ISO 14971 and ISO 31000 Medical Devices Risk Management for Product and Process Training Course

COURSE DESCRIPTION

This course provides a comprehensive introduction to the key elements of Risk Management for Medical Devices, using the harmonised standard ISO 14971:2019, and aims to give delegates a practical foundation in the relationship between risk management, the regulatory requirements and their Quality System.

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

"DESIGNED FOR MEDICAL DEVICE AUDITORS."

LEARNING OBJECTIVES

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

- Understand the key elements required for management of risk as specified in ISO 31000:2018
- Understand the key elements required for management of medical device risk as specified in ISO 14971:2019
- Gain an awareness of how to perform a Product Risk Assessment
- Gain an awareness of how to perform a Process Risk Assessment
- Gain an awareness of risk management requirements for Usability
- Gain an awareness of the differences between the Directives and ISO 14971 (Annex Z)

PRIOR KNOWLEDGE

You are expected to have basic knowledge of ISO 13486:2016 and risk management systems before attending.

COURSE CERTIFICATION

On completion of this course you will receive a Certificate of Attendance.