ISO 13485: 2016 Medical Devices - Quality Management System – Requirements for Regulatory Purposes Training

(Onsite – 5 Phases – 128 Hours Total – Optimum Class Size, 20-25 Participants)

Phase 1: Principles of a Quality Management System (QMS) Description - 2 Days

Training 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.). ISO 13485 is delivered onsite and is intended for all levels of the company.

Training 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 lifelong 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 2: Development of the Quality Management System - 6 Days

Training 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 ISO 13485 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. ISO 13485 is delivered onsite and is intended for all levels of the company.

Training 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.

Phase 3: Implementation and Management of QMS Requirements – 4 Days

Training Description

Employees will learn the process to effectively implement a Quality Management System within the company. In addition, trainees will learn the critical components of effectively managing improvements and compliance of a Quality Management System. ISO 13485 is delivered onsite and is intended for all levels of the company.

Training Objective

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

- How to turn on the 'system' (Roll out of QMS)
- Understanding how the documentation applies to each job
- Why is training important, and how we determine if it has been effective?
- How one fits into the Quality Policy?
- How to manage and continually improve the QMS
- How to recognize compliance?

- How to ensure that the major drivers i.e., Internal Audit, Corrective/Preventive Actions and the Management Review are corresponding

Skill Attainment

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

Phase 4: Internal Quality Auditing for Continual Improvement - 2 Days

Training Description

Trainees will learn that Internal Quality Audits are not performed just because it's a requirement for ISO, but that it can be a major driver for improvement within the company. A stronger company means more job stability, and growth opportunities for them. A group of employees will learn the skills necessary to conduct and complete internal quality audits. Trainees will learn how to develop Internal quality audit schedules, and audit plans with guidelines to address non-conformities, and most importantly how to document opportunities for improvement. ISO 13485 is delivered onsite and is intended for all levels of the company.

Training Objective

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

- Purpose of the Internal Quality Audit
- In-depth study of the ISO standard
- Characteristics of auditors
- How to develop an audit schedule
- How to prepare for the audits
- How to conduct interviews and perform audits
- Processing of the results for correction and or continuous improvement
- Finally, having learned to perform effective process audit

Skill Attainment

Employees will not only learn the skills that are necessary to perform internal audits in the company but will also gain lifelong experiences that they can take with them in any future company they choose to join. ISO13485 is necessary for companies if they wish to stay in business. Employees will receive a certificate for having completed the training. This certificate will remain valid for as long as the standard remains in effect.

Phase 5: ISO / QMS Training for All Employees – 2 Days

Upon completion of the first four modules, the company employees will be exposed to the entire system as created. Training will be provided to educate every employee on the location and use of the documentation for business effectiveness. The training will also address how to properly identify areas for possible improvement and the methods to use for addressing the issues for continued success of the system and the organization. ISO 13485 is delivered onsite and is intended for all levels of the company.