Understanding FDA's QSR (Quality System Regulation) for Medical Devices Industry

Code: QSR
Type: Seminar
Time: 8 hours

Objective:

Understand the requirements of FDA´s Good Manufacturing Practices (GMP), known as Quality System Regulation applicable to Medical Devices.

Audience:

- Managers, professionals, technicians and other staff of medical device manufacturing plants.
- Quality, Regulatory Affairs and Regulatory Compliance professionals and technicians.
- Current or potential suppliers of medical device manufacturers.
- People who do not work in the medical device industry and would like to.

Contents:

- Regulatory map of the United States for medical devices.
- FDA´s definition and classification of medical devices.
- Introduction to the Quality System Regulation.
- General Provisions.
- Requirements of the Quality System Regulation - Realization processes.
- Requirements of the Quality System Regulation - Quality system´s support processes.

Mode:

- Face-to-face or virtual

Methodology:

- The seminar is a combination of presentations and class exercises to reinforce learning.

Equipment and materials:

- No equipment or materials are required.

For additional information, contact us:

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