



MD-QMS ISO 13485:2016 Lead Auditor Course

Learn the knowledge and skills required to conduct audits of a Medical Devices Quality Management System (MD-QMS) against ISO 13485:2016. The tutor will teach delegates how to plan, lead and report internal, supplier and external/certification audits.

🕒 5 days - 08.45-17.30 (13.00 finish on last day)

📊 CQI and IRCA training level - Professional

📄 CQI and IRCA ref - PR369 (ATP number 2759)

Who should attend this course?

- Any new or existing auditors that wish to be able to conduct 1st party (internal), 2nd party (supplier) and 3rd party (external/certification) audits of a quality management system (MD-QMS) that conforms to ISO 13485:2016 for medical devices
- Anyone planning, managing or implementing an ISO 13485:2016 medical devices quality management system
- Staff/managers who need to identify gaps in the effectiveness of an ISO 13485:2016 quality management system to help ensure the organisation remains compliant
- Individuals involved in medical devices quality management, regulatory compliance, manufacturing, engineering or device lifecycle management
- This course satisfies the training requirement for anyone wishing to register as an Auditor with IRCA (International Register of Certified Auditors)

Prior knowledge requirements - anyone attending this CQI and IRCA-certified ISO 13485 Lead Auditor course must have existing knowledge of ISO 13485:2016. It is therefore highly recommended that delegates first attend an MD-QMS ISO 13485 Foundation course to secure this knowledge (we offer a £50 discount when booking both courses together).

What will delegates learn on this course?

- The purpose, structure and intent of a Medical Device Quality Management System based on ISO 13485:2016
- MD-QMS requirements, including risk-based processes and regulatory alignment
- Audit types, audit programme design and risk-based audit planning
- Plan, prepare and manage effective audits, including audit scope, criteria and objectives, audit plans and working documents, opening/closing meetings
- Conduct process-based audits using ISO 19011 best practice
- Collect, verify and record objective evidence
- Lead audit teams and apply interview techniques
- Identify, grade and write traceable and compliant nonconformities
- Produce concise, credible and value-adding audit reports
- Follow up audits, verify corrective actions and evaluate effectiveness

Delegates will also gain insight into auditing areas specific to medical devices, such as design and development controls, risk management (ISO 14971), software lifecycle controls (IEC 62304), sterilisation and cleanroom controls, post-market surveillance and complaints, global regulatory expectations and MDSAP considerations.

MD-QMS ISO 13485:2016 specifically requires personnel to be competent – this course provides essential skills and knowledge to help delegates become fully competent auditors.

What is the format of this course?

- This MD-QMS ISO 13485 Lead Auditor training course combines tutor-led sessions and interactive exercises (approx. 25% theory and 75% practical).
- A case study is used throughout the course to assist with practical skills development

What is the course assessment?

- The tutor will assess a delegate's general participation in the course, including any case study activities and audit simulations.
- On the final day, delegates must complete a 2-hour written MD-QMS ISO 13485 lead auditor exam. If the course is taught via a virtual classroom, the exam will be taken remotely – a webcam, microphone and speakers are required for the exam.
- Delegates are required to attend 100% of the course (a CQI and IRCA requirement).

What certificate is provided?

- A CQI and IRCA certificate

What is included in the course fee?

- Pre-course work to help prepare for training (Training Toolkit)
- Delegate training manual
- Case Study documents
- Post-course notes
- CQI and IRCA certificate
- Lunch and refreshments (applicable when training at one of our venues)

This course has the following learning styles available:



In-house
team training



Traditional
Classroom



Scheduled
public course



Live Virtual
Classroom



Why choose Batalas?

Founded in 1962, we have over 60 years' experience providing specialist consultancy and training in ISO/AS Management Systems.