of product realization
- Production control
- Contamination control
- Infrastructure
- Process validation
- Sterile devices
- Monitoring and measuring equipment
- Documents and records
- Handling, storage and delivery

Syndicate exercise - Product and service controls process

- Feedback and discussion

Purchasing

- Audit tasks
- Planning of purchasing
- Purchasing controls
- Supplier selection
- Verification of purchased product

Syndicate exercise - Purchasing

- Feedback and discussion

Wrap up and Q & A

Presenter

Stuart Angell

Stuart Angell is a joint director in his own consultancy specialising in global regulatory affairs strategy and compliance for in vitro diagnostics and medical devices focusing on the transition to the new IVD/Medical Device Regulations, MDSAP and ISO13485:2016.

He has over 15 years in the IVD industry and in previous roles has been responsible for designing, reviewing and maintaining regulatory frameworks for self-declared and annex list II products including technical documentation for EU and global submissions (FDA, Health Canada, TGA, Russia, Latin America). He has an excellent understanding of risk management, Post Market Surveillance (PMS) and vigilance.

Course dates

10-11 July 2025	**Live online** 09:30-17:30 **UK (London)** (UTC+01) *Course code 14803*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 05 Jun**
26-27 November 2025	**Live online** 09:30-17:30 **UK (London)** (UTC+00) *Course code 15105*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 22 Oct**

How to book

Online:
ipi.academy/2463

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★★

Excellent

Amy Wright
Quality Manager Nox Medical LLC
Nox Medical
Mar 27 2023

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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