

# GMP



## Introduction to GMP

This module provides a solid introduction to control and management of manufacturing and quality of pharmaceutical products.

### Objectives:

- Explain why your company has implemented GMP
- State the purpose of GMP regulations and codes of GMP
- State the four key product quality attributes
- State the GMP requirements for personal hygiene
- Describe the correct way to complete GMP records
- List the essential production and packaging controls

# Course Outline

## INTRODUCTION

- o Welcome
- o Objectives
- o Reviews and assessments
- o What do you think?
- o GMP solution
- o Events that have shaped GMP
- o Evolution of GMP
- o The introduction of codes of GMP
- o Regulatory agencies around the world
- o FDA, MHRA/EMA, TGA
- o PIC/S
- o What does GXP mean?
- o Review

## PRODUCT QUALITY

- o What do you think?
- o GMP solution
- o Overview
- o What is quality?
- o Protecting consumers with GMP rules
- o Quality management
- o Quality assurance
- o Quality control
- o Review

## SCOPE OF GMP RULES

- o What do you think?
- o GMP solution
- o Scope of GMP codes
- o Self inspection/internal audits
- o GMP compliance program
- o Personnel & training
- o Equipment & GMP
- o Facility & grounds
- o Manufacturing & GMP
- o Manufacturing controls
- o Review

## CLEANING & SANITATION

- o What do you think?
- o GMP solution
- o GMP & housekeeping
- o Cleaning & sanitation
- o Personal hygiene & GMP
- o Personal hygiene programs
- o Review

## DOCUMENTATION

- o What do you think?
- o GMP solution
- o GMP and documentation
- o GMP & manufacturing records
- o Rules for completing records
- o Exercise
- o Review

## CONCLUSION

- o Summary