



ISO 13485:2016 Internal Auditor Course

Learn the knowledge and skills required to conduct an internal audit of part of a Quality Management System (QMS) against ISO 13485:2016. The tutor will lead informative sessions and interactive exercises, which help to facilitate an engaging learning environment.

🕒 2 day course - 08.45-17.30

📊 CQI and IRCA training level - Practitioner

■ CQI and IRCA ref - PT247 (ATP number 1731)

Who should attend this course?

- New or existing auditors who want to conduct internal audits of a quality management system (QMS) that conforms to ISO 13485:2016.
- Anyone involved in planning or managing an ISO 13485:2016 quality management system.
- People who are implementing an ISO 13485 QMS.
- Anyone who needs to identify potential gaps in an ISO 13485:2016 quality management system – which in turn will help the organisation remain compliant.
- This course satisfies the training requirement for those who wish to register as an Auditor with the IRCA (International Register of Certified Auditors).

Prior knowledge requirements - anyone new to ISO 13485:2016 would benefit from gaining knowledge of the Standard before attending this Internal Auditor course. This prior knowledge can be achieved via our ISO 13485 Foundation course (we offer a £50 discount when booking both courses together).

What will delegates learn on this course?

- The purpose of a Quality Management System based on ISO 13485:2016 medical devices
- Audit scope, criteria and objectives
- The role and responsibilities of an ISO 13485 Internal Auditor
- How to plan and prepare for an audit
- How to develop a checklist
- How to conduct a process audit
- How to report on audit findings
- Developing interviewing skills and techniques

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?

- Informative tutor-led lessons are combined with individual and team-based exercises (approx. 25% theory and 75% practical).
- The use of a case study throughout the course supports the development of auditing skills.

What is the course assessment?

- People will be assessed based on their overall participation in the course, including any interactive activities.
- There will be a short multiple-choice test on the final day of the ISO 13485 Internal Auditor course.
- Delegates are required to attend 100% of the course (CQI and IRCA rules).

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 on a public course 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.

"The course was interesting and engaging as a group and the trainer was really informed. The training manual and course handouts were good and gave us more scope to work on our own trail of thoughts without giving too much away."

Gladwell Kozak – Great Western Hospital, NHS Foundation Trust

ISO 13485 Internal Auditor