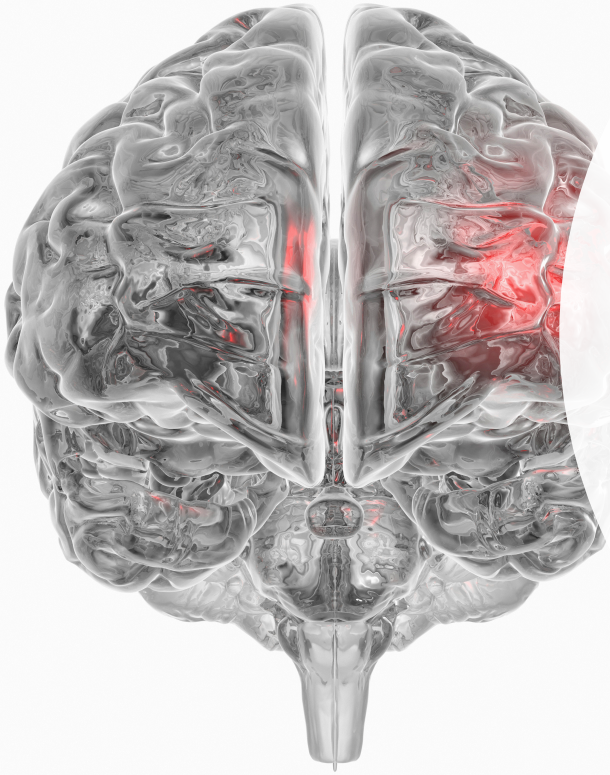
BSI Akademie



ISO 13485:2016

Introduction

1 Day

This course explores the requirements of the ISO 13485:2016 Quality Management System standard, discussing key principles and how the standard interacts with ISO 9001:2015, the European Medical Device Directives and US FDA's Quality System Regulation. The relationship with ISO 14971 'Application of Risk Management to Medical Devices' is also explored during the course.

How will I benefit?

This course will help you:

- Take the first steps towards ISO 13485:2016 certification
- Understand how you can better meet regulatory requirements leading to increased patient safety
- Find ways to increase efficiency and cost savings through quality management
- Monitor supply chains to achieve continuous improvement
- Develop safe and effective medical devices
- Motivate employees through CPD

What will I learn?

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

- Explain the use of ISO 13485:2016 as the basis for a QMS for medical device manufacturers
- Identify the relationship between ISO 13485:2016 and European Medical Device Directives
- Recognize the use of ISO 13485:2016 as the basis of regulatory requirements worldwide

Who should attend?

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

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