



# Introduction to Design Controls

## Course description

The objective of this course is to provide the students with a basic understanding of design controls for medical devices according to international regulations and standards.

Participants will also gain an understanding of how to align the steps in the medical device design process with regulatory and standards requirements, which are essential to ensure that the final product meets quality, safety, and compliance criteria.

### At the end of the course you will be able to:

- Understand the steps that involve the medical devices design process and control.
- Associate the steps in the medical devices design process to the regulation and standards requirements.
- Analyze how the changes proposed in the manufacturing process would impact the approved device design and their implications.
- Successfully interact with the design team, and how to expedite projects that require this interaction.

## Main topics

- 1 General Process Overview.
- 2 Design Planning.
- 3 Design Inputs / Outputs.
- 4 Design Review.
- 5 Design Verification.
- 6 Design Validation.
- 7 Design Transfer.

## Contact

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## Course features

Instructor Led 

Duration: 4 hours 

Tools and templates 

Simulated learning 

Course certification 