

**ISO 13485:2016****Internal Auditor****Two day course**

An ineffective audit can mean severe consequences; resulting in process failure, patient dissatisfaction and regulatory noncompliance. Optimize your auditing skills with the internationally recognized ISO 13485:2016 and boost your internal audit capabilities. Gain confidence in planning and performing an effective audit, as well as reporting and taking corrective action where necessary.

**How will I benefit?**

- Maintain compliance with ISO 13485:2016
- Improve a global benchmark in quality standards
- Be confident that your organization can rely on competent auditors
- Motivate colleagues through CPD and ensure rigorous regulatory internal processes
- Write factual audit reports and suggest corrective actions.

**What will I learn?**

- Structure and scope of ISO 13485:2016 and how it applies to your organization
- Identify the key principles of auditing/auditor responsibilities
- Plan an internal audit
- Conduct an effective audit based on process identification, sampling and questioning
- Determine if corrective action has been effectively implemented.

**Who should attend?**

Medical device professionals with knowledge of ISO 13485:2016 and individuals interested in conducting first-party or second party audits, management representatives, internal auditors and consultants.

Book this course online by visiting [bsigroup.com/training](https://bsigroup.com/training) or call us today on +44 345 086 9000

# BSI Training Academy

## Agenda

### Day 1

- Welcome & introductions
- Course benefits
- Aims, objectives & structure
- Relationship between ISO 13485, ISO 9000 series & ISO 14971
- ISO 13485 compliance with worldwide regulatory requirements
- Introduction to auditing
- Process approach & process auditing
- Managing an audit programme
- Audit activities
- Auditor competence & responsibilities
- Plan an internal audit
- Creating work documents
- Conducting an opening meeting
- Collecting & verifying audit information
- Audit techniques
- Gathering & verifying information
- Audit findings & nonconformities
- Conducting the audit

### Day 2

- Review of Day 1
- Conducting the audit (Part 2)
- Generate audit findings
- Identify & define nonconformities
- Prepare audit conclusions
- Write an audit report
- Closing meeting
- Conduct audit follow-up
- Course review & questions
- Reflection & feedback

## Our knowledge

We don't just train you to meet standards – we create them. As the world's first National Standards Body and a founding member of ISO, no one knows standards like BSI. Our expert knowledge means a lot and when you train with us, you benefit from this expertise.

## Our tutors

Our tutors are the best in the business. As experienced assessors, they'll transfer the knowledge you need to embed standards into your organization and develop them through continual improvement.

## Our approach

Our high impact accelerated learning approach is proven to fast-track learning by improving knowledge retention and skill application. This course is activity based, resulting in a deeper understanding of material and greater impact on job performance.

## Your expertise

Our training courses will give you the knowledge and skills to embed the standards that matter to you the most. To promote your professional development, you'll receive a personalized BSI Training Academy certificate that's recognized worldwide.

Book today by visiting [bsigroup.com/training](https://bsigroup.com/training)

Kitemark Court, Davy Avenue,  
Knowlhill, Milton Keynes, MK5 8PP  
T: +44 345 086 9000  
E: [training@bsigroup.com](mailto:training@bsigroup.com)