GMP05 Good Manufacturing Practice in Processing Medicinal Products

Approximate study time: 1 hour

Level: Introductory/Intermediate

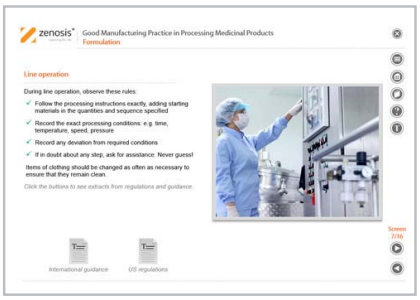
Audience: Manufacturing personnel

Category: GMP/QA/QC

Region: Europe, USA, Other

CPD Points: 1

Module outline
- Module overview
- Dispensing
- Formulation
- Yield and reconciliation
- Assessment



Operations in the dispensary and on processing lines are at the heart of medicinal product manufacturing. This module describes how to carry out such operations in compliance with the requirements of Good Manufacturing Practice.

We discuss how to: dispense starting materials; set up, control, and record formulation processes; evaluate product yield and calculate materials reconciliation. We set out the Good Manufacturing Practice (GMP) requirements that must be met in carrying out these tasks.

Who will benefit from this module?

This module provides essential training for all personnel who work on the processing of medicinal products. Other staff working in a manufacturing environment in the pharma/biotech industry will also benefit from this module.

Learning objectives

- Dispense starting materials in compliance with GMP requirements
- Set up, control, and record formulation processes in compliance with GMP requirements
- Evaluate product yield and check materials reconciliation in compliance with GMP requirements

Module outline

Module overview
An outline of the module's scope and objectives, and notes on terminology.

Dispensing
The dispensary is the place where raw materials entering the processing area are controlled. It is where starting materials coming from the warehouse are weighed and transferred into containers ready to be taken for formulation operations. Dispensing is a critical step in production and must be done with great care. Any error can have a substantial impact on product quality. In this session we discuss good practice in dispensing starting materials.

Formulation
Formulation processes are the prime engines of pharmaceutical manufacturing. Control of these processes is central to the assurance of product quality. In this session we set out the main tasks involved in processing a batch after starting materials or intermediate product have been dispensed, and we describe relevant GMP requirements.

Yield and reconciliation
Product yield evaluation and material reconciliation are two ways of checking the balance between the amount of material input to a process and the amount output from it. If the balance does not lie within acceptable limits, this may indicate a problem with the process. In this short session we discuss the importance of yield and reconciliation, how to check them, and what must be done to comply with GMP requirements with regard to them.

Assessment
Multiple-choice mastery assessment.