COURSE

INTRODUCTION TO MEDICAL DEVICES INDUSTRY

The objective of this course is to provide students with an overview of the history and facts of medical device industry, types of medical device products (classification), general regulatory concepts, and understanding of product market process submission.

COURSE CONTENT

1. **Definition of Medical Devices.**
2. **Regulatory Environment and Classification of Medical Devices.**
3. **FDA Registration Process for Medical Devices.**
4. **Overview Applicable Regulations and Standards.**

Duration
Access to the course for six months

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

COURSE

INTRODUCTION TO MEDICAL DEVICES INDUSTRY

At the end of the course you will be able to

- Gain an immersive understanding of the medical device industry, history and relevant facts and how they compare to other non-regulated industries.
- Learn about the different device classifications per USA FDA and EU MDR.
- Conduct a search to identify a product classification based on the medical specialty per FDA definition.
- Understand about the FDA product submission and registration for 510k, De Novo, PMA, HDE, IDE and EUA.
- Learn and distinguish between the concept of a standard (horizontal/vertical) and a regulation for the medical device industry.
- Recognize the applicable standards and regulations associated to Quality System Regulation to the quality for FDA 21 CFR Part 820 and ISO 13485.