

Course code: A1124

INTERNAL AUDIT FOR ISO 15189-90

ISO 15189 is an international standard for medical laboratories that specifies the quality management system requirements particular to medical laboratories. ISO 15190 address the safety aspects of medical laboratories. This course prepares your staff to serve as ISO 15189-90 Internal Auditors evaluating existing quality systems against the ISO 15189-90 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 15189-90 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 15189-90 auditing.
- To provide knowledge on how internal audit is organized and describe how Risk-Based Thinking is applied in ISO 15189-90 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 15189-90 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.



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