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Industry Expert Training Series * HRD Corp Claimable Course Scheme



NCR / CAPA / Complaint Handling

Training Brochure

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NCR/ CAPA/ Complaint Handling

INTRODUCTION

This course introduces the concepts needed to understand the requirements of NCR, CAPA and complaint handling under ISO 13485:2016 QMS and US FDA Quality Management System Regulation (21 CFR Part 820). It provides guidance on how to address each of them effectively with a step-by-step process that incorporates root cause analysis & problem-solving tools.

COURSE OBJECTIVES

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

- Understand requirements: Learn the key regulations and standards on managing NCR, complaint, and CAPA in the medical device industry.
- Handle NCR effectively: Identify, document, and manage nonconformances to maintain product quality.
- Improve complaint handling: Develop skills to investigate and resolve customer complaints efficiently.
- Strengthen CAPA process: Implement corrective and preventive actions to prevent recurring issues.
- Ensure compliance: Build systems that meet regulatory requirements and improve operational performance.

COURSE OUTLINE

1. Standard and regulatory perspective on NCR, complaint handling and CAPA
2. Nonconformance process flow
3. Tips to prevent nonconformance
4. Sample template for nonconformance
5. How to write an effective nonconformance report
6. Complaint handling process flow
7. Rules of complaint handling
8. Tips for effective complaint handling
9. Sample template for complaint handling
10. Differences between correction, corrective action, and preventive action
11. Steps to create risk-based CAPA process
12. Sample template for CAPA

DURATION

Two (2) full days

MODE OF TRAINING

Remote Online Training or Classroom Training

NCR/ CAPA/ Complaint Handling

COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Definition- NCR, complaint handling, CAPA Standard and regulatory perspective on NCR, complaint handling and CAPA NCR • What is nonconformance? • Example of nonconformance • Nonconformance process flow • Tips to prevent nonconformance • Sample template for nonconformance • How to write an effective nonconformance report
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Complaint handling • What is customer complaint? • Source of complaint • Why do customers complain? • Complaint handling process flow • Rules of complaint handling • Tips for effective complaint handling • Sample template for complaint handling CAPA • What is CAPA? • Risk-based CAPA • Problem of CAPA
2	9.00 am – 12.30 pm	CAPA • Problem of CAPA (Continue) • Cause of confusion • What's the difference between correction, corrective action, and preventive action?
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	CAPA • Steps to create risk-based CAPA process • Sample template for CAPA • Learning from experience - CAPA system effectiveness • How CAPA connects to nonconformance and complaint handling?

NCR/ CAPA/ Complaint Handling

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