

### ISO 13485:2016

# Implementation

## 2 Days

You'll be introduced to the concepts needed to understand, develop and implement a Quality Management System (QMS). This course provides the knowledge and process steps to enable the effective implementation of a QMS that is in line with the requirements for ISO 13485:2016 certification.



#### How will I benefit?

This course will help you:

- · Understand how to implement a QMS as required by medical device directives
- Plan the implementation of ISO 13485:2016 within your organization
- Take the first steps towards ISO 13485:2016 certification
- Identify how you can better meet regulatory requirements
- Find ways to increase efficiency and add value through quality management
- Monitor supply chains to achieve continuous improvement



#### What will I learn?

On completion, you should gain the knowledge and skills to:

- Define a quality management system
- Identify the steps for defining, planning, organizing and scheduling necessary activities
- Implement an effective quality management system
- Conduct a base line review of an organization's current position with regard to ISO 13485:2016



#### Who should attend?

Anyone involved in defining, planning, or implementing an ISO 13485:2016 QMS, as well as management representatives and implementation team members.

You should have a good knowledge of ISO I3485:2016 and the key principles of a QMS. If not, we strongly recommend you attend our ISO 13485:2016 Introduction course.

On completion, you'll be awarded an internationally recognized BSI Training Academy certificate.

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