

# GMP



## Packaging Controls

This module describes the GMP requirements for the control of packaging materials and operations.

### Objectives:

- Define what is meant by mislabelling
- State the critical GMP requirements for packaging controls
- Describe the GMP controls for pre-printed matter
- Identify the GMP requirements of setting up a packaging line
- State the importance of online controls
- Perform basic reconciliation calculations

# Course Outline

## INTRODUCTION

- o Welcome
- o Outcomes
- o Reviews and assessments
- o What do you think?
- o GMP solution
- o Top reasons for drug recalls

## POTENTIAL MISLABELLING

- o What do you think?
- o GMP solution
- o Overview
- o Labelling recalls
- o Packaging controls

## PRINTED MATERIALS CONTROL

- o What do you think?
- o GMP solution
- o Overview
- o GMP controls at the printers
- o Receiving printed matter
- o Printed matter issue, coding and returns
- o Review

## LINE CLEARANCE & SETUP

- o What do you think?
- o GMP solution
- o Overview
- o Line clearances
- o Performing a line setup
- o Clearing the line post-use
- o Review

## ONLINE CONTROLS

- o What do you think?
- o GMP solution
- o Overview
- o Checking fill volume and seal integrity
- o Run charts
- o Control charts
- o Monitoring packaging and deviations
- o Review

## RECONCILIATION

- o What do you think?
- o GMP solution
- o Overview
- o Calculating reconciliation
- o Reconciliation walkthrough
- o Reconciliation example
- o Review

## SUMMARY

- o Summary