



Product Design Controls

Course description

The course focuses on providing the student with a robust knowledge of design controls for medical devices according to international regulations and standards.

Throughout the course, students will engage in hands-on learning experiences, applying their knowledge of the design control process (planning, inputs/outputs, review, verification and validation) in the medical device industry, ensuring regulatory compliance and addressing real-world challenges.

At the end of the course you will able to:

- Understand the steps and controls that involves the medical devices design.
- Associate the steps in the medical devices design process to the regulation and standards requirements.
- Articulate an appropriate design process for a medical device.
- Assess changes proposed to a medical device, based on the regulations and standards requirements.

Main topics

- 1 General Process Overview.
- 2 Design Planning.
- 3 Design Input/outputs.
- 4 Design Reviews.
- 5 Design Verification.
- 6 Design Validation.
- 7 Design Transfer.

Contact

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Course features

- Instructor Led 
- Duration: 24 hours 
- Tools and templates 
- Simulated learning 
- Course certification 