COURSE PACKAGING AND LABELING

Packaging and labeling design for the medical device industry is a complex and highly regulated knowledge area. This course helps students to understand the standards and regulations that apply to the packaging and labeling design, the necessary steps for design and testing, sterilization options and implications, materials and other main concerns for this interesting topic.

COURSE CONTENT

1. Overview and Quality System (ISO 11607)
2. Regulations (EU MDR)
3. ASTMs and ISTA Standards
4. Design Inputs – Outputs
5. Sterilization
6. Distribution Testing
7. Packaging Materials
8. Packaging Process, Labeling & UDI

Duration
24 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 different standards for the packaging and labeling design in the medical devices industry.
- Comprehend the established requirements by the regulatory organizations for the packaging and labeling design in the medical device industry.
- Understand the expected outcome from the packaging and labelling design process and the input required to properly perform this process.
- Compare the different sterilization options accepted by the standards and regulatory organization and understand the related packaging design considerations.
- Learn how the tests distribution represents a challenge for packaging design in the medical device industry.
- Identify the packaging materials options and their implications for the device protection and manufacturing process.