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Online GMP Training

GMP9 | Quality Assurance and Quality Control

This module provides an introduction to the functions of Quality Assurance (QA) and Quality Control (QC) in the effective and safe production and control of medicinal products.

OBJECTIVES

- Recognise how attention to manufacturing quality products reflects on daily operations
- Identify the role of QA in pharmaceutical manufacturing
- Recognise how companies use GMP rules to minimise errors in manufacturing
- Identify main roles & responsibilities of QC
- Recognise the key elements of a PQS

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CONTENT

Introduction

- Objectives
- Reviews and assessment
- Overview

Quality principles

- What do you think?
- What do the GMP rules state?
- What is quality?
- Fundamental GMP rules
- Responsibility for quality
- Knowledge and behaviour

Pharmaceutical Quality System (PQS)

- PQS model
- Key PQS elements
- Management responsibility
- Quality functions within a PQS

Quality Assurance (QA)

- What do you think?
- What do the GMP rules state?
- Overview
- Vendor assurance
- Documents and records
- Traceability
- Training
- Internal audits / self inspections
- Types of audits
- CAPA definitions
- CAPA systems
- CAPA phases
- Change management (change control)
- Deviations
- Release for supply
- Release for supply checks

Quality Assurance (QA) (continued)

- True or false?
- Vendor assurance is...
- Select all that apply for GMP compliant documents

Good Manufacturing Practice (GMP)

- What do you think?
- What do the GMP rules state?
- Overview
- Scope of GMP rules
- Documentation and records
- Introduction to validation
- Cleaning validation (example)
- Process control
- Contamination control
- Which documentation provides information on whether or not a process remained in control?
- True or false?
- Select all options that need validating?

Quality Control (QC)

- What do you think?
- What do the GMP rules state?
- Overview
- QC responsibilities
- Good (Quality Control) Laboratory Practices
- Laboratory documentation system
- Sampling
- Reliable test methods
- Specifications
- Checking results
- Limitations
- Select all options that QC is responsible for
- Is there inherent risk in conclusions from sample results?
- Fill in the blanks

Conclusion

- Summary