Medical Devices Quality System Requirements Course

This course will review the fundamentals of how to establish a Culture of Quality and build a Quality System According to ISO 134852016 and 21CFR820, including Document and Record controls (DHF, DMR, DHR, QMS records), Management responsibility, Resource management, Quality review, Purchasing controls, Evaluation, and selection of suppliers, Acceptance sampling inspection principles, Design control, Production & service control, and Measuring equipment control.
Including Principles for statistical sampling selection.

How will I benefit?

The real benefit is that the course **will save you time** by understanding quality and regulation requirements in simple terms and practical examples according to 2016:ISO13485 and 21CFR820.
This course was developed by Gsap Quality and Regulatory Affairs professionals currently working in the industry, so this course focuses on the most common issues and questions we receive from medical device manufacturers placing products.

Target Audience

- Junior Quality/ Regulatory Affairs professionals
- QA Engineers with medical device experience
- Medical device project team members
- Medical Device Engineers
- Entrepreneurs or small and medium start-up companies intend to develop a new medical device.
- Marketing teams within the medical device industry

Link to Syllabus

Certification seminar

For more information
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