# ISO 13485 Lead Auditor

Learn how to audit a complete quality management system against the requirements of ISO 13485 and associated regulations on this CQI and IRCA certified ISO 13485 Lead Auditor training course.

This ISO 13485 Lead Auditor course provides in-depth knowledge and hands-on experience in auditing medical device quality management systems (MD-QMS).

The 5-day course is designed to provide learners with the knowledge and skills required to perform 1st, 2nd and 3rd-party audits of medical device quality management systems against ISO 13485 and applicable international regulatory standards, in accordance with ISO 19011 and ISO/IEC 17021.

**COURSE DURATION**
5 days

**CPD**
Equivalent to 40 hours

**COURSE PRICE**
From £2195 + VAT

**DATES & VENUES**
View dates & venues

**CERTIFICATES**
All delegates will receive a certificate on completion.

Course ID: 17954

Course details >

## Who should attend?

This course is suitable for those with a wide range of job roles and tasks, including:

- individuals involved in internal, supplier, or certification audits of medical device quality management systems
- managers responsible for leading or managing audit teams
- management representatives or those developing or implementing an MD-QMS
- individuals aspiring to become IRCA-certified MD-QMS auditors

Before attending the course, participants should have a basic understanding of ISO 13485 and quality management systems, and be aware of related regulations. Assess your readiness with our ISO 13485 Quiz.

For those new to ISO 13485, we suggest pairing this course with our Introduction to ISO 13485 training course, available at a discounted rate when booking both courses together.

## Key topics

Topics covered on the course include:

- fundamentals of auditing and the audit process
- PDCA cycle and application to a medical device quality management system
- processes included in a medical device quality management system
- role of the auditor
- documentation and records requirements
- relationship between ISO 13485 and medical device regulations
- related standards, including ISO 14971
- IMDRF Medical Device Single Audit Program
- planning, conducting, reporting and follow up of an audit
- risk-based audits
- auditor responsibilities

## Skills gained

By the end of the ISO 13485 Lead Auditor training course, delegates will have learned how to:

- explain the purpose, requirements and business benefits of a medical device quality management system (MD-QMS)
- plan, conduct, report, and follow-up an audit of a medical device quality management system to establish conformity or nonconformity with ISO 13485 and applicable medical regulations
- explain the role and responsibilities of an auditor to plan, conduct, report, and follow-up a quality management system audit


Following successful completion of the course, delegates with receive a CQI and IRCA Certificate of Achievement.

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
- Course introduction
- Introduction to auditing
- Management systems and ISO 13485
- Processes and process auditing
- ISO 13485 documentation requirements
- Overview of the audit process
- Auditor roles and responsibilities
- Audit meetings
- Stage 1 audit
- Case study: Introduction to the case study
- Evening work
- Learning review
- Case study: Pre audit activity
- Case study: Stage 1 document review
- Stage 2 audit, risk-based audit planning
- Case study: Prepare a stage 2 audit plan
- Audit checklists and sampling plans
- Case study: Checklist and sampling plan preparation
- Evening work
- Learning review
- Performing the audit and audit skills
- Case study: Top management interview
- Case study: Internal communication
- Evaluating audit evidence
- Audit reporting and nonconformities
- Evening work
- Learning review
- Corrective action
- Following up and close out corrective actions
- Case study: Tasks and simulated audits making use of MD-QMS materials and information representative of those that auditors can expect to find in real audits of MD-QMS which are based on ISO 13485
- Evening work
- Learning review
- Planning routine surveillance audits
- Case study: Using a risk-based approach, produce a plan for surveillance audits
- Case study: Present audit conclusions and recommendations to the auditee
- Course review and exam preparation
- Exam

## 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.

The course content was heavily practical rather than simply being a presentation. This made the experience much more engaging.

**Omega Diagnostics Group Plc**

The training was extremely insightful and the workshops allowed me to understand what actually happens during an audit and how auditors reviews documents.

**Early Health Ltd**

Our tutor was very knowledgeable and helpful. They had an incredible ability to break down complex topics into easy-to-understand concepts. Their patience and engaging teaching style made learning enjoyable.

**Dartford And Gravesham NHS Trust**

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**

Bywater