

I3 Consulting

Clean rooms for Pharmaceuticals & Medical Device
Manufacturing



Introduction to Clean Rooms

A cleanroom is a controlled environment where Pharmaceuticals, APIs, Medical Devices, Food, Cosmetics, Ayurvedic products are manufactured. It is a room in which the concentration of airborne particles is controlled to specified limits by using HEPA and filters. These contaminants are generated by external environment, people, process, facilities and equipment.

Federal Standard 209E is the widely referred standard for air cleanliness for Cleanrooms and Clean Zones. Using strict protocol and methods in installation and assembly this can be achieved for critical manufacturing environments.

It only takes a quick monitor of the air in a cleanroom compared to a typical office building to see the difference. In typical office building air contains 5,00,000 to 10,00,000 particles (0.5 microns or larger) per cubic foot of air. A Class 100 cleanroom is designed to never allow more than 100 particles (0.5 microns or larger) per cubic foot of air. Class 1000 and Class 10,000 Cleanrooms are designed to limit particles to 1000 and 10,000 respectively.

Once a cleanroom is built it must be maintained and cleaned to the same high standards.

Sources of Contamination

The below mentioned are commonly known contaminants that can cause problems in some cleanroom environments. It has been found that many of these contaminants are generated from five basic sources. The facilities, people, tools, fluids and the product being manufactured can all contribute to contamination. Review this list to gain a better understanding of where contamination originates.

1. Facilities

- ✓ Man movement
- ✓ Material movement
- ✓ Entry and Exit
- ✓ Nature of construction
- ✓ Flooring/Walls
- ✓ Construction material
- ✓ Air conditioning
- ✓ Spills and leaks

2. Human Factor

- ✓ Hygiene of personnel
- ✓ Skin flakes and oil
- ✓ Cosmetics and perfume
- ✓ Spittle
- ✓ Sweat
- ✓ Clothing debris (lint, fibres' etc.)
- ✓ Hair

3. Tool Generated

- ✓ Friction and wear particles
- ✓ Lubricants and emissions
- ✓ Vibrations
- ✓ Brooms, mops and dusters

4. Fluids

- ✓ Particulates floating in air
- ✓ Bacteria, organics and moisture
- ✓ Floor finishes or coatings
- ✓ Cleaning Agents
- ✓ Water

Contamination Control methods

High Efficiency Particulate Air Filter (HEPA) - These filters are extremely important for maintaining contamination control. They filter particles as small as 0.3 microns with a 99.97% minimum particle-collective efficiency.

CLEAN ROOMS Design - Clean rooms are designed to achieve and maintain a uniform velocity along parallel flow lines called laminar flow. The more restriction of air flow the more turbulence.

AIR FILTRATION - In addition to the HEPA filters commonly used in Clean rooms, there are a number of other filtration mechanisms used to remove particles from gases and liquids. These filters are essential for providing effective contamination control.

CLEANING AGENTS - Cleaning is an essential element of contamination control.

CLEANROOM GARMENTS - The requirements for cleanroom garments will vary from location to location. It is important to know the local garment requirements of the cleanroom management. Gloves, face masks and head covers are standard in nearly every cleanroom environment.

HUMANS IN CLEANROOMS - There are both physical and psychological concerns when humans are present in clean rooms. Psychological concerns like room temperature, humidity, claustrophobia, odours and workplace attitude are important. Below are several ways people produce contamination:

1. **Body Regenerative Processes**-- Skin flakes, oils, perspiration and hair.
2. **Behaviour**-- Rate of movement, sneezing and coughing.
3. **Attitude**-- Work habits and communication between workers.

People are a major source of contamination in the cleanroom.

COMMODITIES - Care is taken when selecting and using commodity items in clean rooms. Wipers, cleanroom paper and pencils and other supplies that service the cleanroom should be carefully screened and selected.

COSMETICS - Many cosmetics contain sodium, magnesium, silicon, calcium, potassium or iron. These chemicals can create damaging particles.

TELEPHONE - Some important measurements related to contamination control are excess usage of telephone/Intercom.

ELECTROSTATIC DISCHARGE (ESD) - When two surfaces rub together an electrical charge can be created. Moving air creates a charge. People touching surfaces or walking across the floor can create a

List of Some of Equipment and Supplies Needed to Clean the Cleanroom

(All supplies must meet the Class 10,000 minimum requirements)

1. Cleaning and disinfectant solutions
2. Cleanroom mops
3. Cleanroom vacuum cleaner (if allowed)
4. Cleanroom wipers
5. Cleanroom mop bucket and wringer

General Cleanroom Regulations

For the better performance of the clean room personnel entering the clean room should be aware and follow these regulations at all times.

1. All personal items such as keys, watches, rings, matches, lighters and cigarettes should be stored in the personal locker outside the gowning room.
2. Valuable personal items such as wallets may be permitted in the cleanroom provided they are NEVER removed from beneath the cleanroom garments.
3. Eating, smoking or chewing gums, pans etc. strictly prohibited inside the cleanroom.
4. Should enter the cleanroom only by wearing the garments approved for the cleanroom.
5. NO cosmetics shall be worn in the clean rooms. This includes: rouge, lipstick, eye shadow, eyebrow pencil, mascara, eye liner, false eye lashes, fingernail polish, hair spray, mousse, or the heavy use of aerosols, after shaves and perfumes etc.
6. Only approved cleanroom paper shall be allowed in the cleanroom.
7. Approved ball point pens shall be the only writing tool used.
8. Use of paper or fabric towels is prohibited. Use of hand dryers equipped with HEPA filters are suggested.
9. Filthy gloves or finger coats should not be allowed to wear and touch on any item or surface.

10. Only approved gloves, finger cots (powder-free), pliers, tweezers should be used to handle product. Finger prints can be a major source of contamination on some products.
11. Solvent contact with the bare skin should be avoided. They can remove skin oils and increase skin flaking.
12. Approved skin lotions or lanolin based soaps are sometimes allowed. These can reduce skin flaking.
13. All tools, containers and fixtures used in the cleaning process should be cleaned to the same degree as the cleanroom surfaces. All of these items are a source of contamination.
14. No tool should be allowed to rest on the surface of a bench or table. It should be placed on a cleanroom wiper.
15. Only cleanroom approved wipers are allowed to be used. The wipers must be approved for the Class of cleanroom being cleaned.
16. ALL equipment, materials and containers introduced into a sterile facility must be subjected to stringent sterilization prior to entrance.
17. NO ONE who is physically ill, especially with respiratory or stomach disorders, may enter a sterile room. This is a good practice in any cleanroom environment.

Personal Actions Typically Prohibited in Cleanrooms

1. Fast motions such as running, walking fast or horseplay.
2. Sitting or leaning on equipment or work surfaces.
3. Writing on equipment or garments.
4. Removal of items from beneath the cleanroom garments.
5. Wearing the cleanroom garment outside the cleanroom.
6. Wearing torn or soiled garments.

[More Information](#)

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