BATALAS® EST. 1962

CQI | IRCA CERTIFIED COURSE

MEDICAL DEVICES

ISO 13485:2016 Lead Auditor Course

Learn the knowledge and skills required to conduct audits of a Quality Management System (QMS) against ISO 13485:2016. The tutor will teach delegates how to plan, lead and report internal (1st party), supplier (2nd party) and external (3rd party) audits.

- 5 days - 08.45-18.15 (13.00 finish on last day)
- CQI and IRCA training level - Professional
- CQI and IRCA ref - PR350 (ATP number 1746)

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) audits of a quality management system (QMS) that conforms to ISO 13485:2016 for medical devices.
- Anyone planning, managing or implementing an ISO 13485:2016 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.
- 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 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?

- Purpose of a Quality Management System based on ISO 13485:2016 for medical devices
- The audit process and types of audit
- Audit scope, criteria and objectives
- The role and responsibilities of an ISO 13485 Lead Auditor
- How to plan, prepare and manage audits
- The opening and closing meetings
- Checklist development and document review
- How to conduct and lead audits
- How to report on audit findings
- Team Leader and interviewing skills

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 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 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.

"We had an excellent trainer, animated, focused and his delivery methods were perfect. I loved the way he made the training so varied, with lots of opportunities to interact. Second to none. Highly recommendable."

Kirsti Parker – Summit Medical Ltd.

ISO 13485 Lead Auditor