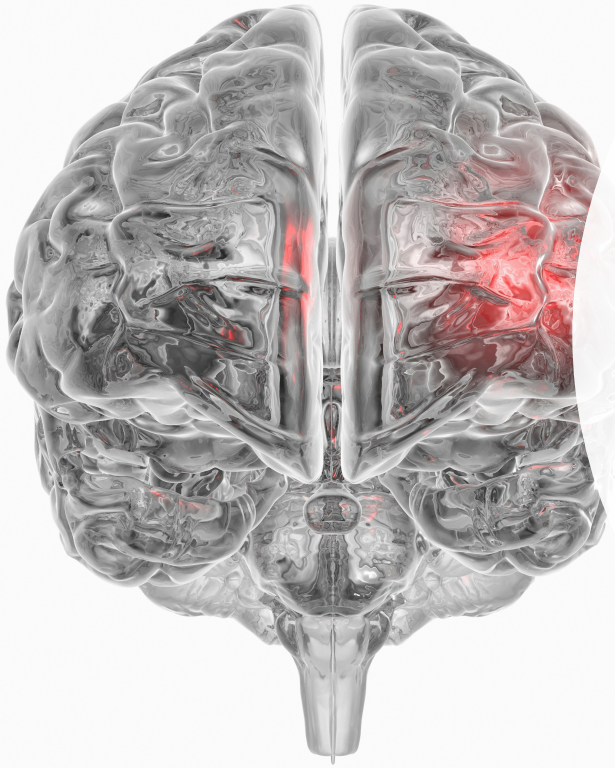
BSI Akademie



ISO 13485:2016

Lead Auditor

2 Days

Develop the knowledge and skill required to conduct a full audit of an organization's Quality Management System (QMS) to ISO 13485:2016.

Gain the confidence to effectively audit a QMS in accordance with internationally recognized best practice techniques. Demonstrate your commitment to the quality of medical devices by transforming existing auditor skills to ISO 13485:2016. Consolidate your expertise with the latest developments and contribute to the continuous improvement of the business.

You'll grasp the key principles and practices of effective QMS audits in line with ISO 13485:2016 and ISO 19011 "Guidelines for auditing management systems". Using a step-by-step approach, you'll be guided through the entire audit process from initiation to follow-up. Over 5 days, you'll gain the knowledge and skills required to undertake and lead a successful management systems audit. Learn to describe the purpose of an ISO 13485:2016 QMS audit and satisfy third-party certification. Acquire the skills to plan, conduct, report and follow up a QMS audit that establishes conformity and enhances overall organizational performance.
On completion, you'll be awarded an internationally recognized BSI Training Academy certificate.

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.

Book now bsigroup.de/akademie/medical-device
or give us a call +49 (0) 69 2222 89 299

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...making excellence a habit.™

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How will I benefit?

This course will help you:

- Identify the aims and benefits of an ISO 13485:2016 audit
- Interpret ISO 13485:2016 requirements for audit application
- Plan, conduct and follow-up auditing activities that add real value
- Grasp the application of risk-based thinking, leadership and process management
- Access the latest auditor techniques and identify appropriate use
- Build stakeholder confidence by managing processes in line with the latest requirements
- Understand the arrangements for BSI certification

What will I learn?

You will learn to:

- Gain the skills to plan, conduct, report and follow up an audit in accordance with ISO 19011
- Identify the purpose and benefits of an ISO 13485:2016 QMS
- Explain the role of an auditor to plan, conduct, report and follow up an audit in accordance with ISO 19011 (and ISO 17021 where appropriate)

Who should attend?

Anyone with the need to audit an organization's ISO 13485:2016 QMS.

Book now
bsigroup.de/akademie/medical-device

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

A written exam will be conducted at the end of the course to test your knowledge and skill.