Review Article

Design Considerations for Parenteral Production Facility

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ABSTRACT

Rational of this review article is to maintain principal of design, facility design, building a clean room is a complex exercise carried out in order to assure the product quality within the overall guidelines of FDA, WHO, ISO and Good Manufacturing Practices in the pharmaceutical industry. Poor cGMP conditions at a manufacturing facility can ultimately pose a life-threatening health risk to a patient. Parenteral dosage forms differ from other dosage form. Parenteral product directly enters into systemic circulation. Parenteral preparation should be free from any type of pyrogen, micro-organisms and particulate matter. In parenteral industry control of contamination and cross contamination plays important role by design consideration. Design of room, sterile processing department, air handling system, environmental contamination control system like HVAC system, RTRH, aerosol behavior, ventilation, entry and exit procedure, and their design methodology, equipments like high efficiency particulate air (HEPA) filter remove at least 99.97% of airborne particles 0.3 micrometers (μm) in diameter. A laminar air flow (LAF) system is combination of HEPA filters and lamination of air flow. It has 99.97% efficiency with offering uni-directional flow in aseptic area. There are various types of class HEPA filter and LAF system used in aseptic area depends upon their need they classify and with their optimum parameters, applications, specifications. So it is imperative to ensure that the design is undertaken in a systematic and organised manner so that on completion, the clean facility meets with the specifications and requirements of the end-user and regulatory authorities.

Keywords: Design considerations for parenteral production facility, design considerations for parenteral, design facility, parenteral, parenteral production facility

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INTRODUCTION

In parenteral industry control of contamination and cross contamination plays important role by design consideration. Poor cGMP conditions at a manufacturing facility can ultimately pose a life-threatening health risk to a patient. Parenteral dosage forms differ from other dosage form. Parenteral product directly enters into systemic circulation. Parenteral preparation should be free from any type of pyrogen, micro-organisms and particulate matter. Rational of this review article is to maintain principal of design, facility design, building a clean room is a complex exercise carried out in order to assure the product quality within the overall guidelines of FDA, ISO and Good Manufacturing Practices in the pharmaceutical industry. "Environment design of drug preparation rooms." The critical elements we are going to focus on here are room design, material/personnel flow, equipment layout, surface materials and service ability. The design criteria will depend on the needs of the operating room such as the number of operating suites, expected use, the type of cases that will be performed and the distance between or and sterile processing and new facility or upgrading an existing facility. Design of clean space or clean room encompasses much more than the traditional control of

temperature, humidity & make up air to keep the environment acceptably "clean" other parameters that must be included in to the design of contamination control such as suspended particulates both viable and non viable, air flow velocity and air flow patterns, cross contamination, noise, vibration & electro Static discharge within the clean cell (1-3).

GENERAL ENVIRONMENTAL DESIGN

Principels of Desigen of Environmental Control facilities for Parenteral

1. Only sterile items are used within the sterile field.
2. Gowns are considered sterile only from waist to shoulders level in front and the sleeves and tables are sterile only at table level.
3. Persons who are sterile touch only sterile items or areas; persons who are not sterile touch only unsterile items or areas and unsterile persons avoid reaching over a sterile field; sterile persons avoid leaning over an unsterile area.
4. Edges of anything that encloses sterile contents are considered to be sterile and sterile field is created as close as possible to time of use.
5. Sterile areas are continuously kept in view and sterile persons keep well within the sterile area (2,4).

Figure 1: Sterile items

Figure 2: Sterile person with gowning

Facility Design

1. Manufacturing areas designed for aseptic processing smooth, easily cleaned surfaces.
2. Designed to control the manufacturing environment (personnel and process).
3. Adequate and separate areas, for various activities (testing, manufacturing).
4. HEPA-filtered air in manufacturing areas; higher control (classification) for critical manufacturing steps.
5. Product type and makeup. • Stage of manufacturing. • Scale of manufacturing.
6. Material and personnel flows designed to maximize efficiency and minimize product mix-ups and concurrent vs. campaigning –impact on HVAC, cleaning and personnel (2,4).

Controls for preventing contamination and cross contamination

1. Campaign manufacturing and area/equipment clearance and labeling system.
2. Use of sterile transfer connecting devices and cleaning and sanitization.
3. Flow of product and waste material and personnel performance.
4. Environmental quality and control, validated, controlled sterilization of all product and added ingredients, container/closures, equipment, utensils, product-contract surfaces, routine dynamic environmental monitoring, equipments, environmental capabilities, sterility needs (2).

Design Objectives

1. Temperature and relative humidity should be controlled and air pressure regulated.
2. Contamination due to air borne particles should be controlled by an efficient filtration system (4).

Need of Desigen of Environmental Control facilities for Parenteral

1. For control on air, temperature, humidity and pressure.
2. For product free from pyrogen, microorganisms, particulate matter.
3. Suggest facility be designed to accommodate current and future needs.
4. Suggest facility be designed to be as flexible as possible and suggest that the facility be designed, operated and controlled to the highest level possible.
5. Effective monitoring of the conditions and Good Manufacturing Practices (GMP) requirements by governmental agencies like the FDA, and pharmaceutical companies (5-8).

Building Design, Construction And Layout

The building layout and its construction are poor there is very little that an air conditioning system designer can do to satisfy the end-user of the sterile areas.

Sterile zones are normally divided into three sub zones;

1. Main sterile zone or white zone.
2. Cooling zone which is also a white zone
3. Set of three change rooms: black, grey and white in ascending order of cleanliness.

   In order to achieve a pressure gradient, it is imperative that zones are located such that the gradient is unidirectional, i.e. the room with the highest pressure should be located at one end and the room with the lowest pressure should be located near the opposite.

   Entry for people to the main sterile room should be from a set of three change rooms: black, gray and white. Entry for equipment and material must be through airlocks. In case any wall of the sterile area is exposed to the outdoor, care should be taken that no glass is provided. Any glass window provided in an internal partition should be sealed.

1. Sharp corners should be avoided between floors, walls and ceiling.
2. Tile joints in the floor should be carefully sealed and epoxy painting should be carried out in these areas and special attention should be given to the type of ceiling.

In such cases the air conditioning system is required to be designed before slab construction is started in order to provide the following

a. Location and size of the cutouts for terminal filters.
b. Location and size of the cutouts for return air risers and inserts in the slab.
c. Provide floor drain locations for air handling units and sleeves for drain line and cabling should be provided in inverted beams.

In areas where air handling units are located water proofing must be carried out.

Additional cut outs are required to be left for other services.

a. All cutouts should have curbing at the edge to prevent water seepage into the working area and mounting frames for terminal filters/terminal filter boxes should be grouted at the time of casting the slab.
b. Lighting layout and equipment should be matched with the cut-out location and size. The ceiling slab should have inverted beam construction in order to avoid projections into the clean rooms.

In the case of a false ceiling in the sterile area, the following points should be considered:

a. Inserts should be provided for false ceiling supports and mounting of filters.
b. To prevent fungus growth and eliminate air leakage, the false ceiling should be of non shedding variety, such as aluminium or PVC coated CRCA sheet. False ceiling members should be designed to support part of the weight of terminal filters and proper sealing must be provided between panels and between filters and panels to avoid air leakage (1,4,9-11).

Compounding and room design

The ante room or area can be achieved with something as simple as a strip curtain, preferably outside of the clean room. The ante room/area should be sized based on the number of technicians that will be working in the compounding room at any given time (12).

Figure 3: Building and room design

Works room

The key to a controlled environment is control. The room itself should be well thought out in regards to material handling, personnel flow and equipment layout (2).

Designing the Sterile Processing Department

The first step should be defining the function of sterile processing. The goal is to create an efficient infrastructure to support the processing of instruments and supplies for the operating room (OR).The next step is the selection of fixtures and support equipment for the decontam area. The type and number of washers will dictate the number of sinks, washer-ultrasonics, hoppers etc. Moving on to the clean side, again, based on the number of washers, it is possible to determine the number and type of steam-sterilizers, gas-sterilizers, plasma sterilizers and other equipment. The number of washers and sterilizers will determine the number of workstations.

Limit the number of staff.

Limit the movement of staff + Proper layout of surgical instruments (2,12).

Definition of clean room

PART 1: Specification for control environmental clean rooms, work stations and clean air devices.

PART 2: Guide to construction and installation of clean rooms, work stations and clean air devices.

PART3: Guide to the operational procedure and disciplines applicable to clean rooms, work stations and clean air (2,4).

Objectives in cleaning a clean room

The objectives in cleaning a clean room can vary between industries but the contamination that should be removed may one, two or all of the following types:

1. Particles and fibers.
2. Chemicals.
3. Bacteria.
4. Electrostatic charges.

Particles and fibers are undesirable although the minimum size of particle.

The Critical and General area of a clean room

The clean room divides into;

1. Critical Area and
2. General Area.

The critical area is the area around the point of the production where contamination can gain direct access to the process. This area often protected by localized laminar flow clean benches and workstations. The "General" area is the rest of the clean room where contamination will not gain direct entry into the product but should be kept clean because of the transfer of contamination into the critical area. It is necessary that the critical area be cleaned most often with the best cleaning ability without introducing contamination (2,12,13).

Classification of Clean Rooms

The class is directly related to the number of particles per cubic foot of air equal to or greater than 0.5 micron.

(1) Class 100,000:

Particle count not to exceed a total of 100,000 particles per cubic foot of a size 0.5µ and larger or 700 particles per foot of size 5.0µ and larger.

(2) Class 10,000:

Particle count not to exceed a total or 10,000 particles per cubic foot of a size 0.5µ and larger or 65-70 particles per cubic foot of a size 5.0µ and larger.

Figure 4: Class 10,000 Clean room

(3) Class 1,000:
Particles count not to exceed a total of 1000 particles per cubic foot of a size 0.5µ and larger or 10 particles per cubic foot of a size 5.0µ and larger.

(4) Class 100: Particles count not to exceed a total of 100 particles per cubic foot of a size 0.5µ and larger (2,14,15).

Figure 5: Class 100 Clean room

Class 1: The particle count shall not exceed a total of 3000 particles/$m^3$of a size 0.5µ.
Class 2: The particle count shall not exceed a total of 3000 particles/$m^3$of a size of 0.5 µ or greater; 2000 particles/m^3 of size 0.5 µ or greater; 30 particles of a size 10 µ.
Class 3: The particle count shall not exceed a total of 1,000,000 particles of a size of 1 µ or greater; 20,000 particles/m^3 of size 5 µ or greater; 4000 particles/m^3 of a size 10 µ or greater; 300 particles of a size of 25 µ or greater.
Class 4: The particle count shall not exceed a total of 200,000 particles of a size of 5 µ or greater (2,16,17).

For the manufacture of sterile medicinal products normally 4 grades can be distinguished.
GRADE "A": The local zone for high risk operations. eg. Filling zone, stopper bowls, open ampules and vials.
GRADE "B": In case of aseptic preparation and filling, the back ground environment for grade "A" zone.
GRADE "C" &"D": Clean areas for carrying out less critical stages in the manufacture of sterile produce (2,17,18).

Table 1: Air bore particulate classification for Grade A, B, C & D

	Maximum permitted number of particles /m³			
Grade	At rest		In n operation	
	0.5mm	5mm	0.5mm	5mm
A	3500	0	3500	0
B	3500	0	350,000	2000
C	350,000	2,000	3,500,000	20,000
D	3,500,000	20,000	Not defined	Not defined

ISO Standards (16,19-21)

Table 2: ISO standards for clean room

Numbers maximum concentration limits (particles/m³ of air) for Particles (N) equal and larger than the considered size						
	0.1 mm	0.2 mm	0.3 mm	0.5 mm	1.0 mm	5.0 mm
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1000	237	102	35	8	
ISO 4	10,000	2370	1020	352	83	
ISO 5	100,000	23700	10200	3520	832	29
ISO 6	1,000,000	237000	102000	35200	8320	293

Table 3: Clean room classification

FS209 Cleanroom Classification	ISO 14644-1 Cleanroom Classification	NMT 0.5um Particles/m3	Viable Microbes (cfu/m3)	Average Airflow Velocity (fpm)	Air Change/hr
100,000	8	3,520,000	100	5-10	5-48
10,000	7	35,200	10	10-15	60-90
1000	6	35,200	7	25-40	150-240
100	5	3,520	1	40-80	240-480

DESIGN FOR CLEAN FACILITY

Air Handling System Design

While designing the air handling system the following points should be taken into consideration.

1. Motors for supply air/return air fans should have two speeds, since during non-working hours even though air conditioning is not required it is necessary to have pressurisation in the clean room for all 24 hours in order to ensure sterility.
2. Trend is to use VFD's (Variable Frequency Drives) on AHU and run the AHU at lower speeds at night/ holidays. This helps as a energy saving measure as well.
3. Cooling coil section should be provided with sandwich type of drain pan to collect condensate.
4. In case of a heating coil, at least a 0.5 meter space should be kept between coils.
5. Two sets of fresh air dampers should be provided, one for 10% to 20% and the second for 100% of fan capacity (6, 22, 23).

Air Flow Pattern

Air flow velocities of 0.36 m/s to 0.56 m/s (70 fpm to 110 fpm) are recommended as standard design for laminar flow clean room systems. Air is supplied at a much higher pressure than its surrounding area ensuring a higher velocity and pressure in the clean zone relative to the parameter. In

pharmaceutical plants use of laminar flow work benches is quite common to obtain class 100 at the work place (22).

ENVIRONMENTAL CONTAMINATION CONTROL SYSTEM AND DESIGN

Heating Ventilation and Air Conditioning (HVAC) Systems

HVAC systems are an internal part of environmental control system design. The primary purpose of an HVAC system is to provide a specific set of environmental conditions required for the manufacturing process. To properly design HVAC system it is importantly to define the required operational parameters. The parameters discussed in the following sections are to be determined prior to designing an effective HVAC system (23-27).

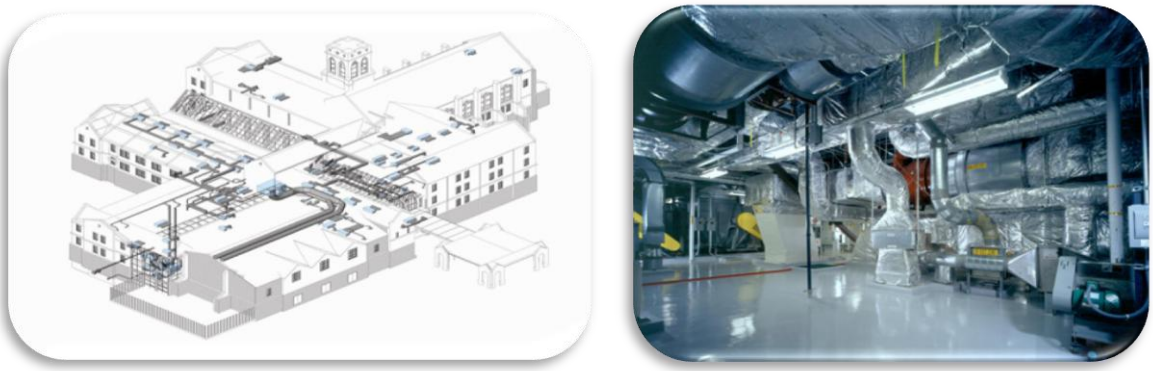

Figure 6: HVAC System

Temperature and Humidity Control

Temperature in the 68-74°F (19-23°C) range are considered acceptable. Lower temperature are normally selected in manufacturing environments used .Humidity control in most cases is also a comfort requirement. Comfort levels are in the 45-55% RH range. Humidity range 15-30% this is the case with many freeze dried substances. Normal humidity levels achieved with air conditioning systems (2).

Aerosol Behavior

These particles are subject to various physical forces as follows

1. Gravitational forces-setting action due to gravity.
2. Electrostatic forces-particle attraction because of differences in electrical charge.
3. Frictional forces-rubbing of particles against each other and inertial forces-particle tendency to not deviate from the airflow and diffusion forces-particles in continuous and disorganized motion (Brownianmotion).
4. Thermal forces-kinetic energy change as a result of differences in the temperature of the air masses (2).

Air Filtration

The main method for airborne contamination control in production areas is air filtration. The existence of various types of air filters, each with different design, construction and efficiency (2).

Air in controlled environment shall have

1. A per-cubic-foot particle count of not more than 100,000 in a size range of 0.5 micron and larger when measured with automatic counters or 700 particles in a size range of 5.0 microns or larger when measured by a manual microscopic method.
2. A temperature of 72^0F +_5^0 or 22^0C +3^0C and maximum relative humidity of 50 percent and a minimum of 30 percent.
3. A positive pressure differential of at least 0.05 inch of water with all (2,16).

Ventilation

Ventilation requirements for a controlled environment are determined by the number of people working in the environment, the number of air changes per hour required to achieve the desired level of cleanliness, the amount of air added for pressurization, and the nature of the manufacturing process (28).

Entry and Exiting

Entry and exit passage ways are also required for the transfer of personnel, equipment, and materials, locations of these rooms, sometimes referred to as “airlocks,” must satisfy the internal and external

requirements for the flow of materials and personnel (29).

Design Methodology

This step by step approach is briefly as follows:

1. Analyse the production process, especially the flow of materials and personnel. This helps to define the activities in the various rooms and group the rooms having similar environmental requirements.
2. Define the HVAC requirements system-wise and then room-wise. The requirements defined are cleanliness level, room temperature and relative humidity.

Room pressure, air movement direction and carry out detailed heat load calculations room-wise taking into account fresh air quantity requirements.

a. Air handling system design and selection.
b. Prepare air flow diagrams based on develop detailed layouts, after preparation of design specifications. The efficacy of the system design is based on proper consideration of the following factors:- the above mentioned load calculations and room pressure requirements.

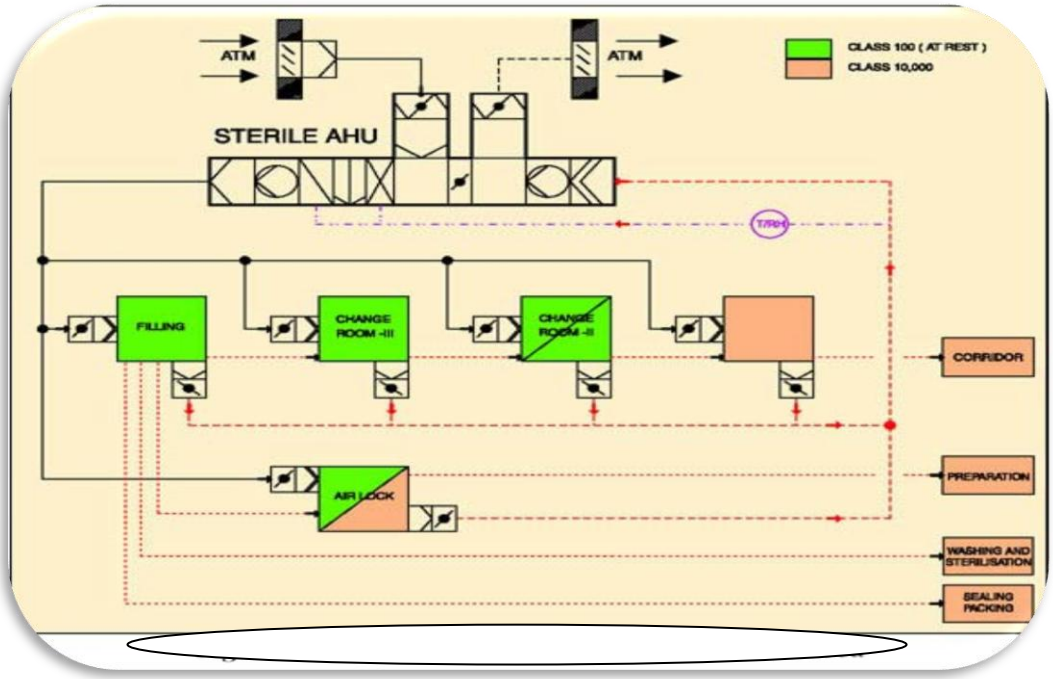

Figure 7: Typical Air flow for Sterile Area

The efficacy of the system design is based on proper consideration of the following factors:

1. Building construction and layout design and air handling system.
2. Selection of air flow pattern and pressurisation of rooms and fresh air quantity.
3. Duct system design, construction, selection, location and mounting of filtration system.
4. Defumigation requirement, operational qualification, performance qualification and validation.

The following measures are normally taken to control the air flow pattern and hence the pressure gradient of the sterile area.

1. To cater for the proper supply air quantity, balancing dampers should be installed at critical points.
2. Return air grilles are located near the floor and made as long as convenient to increase the collection of dust particles over a larger area.
3. Return air grilles in the main sterile zones are located to avoid dead air pockets. While locating the return grille, care should be taken to avoid placing the grille near a door opening into an adjoining lower pressure room. This is done to prevent creation of a low pressure zone near the door, thus preventing air leakage from the low

pressure to high pressure room at the time of door opening.

This is done to prevent creation of a low pressure zone near the door, thus preventing air leakage from the low pressure to high pressure room at the time of door opening.

Return air grilles in the "cooling zone" are oversized to take care of supply air of the cooling areas as well as the leakage air of the main sterile area (23,25,30,31).

HEPA Filter:

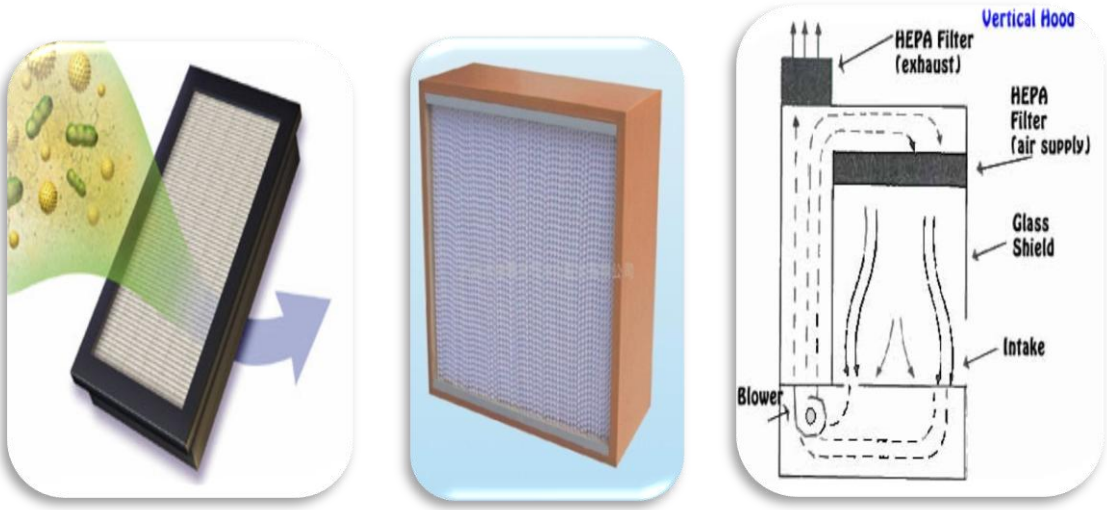

Figure 8: HEPA Filters

A High efficiency particulate air, or HEPA filter is a type of air filter that satisfies standards of United States Department of Energy (DOE).

Definition: A screen that filters out particles in the air by forcing them through microscopic pores.

HEPA filters have different ratings for efficiency, which are generally posted on the filter itself. HEPA filter is so efficient that for every 10,000 particles that enter the filter within its filtering range, only 3 particles will get through (2,9,23).

OPTIMUM PARAMETERS

Air changes per hour (fresh + re-circulating)

Total 20-25 ACH = Fresh air 10 + 15 total 15-25 Velocity 0.2 m/sec.

Air filtration HEPA 99.97% efficiency and pressure relationship to adjacent areas positive.

Optimal temperature 18 -25^{0}C and optimal humidity 15-20%.

HEPA filters Specifications

HEPA filters remove at least 99.97% of airborne particles 0.3 micrometers (μm) in diameter. The filters maximum resistance to airflow or pressure drop is usually specified around 300 Particals and its nominal flow rate used to prevent the spread of airborne radioactive contaminants. To satisfy the higher and higher demands for air quality in various high technology industries, such as aerospace, pharmaceutical processing, hospitals, health care, nuclear fuels, nuclear power, and electronic microcircuitry (computer chips) (2, 23, 27).

Function

The common assumption that a HEPA filter acts like a sieve, HEPA filters are designed to target much smaller pollutants and particles. Diffusion predominates below the 0.1 μm diameter particle size near to the Most Penetrating Particle Size (MPPS) 0.3 μm, both diffusion and interception are comparatively inefficient (2,9).

Biomedical applications of HEPA filters

HEPA filters are critical in the prevention of the spread of airborne bacterial and viral organisms and infection. Medical-use HEPA filtration systems also incorporate high-energy ultra-violet light units to kill off the live bacteria and viruses trapped by the filter media (2,9).

Five classifications of HEPA filters exist

Type A HEPA filters: Also referred to as industrial filters. An efficiency performance of 99.97 % retention of particulate matter 0.3 micrometers in size at an airflow of 85 L/minute.

Type B HEPA filters Known as nuclear type are designed to handle nuclear containment. Filters are tested for pinhole leaks, as significant numbers of these leaks lead to an efficiency drop at slower air flows. The test checks for 99.97 % retention of particulate matter 0.3 micrometers in size, but at 20 % the normal airflow.

Type C HEPA filters Called laminar flow filters due to their mostly exclusive use in biological laminar flow systems, filters are tested for particulate matter of larger sizes. filter has an efficiency of 99.99 % .

Type D HEPA filters Known as ultra-low penetration air.an efficiency rating of 99.999 % retention of particulate matter 0.3micrometers in size at airflow of 85 L/minute.

Type E HEPA filters Referred to as biological filters. These filters are created with a focus on stopping toxic, nuclear, chemical and biological threats (2,9).

Type of HEPA Filter

Horizontal Flow (Laminar Flow Hood)

1.Air blows towards worker.

2.Used for non-chemotherapy preparations.

Vertical Flow (Biological Safety Cabinet or Chemotherapy Hood)

1. Air blows from top to bottom maintain sterility and protect the worker.
2. Used to make chemotherapy.
3. The HEPA filter is located in the fragile mesh between thin metal strips at the back of the hood behind the HEPA filter screen.
4. Nothing should be permitted to come in contact with the HEPA filter.
5. No cleaning solution, aspirate from syringes, fluids, even if sterile touch HEPA filter, glass from ampoules (2,9,23).

Good aseptic technique is still required barrier isolators are exempted from placement restrictions of materials within the workspace. Barrier isolator workstations consist of physical structure, internal environment, and interaction technology, monitoring systems.

Physical

Hard shell or soft shell.

Hard shell (plastic, plexiglas, stainless steel) and Soft shell (soft plastic film).

Internal Environment

Less airflow required to achieve ISO 5 (Class 100) conditions and entering and exiting air is to be HEPA filtered. Isolators for cytotoxic preparations should capture vapour and positive pressure maintained for non-chemotherapy products (2, 23, 32).

Monitoring Systems

Gauges to monitor positive pressure environment and surface sampling for contamination.

Aseptic Technique

Vials and ampules. To prevent contamination.

Swab rubber closure with 70% alcohol using firm strokes in the same direction (32, 33).

LAMINAR AIR FLOW (LAF) SYSTEM

High efficiency particle air filtration. “HEPA” filters + Lamination of Air flow. Laminar flow ensures a directional air flow for a distance of 140-200cm Combined by HEPA filters remove particles > 0.3 micron in an efficiency of 99.97% over the aseptic operating field in a uni-direction flow offering. Laminar airflow system should provide a homogenous air speed of 0.45 m/s ±2.0% at the working position. “AN ULTRA CLEAN AIR” (2, 23).

Laminar Flow Clean Air Benches

Laminar flow clean air benches used in pharma labs, food (quality control) parenteral feeding. Tissue culture, horticulture, sterile testing, IVF, optics, micromechanics, Electronics industries. Laminar flow benches are specially designed for particulate and bacterial free sterile atmosphere to handle non hazardous non pathogenic samples, cell & tissue cultures, alimentation controls in microbiology (2, 29).

Applications:

Enhanced recovery of fastidious gram positive organism and filtration of enzyme solutions and diagnostic cytology (23, 29).

Specifications

Table 4: LAF Specifications

PARAMETER	SPECIFICATION
Prefilter	Efficiency - 99.9 % down to 5 microns
Final filter	Efficiency - 99.997% down to 0.3 microns
Fans	Direct driven motor
Filter grills	Made of anodized perforated aluminium sheet
Side panels	Removable type
Electrical	Single phase 220 / 250 V
Air flow	90 ft. per min (0.45m / sec)
Noise level	40-50 db
Vibration level	Less than 40 micro-inches (1 micron)
Lighting	Minimum 645 lux

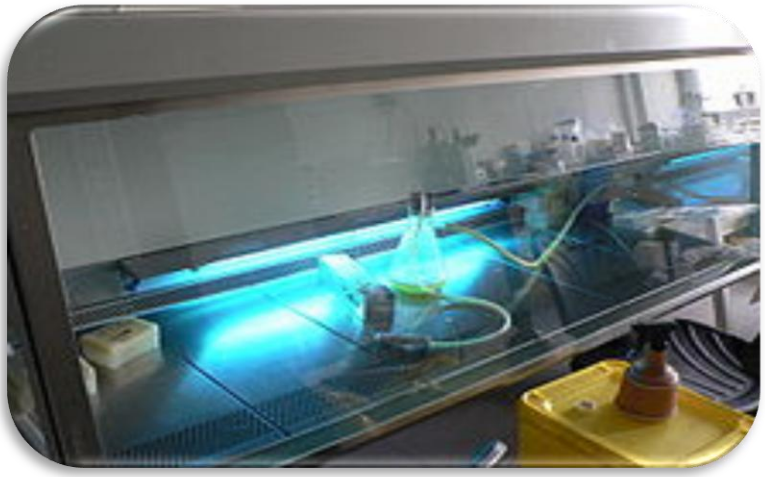

Figure 9: Laminar flow cabinet

A laminar flow cabinet or laminar flow closet or tissue culture hood is a carefully enclosed bench designed to prevent contamination of semiconductor wafers, biological samples, or any particle sensitive device. Air is drawn through a HEPA filter and blown in a very smooth, laminar flow towards the user. The cabinet is usually made of stainless steel with no gaps or joints where spores might collect (32, 33).

Classifications

All the vertical laminar air flow benches are classified into three broad categories.

Vertical Laminar Air Flow Class 100

The particle count of size 0.5 micron and larger is less than one hundred particle/ cubic feet, in the area of work.

Vertical Laminar Air Flow Class 10,000

The particle count of size 0.5 micron and larger, is less than ten thousand particle per cubic feet.

Vertical Laminar Air Flow Class 1,00,000

The particle count of size 0.5 micron and larger is less than one lac particle per cubic feet.

Basic Construction of Vertical Laminar Air Flow

Vertical laminar air flow bench are designed to conform to the united states federal standard and meets the class 100 conditions. Units are fabricated of industrial grade wooden boards covered with mica sheets. The inner portions of all our laminar air flows are painted with epoxy paint coating for extra long life (34, 35).

Vertical Laminar Air Flow

All our laminar air flows are fitted with fully washable synthetic pre-filter units and secondary high efficiency perfect air filters

made of mini pleated non woven fabric. The efficiency of our filters have a rating better than 99.99% at DOP (cold) and 99.97% at DOP (Hot). Units have the capacity to hold all suspended particles of size 0.3 micron (33, 34).

Vertical Laminar Flow Workstation

Figure 10: Vertical Laminar Flow Workstation

The cabinet work on a recirculating principle. It is a self balancing unit, drawing its make up air through the front aperture; approximately 70% of the airflow within the working area is then recirculating via the main HEPA filter, with they remaining 30% being exhausted out via the exhaust HEPA filter.

This workstation offers:

Product protection and safety parameters constantly monitored.

Operator friendly front screen.

Vertical laminar air flows are widely used for day to day clean rooms activities, pathogen handling, microbiology and biotechnology applications in various laboratories.

Process Explanation: Laminar Air Flow Technology

Laminar air flow are clean benches which have their own supply of highly purified air in which the total air present in the enclosure moves in a unidirectional velocity flowing in parallel lines, which is free from macroscopic fluctuations and towards the specimen and away from the user, giving ultimate protection to the user who is susceptible to contamination induced by diffusion of contaminated air, generated while handling hazardous pathogens, bacteria, viruses etc (33,34).

Motor and Blower Assembly

All our vertical laminar air flow units are provided with perfectly balanced (Static as well as dynamic) motor and blower motors bearing ISI mark. The rating of the assembly is 1/5 HP.

Illumination

This light arrangement conforms to the guidelines laid down in US federal standard. The illumination at the work table is approx 800 lux.

Ultra Violet Light

Optimal wattage ultra violet light is incorporated in the illumination panel of our laminar air flow to take care of the sterilization of the existing air present in the enclosure.

Noise Level

Laminar air flow benches are designed to ensure that the work enclosures have minimum possible vibration levels and noise level is also contained below 55 db.

Salient Features of Vertical Laminar Air Flow

Ergonomic design and versatile usage.

Low noise, vibration levels and conforms to US Federal Standard 209 B.

Calibration and protocol documentation.

Application (Vertical Laminar Air Flow)

Vertical laminar air flows have a variety of applications such as quality control labs of pharmaceutical industries, micro circuit, electronic assembly, manufacturing applications and deoxy ribonucleic acid thermo cycling.

General laboratory applications in biotechnology, tissue culture microbiology and genetic engineering (33,34).

Figure 11: Ultra Violet Light

CONCLUSION

Contamination control plays an important role in pharma industries (to maintain GMP), building a clean room. Principal of design, facility design, building a clean room is a complex exercise carried out in order to assure the product quality within the overall guidelines of FDA, WHO, ISO and Good Manufacturing Practices in the pharmaceutical industry. Design of room, sterile processing department, air handling system, environmental contamination control system like HVAC System, RTRH, aerosol behavior, ventilation, entry and exit, and their design methodology, equipments like High Efficiency Particulate Air (HEPA) filter and Laminar Air Flow (LAF) Systems is combination of HEPA filters and Lamination of Air flow. In parenteral industry control of contamination and cross contamination plays important role by design consideration. It is imperative to ensure that the design is undertaken in a systematic and organised manner so that on completion, the clean facility meets with the specifications and requirements of the end-user and regulatory authorities.

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