ISO 14971:2019 Risk Management for Medical Devices Introduction Training Course

COURSE DESCRIPTION

The purpose of this course is to familiarise learners with an overview of ISO 14971:2019 Medical Devices — Application of risk management to medical devices and the differences between the 2012 and 2019 version.

DURATION: 1 Day 8 hours	ACCREDITATION: SGS
DELIVERY: Face to Face VILT	LANGUAGE: English

"FOR MEDICAL DEVICE PROFESSIONALS"

LEARNING OBJECTIVES

Upon completion of this course, learners will be able to:

- Identify the key elements required for management of medical device risk as specified in ISO 14971:2019
- Identify the key changes in the third edition of ISO 14971:2019
- Explain at what stage in the process each of their Medical Devices is within the lifecycle of risk
- Gain an awareness of how to perform a Product Risk Assessment
- Explain the risk management requirements for Usability
- Identify the differences between the Directives and EN ISO 14971:2012 (Annex Z), and why they remain applicable

AUDIENCE

This course is designed for:

- Medical professionals involved in the development and implementation of ISO 14971:2019 Risk Management for Medical Devices

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COURSE CONTENT

- Introduction to ISO 14971:2019
- Planning for risk management
- Risk analysis and evaluation
- Risk control
- Usability and risk management
- Report and post-production information

PRIOR KNOWLEDGE

It will benefit learners if they have a knowledge of the following principles and concepts:

- Experience and knowledge of quality management systems for medical devices and medical device development
- Basic awareness of quality assurance and ISO 13485:2016

COURSE CERTIFICATION

On completion of this course:

- Learners will be issued with a "Certificate of Attendance"

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