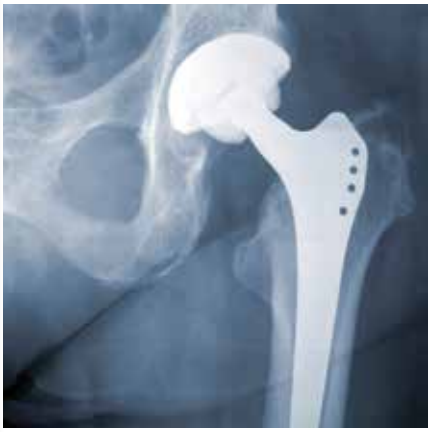
QUALITY

RISK MANAGEMENT



COMPETITIVE ADVANTAGE

EXPERTISE

FURTHER EXCELLENCE

KNOWLEDGE

REGULATORY COMPLIANCE

RECOGNITION

QUALIFICATION

E-LEARNING PROGRAMMES FOR ISO 13485:2016

ONLINE TRAINING SOLUTIONS FOR MEDICAL DEVICE PROFESSIONALS

SGS ACADEMY

In partnership with

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SGS

SGS ACADEMY and the World Medical Device Organisation (WMDO) offer a programme of more than 200 e-learning sector-specific professional courses. The WMDO learning portal, medical device industry's most trusted source for professional online training, consists of an unparalleled range of courses. These are suitable for regulatory affairs, quality, marketing and commercial, clinical, manufacturing and design staff within organizations of any size.

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ISO 13485:2016 – MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR REGULATORY PURPOSES

This course introduces the updated 2016 version of the ISO 13485: "Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes," the international reference standard for quality systems for medical device manufacturers in regulatory systems across the globe.

This course covers the following topics:

- Basic principles of ISO 13485:2016
- A step-by-step guide of ISO 13485:2016 requirements
- Detailed explanations of each requirement and quality system links between the requirements

Get up-to-date and log-on to this online course which will provide you with practical insights of the latest requirements with regards to quality management systems.

Cost: € 360 - For volume rebate proposals, please contact us.

HOW TO NAVIGATE THE ISO 13485 CERTIFICATION PROCESS

This course explains the quality system certification process for medical device manufacturers who wish to obtain ISO 13485 certification. It briefly examines the aspect of use of ISO 13485 in Europe for requirements from the Medical Device Directive.

The course also provides a step-by-step guide through the certification process, starting with manufacturers who already have a compliant quality system in place. It explains the role of certification bodies and accreditation requirements, and discusses which elements to take into account when choosing a certification body. Additionally, the course examines the steps of the certification process and the maintenance of the certification once it is obtained.

With regard to the European regulatory system, this course also explores the specific requirements of the MDD covered by the ISO 13485 system and additional aspects for CE certification reviews.

Cost: €176 - For volume rebate proposals, please contact us.

ISO 14971 INCLUDING AN UPDATE ON THE 2012 VERSION

This program provides a comprehensive review of the basics of risk management, including the requirements outlined in the ISO 14971 standard.

It covers the following topics:

- Practical setup of risk management files
- Explanation of the different techniques to apply to risk management files
- How to integrate risk management into quality systems
- Overview of the implications of the ISO 14971: 2012 version

Cost: € 218 - For volume rebate proposals, please contact us.

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WHEN YOU NEED TO BE SURE

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