COURSE

RISK MANAGEMENT ISO 14971

From the perspective of ISO 14971 for the management of risks for medical devices, this course seeks to provide the student with an understanding of the risk management process from the identification of hazards to its connectivity with the application and evaluation of risk in the manufacturing process.

COURSE CONTENT

1. What is Risk and the importance for medical devices.
2. General Requirements for Risk Management System (Structure).
3. Risk Management Process.
4. Risk Assessment and Identification.
6. Risk Control.
7. Residual Risk Evaluation.
8. Reporting.
9. Production and Post-Production Activities.
10. Application to Process FMEA.

Duration
6 hours

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

At the end of the course you will be able to

- Understand the impact that ISO 14971:2019 has on the decision-making process when manufacturing medical devices.
- Understand the elements associated with maintaining the risk management process.
- Understand key concepts such as harm, hazards and hazardous situations and its linkage to device risk assessment.
- The application of risk management to process and its connection with device performance and hazards.
- Understand how risk management relates to the product lifecycle.