21 CFR 820 - FDA Quality System Regulation

Course description

The objective of this course is to provide the students with top to bottom understanding of the 21 CRF 820 regulation and the interpretation clause -by clause of this regulation for a medical device manufacturer.

Throughout the course, students will engage in hands-on learning experiences, applying their knowledge of FDA Quality System Regulation requirements to tackle real-world case scenarios typical of the medical device industry.

At the end of the course you will able to:

- Understand the importance, purpose, and the framework of general requirements for the design and manufacture of medical devices per FDA 21 CFR Part 820 regulation (QSR).
- Know key factors to comply and maintain compliance to the QSR.
- Understand how the company's quality management system fulfils and is connected to the FDA QSR.
- Learn the general requirements from all Sub-parts of 21 CFR Part 820 and how they correlate to the company quality system to support day-to-day activities.
- Experience and apply FDA QSR requirements to solve in class real case situations that could be faced by a professional in this industry and to maintain compliance according to the standards.

Main topics

1 Overview.
2 Subpart B — Quality System Requirements.
3 Subpart C — Design Controls.
4 Subpart D — Document Controls.
5 Subpart E — Purchasing Controls.
6 Subpart F — Identification and Traceability.
7 Subpart G — Production and Process Controls.
8 Subpart H — Acceptance Activities.
9 Subpart I — Nonconforming Product.
10 Subpart J — Corrective and Preventive Action.
11 Subpart K — Labeling and Packaging Control.
12 Subpart L — Handling, Storage, Distribution, and Installation.
13 Subpart M — Records.
14 Subpart N — Servicing.
15 Subpart O — Statistical Techniques.

Course features

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

Contact

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