



## MD-QMS ISO 13485:2016 Foundation Course

A short, interactive course that is perfect for anyone who needs an understanding of ISO 13485. Delegates will learn the fundamentals of a Medical Devices Quality Management System and the MD-QMS ISO 13485:2016 Standard requirements.

🕒 1 day course - 08.45-17.30

📊 CQI and IRCA training level - Foundation

📄 CQI and IRCA ref - FD132 (ATP number 2427)

### Who should attend this course?

- New auditors who wish to have an understanding of a medical devices quality management system against MD-QMS ISO 13485:2016.
- Anyone who participates in planning or managing an MD-QMS ISO 13485:2016 medical devices quality management system.
- Delegates who plan to book onto an ISO 13485:2016 Internal Auditor or ISO 13485:2016 Lead Auditor course but don't have sufficient knowledge of the Standard.
- People who are implementing an MD-QMS ISO 13485 MD QMS.
- Existing auditors who need refresher training on MD-QMS ISO 13485:2016 or who need to update to the MD edition.

This course contributes to the development of personnel wishing to join the CQI or those wishing to register as an Auditor with the IRCA (International Register of Certified Auditors).

### What will delegates learn on this course?

- Quality management systems, principles and terminology, as applied to Medical Devices
- Interpreting the structure and requirements of MD-QMS ISO 13485:2016
- The Process Approach
- Core business processes for Medical Device manufacturing
- Regulatory compliance
- Medical device risk management

ISO 13485 requires personnel to be competent – this course provides knowledge to enable personnel to have an understanding of the Standard while performing their job role.

### What is the format of this course?

- Combining engaging activities and tutor-led sessions, the course is 25% theory and 75% practical.

### What is the course assessment?

- During the ISO 13485 foundation training, participants will be assessed on their general engagement with the course and involvement in the interactive activities.
- Delegates are required to have 100% course attendance (in accordance with 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
- Post-course notes
- A CQI and IRCA certificate

### 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 very detailed and covered in great depth by the tutor, he always had the time and knowledge to answer any questions put forward and he kept the whole group engaged throughout the day. Top marks!!"*

**Sam Limmack - Orthoplastics**

ISO 13485 Foundation