ISO 13485:2016 MEDICAL DEVICES INTERNAL AUDIT TRAINING

Overview

ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g., technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Hence, this consultancy project is to train and to guide the organization working committee members towards the certification of this international standard.

What will be covered in ISO 13485:2016 standard? This course will discuss **understanding** revolving around ISO 13485:2016 and the PDCA approach, aspect and impact analysis, operation controls, and **Internal auditing.**

ARGI'S training course will empower you with the principles, techniques, and processes of planning, conducting, and implementing an audit to comply with and become personally or institutionally certified in ISO 13485.

Course Objectives & Learning Outcome

Upon completion of the training program, the participants should be able to:

ISO 13485:2016 Internal Auditing Training Program

- Learn the basic concept of auditing QMS for Medical Devices
- Learn and practise the process of auditing QMS based on ISO 13485:2016
- Go through practical learning of the required skills for performing internal audit on ISO 13485:2016
- Learn the questioning approach during audit, make observations for gap analysis that initiating corrective actions (CA) for effective closure of the gaps
- Master the techniques of preparing and generating audit reports
- Conduct internal quality auditing as an internally qualified competent auditor

Who Should Attend (Target Groups)

- All the working committee members of the ISO 13485:2016 Certification project, and the respective functional department representatives.

Course Methodology

This ISO 13485 Medical Devices & Internal Audit Training Program will comprise the following training methods:

- Lectures
- Presentations
- Group Discussions
- Quizzes
- Workshops

ARGI follows the 'Do-Review-Learn-Apply' model.

Course Duration

This is a 2 days training program (9.00am to 5.00pm)

Organizational Benefits

Companies who nominate their employees to participate in this ISO 13485:2016 Medical Devices Awareness and Internal Audit Training program can benefit in the following ways:

- Improve your company's credibility and identity
- It will demonstrate Evidence -Based decision making
- Promotes continual improvement
- Increase employee involvement in the standard and implementation
- Enhance customer satisfaction
- Demonstrate environmental commitment to key organisational stakeholders
- Develop a solid QMs for Medical Devices plan and determine the resources required
- Apply and benefit from good medical device practices using proven tools and techniques
- Implement and apply a system that considers socio-economic needs and medical device stipulations
- Provide products and services that meet regulatory medical device requirements

Individual Benefits

Individuals who participate in this ISO 13485 Medical Devices Awareness and Internal Audit Training Program can gain from it in the following ways:

- Identify the key requirements and advantages of ISO 13485
- Gain the knowledge to lead a team to obtain an ISO 13485 certification for your workplace
- Learn how to thoroughly plan for an audit and prepare an on-site plan that establishes effective audits
- Explain the purpose of Medical Device standards, audit third-party certification, and understand the business benefits of improved performance of medical device management systems
- Develop the management skills to effectively lead or support the implementation of an effective ISO 13485 management system within your organisation

COURSE CONTENT OF ISO 13485:2016 INTERNAL AUDIT PROGRAM

Day 1

MODULE 1: INTRODUCTION

- Definition of Quality Auditing
- Why Audit?
- Process and Process Approach for Audit
- The purpose of audit
- Benefits of Audit

MODULE 2: Auditor Competence, Audit Fundamental and Type of Audits

- Auditor Competence
- Auditing Types
- Audit Management
- Audit Techniques

MODULE 3: Stages of Internal Audit and Activities

- Audit Planning
- Audit Preparation
- Conduct On-Site Audit
- Audit Review
- Audit Reporting and Follow Up

Day 2

MODULE 4: AUDIT WORKSHOP - ONE FULL DAY

- Audit by process
- Audit by documentation
- Audit on Verification and Validation
- Audit by specific requirements for Medical Devices
- Preparing audit report

The intention is to drill the participants on workshops so that they will be very well verse on the Internal Audit process.