



Basics of Design for a Clean Room Environment

WHAT IS A "CLEAN ROOM"?

"A room in which the concentration of air-borne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters, e.g. temperature, humidity and pressure, are controlled as necessary".

BASICS OF DESIGN CONSIDERATIONS

Strict procedures are must followed to prevent contamination to the product by controlling the total environment. Air flow rates and air flow direction, pressurization, temperature, humidity, non-viable airborne particle and viable particle counter to be complies with regulatory.

THE STEPS OF CLEANROOM DESIGN AND CONSTRUCTION OF A CLEAN ROOM ARE GENERALLY DEFINED AS FOLLOWS:

1. The materials of construction of a clean room should be smooth on the surface facing the inside of the clean room. Color selection for ceiling, walls and doors is typically white. Commonly used materials include sandwich panel filled with Polyurethane or polystyrene complete with steel plate coated baked finishes and FRP.
2. The surface should be free of ledges and easily wiped free of any contamination that is deposited. The surface finish in a clean room must not break up easily and disperse chips or particles of material which may contaminate the cleanroom.
3. The butts and joints, as seen from the inside of the clean room, should not show openings that may harbor, and then disperse, dirt. Penetration point (e.g. for utility services, sprinklers or other devices and light fixtures) should be kept to the minimum required, and be sealed with proper silicon type (eg. anti-fungal, FDA approved)
4. Utility services supplied to process equipment are piped in with piping and cables hidden (eg. in raceways with coated steel plate panels complete with proper label such as direction flow and tagging).
5. Wall, floor and ceilings in clean rooms should be designed and constructed in such a way that the surfaces are accessible for cleaning. Frequently this means seamless vinyl or poured epoxy substrates, often coved to the walls.
6. Clean room surface, especially floor, should be able to withstand chemical disinfectant that used in clean room or liquid products. Some processes use strong acids or solvents that will attack surface.
7. Flooring type for clean room shall be easy cleanable, chemical resistance; corner and junction may provide flush coving especially at floor-to-wall and wall-to-wall junction for floor to wall to ceiling.
8. Ceiling system shall be not obstructing personnel from inspection or provision for other services and should be consistent with the level of cleanliness required.
9. Pass through boxes both active and standard, should include double interlocks with indicator lights.
10. Air diffusers in the corridors and processes rooms should be design in such a way to prevent dust contamination.

11. Air showers for dedicated areas with sensitizing drug substances. These are generally only placed at exits from processing zones.
12. Restricted access to authorized Production, Engineering staff by means of Proximity Card Readers and magnetically locked doors or equivalent. These devices are placed at the entrance to the clean room production area
13. Fire sprinklers, recessed type designed for cleanrooms and dome type smoke detectors are required. Fire extinguishers (powder type), should be boxed in, flush and sealed and should be access easily and visible during emergency.
14. Consideration should be given to the location and configuration of components such as lights and sprinklers to avoid disturbance of the intended airflow.
15. Ceilings should be sealed to prevent ingress of air borne particles, or other contaminants, from the ceiling void/plenum.

FLOORING

1. Floor surface layers should be non-porous, slip-resistant, abrasion-resistant, non-conductive if necessary; resistant to the chemical and easy to clean.
2. The self leveling epoxy flooring typically with 3.5 mm thick 2-part epoxy with excellent mechanical and chemical resistance and covering with flush coving from wall to floor.
3. The floor should support heavy static and dynamic loads with the required durability.

WALL PANEL

1. Wall system shall be flush structure, made of panel material with flush coving. Safety glass window can be integrated flush in a panel.
2. Cover strips or seals between panels should be smooth, with flush fitting to facilitate efficient cleaning and limit retention of contaminant.
3. Where glazing in wall or door, it should be of the non-opening type. If binds or shutters are required, these should be fitted outside the clean zone. Glazing frame should be smooth.

DOORS

1. Door handles, lever type, where required, should be smooth, non-staging and easy to clean. Doors are single or double leaf swing, half glass type with door closer and lock set. Doors shall be reasonably air sealed tight with a self-rising/gravity-fall bottom flap to prevent air leakage.
2. Doors complete with Retractable Bottom Flap Seal, single glazed flush.
3. Doors complete with automatic closer/ door closer.

LIGHTING

1. The lighting levels and uniformities design is required to provide good architecturally room lighting and the lighting position above ceiling. Certain level of lux to be defining for sufficient luminaires during manufacturing/ processes. Variable lux LEDs are frequently preferred.
2. The color rendering of light should be specified and should provide significant effect on the comfort of personnel and manufacturing process.
3. The lighting system design should be consistent with the effective of the clean room. Light fitting should free of contamination may be released. Commonly the cleanroom lighting comes with dense gasket (neoprene) for airtight closure.
4. The used of sealed or flush fitting should be selected. This type of lighting may come with top access (maintenance will be external cleanroom which will not interrupt the process or cleanroom integrity remains).
5. For unidirectional airflow area or room, the design and positioning of light fitting and associated diffuser should be such as to minimize or negate turbulence. Tear drop type commonly use for the Unidirectional flow areas (Grade-A Clean room classification).

6. The lighting should be serviceable in a manner such that the integrity of the clean room is not violated and excessive contamination is not produced.
7. The effect of glare should be considered within the context of the work being carried out.

This document is a summary guideline of factors to be considered when planning clean room spaces. It is not intended to be complete or to ensure regulatory compliance. Care should be taken to further investigate the specific requirements to comply with your application and/or regulatory certification.