ISO 13485:2016 Internal Auditor Training Course

Aim of the Course: The training course is designed to get the zest of how to audit the processes of an ISO 13485:2016 Quality Management System (QMS). This course will provide insight and experience in planning, executing, reporting and audit follow-up of an internal audit while monitoring the effectiveness and conformity of the ISO 13485:2016 compliant QMS.

Course Description: An ineffective audit can lead to severe consequences along with process failure, patient dissatisfaction and regulatory noncompliance. This course is designed to optimize your auditing skills with regard to ISO I3485:2016. This will help you to gain confidence in planning and performing an effective audit, reporting and inculcating corrective action where necessary.

Who should Attend?: The course is intended for medical device quality professionals who want to build on their current knowledge of ISO 13485:2016 and are keen to evaluate the effectiveness of their QMS. Therefore, any medical device quality

professionals who want to gain knowledge of quality management systems and ISO 13485:2016, as well as the individuals interested in conducting first or second-party audits, management representatives, internal auditors and consultants can attend this course.

Learning and Benefits:

On completion of the course, you will gain the knowledge and skills to:

- Explain the structure and scope of ISO 13485:2016 and how it is applied in the organization seeking regulatory compliance
- Recognize the key principles of auditing and auditor responsibilities
- How to plan an internal audit
- Plan an effective audit based on process identification, sampling and questioning
- Determine if the corrective action has been effectively implemented in each step or not

This course will help you:

- In maintaining compliance with ISO 13485:2016
- Improvement in quality standards
- Boosting confident that your organization can rely on competent auditors

Course Structure:

The course is structured in 4 modules. Each module is explained with reference to ISO 13485: 2016 which is the latest version. Games are also included for making it more engaged and fun.

MODULE 1

CLAUSE 1 – 4 Are explained which include :

- Introduction
- Purpose
- Scope
- Terms and definitions
- Quality management system

MODULE 2

CLAUSE 5 -6 Are explained which include :

- Management responsibility
- Resource management

MODULE 3

CLAUSE 7 is explained which include :

- Product realization :

1. Planning
2. Customer related processes
3. Design and development
4. Purchasing
5. Product and service provision
6. Control of monitoring and measuring equipment

MODULE 4

CLAUSE 8 is explained which include :

- Measurement, analysis and improvement

1. General
2. Monitoring and measurement
3. Control of non-conforming products
4. Analysis of data
5. Improvement