CQE Training & Consultancy Plt (Reg No. : LLP 000368 LGN)
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ISO13485:2016 MEDICAL DEVICES QMS INTERNAL AUDIT TRAINING

(PUBLIC / IN-HOUSE TRAINING PROGRAMME)

SBL Scheme

Introduction

The need to maintain competitiveness and the emergence of systems thinking and approach has guided many organizations to adopt the use of applicable international standards in the implementation of management system. With the right methodology and concept to integrate the requirements of the standard into the organization's business activities, the system can provide framework in helping an organization achieve functional clarity and to reach its goals.

Implementation of a management system and obtaining certification is not a once-off activity, but rather, its mark the beginning of the journey towards continual improvement. The practice of ISO13485:2016 Medical Devices QMS cannot be executed by our convictions or good will alone, but have to include the requirements and concerns from legal and regulatory needs and purpose. This training course has been designed to provide an insight into the use of ISO 13485 as the basis for a quality management system implemented by medical device manufacturers. Time will be spent during the course reviewing requirements of ISO 13485 and making comparisons to ISO 9001 and the FDA's Quality System Regulation. In addition to this, participants will also gain an awareness of the relationship between ISO 13485 and ISO 14971, Application of Risk Management to Medical Devices.

This course teaches the principles and practices of effective quality management systems and process audits in accordance with ISO 13485 and ISO 19011:2011, "Guidelines for Quality and/or Environmental Management Systems Auditing."

Experienced instructors guide students through the entire audit process, from managing an audit programme such as planning, organizing, communicating, executing and evidence gathering, NCRs preparation, report writing and follow-up actions. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, practical role-playing, group workshops, and open forum discussions.

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Learning Outcomes/Objectives

Also available as in-house programme

The purpose of this training is to equip delegates with the knowledge and skills needed to perform internal audits on Medical Devices Management Systems (MDMS) and to contribute to the continual improvement of the management system. On training completion participants will be able to:-

- ✓ Brief understanding on the latest ISO13485:2016 Medical Devices QMS Requirements;
- ✓ Compare the requirements between ISO 13485 and ISO 9001;
- ✓ Recognize the relationship between ISO 13485 and ISO 14971;
- ✓ Compare the requirements between ISO 13485 and FDA's Quality System Regulation
- ✓ Describe the responsibilities of an internal auditor and describe the role of internal audit in the maintenance and improvement of management systems;
- ✓ Plan and prepare for an internal audit, gather audit evidence through observation, interview and sampling of documents and records, write factual audit reports that help to improve the effectiveness of the management system according to the ISO1901:2011 auditing guidelines
- ✓ Establishing, implementing, maintaining, reviewing and finally continually improving the auditing related business operation fulfilling the legal and regulatory requirements

COURSE CONTENTS

Day 1

- Registration
- Introduction
- Ice-breakers (Warm-up exercise)
- Historical of ISO13485 Standard Development (brief overview)
- Why have this standards?
- Who do these standards apply to?
- What does this ISO 13485 series cover?
- Differences between ISO13485 versus and ISO9001 QMS
- Overview and understanding of FDA's Regulation
- Relationship between ISO 13485 and ISO 14971 – Risk Management

Day 2

- Ideal attributes and characters of Internal Auditors.
  - Principle of Quality Auditing
  - Ethical Conduct
  - Fair Presentation
  - Due Professional Care
  - Independence
  - Evidence Based Approach
- What is Accreditation and Certification?
  - Definition
  - Roles and Functions
- Managing Internal Audit Programme
  - Quality Management Representative (QMR) roles
  - Recommended good practices in Internal Audit Programme
- Audit planning and preparation. (Effective Auditing)
  1. Steps in conducting audit.
  2. Non-conformance writing
  3. Audit reporting process.

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- Documentation requirements
- Implementation Steps
- Auditing as a Management Tools for Improvement.
- What is Quality Audit ? Differences with Environmental Auditing
- Types of audits (System, Product and Process)
  - Example of System, Product and Process Audits
  - Sample Checklists
- Who are involved in Internal Auditing ?
- Parties involved in Internal Audit and their relationship
- What are the roles of Internal Auditor, Auditee and Client ?

4. Post audit activities (corrective actions, verification and follow-up).
5. Record retention.

- New Process Approach Auditing Methodology
- ISO19011:2011 Standard on Quality and Environment Auditing Systems.
- Evaluation exercise / discussions.
  1. Workshop 1 – Fact of Fiction Exercise?
  2. Workshop 2 – ISO13485:2016 Non-Conformity Clause Identification Exercise (5 Questions)
  3. Workshop 3 – ISO13485:2016 Non-Conformity Report (NCR) Statement Writing Exercise
- Workshop Case Study and Audit Trails
  1. Role play (auditor and auditee).
  2. Reporting.
  3. Review and discussions.

Who Should Attend

Production and Operation Managers, Executives and Supervisors, Quality and Safety Managers , Executives, Engineers and Supervisors, EMS Management Representative and those who are involved in the day-to-day operations of a manufacturing plan that related to environmental issues.

Duration

2 days

Training Methodology

The program would be conducted by using the following materials / aids :-

- ✓ Course Note
- ✓ LCD Presentation
- ✓ Group Activities / Workshop / Role Plays
- ✓ Lecturettes

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