☑ Quality Systems Compliance L.L.C.

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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.

Contact:

Mark Durivage, Managing Principal Consultant and Member
mark.durivage@qscompliance.com
www.qscompliance.com
419-265-2862

Quality Systems Compliance LLC

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