SeerPharma®
CONFIDENCE IN COMPLIANCE

E-LEARNING

GMP

10

Pharmaceutical CAPA

This module addresses identification and interpretation of the requirements of a pharmaceutical CAPA system. CAPA is a fundamental management tool that is integral to an effective quality management system.

Objectives:

- Identify the regulatory requirements for a CAPA system
- List the various phases and the processes of a successful CAPA system
- Explain the critical elements of a CAPA system
- Explain the importance of risk assessment and investigation
- Describe tracking and escalation processes in a CAPA system
- Recognise the requirements of ICH Q10 - Pharmaceutical Quality System (PQS)

Course Outline

INTRODUCTION
- Welcome
- Introduction
- Reviews and assessments
- Overview
- Pharmaceutical Quality System (PQS) Model
- Key areas of the QMS

- REGULATIONS
- Overview
- Compliant CAPA systems
- Activity: Looking for CAPA requirements within GMPs
- FDA QSIT inspections of CAPA systems
- Important definitions
- Examples of different CAPAs
- Review

- THE CAPA SYSTEM
- Overview
- Features of a CAPA system
- CAPA flowchart
- Phases of a CAPA system
- Review

ELEMENTS OF CAPA SYSTEMS
- Overview
- CAPA system inputs
- Risk assessment and CAPA
- Risk assessment process
- CAPA documentation
- The CAPA procedure
- CAPA request/record
- Correction/containment
- Corrective action
- Preventive action
- Verification and closeout
- Completed CAPA report
- Review

ROOT CAUSE ANALYSIS
- Symptom or Root Cause?
- When to conduct RCA/CAPA
- Root Cause Analysis (RCA)
- Investigation & Analysis

TRACKING AND ESCALATION
- Overview
- Progress tracking and escalation
- CAPA trending
- Review

CONCLUSION
- Summary

Contact us for more information

SeerPharma®
CONFIDENCE IN COMPLIANCE