



Online GMP Training

GMP10 | Corrective and Preventive Action (CAPA)

This module addresses identification and interpretation of the requirements of a Corrective and Preventive Action (CAPA) system. CAPA is a fundamental management tool that is integral to an effective Pharmaceutical Quality System (PQS).

OBJECTIVES

- identify regulatory requirements of CAPA
- list the phases and processes of a successful CAPA system
- explain a CAPA system's critical elements
- explain the importance of documentation
- describe tracking and escalation processes
- recognise ICH Q10 requirements of CAPA, including root cause and risk assessment

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CONTENT

Introduction

- Objectives
- Reviews and assessment
- Overview
- PQS model
- Key PQS elements
- CAPA definitions
- What do the GMP rules state?
- Match the actions

CAPA systems

- Overview
- Compliant CAPA systems
- CAPA phases
- Closed loop CAPA system
- Features
- Select all that apply to a compliant CAPA system
- What determines whether a CAPA is required or not?
- Fill in the blanks

CAPA system elements

- Overview
- Sources of data
- Risk management
- Risk assessment
- SOP

CAPA system elements (continued)

- CAPA request
- Correction
- Corrective action
- Preventive action
- Verification and close-out
- CAPA report
- True or false?
- Why is risk management important to CAPA?
- Put these CAPA steps in order
- Which action is immediate when a problem arises?

Root Cause Analysis (RCA)

- Example scenario
- Overview
- Root Cause Analysis (RCA)
- Investigation tools
- When to conduct RCA and CAPA
- What must be defined before a RCA?
- Match the terms

Tracking and escalation

- Overview
- Progress tracking and escalation
- CAPA system effectiveness

Conclusion

- Summary