ISO 13485 - Medical Devices-Quality Management System-Requirements for Regulatory Purposes Training

Phase I
"Principles of a Quality Management System (QMS)" 2 days
Description

This training will educate key process owners on the key characteristics, advantages, and impact of ISO 13485. The entire standard will be presented a section at a time for proper understanding of the requirements, and what is required of the company to achieve registration. Trainees will learn why ISO is needed, and what it means to be ISO registered as well as the benefits of being registered, and how to maintain registration for long-term success and competitiveness. Trainees will learn about Quality Management System planning, implementing, reviewing, and improving the actions they take to meet customer requirements. (Training is strictly for the QMS. Training on other support processes is not included. i.e. Risk Management, product compliance, CE marking, etc.)

Objective
Upon completion of the training, each trainee will have a comprehensive understanding of quality, compliance and continuous improvement along with the contents of ISO13485. Most importantly they will understand how all actions contribute to the bottom line of the company.

- Why do we need ISO?
- What is the Process Approach?
- The 8 Quality Management Principles
- How the 5 major Clauses of ISO work as a process
- Why having a Vision, Mission and Quality Policy is important?
- Using the Plan-Do-Check-Act (PDCA) process to establish sustainable change and improvement
- Preparing for ISO registration

Skill Attainment
Employees will not only learn the skills that are necessary to perform in the company, but will also gain life long experiences they can take with them in any future company they choose to join. ISO13485 is necessary for companies if they wish to work with major OEMs. Trainees will receive a certificate for having completed the training. This certificate will remain valid for as long as the standard remains in effect.

Phase II
"Development of the Quality Management System 4 days

Description
Attendees will learn how to properly document a Quality Management System via a quality manual (including the company's Quality Policy), procedures and flowcharts – ensuring compliance with ISO13485 requirements with the involvement from management. Key processes from customer support to manufacturing, purchasing, engineering and others will be educated on how to document their processes as required by the standard.

Objective
Success will be measured by the successful completion of this module and having learned about;

- Management responsibilities
- Creating a Timeline and Project Plan
- More specific ISO/clause training as it pertains to each job type
- How to develop a Quality Manual, Procedures and Work Instructions
- How to set up a Documentation Control System that also helps to improve the efficiency of the documentation
- How to Flowchart company processes (Using Visio)
- How to use the Key Performance Indicators (Goals/Objectives) to measure processes

Skill Attainment
Employees will not only learn what is necessary for ISO, but will learn how to develop a system for the long term success of our company and any future organization they join by taking with them the ISO training.