

Course code: S1124

ISO 15189 QMS

Requirement for Medical Laboratory

ISO 15189 is the requirements of a quality management system for organizations in the medical laboratory. The standard is applied to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements of the medical laboratory. This course helps aspiring participants to understand how ISO 15189 helps to continually improve organisational Quality Management System using its best practice to deliver products and services that meet customer and regulatory requirements. Participants learn the details of each HLS (High Level Structure) of the standard requirement to be able to apply within their organization.

OBJECTIVE

- To describe the concept overview of the ISO 15189 requirement.
- To provide knowledge on quality management system (QMS) and describe how Risk-Based Thinking is applied in ISO 15189.
- To explain the importance of customer-specific requirements in the quality management system.
- To build awareness in quality and build continual improvement.

CONTENT

• Session 1: Introduction

Describe quality management 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 quality system.

• Session 3: Risk-based thinking and tools of Related Standards

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

• Session 4: Interpretation of standard requirement

Describe the ISO 15189 requirement clause by clause that implemented in conjunction with quality management system. Explain concept and awareness to improve effectiveness of the quality system.

• Session 5: Conclusion

Conclude requirement and explain step to implement the system.

Exercise workshop will also be delivered in each key sessions

PREREQUISITES

Basic knowledge in quality is optional. Experience in any industry will be more benefit.



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