MAKING BOTTOM LINE IMPACT

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QMS Internal Auditor for ISO 13485:2016

Course No. 106B
Participants will learn how to plan, conduct, and assess compliance to ISO 13485:2016 and FDA CFR 820 by understanding how to ensure efficient and effective audits.

Prerequisites
QMS auditing background.

Duration
Three Days (21 hours)

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

1. Understand the development and deployment of the Quality Management System for medical devices
2. Understand all levels of documents required including interpretation of each clause of ISO 13485:2016
3. Understand the differences between FDA 21 CFR 820, ISO 13485:2016, and ISO 9001:2015
4. Audit and demonstrate conformity to the requirements.
5. Evaluate the effectiveness of the entire QMS, including the process approach
6. Know how planning, processing, and supporting activities can be evaluated effectively.
7. Understand the importance of leadership, risk-based auditing, management review, internal auditing, and the monitoring and measurement of the QMS.
8. Understand the audit process and responsibilities.
9. Plan, perform, report, and follow-up on audits.
10. Describe the role and responsibility of the auditor, lead auditor, and the auditee at all stages.

Topics Covered:

- Introduction
- QMS Terminology and Definitions
- QMS Background
- QMS Requirements and Analysis
- Documents and Resources

- The Audit Process and ISO 19011:2014
- Pre Audit Activities
- On Site Audit Activities
- Reporting and Follow-up

Instructor
The course instructor leader will be a Certified Lead Auditor and have 10+ years' experience in implementing/training ISO 13485:2016 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 13485:2016 compliance activities in their organizations. This is also for those involved with corporate internal auditing activities who wish to broaden their knowledge of the 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