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Industry Expert Training Series * HRD Corp Claimable Course Scheme

Medical Device Quality System: ISO 13485:2016 & US FDA Quality Management System Regulation

Training Brochure

HRDCORP CLAIMABLE

Medical Device Quality System: ISO 13485:2016 & US FDA Quality Management System Regulation

INTRODUCTION

The medical device regulatory landscape is evolving toward global alignment. With the release of the US FDA Quality Management System Regulation (QMSR), which formally incorporates ISO 13485:2016 by reference, manufacturers now face a harmonized quality system framework that supports compliance across both U.S. and international markets.

This training provides a comprehensive understanding of ISO 13485:2016 requirements and the new US FDA QMSR (21 CFR Part 820), highlighting how these two systems are interconnected. Participants will gain insight into the key similarities, differences, transition expectations from the previous US FDA Quality System Regulation (QSR) to the new QMSR model, and best practices for inspection readiness.

Through structured explanations, the course will help participants build practical knowledge on how to apply both ISO 13485:2016 and US FDA QMSR requirements effectively in their quality management systems.

COURSE OBJECTIVES

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

- Understand the structure, purpose, and intent of ISO 13485:2016 as a quality management standard for medical devices.
- Interpret ISO 13485:2016 requirements clause by clause.
- Understand the key functions and roles of the US FDA in medical device regulation.
- Overview of FD&C Act and CFR.
- Prepare for FDA inspections and audits.
- Understand key highlights of the new Quality Management System Regulation (QMSR).

COURSE OUTLINE

1. Introduction of ISO 13485:2016
2. 7 Quality Management System Principles
3. Clause by clause interpretation of ISO 13485:2016
4. Introduction of US FDA
    - The US Food and Drug Administration (FDA)
    - The Federal Food, Drug, and Cosmetic Act (FD&C Act)
    - The Code of Federal Regulations (CFR)
    - Importance of compliance with US FDA QMSR
5. FDA inspection
    - Introduction
    - FDA inspection flow
    - Quality System Inspection Techniques (QSIT)

- Preparation and expectation
- FDA inspection outcome
- Response to FDA Observations/ Form 483

6. Quality Management System Regulation (QMSR)
   - Introduction
   - Overall highlight of main changes
   - Summary of key changes
   - QSR vs QMSR section comparison
   - QMSR section by section requirements interpretation
   - Executive summary for medical device manufacturer

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 System Principles Clause by clause interpretation of ISO 13485:2016
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Clause by clause interpretation of ISO 13485:2016 (Continue) Introduction of US FDA
2	9.00 am – 12.30 pm	FDA inspection
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Quality Management System Regulation

CONTACT

For enquiries, please email to Medsociate Sdn Bhd

Authorised training provider of AMMI

Email: learning@ammi.com.my / admin@medsociate.com

Tel: +6012 539 4194