MAKING BOTTOM LINE IMPACT

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Documenting & Implementing ISO 13485:2016

Course No. 106D
This course is to document and Implement ISO 13485:2016. Participants will learn how to document policies, process procedures & work instructions. Participants will apply learned skills to document 5 types of documentation.

Prerequisites
QMS background.

Duration
Two Days (14 hours)

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

1. Understand the development and deployment of the Quality Management System for medical devices
2. Understand documents & records required including interpretation of each clause of ISO 13485:2016
3. Understand the differences between FDA QSR, ISO 13485:2016, and ISO 9001:2015
4. Evaluate the effectiveness of the entire QMS, including risk.
5. Understand how planning, design, & development activities can be documented effectively
6. Understand the management review process and responsibilities
7. Describe the role and responsibility of the auditor, lead auditor, and the auditee at all stages
8. Understand the risk-based process approach and ISO 14971 standard requirements
9. Document and implement the purchasing & supplier selection/evaluation process
10. Document QA/QC processes

Topics Covered:

- Introduction
- 13485:2016 Overview
- Risk Management
- Process Validation

- Documentation Management
- How to Improve QMS
- Record Management
- CAPA & Complaints

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.

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