Risk Management Fundamentals

Course description

The objective of this course is to level and harmonize risk management knowledge for the entire population using risk documents within the context of the medical device industry. Through hands-on activities and case studies, students will gain valuable experience in real-life risk situations.

At the end of the course you will able to:

- Understand the notion of risk and its relevance in the context of the medical devices industry.
- Become familiar with the legal and regulatory requirements related to risk management in the medical field.
- Learn the key terms and definitions related to risk management, establishing a solid knowledge base.
- Explore the principles and guidelines of ISO 14971:2019, which is used for risk management in medical devices.
- Learn about common tools used to control and mitigate risks associated with products and production processes.
- Learn how to effectively maintain and update risk documentation to ensure it is current and accurately reflects the current situation.
- Understand how to assess and manage residual risk in a global context, taking into account all factors involved in medical devices risk management.

Main topics

1. What is Risk and the importance for medical
2. Regulatory Requirements for Risk Management
3. Key Terms and Definitions
4. Overview of ISO 14971:2019
5. Typical Product and Production Risk Control Tool
6. Risk Documents Sustaining and Update
7. Overall Residual Risk

Course features

- Instructor Led
- Duration: 9 hours
- Tools and templates
- Applied learning
- Course certificate

Contact

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