



## **21CFR820 Quality System Regulation**

### **Course Overview**

21CFR820 is required for companies that design, manufacture and sell Medical Devices in the United States. If you need a comprehensive overview of the QSR, then this course is for you. An overview of the QSR requirements will be provided and compared to other Quality Management System standards. Hands on working sessions will be used to dissect and interpret the requirements. Discussions on when compliance is required or desirable will be made. Information on implementation and steps towards complying with the QSR will be provided.

### **Course Objectives**

After attending this 8-hour workshop, you will:

- Know when and how to implement your Quality System
- Be able to share your understanding of the QSR and related standards with others
- Understand the other standards that the FDA requires you to comply with
- Know who needs to be compliant
- Understand the details and intent of each requirement
- Know what is needed to become and stay compliant