

Preventing Cross Contamination

Regulatory Basis:

FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion

This document provides guidance for the prevention of cross contamination in production processes, warehousing, material transfer, and distribution.

1. Facility Design should include consideration of, and not be limited to, the following items:
 - Room and equipment layouts that minimize potential cross contamination of products (e.g., use of airlocks);
 - Use of closed processing equipment;
 - Air quality, airflow requirements, and air recirculation controls;
 - Product and material flow;
 - Personnel flow and gowning requirements;
 - Collection, transportation, and storage of waste;
 - Drainage systems; and
 - Cleanable continuous, smooth, and non-porous floors, walls, doors, and ceilings with surfaces able to withstand repeated application of cleaning agents.
2. In Cases Where Product or Components are Exposed, Material Flow should be designed to avoid cross flow of exposed materials and to minimize activities that increase the potential for cross contamination.
3. Products Requiring Special Containment Measures should be classified as follows:
 - Special Precautions Required: Occupational Exposure Band (OEB) classification 4 or classification 5 products (e.g., corticosteroids) that are not beta-lactams, cytotoxics or sex hormones.
 - For these products, the requirements should be established as the operational (e.g., procedures, material flows) and design principles (e.g., air handling, airlock use) for containment and prevention of cross contamination. In addition, Environmental Health and Safety guidelines should define containment measures that provide additional assurance to prevent cross contamination;
 - Dedicated Manufacturing Suite Required: cytotoxics and sex hormones classified as OEB 4 or 5 products. Dedicated Manufacturing Suite Specifications include, but are not limited to:
 - Processing areas at negative pressure with respect to adjacent rooms;
 - Air handling systems designed to prevent cross contamination;
 - Suite dedicated equipment;
 - Suite dedicated sampling/dispensing area;
 - Use of airlocks;
 - Suite dedicated clothing and shoes; and