Online GMP Training
GMP8 | Packaging Controls

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

OBJECTIVES

- Define mislabelling
- State requirements for packaging controls
- Describe GMP controls for pre-printed matter
- Identify GMP requirements of setting up a packaging line
- State the importance of on-line controls
- Perform basic reconciliation calculations

CONTENT

Introduction
- Objectives
- Reviews and assessment
- Overview

Mislabelling
- What do you think?
- What do the GMP rules state?
- Overview
- Packaging controls
- Labelling recalls

Printed material control
- What do you think?
- What do the GMP rules state?
- Overview
- Printing
- Receiving printed material
- Issue, coding and returns
- Match the controls to the process stages
- Select true or false for each statement

Line clearance and setup
- What do you think?
- What do the GMP rules state?
- Overview
- Line clearance
- Line setup
- Clean-up

Line clearance and setup (continued)
- Order these steps for a given batch
- True or false?
- What is the difference between line clearance and line clean-up?

Online controls
- What do you think?
- What do the GMP rules state?
- Overview
- Checking fill volume and seal integrity
- Run charts
- Control charts
- For the 5 bottles examined, which is the best deviation description?
- Which checks are required during packaging operations? Select all that apply.

Reconciliation
- What do you think?
- What do the GMP rules state?
- Overview
- Calculating reconciliations
- Reconciliation walk-through
- Unsatisfactory reconciliation may indicate what? Select all that apply.
- Select true or false for each statement.

Conclusion
- Summary