COURSE

21 CFR 820 – UNDERSTANDING OF FDA QUALITY SYSTEM REGULATION FOR MEDICAL DEVICES

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

COURSE CONTENT

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.

Duration
4 hours

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
After successful course completion

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COURSE CONTENT

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.

Duration
4 hours

E-learning platform
Tools and templates

Hands to work
Simulated learning

Certification
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At the end of the course you will be able

- 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).
- 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.