



# Clean Room

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## **Introduction**

Generally clean room is designed to reduce the contamination of processes and materials and is accomplished by removing or reducing the sources of contamination.

## **Definitions:**

### **Clean room**

A clean room or area is a room with different environmental control of particulate and microbial contamination, constituted and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.

In another word, a clean room is a room in which the concentration of air hold particle is controlled to a specified limit.

### **Aseptic area**

Aseptic area is a room or special area within the clean room designed, constructed, serviced and used with the intension of preventing microbial contamination of the product during production.



## **Sources of contamination**

The possible sources of contamination are as follows:

### **1. External Sources**

### **2. Internal Sources:** It encompasses the followings:

#### **A. Atmosphere:** This includes-

- a) Dusts
- b) Droplets
- c) Free Organisms

#### **B. Operator:** This includes-

- a) Breaths
- b) The hands
- c) Clothing
- d) The hair

#### **C. The working surface**

#### **D. Equipment's**

#### **E. Raw materials**



## 1. External Sources

For any given space, external sources exist externally and influence the gross atmospheric contamination.

External contamination is brought primarily through

- a) Air conditioning system
- b) Make up air

In addition, external contaminants can infiltrate through

- Building door
- Windows
- Cracks and wall
- Pipes
- The cables and ducts

Primarily the external contamination is controlled by

- a) High efficiency filtration
  - b) Space pressurization
  - c) Sealing of the space of penetration
- 

## **2. Internal Sources**

### **A. Atmosphere**

The atmosphere has no flora of its own. Because it can't support the growth of microorganisms, but it is usually heavily contaminated with particles. Microorganisms are usually associated many of these. The environment may become contaminated by the following materials.

#### **a) Dust**

A higher percentage of dust particles in the outside air come from the soil and therefore may carry soil borne bacteria. For e.g. *Saprophytes* and *Cocci*. In addition, pathogenic anaerobic sporing rods are quite common. Indoor air may also contain organisms of human origin such as *Staphylococcus* and *B Hemolyticus*

#### **b) Droplets**

Large numbers of droplets are excreted from the respiratory tract by coughing and sneezing and may contain organisms from the nose, mouth, throat and lungs. In this way common cold, Influenza, viral diseases, TB etc are transmitted easily.

#### **c) Free organisms**

Bacteria and viruses free from dusts-droplets are uncommon, but naked yeast and mold spores are often abundant.

## **B. Operator**

This includes the followings

### **a) Breaths**

In normal breathing few organisms are passed into the atmosphere, because they are retained in the fluids lining in the respiratory tract. But coughing and sneezing can cause contamination at a considerable distance by expelling droplets of these fluids.

For e.g. *Staphylococcus aureas*.

### **b) The hands**

These are major means of transmitting infections. It has been estimated that, there are not less than 10,000 organisms per square centimeter (100000/cm<sup>2</sup>) of skin.

### **c) Clothing**

Part of the atmospheric dust that becomes engulfed in the fiber of the fabrics is dislodged by the bod movement and can considerably raise the level of contamination around a person who is working carelessly

### **d) The hair**

Hair is constantly exposed to the atmospheric dust and may liberate dust particles and flaky patches during such motion as the shaking of the head.

## **E. Raw materials**

Raw materials may account for a high proportion of microbial and inert particulate contamination included into the pharmaceutical products.

### **Raw materials come from four sources**

#### **I. Natural sources**

- Bacteria
- Yeast
- Mold

#### **II. Plant origin Bacteria**

#### **III. Animal source Pathogenic bacteria**

#### **IV. Water (A prime source of contamination)**

## **Classification of Clean room**

Clean rooms are classified based on the particle counts per cubic fit of air and are defined in terms of the maximum number of particle is in the range of  $0.5 \mu$  or larger than  $5 \mu$  or larger size.

Generally two systems exists for the classification of clean room

### **1. The British Standard**

### **2. The Unites States Federal Standard**

These two systems are compared in the following table

Maximum no. of particle greater than the stated size				
Particle size in Micron( $\mu$ )	British Standard		Unites States Federal Standard	
	class	No. per cubic fit	class	No. per cubic fit
0.5	1	86	100	100
5		0		0
0.5	2	8495	1000	10,000
5		57		65
10		0		100,000
0.5	0	0	100,000	100,000
5		0		700

***Table: Comparison between British Standard and Unites States Federal Standard.***

## Temperature & Humidity control

One of the things to be careful of in respect to cleanroom temperature and humidity control, is specifying them at too low or too tight of a tolerance. That translates again into the cost of construction and the cost of operating your clean room.

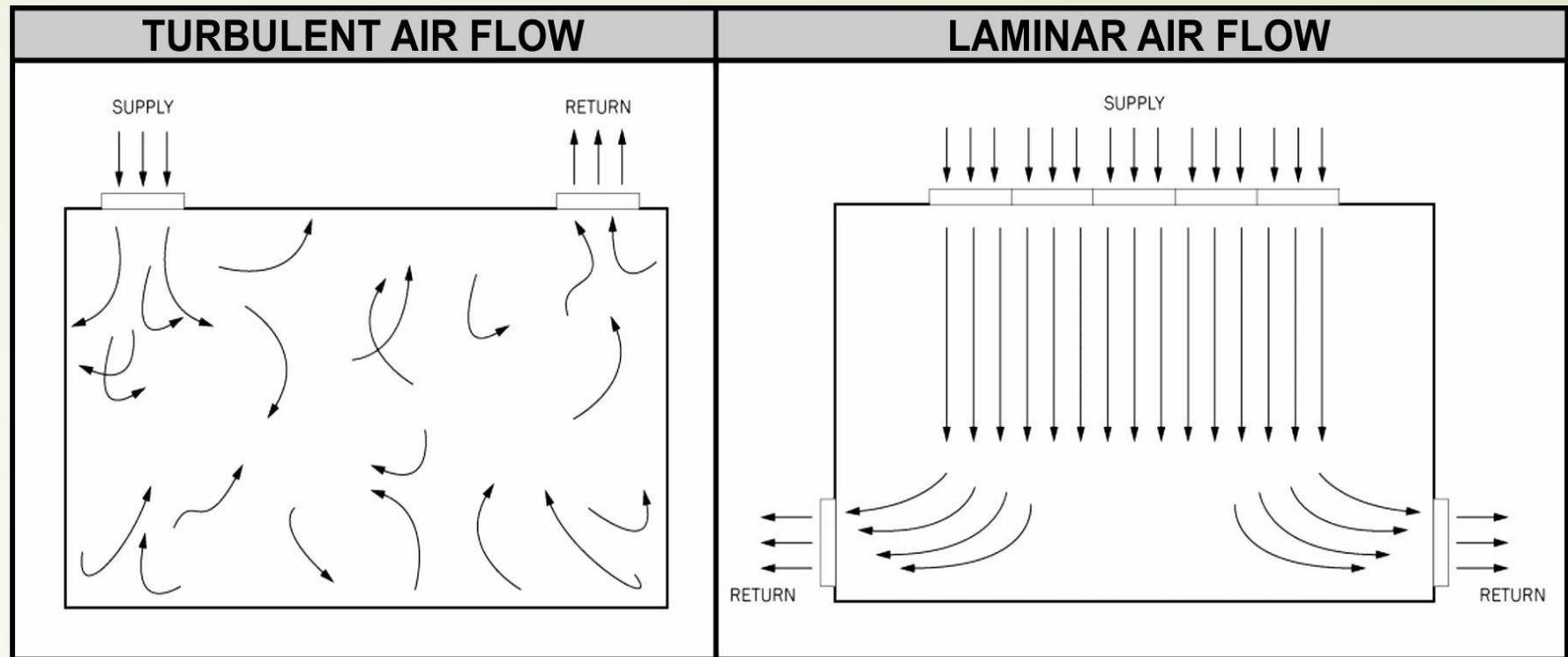
As an example, humidity is relative - It's relative to the temperature it's at. If you were to set your temperature at 70 degrees and 50% relative humidity, at 68 degrees that would be 55% relative humidity. So the difference of those 2 degrees would translate into having to dry that air to get it to a lower moisture content, and that costs significant money.

When you're trying to control humidity to a very tight tolerance, you've got to drive your chilled water down to extract moisture from the environment. Often times this translates into larger chiller because if you try to get it too low you have to do what is referred to as "derate" the chiller. This means that you have to put glycol in that system in order to have the system be able to flow water at a lower temperature or the water closer to freezing. So when you add glycol to it you take the ability for that chiller to transfer heat and you reduce that ability.

So in the example, if you have a 15% glycol mix in your chiller – that takes a chiller that could be 100 tons of cooling and you'll only get 70 effectively tons out of it. Often times clients make a decision to drive to lower temperatures or lower humidity's, without clearly understanding what that costs them in terms of upfront costs and operational costs.

## Air flow in a clean room or typical system of supplying air in the clean room-

There are mainly four methods of controlling the atmospheric contamination.



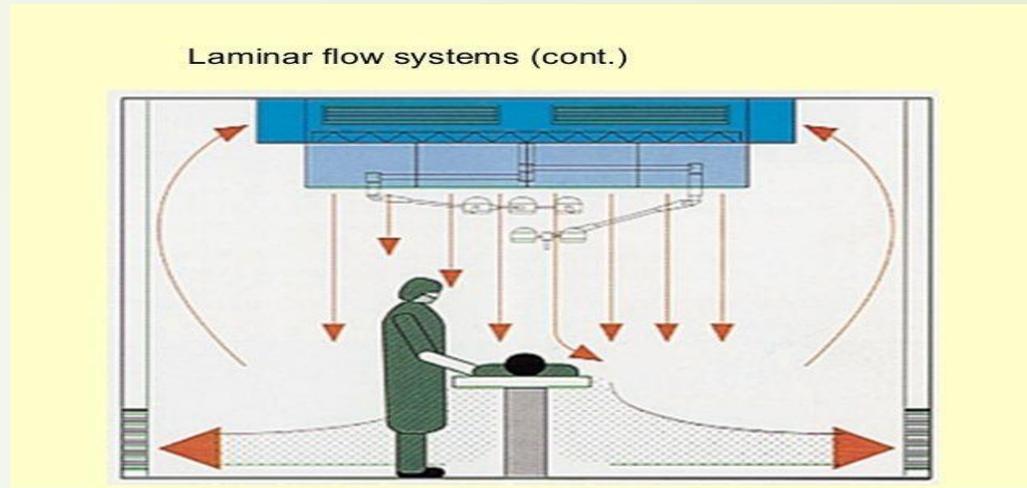
**Figure: Conventional air flow (Turbulent) and Unidirectional/Laminar air flow.**

## Conventional air flow

This is also known as turbulent air flow and is distinguished by its method of air supplying system. In the Conventional air flow system filtered air is pumped into the room to produce a positive pressure, compared to the exterior and in a turbulent fashion. The foreign particles already present may flash out and maintain a clean condition. Air enters into the room through the filter in the ceiling or high up in the wall and leaves from the room through carefully cited outlets or outlet ducts fitted in low down on the opposite wall or in the floor at a distance from the inlet. Conventional air flow is defined in terms of the number of air changes per hour. The air flow should not be less than 2 poise per hour.

## Unidirectional air flow (Laminar air flow)

Here the room is continuously swept by a filtered air. The total air within the room flows ideally with uniform velocity along parallel flow line which may be either horizontal or Vertical.



## **UDA = Unidirectional Air-Flow**

The air enters into the room through a bank of filter which comprises one complete wall or ceiling and exists through a bank of outlet. Laminar air flow is defined in terms of air velocity.

### **A typical system for supplying air involves the following things**

1. Intake of fresh air
2. Pre filtration
3. Temperature adjustment
4. Humidification
5. Final filtration

#### **6. Intake of fresh air**

The air should flow through an intake situated well above the ground level.

#### **2. Pre filtration**

This consists of a coarse filtration to remove the large particles from the air and protect the main filter.

#### **3. Temperature Adjustment**

The air is passed over a coil through which steam or refrigerant is circulated to permit the thermostatic control of the air temperature.

#### **4. Humidification**

The air is passed through a fine atomized spray of demineralized water to increase the humidity to an acceptable level.

## 5. Final filtration

Final filtration is achieved through a high efficiency particulate air (**HEPA**) filter positioned at or as close as possible to the inlet of the room.

### Differences between Conventional and Unidirectional air flow system

	Features	Conventional air flow	Unidirectional air flow
1	Room condition	The filtered air pumped into the room to produce a positive pressure.	The room is continuously swept by a layer of filtered air.
2	The air is pumped	In a turbulent fashion	In a uniform velocity
3	The air enters into the room	In a multidirectional pattern	Along parallel flow lines, this may be vertical or horizontal
4	Air flow type is defined	In terms of the number of air changes per hour.	In terms of air velocity
5	Air is supplied	Through the bank of highly efficient filter	By air diffusion or filter in the ceiling.
6	Air flow pattern	Is less than HEPA.	Is HEPA
7	Turbulenc	Creates significant turbulence.	Uniformly minimizes turbulence

## Air filtration

Filtration is an important aspect of clean room. Most of the filters are define by their particle removal efficiency and air flow rate.

Mainly two types of filters are used in the clean room

1. HEPA Filter
2. ULPA Filter

### **HEPA filter**

High-Efficiency Particulate Air (HEPA), also sometimes called high-efficiency particulate arresting or high-efficiency particulate arrestance, is a type of air filter. Filters meeting the HEPA standard have many applications, including use in medical facilities, automobiles, aircraft and homes. The filter must satisfy certain standards of efficiency such as those set by the United States Department of Energy (DOE). To qualify as HEPA by US government standards, an air filter must remove (from the air that passes through) 99.97% of particles that have a size of 0.3  $\mu\text{m}$ .

### **ULPA Filter**

ULPA is an acronym for "Ultra Low Penetration Air (filter)". An ULPA filter can remove from the air at least 99.999% of dust, pollen, mold, bacteria and any airborne particles with a size of 100 nanometres (0.1  $\mu\text{m}$ ) or larger.

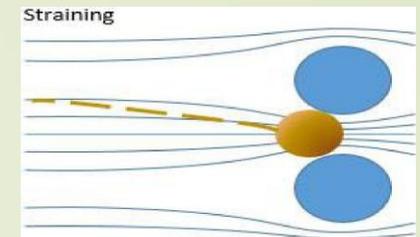
# Mechanisms of Filtration

There are four mechanism of filtration

1. **Straining**
2. **Impingement**
3. **Attractive forces**
4. **Diffusion**

## Straining

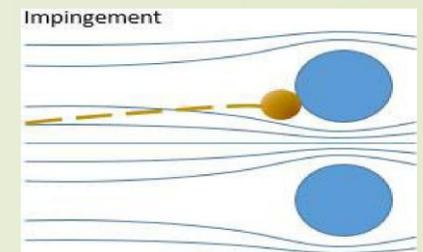
If the pores of the filter medium through which the fluid is flowing are smaller than the material, which is to be removed then the material will be retained. In this case filtration occurs in the surface of the filter.



## Impingement

As a flowing fluid approaches and passes an object, for example a filter fiber, the fluid flow pattern is disturbed as shown in the following figure.

Suspended particles with in-sufficient momentum may not follow the fluid path, but impinge on the filter fibre and are retained due to the attractive forces between the particle and the fibre.



**The effectiveness of the impingement process depends on the following factors:**

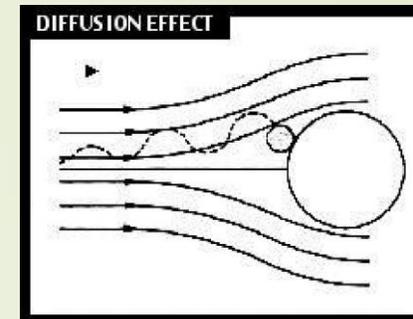
- a. Dust particle size:** larger the particle, greater the inertia.
- b. Density of the dust:** heavier the particle the greater the mass and more inertia.
- c. Depth of the filter:** the thicker the media, the greater the number of times a particle will be exposed to the probability of capture.
- d. Velocity of the airflow**

### **Attractive forces**

Electrostatic and other surface forces may exert sufficient hold on the particles to attract and retain them on the filter medium. For e.g. air can be freed from the dust particles in an electrostatic precipitation by passing the air between two highly charged surfaces which attract the dust particles.

### **Diffusion**

Particles are filtered through the filter media due to the concentration gradient.



## **Key issues to be considered in designing a clean room**

Cleanrooms and aseptic complexes should be designed for optimum flow of material, equipment, personnel, and waste streams so that raw materials and waste streams cannot cross over finished goods. The following points should be considered:

1. Clarity about the GMP and Standard used.
2. Unidirectional air flow specifications and qualifications
3. Clean room classification
4. Air change rates and recovery time in non-unidirectional system.
5. Clean room configuration for the services and maintenance of the process equipment's.
6. Validation of the building controlled system.
7. Real time particle monitoring system.
8. Retest and re-qualification frequency.
9. Bio decontamination by fumigation.
10. HEPA Filter led testing.
11. Floors, walls, and ceilings should be constructed of materials that are smooth, hard, and easy to clean.
12. Temperature and humidity controls in cleanrooms and supporting areas should be sufficient to maintain operator comfort when gowned and maintain adequate humidity for the process.
13. Cleanrooms should be designed to facilitate personnel, equipment, and material flows to prevent microbial contamination of sterilized or sanitized equipment and facilities, sterilized components, and sterile filtered drug product.

## **Necessities or purpose of clean room (The operation of clean aseptic room)**

The aim of the aseptic technique is to prevent the access of microorganism during the preparation and testing of the pharmaceutical products. There are several classes of pharmaceutical products for which the terminal heat treatment is not possible. For these preparations aseptic technique is used. For example

**A. Thermolabile (Destroyed or changed easily by heat; unstable) soluble substance stable in solution:** Solution of these substances can be filtered through a bacteria proof filter, but aseptic technique is required to prevent the contamination of the filtrate during the collection and while it is being filled & packed as well as sealed in the final container. For e.g. Thyamine-HCl injection.

**B. Thermolabile soluble substance unstable in solution:** Filtration through a bacteria proof filter is impracticable because these medications are not sufficiently stable in solutions for longer period. They must be preserved aseptically in a sterile solvent. For e.g. Chronic Gonadotropin injection.

**C. Thermolabile suspension stable in vehicle:**

**Example:** Propylidone and Propylidone Oily injection

**D. Thermolabile powder that require dilution with other powder**

**Example:** Antibiotic dusting powder

**E. Thermolabile powder that require incorporation of a semisolid base**

**Example:** The eye ointment BP Filtration is impossible for the last three cases and therefore the medicaments must be aseptically mixed with the appropriate sterile vehicle.

## Personnel Protective Clothing

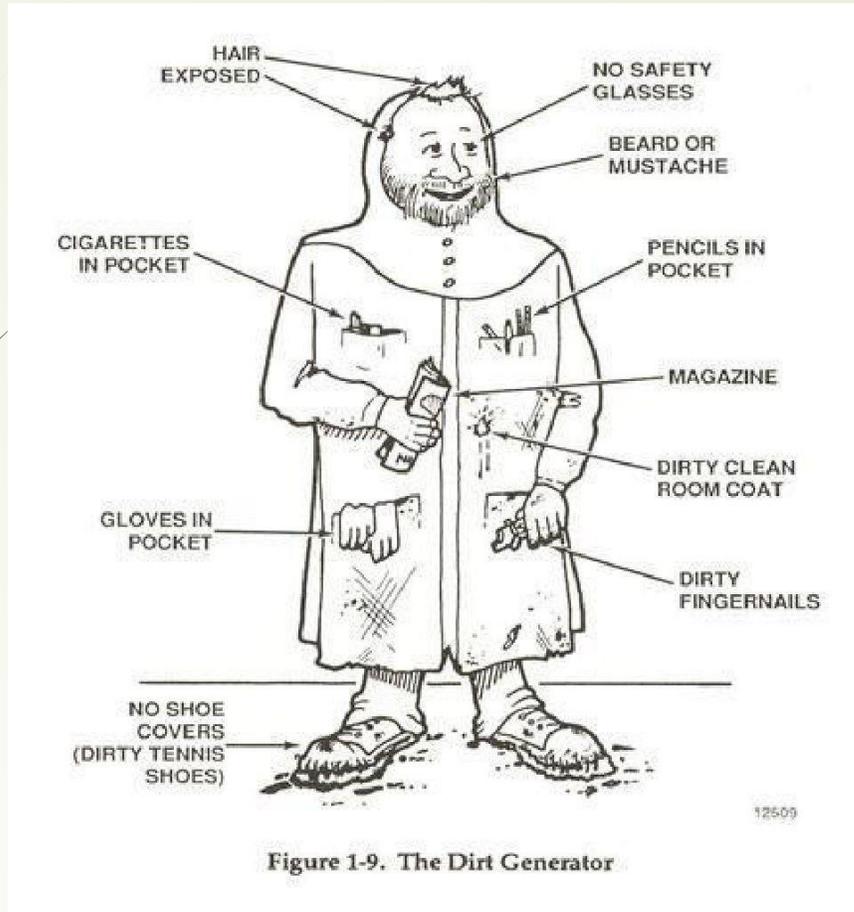
Cleanrooms and aseptic complexes should ensure that, personnel cannot move from less clean to cleaner areas without gowning.

**The following rules are to be observed by all persons qualified to work in the Cleanroom:**

1. Only personnel qualified through the Cleanroom Access Training program are allowed to enter the Cleanroom.
2. No makeup shall be worn inside the Cleanroom.
3. Food and drinks are prohibited in the Cleanroom.
4. No smoking is allowed before entering the Cleanroom.
5. **Clothing Requirements.** Everyone must wear full-length pants and closed shoes, such as safety shoes (no sandals, no open-toed shoes). In addition to that suitable cleanroom gowning, e.g. head-caps and shoe-covers have to be used.
6. Only use pens. Pencils are not allowed in the Cleanroom.
7. Hair nets, shoe covers, safety glasses, mustache/beard masks, and gloves must be worn at ALL times.
8. Nonessential items (tools, books, backpacks etc.) must be kept outside the Cleanroom or in the gowning room lockers.
9. Try not to sneeze, cough or breathe directly on a clean surface or into the product area.

10. Do not let your skin touch any surface in the Cleanroom. Do not touch your face with your gloved hand. Do not touch the outside of a glove (except for the wrist edge) with your ungloved hand.

11. Always clean up your work area before you leave.



## GOWNING

- o Proper gowning order
  - Hair cover
  - Hood
  - Shoe covers
  - Coverall
  - Gloves
  - Face mask
  - Safety Glasses
- o Cotton garments shed fibers. Hence, not used



Decron (polyester)



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# Key factors in clean room operations

## (Facilities of premises for the manufacture of parenteral products)

The preparation of sterile pharmaceutical products requires special facilities, designed to eliminate microbial and microbial and particulate contamination at all stages of manufacture.

1. Premises
2. Storage area
3. Bottle washing area
4. Laundry or Changing area
5. Preparation
6. Filling area
7. Sterilization area
8. Inspection and Labelling
9. Bonded area and release

### **Premises**

The premises in which the manufacturing of sterile products take place should provide sufficient space to allow efficient flow of work through all the necessary operation.

### **Storage area**

Storage space is required for raw materials, Empty containers, Packaging and labeling materials.

### **Weighing area**

The main use of this area is to measure raw materials used for the product.

### **washing area**

All bottles should be washed prior to entry into the clean room. Clean washed areas within the clean room are sometimes used for washing the ampoules, vials and various components just prior to use.

### **Laundry or cleaning area**

Access to clean room or areas is permitted only via the changing area. The operators must exchange their outdoor clothing for working in the clean room.

### **Preparation**

There are Clean room areas for the collection of water, Preparation of solution and final bulk product

### **Filling area**

This is the most critical area. The product is filled into the final container via a filler of suitable size and then sealed and sent out of the clean room area.

### **Sterilization area**

If the product is not aseptically produced, it has to be sterilized in this area.

### **Inspection and labeling**

Once the product has been sterilized, the contents are inspected for defects and then labeled.

### **Bonded area and release**

Lockable area where the product is kept until it passes all the requirements of Q.C. After qualifying the requirements of QC & QA the product is released for use.

# Design: Personnel flow and Material flow

## **Personnel flows considered:**

- Manufacturing personnel
- Maintenance personnel
- Quality control personnel

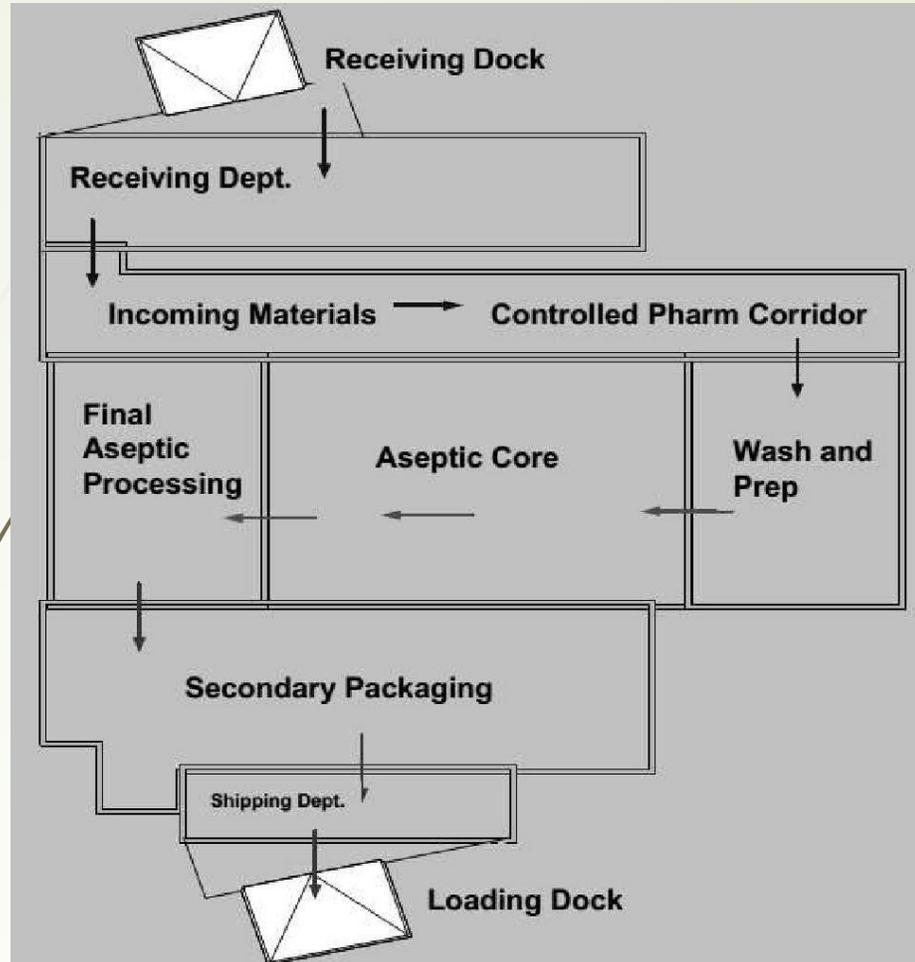
## **Material flows considered:**

- Raw materials
- Finished goods
- Waste
- Product (In-process, Intermediate & Final)
- Equipment

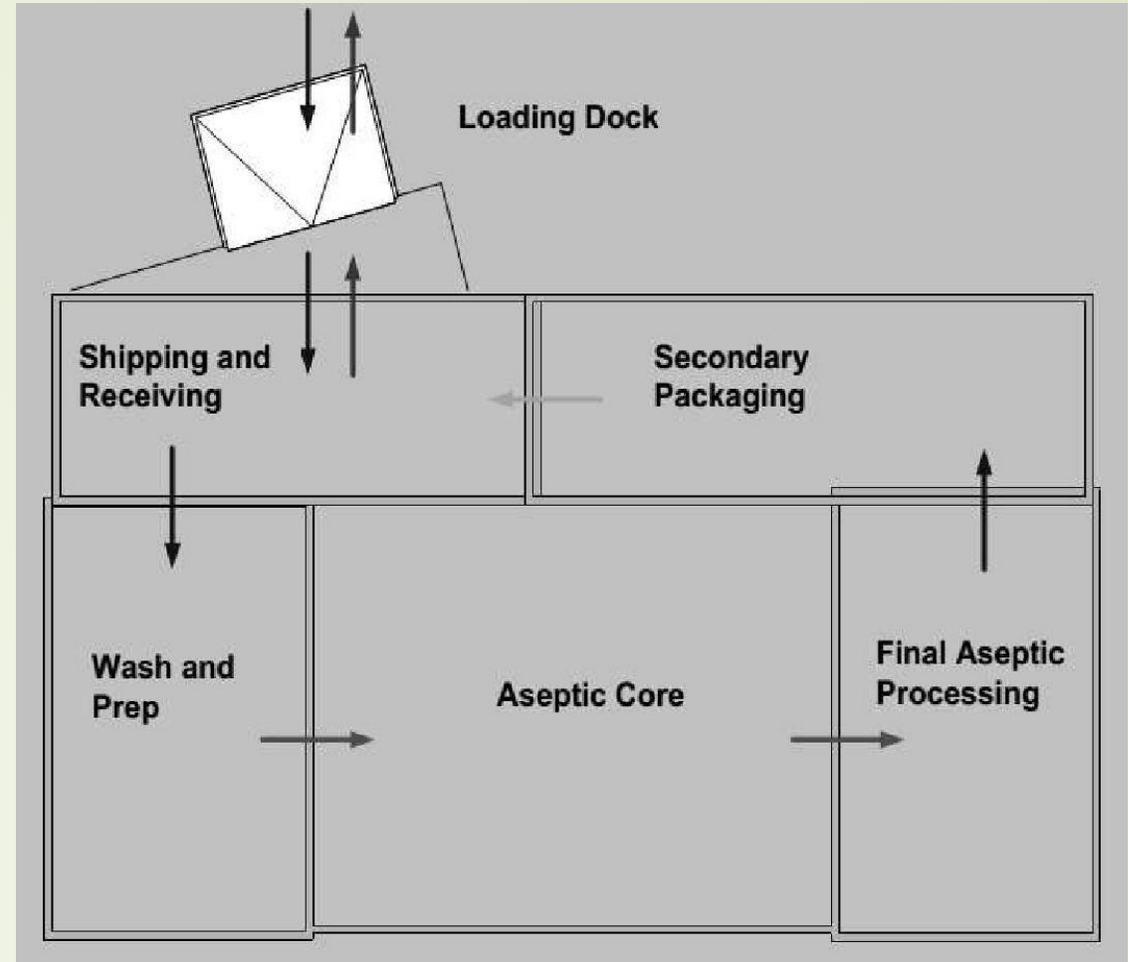
- Clean and dirty components
- Portable equipment
- Product containers

# Personnel flow and Material flow

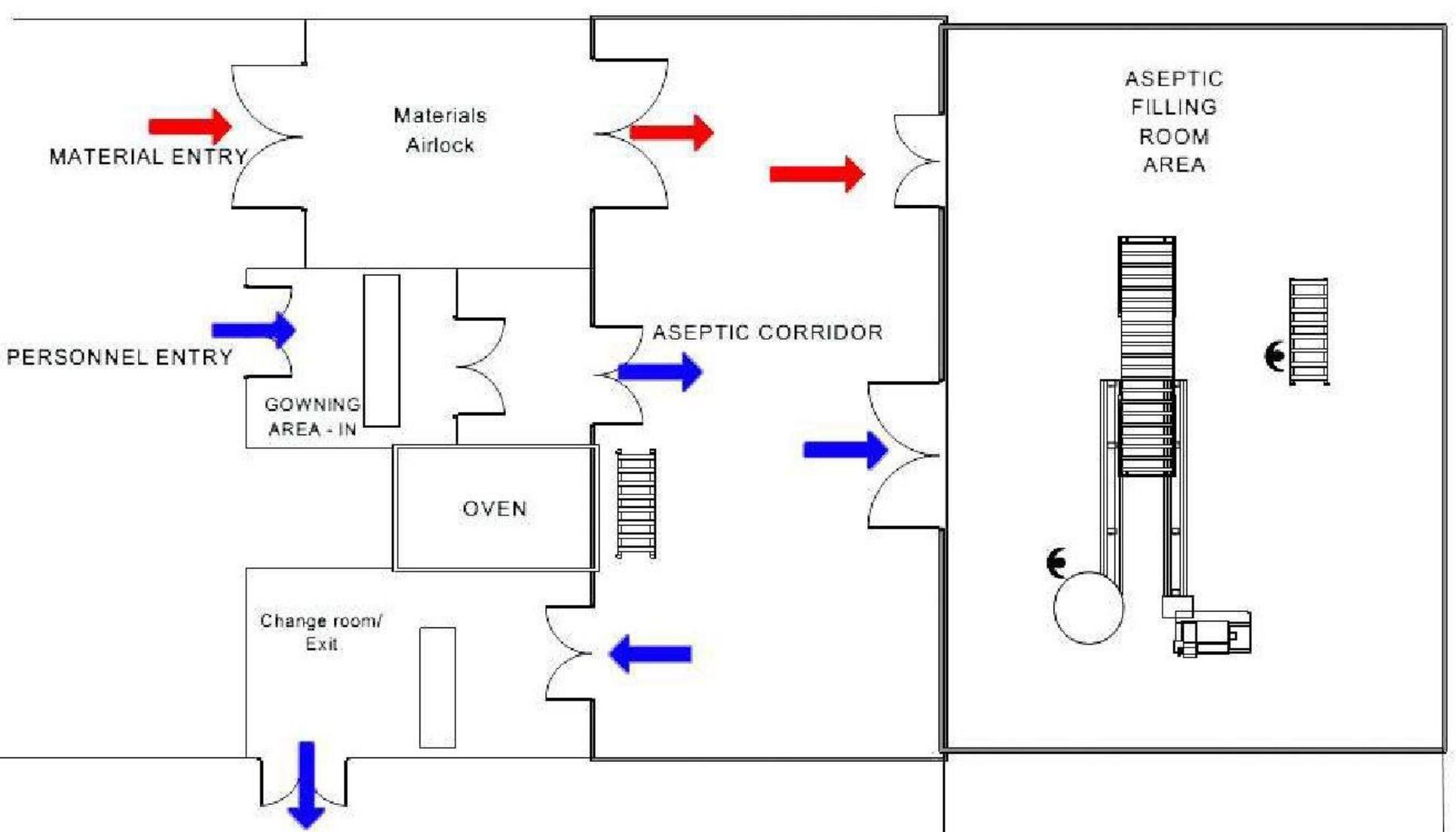
Desirable Layout



Less Desirable Layout



# Design and Operation of Clean Room



# Layout of an installation

## General Considerations:

- **Size:** of cleanroom should be minimum. if a large space is required, it should be divided, with or without physical barriers.
  - **Workstation siting and organization:** critical workstations away from, major traffic pathways. less clean operations site downstream of cleaner operations.
  - **Ancillary areas and adjacent cleanrooms:**
    - Pressure or flow differentials,
    - Access and communication arrangements (such as airlocks, speech panels and intercoms
- cross-contamination from less clean zones does not compromise the cleaner zones

## General Considerations (contd.)

- **Utility services and ancillary equipment**
  - General: Utility services should be designed and installed such that the cleanroom is not compromised by contamination.
  - exposed piping, tubing and cable runs should be minimized,
  - Vacuum-cleaning equipment
  - Sprinkler systems
  - Communication systems: to reduce personnel movement
  - Glazing: Avoid heat loss and solar gain, non-opening double glaze

# Construction

- ❑ The materials used should be selected to meet the requirements of the installation, and should take into account the following:
  - a) the cleanliness class;
  - b) effects of abrasion and impact;
  - c) cleaning and disinfection methods and frequencies;
  - d) chemical/microbiological attack and corrosion.
- ❑ Surface cleanliness and cleanability of materials of construction
- ❑ Fittings in airlocks: Minimum horizontal surfaces

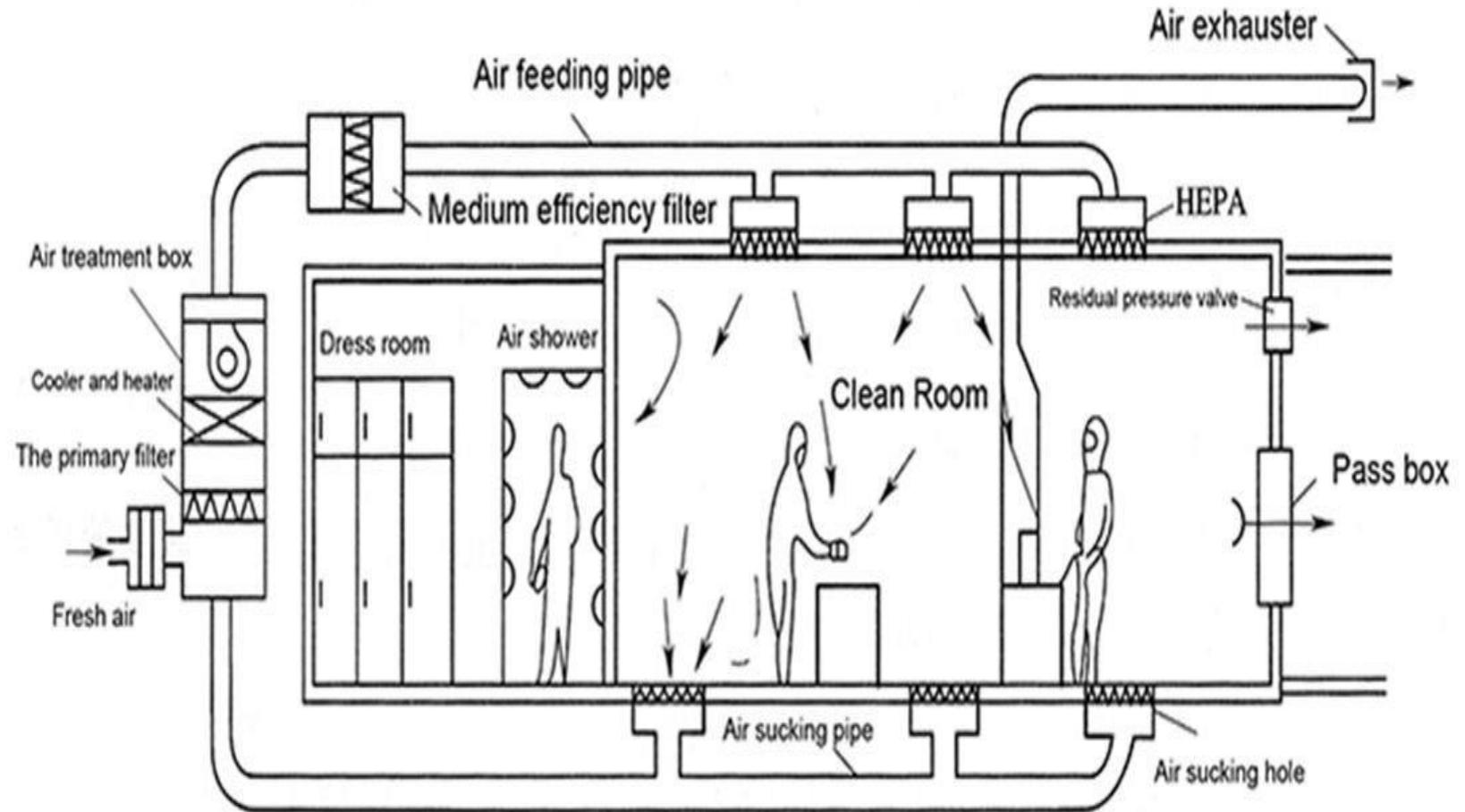
**Ceilings:** Ceilings should be sealed, penetration points should be kept minimum.

**Walls:** Materials and surface finishes should meet all general requirements.

- Particular consideration to impact and abrasion. (rubbing strips, protective bars)
- Cover strips or seals between panels should be smooth, with rounded edges
- Use double glazing, with airtight seal, which can enable flush mounting
- Doors should present as few horizontal surfaces as possible, thresholds avoided.
- Consider use of push plates, automatic openings, or appropriate door-swing

**Floors:** Floors or floor coverings should be non-porous, slip-resistant, abrasion-resistant, conductive if necessary.

# Clean Room Construction



Clean Room Construction

# Test of clean and aseptic area

The tests applied to clean or aseptic room can be classified into two classes

## **1. Commissioning test**

- A. Final filter installation test
- B. Induction leak test
- C. Filter efficiency test
- D. Particulate contamination controlling test
- E. Air pressure test
- F. Temperature and Humidity
- G. Air flow test
- H. Noise level test
- I. Lighting test
- J. Microbiological test

## **2. Monitoring test**

## Commissioning test

British standard 5295 list the tests and procedures which should be used to confirm that the room meets the required designated specifications. These tests and procedures includes the followings-

### **A. Final filter installation test**

This test is carried out to demonstrate that, the filter is not damaged, filter holding frame do not leak at the connection. This test can be performed by the bubble point test.

### **B. Induction leak test**

This test demonstrates that, particle cannot enter into the room through the leak in the construction joint. This is carried out by measuring the size of the leak or by microscopic examination.

### **C. Filter efficiency test**

This is also carried out by the bubble point test.

### **D. Particulate contamination controlling test**

This is used to demonstrate that, the number and size distribution of particulates in the room air do not exceed the level specified for the particular class of room. Microscopic examination and direct reading light scattering photometer are used for such measurement.

### **E. Air pressure test**

This test determines the pressure difference between the clean room and adjacent area. This is usually carried by using a sensitive monometer.



## **Temperature and Humidity**

This test demonstrates that the specified limit for temperature and humidity can be achieved, maintained and usually carried out by a psychrometer.

### **G. Air flow test**

This test is carried out to demonstrate that the air velocity or uniformity or laminar air flow in the room, comply with the required standard.

### **H. Noise level test**

Noise level measurement is taken to determine the sound frequency or noise sound for equipment, especially for oscillatory equipment. The measurements are taken at one meter from air inlet and at work benches.

### **I. Lighting test**

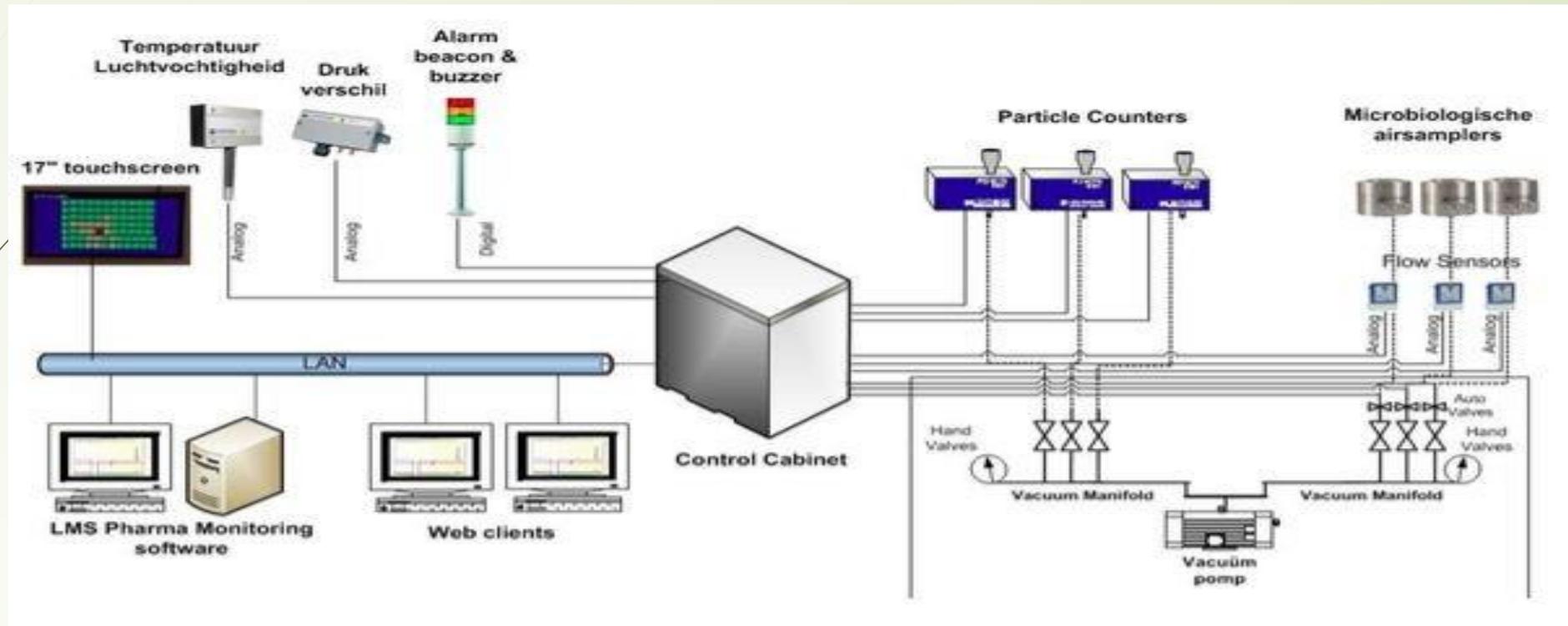
The quality of the general illumination within the area and also at the work benches is measured by using a portable photoelectric photometer.

### **J. Microbiological test**

This test is carried out to determine the number of the microbial contamination resulting from the introduction of the personnel, equipment or other things into the area.

# Monitoring test

Monitoring test is carried out to ensure the performance of the room as well as to ensure that the designed conditions are maintained. The test should be carried out repeatedly and regularly. The British standard recommends minimum interval for repeated testing.



**Fig: Equipment's for Room monitoring system**

## The testing parameters are given below

- a) Air pressure, temperature and humidity measurements should be recorded continuously.
- b) Particulate contamination should be determined daily for aseptic room and weekly for clean room.
- c) Tests for air flow velocity and uniformity should be carried out at the three months interval.
- d) Tests for filter efficiency should be conducted yearly. But, tests should be repeated after repair and maintenance.
- e) It is recommended that, the settle plate, Agar plate, contact plate, sterility test and swab should be carried out during each workshop.
- f) The process simulation should be conducted at three three months interval.

## Cleaning methods

Clearly defined and vigorously enforced cleaning and disinfection procedures are essential elements in the operation of clean and aseptic areas.

The **objectives** of these procedures are to remove microbial and particulate contamination that arises in the area during normal use.

## Recommendations

- ❑ Daily cleaning should take place immediately after the workshop ends and involves cleaning of all work surface and floor. Moreover 'through cleaning' should be arranged on a weekly basis.
- ❑ The cleaning materials should be selected to be compatible with the surface being cleaning and should not cause corrosion. Suitable cleaning agents are the alkaline detergents and non-ionic & ionic detergents.
- ❑ Cleaning materials should always be stored in dry place to prevent microbial growth and all cleaning solutions should be maintained at 65°C temperature during use.

### The cleaning method involves

1. Fumigation of the room with formaldehyde (HCHO) vapor at high relative humidity for a 12 hours period and is undertaken on a weekly or monthly basis, depending upon the extent to which the room is used.

**2. Disinfectants:** Sodium Hypochloride or Organochloride compounds at the concentration of 50-100 ppm; Quaternary ammonium compounds at 0.1- 0.2% W/V; 70% Ethanol or Isopropyl alcohol and 1% W/V Formaldehyde solutions. All these are suitable disinfectants for use in the work surface in the clean room.

**3. Bactericides:** They are used to remove bacteria.

4. UV light is passed through the areas to destroy the microbes.



## **5. Temperature test**

- Capability to maintain the air temperature level within the control
- Measured at a minimum of one location for each temperature controlled zone.
- Measurement time should be at least 5 min with one value recorded at least every minute.
- Comprehensive temperature test:
  - At least 1 h after the air-conditioning system has been operated
  - The number of measuring locations should be at least two.
  - Probe should be positioned at work-level height and at a distance of no less than 300 mm from the ceiling, walls, or floor of the installation.

## **6. Humidity test**

- Capability to maintain the air humidity level
- Expressed as relative humidity or dew point
- The sensor should be located at least at one location for each humidity control zone, and sufficient time should be allowed for the sensor to stabilize.
- The measurement time should be at least 5 min.

## **7. Recovery test**

- Ability of the installation to eliminate airborne particles.
- Only important and recommended for non-unidirectional airflow systems
- This test is not recommended for ISO Classes 8 and 9.
- 100:1 recovery time is defined as the time required for decreasing the initial concentration by a factor of 0,01.

## **8. Containment leak test**

- Determine if there is intrusion of contaminated air into the clean zones from non-controlled areas
- Particle concentration outside should be greater than the cleanroom concentration by a factor of 103. If the concentration is less, generate an aerosol.
- To check for leakage through construction joints, cracks or service conduits, scan inside the enclosure at a distance of not more than 5 cm from the joint, at a scan rate of approximately 5 cm/s.

## **9. Particle deposition test**

- Sizing and counting particles that can be deposited from the air onto product or work surfaces in the installation.
- Particles are collected on witness plates with surface characteristics similar to those of the at-risk surface
- Are sized and counted using optical microscopes, electron microscopes, or surface scanning apparatus.
- The witness plate should be placed in the same plane as the at-risk surface. And at the same electrical potential as the test surface.