Introduction to FDA 21 CFR 820 Quality System Regulations

Course Description
The one day course Introduction to the FDA Quality System Regulations for Medical Devices, provides an overview of the purpose of the regulations and how to build and implement a quality system that meets and exceeds the requirements of the regulation. The goal is to build a quality system that becomes a business system that provides value beyond compliance with basic regulations. Participants will gain an understanding of the value of a quality system as a key element of a successful business model.

Learning Objectives
On completion of the training, participants will be able to:

- Understand the scope and use of 21 CFRR 820 as basis of Medical Device Regulations Worldwide
- Recognize the role and responsibilities of management, R&D, operations, and sales and support elements in an effective and well-run quality system

Examination or testing
During the course cases are used to verify the gained knowledge.

Program overview
- Authority and scope of the FDA
- Introduction to 21 CR 820
- QSIT approach
- Documentation of a Quality Management System
- Responsibilities of Management
- Management of resources
- Product realization
- Measurement, Analysis and Improvement
- Questions & Answers
- Evaluation of the course and Closing

Who should attend
- Senior Management
- Quality Managers
- Regulatory Affairs Managers
- Internal and external Auditors
- Anyone involved with the implementation of a quality system

The number of participants is maximized to twelve to provide a stimulating and practical working environment.

Level
There is no prerequisite for this course but participants will benefit from a basic knowledge of quality management systems, e.g. ISO 9001 or ISO 13485

Duration
1 day.

Training material
Course notes are provided on a USB stick.