Introduction to Medical Devices Industry

Course description

The objective of this course is to provide students with a comprehensive understanding of the medical devices industry, including an overview of its historical evolution and understanding the categorization of medical device products, considering criteria from both the USA FDA and EU MDR.

Participants will also gain an understanding of general regulatory principles, the FDA's product submission and registration processes, and explore the relevant standards and regulations related to Quality System Regulation.

At the end of the course you will 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.

Main topics

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.

Course features

- Instructor Led
- Duration: 4 hours
- Tools and templates
- Simulated learning
- Course certification

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