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Course code: S1034

ISO 13485 QMS

for Medical Device Industry Requirement

ISO 13485 is the medical industry's medical device standard, which ensures that all medical devices meet the proper regulatory compliance laws and customer needs. The standard requires that such organizations prioritise excellent quality practices and develop a reliable quality management system to establish and demonstrate their competence. This standard is applicable to all organizations, regardless of size or complexities. The standard is applied to demonstrate the ability to consistently manage quality that meet regulatory requirements. This course helps aspiring participants to understand how ISO 13485 helps to continual improve organisational quality management system using its best practice. Participants learn the details of each clauses of the standard requirement to be able to apply within their organization.

OBJECTIVE

- To describe the concept overview of the ISO 13485 requirement.
- To provide knowledge on quality management system (QMS) and describe how Risk-Based Thinking is applied in ISO 13485.
- To explain the importance of customer-specific requirements in the quality management system.
- To build awareness in QMS and encourage continual improvement within organization.

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 13485 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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