Risk Management for Medical Devices

Code: RIS1
Type: Workshop
Time: 16 Horas

Objective:

- By attending this course, participants will be able to apply concepts and requirements of Risk Management process established in ISO 14971:2019 and ISO 13485:2016 standards that apply in product realization processes and other processes of a Quality Management System.

Audience:

- Professionals and technicians of Design, Development, Production, Materials or Quality who need to know about the risk management process
- Professionals of other disciplines, faculty staff and students who need to have this knowledge.

Contents:

- Definitions and key terms
- Regulatory framework of Risk Management
- ISO 14971:2019 standard review
- The Risk Management process
- Risk Analysis
- Risk Assessment
- Risk Control
- Production and post-production information
- Risk Management in other processes of Quality Management System—ISO 13485
- Tools used in Risk Management

Methodology:

- The course is a combination of keynote presentations, individual and group exercises and application examples.

Equipment and materials

- Computer with MS Office, MS Teams and Internet for virtual mode

Contact us for more details:

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