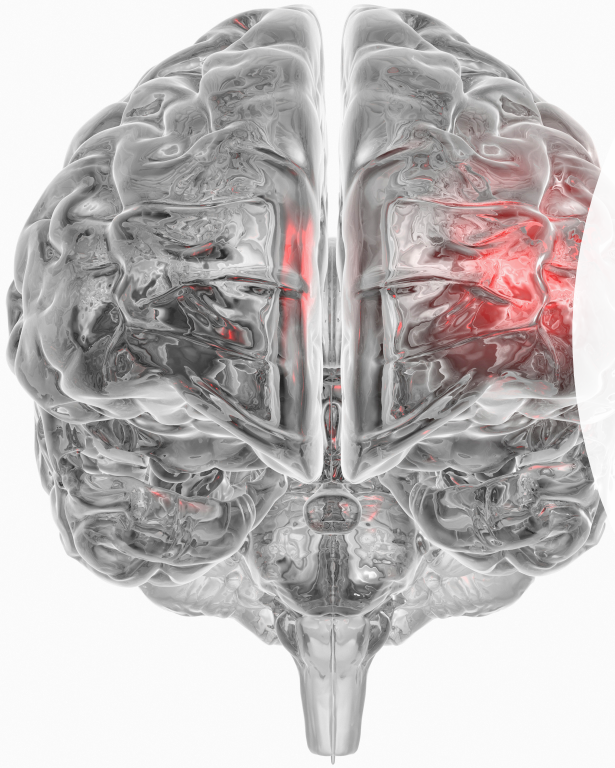
BSI Akademie



ISO 13485:2016

Internal Auditor

2 Days

Learn how to audit the processes of an ISO 13485:2016 Quality Management System (QMS). This course provides guidance and practical experience in planning, executing, reporting and audit follow-up of an internal audit when monitoring the effectiveness and conformity of a ISO 13485:2016 compliant QMS.

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 I3485:2016 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.

This course is intended for medical device quality professionals wishing to build on their current knowledge of ISO 13485:2016 and evaluate the effectiveness of their QMS. It teaches the principles and practices of effective audits in accordance with ISO 13485:2016 and ISO 19011:2011. On completion, you'll be awarded an internationally recognized BSI Training Academy certificate.

Our high impact accelerated learning approach increases learning by improving knowledge retention and skill application. This course is activity-based, resulting in a deeper understanding of the material and a 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:

- 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

Who should attend?

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

What will I learn?

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

- Communicate the key requirements and concepts within the Regulation
- Reference the necessary aspects to evaluate if and how your company is affected by MDR and to what extent (e.g. what products, roles, activities)
- Understand the vocabulary used within MDR
- Explain the structure and administration of the Regulation
- Recognize partners of manufacturers affected by the Regulation
- Describe key steps of Conformity Assessment

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 or Clause by Clause course.

Book now

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