

# Construction Features and Interior Finishes In cGMP and Pharmacy Compounding Facilities

## Overview

The following is intended to be a general overview of compliant standards and regulations for the construction features and the interior finishes typically used in Current Good Manufacturing Practice (cGMP) and Pharmacy Compounding facilities.

Federal regulations govern the design, facility operations and practices of cGMP facilities. 21 CFR 211 contains the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals. Subpart C of the 21 CFR 211 covers buildings, and facilities including design construction, architectural features, sanitation and maintenance.

United States Pharmacopeia, USP <797> and USP <800> applies to Pharmacies in which compounded sterile preparations (CSPs) and non-sterile preparations are prepared, stored and dispensed. USP <800> specifically applies to hazardous drugs.

## Construction Requirements

Regulations require that facility should be easily cleaned and promote good operational activities. Surfaces, finishes and components should be accessible, cleanable, and not react with cleaning agents or be degradable, which might affect the operation or ultimately quality of the drug substance. It is incumbent on the designer of the facility to investigate the latest materials and details and not rely on dated designs or practices.

## Finishes

All finishes throughout these facilities shall be smooth, monolithic and easily cleanable. Sharp corners (particularly inside corners), joints, crevices and other conditions that can collect dirt shall be minimized, and all joints shall be sealed. Horizontal surfaces shall be minimized.

**Floor** finishes shall be monolithic seamless material, either poured 2-part epoxy resin or sheet goods such as seamless vinyl or seamless rubber, based on factors such as level of traffic (foot and wheeled), loading and use of cryogenics. All floor to wall junctions shall be provided with integral coved bases and crowns for enhanced cleaning.

**Wall** finishes shall be either sheet vinyl, fiberglass reinforced plastic (FRP) with sealed joints or gypsum wall board with high performance coating (reinforced hi-build 2 part epoxy paint). If gypsum wall board is used it must be anti-microbial, anti-mold type. Colors must be carefully selected to prevent eye fatigue, but readily show

dirt or contamination. All outside corners must be protected by stainless steel corner guards mounted flush to adjacent surfaces. Inside corners must be radiused.

**Ceiling** systems can be one of 3 types:

- 1) Specialty suspended tile system, aluminum grid with clean room type acoustical tiles, gaskets and hold down clips.
- 2) FRP gasketed grid with FRP tiles and hold-down clips.
- 3) Suspended gypsum wall board with high performance coating (hi-build epoxy paint).

Ceiling penetrations for air and light diffusers must be sealed to ceiling finish with sealant at perimeter frames as well as door and window frames sealed to abutting wall surfaces. The design of engineering systems shall minimize the number of valves, junction boxes and other points requiring access above the ceiling to minimize the need for access panels.

All joints between materials and systems must be flush wherever possible and gasketed or sealed. Inside and outside 90 degree corners must be coved for enhanced cleaning and finish adhesion.

**Doors and Frames** shall be suitable for cGMP environment. Frames shall be welded stainless steel (no knock-down frames permitted), or FRP. Doors shall be stainless steel or FRP with half glass vision panels. Specialty doors such as all glass automatic operating folding doors, which are used as space savers in tight spaces, may be allowed only if fully cleanable and do not promote dirt collection. Hands-free infrared motion detector activation is preferred over push plates. Interior windows are desirable within the cGMP area for safety, visual inspection, aesthetics and providing borrowed light. Door frames should be flush with the adjacent walls to eliminate corners and horizontal surfaces.

**Furnishings:** Loose, clean-room specific furniture should be used in lieu of built-in wherever possible. Tables, benches, shelves and other required items should be welded stainless steel or other appropriate seamless material. Items should be easily removable for flexibility and to allow for cleaning and decontamination.

## References:

1. CFR21 (Code of Federal Regulations) for cGMP spaces.
2. FS209E and ISO14644 - Clean Room standards.
3. USP 797 - Pharmaceutical Compounding—Sterile and Non Sterile
4. USP 800 - Pharmaceutical Compounding—Hazardous Drugs

