

## Production Controls

This module discusses the controls for starting materials, dispensing and processing, what actions to take when confronted with non-conforming materials, products and processes, and how to calculate yields and reconciliations.

### Objectives:

- Identify the controls required for receiving, storing, and dispensing raw materials
- Identify the process controls in room and line clearance, formulation, in-process checks, and batch records
- State the GMP requirements for handling manufacturing deviations
- Recognise how yield and reconciliation are calculated

# Course Outline

## INTRODUCTION

- o Welcome
- o Objectives
- o Reviews and assessments
- o What do you think?
- o GMP solution
- o GMP and production

## STARTING MATERIAL CONTROL

- o What do you think?
- o GMP solution
- o Overview
- o Receiving and issuing raw materials
- o Receiving materials
- o Storing received materials
- o Sampling and testing
- o Status labelling
- o GMP storage requirements
- o Protecting raw materials
- o Issue of materials
- o Review

## DISPENSING CONTROL

- o What do you think?
- o GMP solution
- o Overview
- o The dispensing process
- o Dispensary room clearance
- o Setup
- o Weighing
- o A dispensing step
- o Identifying dispensed material
- o Clean-up
- o Review

## PROCESSING CONTROL

- o What do you think?
- o GMP solution
- o Overview
- o Room and line clearance
- o Introducing materials
- o Formulation controls
- o In-process checks
- o Monitoring processes
- o Testing line samples
- o Batch records
- o GMP and batch records
- o Post-processing clean-up
- o GMP regulatory citations
- o Review

## PROCESS MONITORING

- o What do you think?
- o GMP solution
- o Overview
- o Handling process deviations
- o Controlling a process
- o GMP and handling deviations

## YIELD & RECONCILIATION

- o Overview
- o Theoretical yield & expected yield
- o Actual yield
- o Calculating reconciliation
- o GMP and yield/reconciliation
- o Review

## CONCLUSION

- o Summary
- o Summary II