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ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA
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Authorised Training Provider

Industry Expert Training Series * HRD Corp Claimable Course Scheme

ISO 13485:2016
Quality Management System
Training Brochure

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ISO 13485:2016 Quality Management System

INTRODUCTION

ISO 13485:2016 is the internationally recognized Quality Management System (QMS) standard specifically developed for organizations involved in the design, manufacture, installation, and servicing of medical devices. It places strong emphasis on regulatory compliance, risk-based thinking, process control, and continual improvement to ensure the safety, performance, and reliability of medical devices throughout their lifecycle.

This training provides participants with a practical and structured understanding of ISO 13485:2016 requirements, focusing on how the standard is applied in real manufacturing and quality system environments. The course bridges the gap between standard requirements and day-to-day operations, helping organizations establish, implement, maintain, and improve an effective medical device QMS.

Through interactive discussions, real-life examples, and industry best practices, participants will gain clarity on key QMS elements such as management responsibility, resource management, risk management, product realization, supplier control, documentation, internal audit, CAPA, and regulatory alignment. The training is designed to support organizations in achieving compliance with global regulatory expectations, and improving operational effectiveness.

COURSE OBJECTIVES

After participating in the training, you will be able to:

- Understand the key requirements and intent of ISO 13485:2016.
- Recognize how ISO 13485 applies to daily work activities in the medical device industry.
- Understand and interpret the ISO 13485:2016 requirements.
- Learn the practical implementation examples.

COURSE OUTLINE

1. Introduction of ISO 13485:2016
2. 7 Quality Management Principles
3. Clause by clause interpretation of ISO 13485:2016
    - Clause 0: Introduction
    - Clause 1: Scope
    - Clause 2: Normative References
    - Clause 3: Terms and Definitions
    - Clause 4: Quality Management System
    - Clause 5: Management Responsibility
    - Clause 6: Resource Management
    - Clause 7: Product Realization
    - Clause 8: Measurement, Analysis and Improvement

ISO 13485:2016 Quality Management System

DURATION

Two (2) full days

MODE OF TRAINING

Remote Online Training or Classroom Training

COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Introduction of ISO 13485:2016 7 Quality Management Principles Clause by clause interpretation of ISO 13485:2016 Clause 0: Introduction Clause 1: Scope Clause 2: Normative Reference Clause 3: Terms and Definitions
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Clause 3: Terms and Definitions (Continue) Clause 4: Quality Management System
2	9.00 am – 12.30 pm	Clause 4: Quality Management System (Continue) Clause 5: Management Responsibility
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Clause 6: Resource Management Clause 7: Product Realization Clause 8: Measurement, Analysis and Improvement

CONTACT

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