Medical Device - Risk Management (ISO 14971:2019)

The aim of this seminar is to provide concise but complete knowledge and skills required for medical device risk management, according to ISO14971:2019.

How will I benefit?

- You will know the basics of risk management for medical devices based on the ISO 14971:2019 standard.
- You will be able to correctly implement the risk management process in your company.
- You will know the objectives of the risk management plan, how to proceed with the risk analysis and how to properly document results.
- Enables greater understanding of the impact that ISO 14971:2019 has on the decision-making process when manufacturing medical devices.
- Provide medical device manufacturers with knowledge of how ISO 14971:2019 links with the ISO 13485:2016 standard and the MDR 2017/745.
- Practical activities will give you the opportunity to apply your skills, so that these can be embedded within your organization on completion of the seminar.

Target Audience

- Junior Regulatory Affairs professionals
- QA Engineers with medical device experience
- Medical device project team members
- Medical Device Engineers
- Entrepreneurs or small and medium start-up companies intend to develop a new medical device

Link to Syllabus

Certification seminar

For more information
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