Risk Management for Practitioner

Course description

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.

At the end of the course you will able to:

- Understand and comply with regulatory requirements such as ISO 13485:2016, Medical Device Directive (MDR), and FDA - 21 CFR 820, ensuring adherence to industry standards.
- Create comprehensive risk management plans, covering key elements like risk analysis, evaluation, and estimation, in accordance with ISO 14971:2019.
- Design and apply risk controls for both product and production, utilizing methodologies like Preliminary Hazard Analysis, Hazards Analysis, and Use FMEA.
- Apply ISO 14971 and software-specific standards to manage risks associated with medical device software, considering factors such as FDA Level of Concern and cybersecurity.
- Understand the principles of sustaining risk management systems, including management reporting, production, and post-production activities, and effectively manage feedback from various sources.
- Evaluate overall residual risk and perform benefit-risk analysis to make informed decisions regarding the safety and efficacy of medical devices, considering individual and overall risk factors.

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. General Requirements for Risk Management System
6. Risk Analysis and Evaluation
7. Product and Production Risk Controls
8. Sustaining The Risk Management System
9. Overall Residual Risk
10. Benefit-risk analysis
11. Medical device software risk management
12. Application of ISO 14971 and Software specific standards

Course features

- Instructor Led
- Duration: 16 hours
- Tools and templates
- Simulated learning
- Course certification

Contact

www.smdlearning.com

info@smdlearning.com

+506 8544 7000

Costa Rica