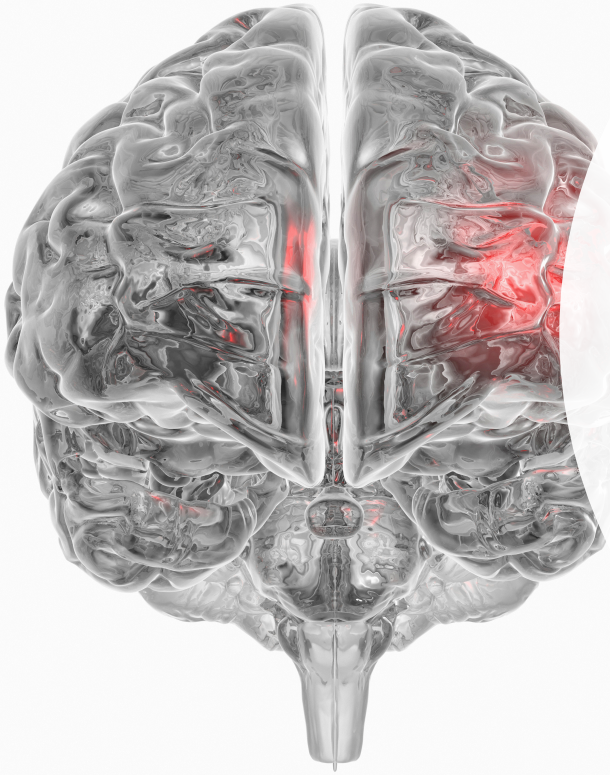
BSI Akademie



ISO 13485:2016

Clause by Clause

2 Days

To address the requirements of Medical Device Directives, manufacturers must demonstrate their commitment to the safety and quality of their medical devices. This course enables a clause by clause understanding of ISO 13485:2016, which provides an effective solution to meet the comprehensive requirements of an effective QMS. Learn to apply your knowledge to the development of an ISO 13485:2016 compliant QMS and maintain the on-going certification of your organization.

How will I benefit?

This course will help you:

- Describe the requirements and structure of ISO 13485:2016
- Interpret and apply requirements relevant to your organization
- Appreciate how a QMS can be applied as a framework to produce safer medical devices
- Evaluate how requirements can be effectively implemented to meet and maintain regulatory compliance

What will I learn?

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

- Explain the scope and the structure of ISO 13485:2016
- Describe the requirements of ISO 13485:2016
- Explain how to interpret the requirements of the standard within your organization
- Develop your knowledge of how the requirements of ISO 13485:2016 are established and maintained in an organization
- Identify the systems that are required to implement an ISO 13485:2016 QMS in order to gain or maintain certification to ISO 13485:2016

Who should attend?

Senior management, quality managers, regulatory affairs managers, internal and external auditors, consultants and anyone involved with the implementation of the standard.

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

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