

# GMP



## Contamination Control

This module provides an introduction to the types, sources, risks and control measures of contamination relating to pharmaceutical products.

### Objectives:

- Recognise why contamination controls are critical to product quality
- Identify different types of contaminants
- Identify the potential sources of contamination
- Identify the key types of contamination controls within a manufacturing facility

# Course Outline

## INTRODUCTION

- o Welcome
- o Objectives
- o Reviews and assessments

## CONTAMINATION & QUALITY

- o What do you think?
- o GMP solution
- o Overview
- o Responsibility to patients
- o Why are contaminants dangerous?
- o Why is contamination not detected by QC?
- o Microbial control
- o Review

## CONTAMINATION SOURCES

- o What do you think?
- o GMP solution
- o Overview
- o Routes of transmission
- o Micro-organisms
- o Personnel
- o Manufacturing
- o Factory air
- o Equipment
- o Water
- o Cross-contamination
- o Examples
- o Review

## CONTAMINATION CONTROL I

- o What do you think?
- o GMP solution
- o Overview
- o Personal hygiene
- o Buildings and premises
- o Housekeeping
- o Facility cleaning
- o GMP issues when cleaning
- o Equipment cleaning I
- o Equipment cleaning II
- o What's wrong with this cleaning method?
- o What's wrong with this storage area?

## CONTAMINATION CONTROL II

- o Starting materials
- o Protecting raw materials
- o Pharmaceutical water
- o Environmental monitoring
- o Air control
- o Cleanrooms
- o Controlling cross-contamination
- o Contamination scenarios
- o Room clearance
- o Packaging line clearance
- o Review

## CONCLUSION

- o Summary