Corrective and Preventive Action (CAPA) in Medicinal Products Manufacture - E-Learning Module

Description: A company’s Corrective and Preventive Action (CAPA) system establishes how personnel should deal with manufacturing problems that have occurred or that may occur if not prevented. This module explains the principles of corrective and preventive action and describes typical CAPA procedure. It goes on to introduce root cause analysis and outline the role of progress tracking, escalating, and trending of CAPA procedures.

Who will benefit from this module?

This module provides essential training for all personnel who work in a manufacturing environment in the pharma/biotech industry.

Learning objectives

- Explain what a CAPA system is and describe how it operates in a company’s Quality Management System
- Describe how a typical CAPA procedure is carried out
- Outline the purpose and practice of root cause analysis
- Discuss the role of progress tracking, escalating, and trending of CAPA procedures

CPD Points: TBD

Assessment: Multiple-choice mastery assessment.

Contents:

Module overview - An outline of the module’s scope and objectives, and notes on terminology.

CAPA principles - In this session it’s explained what a CAPA system is and why it is important. The differences among correction, containment, corrective action, and preventive action are explained. Sources of information are specified about manufacturing problems, and the importance of documentation of a CAPA system is emphasised.

CAPA procedure - Problems that may give rise to CAPAs are best tackled by systematically progressing through a number of stages of procedure. In this session the typical stages of a CAPA procedure are set out, along with the questions to be addressed and the actions taken at each stage.

Root cause analysis - Root cause analysis is a rigorous approach to finding the deepest causes of problems. In this session the value of applying CAPA to root causes is emphasised rather than their symptoms. Stages of a typical analysis are set out, and examples of tools for finding causes and studying trends are listed.

Tracking, escalation, and trending - One of the most common findings of regulatory inspectors is the lack of effective and timely closure of CAPA reports. In this short session the importance of tracking the progress of CAPA procedures, escalating issues, and reviewing trends in the CAPA system is emphasised.

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