

Course code: A1034

INTERNAL AUDIT FOR ISO 13485

INTRODUCTION

ISO 13485 is the internationally recognized standard for quality management systems in the design and manufacture of medical devices. It outlines specific requirements that help organizations ensure their medical devices meet both customer and regulatory requirement. This course prepares your staff to serve as ISO 13485 Internal Auditors evaluating existing quality systems against the ISO 13485 standard. Participants learn the details of each of steps of conducting an internal audit, but specifically how to use a process focus as required by the ISO 13485 standard. The course includes exercise workshop session to help trainee to understand and be able to perform auditing so they can assess for continual improvement.

OBJECTIVE

- To describe the concept overview of the ISO 13485 auditing.
- To provide knowledge on how internal audit is organized and describe how Risk-Based Thinking is applied in ISO 13485 Internal Audits.
- To describe the guidelines of management system auditing according to ISO 19011.
- To explain the importance of customer-specific requirements in the internal audit process.
- To explain role and responsibility of the internal auditor.

CONTENT

• Session 1: Introduction

Describe process approach and how to use process mapping to understand a process. Identify which elements impact process performance and determine measures that can be used to monitor and improve the performance of the process.

• Session 2: Terms and Definitions

Describe relevant terms and definitions that normally use in the internal audit system.

• Session 3: Internal Audit Perspective of Related Standards

Describe ISO 13485 standard requirement is implemented in conjunction with quality management system. Explain risk-based thinking fosters a proactive culture of prevention and improvement

• Session 4: Internal Audit Process and Practice

Describe internal auditing process that implemented in conjunction with quality management system. Explain each steps of internal audit process to improve effectiveness of the audit result. How to issue nonconformity and evaluate itemize nonconformities.

• Session 5: Conclusion

Conclude techniques that can lead to more effective audits and efficient outcomes.

Exercise workshop will also be delivered in each key sessions

PREREQUISITES

Knowledge in quality/safety/technical is necessary. Experience in medical laboratory will be more benefit.

