SeerPharma®
CONFIDENCE IN COMPLIANCE

E-LEARNING

GMP

9

Quality Assurance and Quality Control

This module provides an introduction to the roles of QA and QC in the effective and safe production and control of medicinal products.

Objectives:

- Recognise how attention to manufacturing a quality product reflects on day-to-day operations
- Identify the role of QA in pharmaceutical manufacturing
- Recognise how companies use GMP rules to minimise errors in manufacturing
- Identify the main roles and responsibility of Quality Control
- Recognise the key elements of a pharmaceutical quality system

Course Outline

INTRODUCTION
- o Welcome
- o Outcomes
- o Reviews and assessments
- o PQS overview

QUALITY PRINCIPLES
- o What do you think?
- o GMP solution
- o What is quality?
- o Protecting consumers
- o Responsibility for quality
- o Knowledge and GMP behaviour
- o GMP compliance program

QUALITY ASSURANCE
- o What do you think?
- o GMP solution
- o Overview
- o Traceability
- o Documents and records
- o Training
- o Internal audits
- o Effective audits
- o Corrective action
- o Vendor assurance
- o Change management
- o Release for supply
- o Review

GMP
- o What do you think?
- o GMP solution
- o Overview
- o Scope of GMP rules
- o GMP & documentation
- o Essential requirements
- o Why validate?
- o What needs validating?
- o GMP and process control
- o Process deviations
- o Contamination control
- o GMP rules and cleaning
- o Review

QUALITY CONTROL
- o What do you think?
- o GMP solution
- o Overview
- o Role of the laboratory
- o G(QC)LP
- o Lab documentation
- o Specifications
- o Sampling
- o The sampling game
- o Sampling limitations
- o Altering records
- o Review

PHARMACEUTICAL QUALITY SYSTEM (PQS)
- o ICH Q10 Guidance
- o PQS key elements
- o Management responsibility
- o CAPA systems
- o CAPA processes

CONCLUSION
- o Summary

Contact us for more information

SeerPharma®
CONFIDENCE IN COMPLIANCE