MAKING BOTTOM LINE IMPACT

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QMS Lead Auditor for ISO 13485:2016

Course No. 106A
Participants will learn how to audit and lead an audit team including how to assess compliance to ISO 13485:2016 and understanding how to plan, conduct, follow-up on, and work with audited organizations to ensure efficient and effective audits. Participants gain necessary auditing skills through formal class work, role playing, group workshops and open forum discussions.

Course Benefits
Attendees will learn how to audit including how to assess compliance to ISO 13485:2016 and understanding how to plan, conduct and lead/manage audits, follow-up on, and work with audited organizations to ensure efficient and effective audits. Students gain necessary auditing and Lead Auditor skills through formal class work, role playing, group workshops and open forum discussions.

Prerequisites
Knowledge of QMS, relevant work experience, auditing training.

Duration
Four days (28 hours)

Learning Objectives
At the end of this course, participants will be able to:

1. Understand the purpose and intent of ISO 13485 series of standards and how they are related to each other.
2. Describe the continuing process of the development of the ISO 9000 series and ISO 19011 and the impact on the audit process.
3. Understand the seven quality management principles.
4. Understand the requirement and interpretation of each clause of ISO 13485
5. Identify audit evidence that is needed to demonstrate conformity to the requirements.
6. Evaluate the effectiveness of the entire QMS, including process approach, customer focus, and continual improvement.
7. Know how planning, control process, and supporting activities can be evaluated effectively.
8. Understand the importance of leadership, risk-based auditing, management review, internal auditing, and the monitoring and measurement of the QMS.
9. Audit processes controls.

10. Understand audit processes, methods and responsibilities.
11. Plan, perform, report, and follow-up on audits.
12. Describe the role and responsibility of the auditor, lead auditor, and the auditee at all stages.
13. Lead an audit team and perform duties of Lead Auditor

Topics Covered:

- Introduction
- QMS Terminology and Definitions
- QMS Background
- QMS Requirements and Analysis
- Documents and Resources
- The Audit Process and ISO 19011
- Pre Audit Activities
- On Site Audit Activities
- Reporting and Follow-up
- Lead Auditor Responsibilities
- Audit Team Management

Instructor

The course instructor will be a Certified Lead Auditor and have 10+ years' experience in implementing/training ISO 13485, and other QMS methodologies**.**

Who Should Attend?

This course is designed for first, second, or third-party auditors and professionals who may be leading ISO 900113485 compliance activities in their organizations. This is also training for those involved with corporate internal auditing activities who wish to broaden their knowledge of a total audit process. This course is also recommended to anyone involved with supply chain management or supplier quality control or assurance.

For More Information

Contact the Training Administrator: training@qpsinc.com or call (508) 786-0777