



Approximate study time: 1 hour



Level: Introductory/Intermediate



Audience: Manufacturing personnel



Category: GMP/QA/QC



Region: Europe, USA, Other

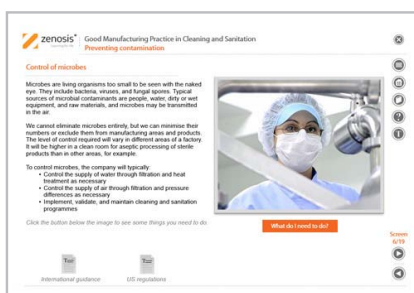


CPD Points: 1



Module outline

- Module overview
- Preventing contamination
- Cleaning and sanitation of premises
- Cleaning and sanitising of equipment
- Assessment



Cleaning and sanitation of premises and equipment are essential to efforts to prevent contamination of product, and they need to be done in compliance with Good Manufacturing Practice (GMP) regulatory requirements. This module shows why it is so important to do a good job, what to consider before and during each job, and how best to go about the work.

We begin by explaining how product may become contaminated and what can be done to prevent contamination through effective cleaning and sanitation procedures. We set out good practices to keep the factory clean and sanitary, and we describe how to prepare for and carry out cleaning and sanitation of premises. Finally we turn to the vitally important subject of cleaning and sanitising of production equipment.



Who will benefit from this module?

Everyone who works in a manufacturing environment in the pharma/biotech industry will benefit from this module.



Learning objectives

- Understand why cleaning and sanitation are so very important in preventing contamination of product
- Adopt good practices in preparing for, carrying out, and recording the cleaning and sanitising of premises and equipment



Module outline

Module overview

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

Preventing contamination

Preventing contamination of product is one of the highest priorities in the factory, and effective cleaning and sanitation are essential to these efforts. In this session we describe sources of contamination and how to deal with them. We discuss the agents and equipment used, precautions to be observed, and the principles of the work required.

Cleaning and sanitation of premises

The whole factory must be kept clean and sanitary. In this session we discuss how to contribute to general cleanliness of the premises and how to go about cleaning surfaces in the buildings. We also outline pest control measures.

Cleaning and sanitising of equipment

Production equipment must be thoroughly cleaned, and sanitised as necessary, to prevent contamination of product. In this session we describe how to go about this vital task in compliance with GMP requirements. We discuss how the grade of work required may vary according to the use of equipment, and we emphasise that written and validated procedures must be followed exactly. We focus on equipment parts that require particular attention, and we explain the significance of hold and dwell times. We end with the completion of cleaning status tags and records, and we outline the use of automated clean-in-place systems.

Assessment

Multiple-choice mastery assessment.