

ISO13485:2015 for Healthcare Industry

The ISO 9001:2015 Standard has been revised to better address the Healthcare/Medical industry. Find out how this powerful, proven process approach model can be used to help you get the most out of your Quality System. Case studies and examples specifically focus on the health care and medical device industry. The ISO13485:2015 standard documents the specific requirements above those in ISO9001:2015. Workshops in this seminar focus on identifying and addressing your organization's key goals and challenges, to help ensure you receive significant bottom line improvements.

Hours: 8 a.m. – 4 p.m.

Length: Two days

Course Objectives

Participants will learn:

- What the process approach is and why it's important
- What are the significant differences in ISO9001:2015?
- The benefits of managing process as systems
- How employees fit into a typical Quality Management System.
- What role do employees play in maintaining the Quality Management System?
- What role do employees have in developing a Quality Management System?

Who Should Attend:

Manager, team leaders and others directly involved in the design, evaluation or implementation of a quality system to the new ISO 9001:2015 standards.

Related Seminars:

- ISO 9001:2015 Internal Quality System Auditing
- ISO9001:2015 Overview
- PFMEA
- DFMEA



Seminar Content

The Process Approach

- Why the Process Approach
- Processes, Activities and Quality
- Benefits of the Process Approach

Introduction to ISO 9001:2015 and the Seven Quality Management Principles

- The Structure of ISO 9001:2015
- The ISO 9001 Series

4 Context of the organization

- Organizational requirements
- Documentation requirements

5 Management requirements

- Commitment requirements
- External requirements
- Policy requirements
- Planning requirements
- Managerial requirements
- Review

6 Resource requirements

- Allocation requirements
- Personnel requirements
- Infrastructure requirements
- Environment requirements

7 Realization requirements

- Planning requirements
- Customer requirements
- Development requirements
- Purchasing requirements
- Production requirements
- Measurement Requirements

8 Remedial requirements

- Planning requirements
- Research requirements
- Product requirements
- Analytical requirements
- Improvement requirements

9 Performance evaluations

- Monitoring, measurement, analysis and evaluation
- Internal Audit
- Management review

10 Improvement

- General
- Nonconformity and corrective action
- Continual improvement