



# Quality Systems Compliance L.L.C.

Your compliance partner...

## TRAINING COURSE OVERVIEW

**Topic:**

ISO 13485:2016 System Overview Training Agenda

**Course Description:**

This course is intended to provide an overview of the ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing, and final decommissioning and disposal of medical devices.

This course can be used to formally document training to the ISO 13485 International Standard for internal auditors and external (supplier) auditors.

**Course Topics:**

- Discuss the history of ISO Standards
- Evaluate the Seven Quality Management Principles
- Understand the process approach
- Understand risk-based thinking
- Identify and discuss common risk management tools
- Identify and discuss the ISO 13485 clauses including best practices

**Duration:**

1 Day (8 hours)

**Location:**

TBD

**Audience:**

Internal Auditors  
External Auditors  
Directors  
Managers  
Supervisors  
Engineers  
Technicians  
Inspectors

**Other:**

Participants will be administered a pre-test proficiency assessment as well as a post-test knowledge assessment.

A certificate of completion will be issued for each course participant.

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## Contact:



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