ISO 13485 Internal Auditor

Acquire the knowledge and skills to carry out effective, value-adding ISO 13485 audits on our ISO 13485 Internal Auditor training course.

This 2-day interactive course will help individuals understand the purpose of the quality management system, and the structure and content of ISO 13485, including its relationship with regulatory requirements such as the European Medical Devices Regulations (MDR) and the USA's FDA Quality System Regulation (QSR). Through a central case study, participants will learn how audits can support the implementation and improvement of a management system and will develop audit skills and techniques to evaluate the conformance and effectiveness of processes.

On completion of the course students will have learned practical and effective auditing techniques and increased their understanding of audit principles, enabling them to audit against ISO 13485 and other important global standards.

COURSE DURATION
2 days

CPD
Equivalent to 14 hours

COURSE PRICE
From £1045 + VAT

DATES & VENUES
View dates & venues

CERTIFICATES
All delegates will receive a certificate on completion.

Course details >

Who should attend?

This course focuses on internal audits but will also be helpful for those conducting supplier audits or preparing for certification/notified body audits. Those who can benefit from attending the course include:

- internal quality management system auditors
- supplier auditors
- medical device professionals
- quality, audit, compliance, and/or regulatory affairs managers
- auditees preparing for certification audits, including:
  - senior management
  - heads of departments
  - process owners

The ISO 13485 Internal Auditor course is designed to build upon delegates' prior knowledge of ISO 13485 and teach them the skills to undertake internal audits of part of a QMS based on ISO 13485.

For those with little or no prior knowledge of ISO 13485 we recommend attending our Introduction to ISO 13485 training course (delivered the day before the Internal Auditor course) to gain an understanding of ISO 13485. We offer a discount of £100 when booking these courses together.

Test your understanding with our ISO 13485 Quiz.

Key topics

Topics covered on the course include:

- overview of quality management systems and the purpose, structure and content of ISO 13485
- what internal audits are and the benefits they can bring
- internal audit requirements of ISO 13485
- medical device requirements
- a structured, step-by-step approach to planning and preparing for an audit
- auditing skills, including:
  - preparing a checklist and sampling plan
  - building rapport with the auditee and creating a constructive environment for the audit
  - questioning, listening and note taking
  - gathering audit evidence and evaluating it against defined criteria/requirements
  - writing clear, concise audit reports
- the correction and corrective action process
- follow up and close out of non-conformances
- overview of Medical Device Regulations including the Medical Device Regulation 2017/745 and Medical Device Regulation 2017/746
- UK MDR
- EU Medical Device regulations overview
- MD SAP (Medical Devices Single Audit Programme), IMDRF (International Medical Device Regulators Forum) and MDCG (Medical Devices Coordination Group)
- placing medical devices on the marking – CE marking, UKCA marking and FDA requirements

Skills gained & 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
- Module 1 Quality Management Systems and ISO 13485
- Module 2 Audit Overview
- Module 3 ISO 13485
- Module 4 Audit Planning
- Module 5 Checklists and Sampling
- Module 6 Medical Device Regulations
- Module 7 USA Regulations and MD Single Audit Programme
- Module 8 Audit Process and Skills
- Workshop 1 Conduct Nebulex Audit
- Workshop 2 Review Case Study
- Module 9 Nonconformity Recording
- Module 10 Corrective Action and Follow Up
- Course Review & Evaluation

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.

Skills gained

By the end of this course ISO 13485 Internal Auditor training course, participants will be able to:

- explain the purpose, structure and content of ISO 13485:2016 Medical Devices
- outline the content of EU MDR and the USA FDA requirements for medical devices and their relationship with ISO 13485
- describe the roles and responsibilities of an auditor
- plan, conduct, report and follow up an internal audit in accordance with ISO 13485
- evaluate conformance of processes to ISO 13485 and related internal and regulatory requirements

Delegates who attend and fully participate in the whole course will receive a certificate of completion, in recognition of their new knowledge and skills in ISO 13485 internal auditing.

Reviews & Booking >

The tutor demonstrated deep knowledge of ISO 13485 and auditing practices. They used real-world examples and case studies to bring the content to life and encouraged active participation. Their delivery made complex topics easy to understand and apply.

Riverside Medical Packaging Ltd

Very knowledgeable tutor, gave interesting examples for the content of the course. Created a positive environment to learn.

James Paget University Hospital

The tutor was exceptionally knowledgeable, professional yet friendly, open and approachable.

Talarmade Ltd

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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