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Online GMP Training

GMP6 | Contamination Control

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

OBJECTIVES

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

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CONTENT

Introduction

- Objectives
- Reviews and assessment

Contamination and quality

- What do you think?
- What do the GMP rules state?
- Overview
- Responsibility to patients
- Impure products are dangerous
- What about Quality Control (QC)?
- Select all the statements that are true

Contamination sources

- What do you think?
- What do the GMP rules state?
- Where does contamination come from?
- More about microbes
- Personnel
- Manufacturing environment
- Factory air
- Equipment
- Water
- Cross contamination
- Examples
- How does contamination get into products?

Contamination control

- What do you think?
- What do the GMP rules state?
- Written programs
- Buildings and premises
- Air control
- Cleanrooms
- Personal hygiene and gowning
- Environmental monitoring
- Housekeeping
- Facility cleaning
- Equipment cleaning
- Common versus dedicated equipment
- Cleaning equipment/utensils
- Starting materials
- Storage of materials
- Pharmaceutical water
- Controlling cross-contamination
- Room clearance
- Line clearance
- Example keg
- Which of the following are controls to address building and premise contamination?
- How should equipment be stored?
- Select True or False for each statement

Conclusion

- Summary