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Overview of HVAC System: Operational Significance of HVAC Provision for Pharmaceutical Facilities

Mohammad Umair Zaki

Faculty of Mechanical engineering
Noida International University
Greater Noida, India
E-mail umairzaki@yahoo.com

Dibya Prakash Mishra

Department of Mechanical engineering
Noida International University
Greater Noida, India
E-mail diba.engg@gmail.com

Abstract: This paper accentuate upon the application of Heating, Ventilation and Air-conditioning system in supporting the manufacture of quality pharmaceutical products. The HVAC system supply conditioned air to coveted areas of indoor surroundings to stimulate and maintain required temperature, humidity, ventilation and air-purity. The Good Manufacturing Practice for HVAC services embraces number of issues as well as determination of key parameters like temperature, humidity, pressures, filtration, airflow patterns and standard heat and cooling conventions. It also regulates the degree of operating various parameters for quality assurance, regulating the acceptance criteria, validation of the facility, and documentation for operation and maintenance. The WHO (World Health organization) as a factor of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over one hundred countries worldwide, suggestively in the modernizing world according to the standards of pharmaceutical industries.

Keywords*: HVAC system, BMS, Pharmaceutical process, Air-flow pattern, heating & cooling loads mathematical pattern*

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Introduction:

Heating ventilation & air-conditioning system is the major energy consuming part in residential or commercial buildings. In countries like India, more than 50% of input energy is consumed by HVAC system of the building.
[1]In Pharmaceutical manufacturing, how space conditions impact the product being made is of primary importance. The pharmaceutical facilities are Closely supervised by the U.S. food and drug administration (FDA), this requires manufacturing companies to conform to cGMP (current Good Manufacturing Practices). These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs to take proactive steps to ensure that their products are safe, pure, and effective. GMP regulations require a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mix ups, and errors. [2]Effective well utilized Building Management Systems (BMS) provide the core management tool required by building managers to ensure compliance with, and achievement of, Green Lease requirements, such as the target NABERS rating, monitoring of the Energy Management Plan (EMP) and reports for the Building Management Committee (BMC). It enables Building Managers to provide the optimal working environment consistent with maintaining the required NABERS rating while minimizing the costs to both landlords and tenants. Effective BMS utilization allows for optimal building performance by extending the operational life of equipment and systems through reducing loads and operating hours. Maintenance and capital costs are therefore reduced and less embedded energy is consumed through equipment replacement and upgrades.

Operational principle:

HVAC systems need to adapt to the changing science and technology in pharmaceutical industries. The three core functions of heating, ventilation, and air-conditioning are interconnected, especially with the need to provide thermal comfort and acceptable indoor air quality within reasonable installation, operation, and maintenance costs. HVAC systems can provide ventilation, reduce air infiltration, and maintain pressure relationships between spaces. The means of air delivery and removal from spaces is known as room air distribution.
[3]HVAC system executes four canonic functions; Control airborne particles, dust and micro-organisms through air filtration using high efficiency particulate air (HEPA) filters. Maintain room pressure (delta P) areas that must remain "cleaner" than surrounding areas must be kept under a "positive" pressurization, meaning that air flow must be from the "cleaner" area towards the adjoining space (through doors or other openings) to reduce the chance of airborne contamination. This is achieved by the HVAC system providing more air into the "cleaner" space than is mechanically removed from that same space. Maintain space moisture (Relative Humidity) humidity is controlled by

cooling air to dew point temperatures or by using desiccant dehumidifiers. Humidity can affect the efficacy and stability of drugs and is sometimes important to effectively mould the tablets. Maintain space temperature which can affect production directly or indirectly by fostering the growth of microbial contaminants on workers.

Air handling unit – [4] [5] the air handler is normally constructed around a framing system with metal infill panels as required suiting the configuration of the components. The metalwork is normally galvanized for long term protection. For outdoor units some form of weatherproof lid and additional sealing around joints is provided. Air handler is a type of device used to regulate and circulate air as part of a heating, ventilating, and air-conditioning for HVAC system shown in fig.1. An air handler is usually a large metal box containing a blower, heating or cooling elements filter racks or chambers, sound attenuators, and dampers. Air handlers usually connect to ductwork ventilation system that distributes the conditioned air through the building and returns it to the AHU. Sometimes AHUs discharge [supply] and admit [return] air directly to and from the space served without ductwork.

Components of AHU:

[4][5]*Filters* - Air filtration is almost always present in order to provide clean dust-free air to the building occupants and to the core areas and manufacturing areas of pharmaceutical firms. Filtration is typically placed first in the AHU in order to keep all the downstream components clean. Depending upon the grade of filtration required the types of filters used are G-4, F-6, F-9 and H-13 hence, G-4 filter is cheaper to replace and maintain thus saving other expensive filters from getting replaced within short interval of time. The span of a filter may be assessed by monitoring the pressure drop through the filter medium at design air volume flow rate. This is done by means of a visual display using a pressure gauge. Failure to replace a filter may eventually lead to its collapse, as the forces exerted upon it by the fan overcome its inherent strength, resulting in collapse and thus contamination of the air handler and downstream ductwork.

[4][5]*Heating & Cooling coils* - Air handling units requires providing heating, cooling, or both to change the supply air temperature, and humidity level depending on the areas and the application. Such conditioning is provided by heating and cooling coils within the air handling unit air stream; such coils are directly influenced to the medium providing the heating or cooling effect. Coils are typically manufactured from copper for the tubes, with copper or aluminum fins to assist heat transfer. Cooling coils will also employ eliminator plates to remove and drain condensate water. The hot water is provided by hot water generator and the chilled water is provided by chiller. Downstream temperature sensors are typically used to monitor and control "off coil" temperatures, in conjunction with an appropriate motorized control valve prior to the coil. Dehumidifier is required, and then the cooling coil is used to over-cool so that the dew point is reached and condensation occurs. A heater coil placed after the cooling coil re-heats the air to the desired supply temperature. This has the effect of reducing the relative humidity level of the supply air. During colder climates, where winter temperatures regularly drop below freezing point, then heating coils are often used as a first stage of air treatment to ensure that downstream filters or chilled water coils are protected against freezing. The control of the chilled coil is such that if a certain off-coil air temperature is not reached then the entire air handler is shut down for protection.

[4][5]*Humidifier* - Humidification is often necessary in colder climates where continuous heating will make the air drier, resulting in uncomfortable air quality and increased static electricity.

[4][5]*Air-mixing Plenum* - In order to maintain indoor air quality, air handlers commonly have provisions to allow the entry of outside air into through fresh air filtered opening regulated by a manual damper, and the exhausting of air from the building. During moderate climates, mixing the right amount of cooler outside air with warmer return air can be used to approach the required supply air temperature. A mixing chamber is therefore used which has manual dampers controlling the ratio between the return, outside, and exhaust air.

[4][5]*Blower fan* - Air handling units generally employ a large-squirrel cage blower driven by an AC induction electric motor to suction the air. The blower is driven by a Variable Frequency Drive to allow a wide range of air flow rates. Flow rate is controlled by inlet vanes or outlet dampers on the fan. These are driven using high efficiency EC (electronically commutated) motors with built in speed control. It is placed behind G-4 filters starting form fresh air opening damper.

[4][5]*Vibration isolators* - The blowers in an air handling unit can create substantial vibration and the large area of the duct system would transmit this noise and vibration to the occupants of the building situated in the core and manufacturing areas of pharmacy plant. To avoid this, vibration isolators or damper block are normally inserted into the duct immediately before and after the air handler and often also between the fan compartment and the rest of the AHU. The rubberized canvas-like material of these sections allows the air handler components to vibrate without transmitting this motion to the attached ducts. The fan compartment is further isolated by placing it on a spring suspension, which will palliate the transfer of vibration through the floor.

[6]*BMS* - It can be abbreviate as Building management system in HVAC control simulation. BMS is a computer-based control system installed in buildings that controls and monitors the building's mechanical and electrical equipment such as ventilation unit, Air handling unit of HVAC systems. A BMS consists of software and hardware; the software program, usually configured in a hierarchical manner, can be proprietary, using such protocols as C-bus, Profibus, and so on. Vendors are also producing BMSs that incorporate using

internet protocols and open standard such as DeviceNet, SOAP, XML, BACnet, Lonworks and Modbus.

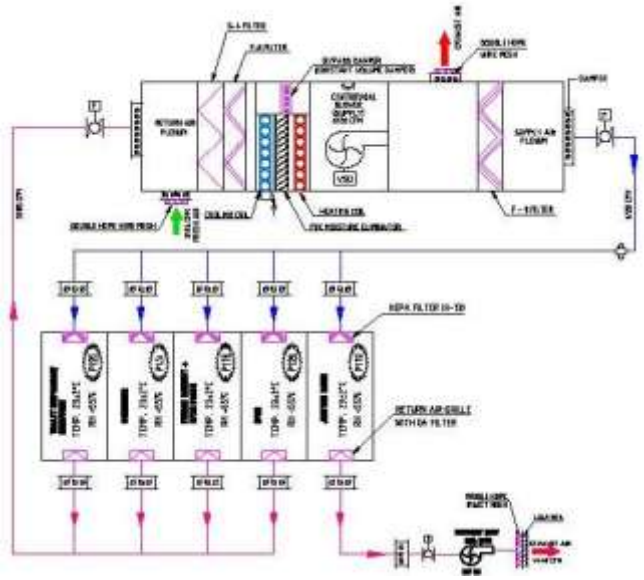
Control Philosophy - To control and monitor various indoor environmental parameters, a micro-Processor based building Automation System shall be installed.

The following control philosophy shall be employed: Temperature control - By regulating chilled / hot water flow through chilled water/hot water coil with the help of temperature sensor (Installed in Return Air Duct) & 2 way modulating valves.

RHControl - By regulating chilled water flow through chilled water coil with the help of humidity sensor (Installed in Return Air Duct) & 2 way modulating valves.

Pressure differential control - By regulating (opening/closing) motorized damper installed in Return Air duct of each room. These motorized dampers shall get command from DDCs upon receiving input pressure signal through pressure sensor / transmitter installed in each room.

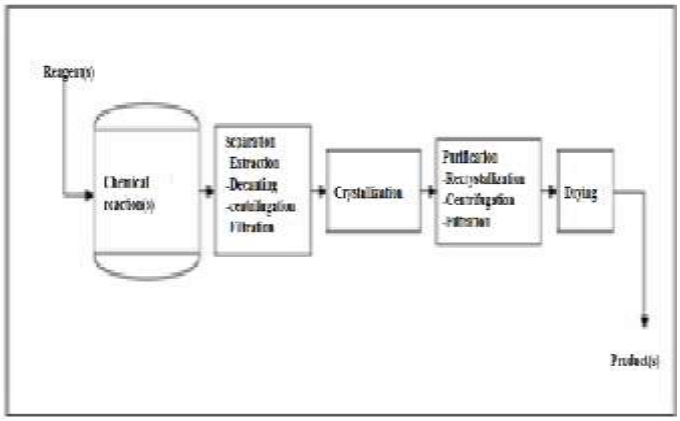
AHU Layout: Figure I



Pharmaceutical Process:

[7]The job of the pharmaceutical manufacturer is to blend the medicinally active agents provided by a fine chemicals plant, or by extraction from vegetable, fruits or other source, with suitable inactive elements so that the resultant product may be used in the correct dosage to produce the effect needed by five primary stages in chemical synthesis; Chemical reaction, Separation, Crystalization, Purification and Drying.

Illustration of a simplified pharmacy process;



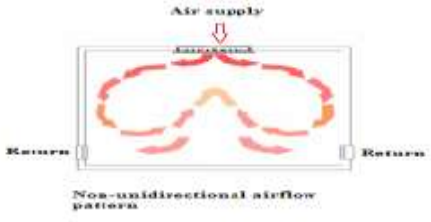
Air-flow Pattern:

[7] Cleanrooms are also categorized by the way supply air is distributed. There are generally two air supply configurations used in clean room design: 1) Non-unidirectional and 2) Unidirectional.

Non-unidirectional air flow;

[7] In this type of airflow pattern, there will be substantial amount of turbulence and it can be used in rooms where major contamination is expected from external source i.e. compose air. This turbulence enhances the mixing of trapped low and high particulate concentrations, producing a homogenous particle concentration acceptable to the process. Air is typically supplied into the space by one of two methods. The first uses supply diffusers and HEPA filters. The HEPA filter is an integral part to the supply diffuser or it may be located upstream in the duct lined out from the AHU. In this way the supply air pre-filtered upstream of the cleanrooms and introduced into the space through HEPA filtered to core and manufacturing areas. Non-unidirectional airflow may provide satisfactory control for cleanliness levels of Class 1000 to Class 100,000 as standards being followed according to ISO 14644-1.

Figure II



Unidirectional air flow;

[7] In this type of airflow pattern is a single pass, single direction air flow of parallel streams. It is also called 'laminar' airflow since the parallel streams are maintained within some angular deviation. Unidirectional cleanrooms are used where low airborne contaminant levels are required, and where internal contaminants are the main concern.

[7] They are generally of two types:

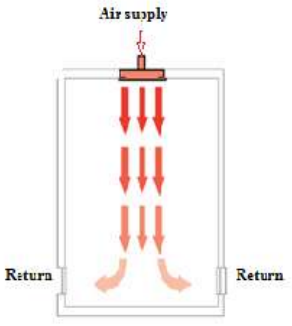
1. Vertical down-flow clean rooms where the air flow is vertical 'laminar' in direction.

2. Horizontal flow where the air flow is horizontal 'laminar' in direction.

In vertical down-flow arrangement, clean composite air is typically brought-in at the ceiling and returned through the base of the side grilled ducted walls. Horizontal flow cleanrooms use a similar approach, but with a supply air duct from ceiling and a return air duct on the side base level of the wall. Normally a down-flow cleanroom consists of HEPA filtered mounted in the ceiling behind the grilled duct of supply air. As the class of the cleanroom gets lower, more of the ceiling consists of HEPA filters, until, at Class 100, the entire ceiling will require HEPA filtration. The flow of air in a down-flow cleanroom suffuse with the room in a downward flow of clean air. Contamination generated in the room is generally swept down and out through the return air duct.

The horizontal flow cleanroom uses the same filtration airflow technique as the down-flow, except the air flows across the room from the supply duct to the return duct. Between the two, the vertical down-flow pattern yield better results and is more adaptable to pharmaceutical production process.

Figure III



Unidirectional airflow pattern

A cleanroom requires a very stringent control of temperature, relative humidity, particle counts in various rooms, air flow pattern and differential pressure between various rooms of the clean air arrangements. All this requires; Increased Air Supply; whereas comfort air conditioning would require about 2-4 air changes/hr, a typical cleanroom, say Class 10,000 would require 50 - 100 air changes. This additional air supply helps, to dilute the contaminants to an acceptable concentration. High Efficiency Filters; the use of HEPA filters having filtration efficiency of 99.97% down to 0.3 microns is another distinguishing feature of cleanrooms. Terminal Filtration and Air Flow pattern; not only are high efficiency filters used, but a laminar flow is sought. Room Pressurization; with the increased fresh air intake, cleanrooms are pressurized in gradients. This is important to keep external particulates out of clean spaces.

Heat Load standard operational expression:

1. Heat Conduction and Thermal Resistance [8] [9]

For steady state conditions and one dimensional heat transfer, the heat q conducted through a plane wall is given by:

$Q = kA (t_1 – t_2)/L$ Btuhr (Eq.1)

Where: L = the thickness of the wall in inches

A = the area of the wall in square feet

$(t_1 – t_2)$ = temperature difference across the wall in degrees Fahrenheit

k = thermal conductivity of the wall material Btu-inhr-ft^2-F

Equation 1 can be put in terms of a unit thermal resistance, R = L/k, or an overall heat transfer coefficient, U = 1/R, to give

$Q = A (t_1 – t_2)/R = UA (t_1 – t_2)$ (Eq.2)

Note that the R in equation 2 is the factor often found on blanket insulation and other building products. Equations 1 and 2 are for a single material so the resistance R must be modified for building walls of several materials.

2. Building Walls [8] [9]

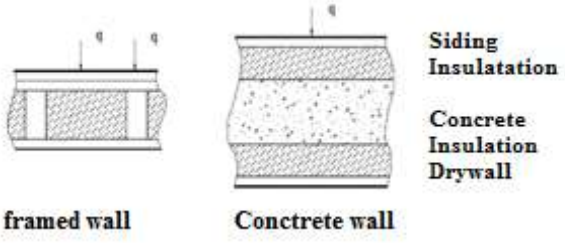
The walls of buildings are constructed of several layers of different thickness, material, and area. In figure no. IV it depict a typical 2x4 framed house wall and a concrete wall with polystyrene insulation on both the interior and exterior surfaces. For the concrete wall, with the vinyl siding and drywall, there are five thermal resistance layers. In addition there are thermal resistances on the inside and outside surfaces of a building wall due to convective air currents and radiation. These resistances are accounted for with film coefficients, f, given by

f_i =6.0 Btu/ (hr-ft^2 -F) = 1/R_i inside surface with still air **(Eq.3)**

F_o = 1.63 Btu/ (hr-ft^2 -F) = 1/R_o outside surface with moving air **(Eq.4)**
Then for the whole concrete wall, the thermal resistance to be used in the conduction equation 2 becomes
$R = R_0 + R_1 + R_2 + R_3 + R_4 + R_5 + R_i$ (Eq.5).

For the framed wall, similar thermal resistance equations would be written for the heat path through the dots and through the insulation path between the studs as indicated in Figure IV.

Figure IV



In addition to the heat conducted through the walls, given by equation 2, a building can have heat gains or losses from the attic and basement.

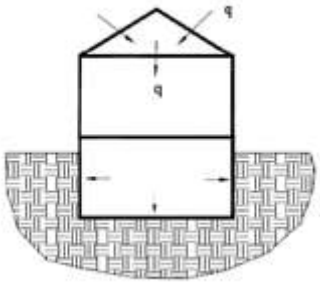
3. Building Attic and Basement [8] [9]

At equilibrium conditions, the heat loss or gain from the attic or basement, as indicated in Figure V, is equal to the heat loss or gain to the building through the ceiling or floor. For an attic, equation 2 gives
$U_r A_r (t_o - t_a) = U_c A_c (t_a - t_i)$ (Eq.6)

Where r = roof properties, c = ceiling properties, a = attic properties
a = attic temperature, o = outside temperature, and i = inside temperature.
Solving equation 6 for the attic temperature gives
$T_a = (U_r A_r t_o + U_c A_c t_i) / (U_r A_r + U_c A_c)$ (Eq.7)

After the attic temperature is found from equation 7, the heat conducted to the building through the ceiling can be found from equation 6. This procedure can also be used to estimate a basement (or attached garage) temperature and heat loss or gain to a building through the floor or wall.

Figure V



4. Building Heat Loads [8] [9]

The total heat load of a building consists of two parts, the sensible heat, Q_s, and the latent heat, Q_l. The sensible heat load comes from the following sources:
1. Heat conducted through the building (walls, ceiling, floor, windows).
2. Internal heat from lights, computers, ovens, and other appliances.
3. Infiltration of outside air through cracks around windows and doors.
4. People in the building.
5. Sun radiation through windows.
The latent heat load to a building comes from the following sources:
1. People in the building.
2. Infiltration through cracks, chimneys.
3. Other appliances.
The sensible heat load results in an air temperature rise in the building. To maintain temperature requirements, the air in the building is circulated over a cooling coil at a certain rate determined from the equation
$Q_s = 1.1 (w) (t_s - t_i)$ (Eq.8)
Where w = cubic foot per minute of air circulation flow
i = denotes inside air temperature
s = denotes supply temperature of the air
The latent heat load determines the amount of moisture that is added to the air in the building and must be removed from the air by the cooling coil to maintain humidity requirements. This is found from the equation
$Q_l = 4840 (w) (G_s - G_i)$ (Eq.9)
Where G_i = pounds of moisture per pound of air in conditioned space
G_s = pounds of moisture per pound of a supply air. Once the sensible heat, Q_s, and latent heat, Q_l, are known, a sensible heat ratio, SHR, can be found from **$SHR = Q_s / (Q_s + Q_l)$ (Eq.10).**

[10] Operational expression for Cooling loads by using CLTD/SCL/CLF method:
External Cooling Load;
Roofs, walls, and conduction through glass

Q = UA*(CLTD)
U = design heat transfer coefficient for roof or wall
A = area of roof, wall, or glass, calculated from building plans
CLTD = cooling load temperature difference, roof, wall, or glass
Solar load through glass
Q = A*(SC)*(SCL)
SC = shading coefficient
SCL = solar cooling load factor with no interior shade or with shade
Cooling load from partitions, ceilings, floors

$Q = UA*(t_o - t_{rc})$
U = design heat transfer coefficient for partition, ceiling, or floor
A = area of partition, ceiling, or floor, calculated
T_b = temperature in adjacent space
T_{rc} = inside temperature (constant) in conditioned space

Internal Cooling Load;
People
$Q_{sensible}$ = N (Sensible heat gain) CLF
Q_{latent} = N (Latent heat gain)
N = number of people in space, from best available source.
Sensible and latent heat gain from occupancy
CLF = cooling load factor, by hour of occupancy
Note: CLF 1.0 with high density or 24-hr occupancy and/or if cooling off at night or during weekends.

Lights;

$Q_{el} = W F_{ul} F_{sa}$ (CLF)
W = watts input from electrical plans or lighting fixture data
F_{ul} = lighting use factor
F_{sa} = special allowance factor
CLF = cooling load factor, by hour of occupancy
Note: CLF = 1.0 with 24-h light usage and/or if cooling off at night or during weekends.
Power;
$Q_p = PE_f$ CLF
P = horsepower rating from electrical plans or manufacturer's data
E_f = efficiency factors and arrangements to suit circumstances
CLF = cooling load factor, by hour of occupancy
Note: CLF = 1.0 with 24-h power operation and/or if cooling off at night or during weekends

Appliances;

$Q_{sensible} = q_{input} F_u F_r$ (CLF) or $q_{sensible} = q_{input} F_l$ (CLF)
Q_{input} = rated energy input from appliances or manufacturer's data
F_r, F_r,
F_l = usage factors, radiation factors, and load factors
CLF = cooling load factor, by scheduled hours and covered or not;
Note 1: CLF = 1.0 with 24-h appliance operation and/or if cooling off at night or during weekends.
Note 2: Set latent load = 0 if appliance under exhaust hood.

Ventilation and Infiltration Air;

$Q_{sensible} = 1.23Q (t_o - t_i)$
$Q_{latent} = 3010Q (W_o - W_i)$
$Q_{total} = 1.20Q (h_o - h_i)$
Q = ventilation from ASHRAE handbook, infiltration Liters per second.
T_o, T_i = outside, inside air temperature, °C
W_o, W_i = outside, inside air humidity ratio, kg (water)/kg (dry air)
H_o, H_i = outside, inside air enthalpy, kJ/kg (dry air)

[11]Pharmaceutical buildings as a rule are totally enclosed without any fenestrations. This is to maintain a 'tight' building to minimize uncontrolled infiltration. As a result, the room sensible loads are essentially a contribution from process equipment, lighting and personnel. Fan heat from recirculating fans can also be a large heat contributor in clean spaces. The density of equipment loads is low excepting in the tablet manufacturing facility covering granulation, drying and tabletting. Heat-loss calculations must also be made to determine heat loss through walls, roof, and floor. No credit should be taken for process heat gain in this calculation, since the process could be dormant and the space would still need to be maintained at proper temperature. A major contribution of the cooling load comes from outside air entering the air handling unit.

Intuitive assumption:

[12]The HVAC industry is a worldwide enterprise, with roles including operation and maintenance, system design and construction, equipment manufacturing and sales, and in education and research. The HVAC industry was historically regulated by the manufacturers of HVAC equipment, but regulating and standards organizations such as HARDI, ASHRAE, SMACNA, ACCA, Uniform Mechanical Code, International Mechanical Code, and AMCA have been established to support the industry and encourage high standards and achievement. HVAC systems in manufacturing part of facilities are closely supervised by the FDA and must meet other global current good manufacturing practices (cGMP's), sterile area clean-rooms have the following distinct aspects:

a. Air should be of a high microbial quality.

b. Air handling system is provided with a central HEPA filter bank along with mandatory terminal filters in order to extend the life of terminal filters.

c. The filtration regime is generally three stages with two stages of pre-filters, 10µ (G-4), 5µ (F-6) and one primary filter 0.3µ (F-9) along with terminal HEPA filter.

d. All aseptic critical operations shall be in a laminar flow work station.

e. Critical areas should have a positive pressure differential relative to adjacent less clean areas: a positive pressure differential of 0.06 inch of water (15 Pa) is acceptable.

f. Supply air outlets are provided flush at the ceiling level with perforated stainless steel grilles and terminal absolute filters. Return air grilles to be provided at the floor level with a return air riser for better scavenging

g. Walls, floors, and ceilings for cGMP areas are to be constructed of smooth, cleanable surfaces, impervious to sanitizing solutions and resistant to chipping, flaking, and oxidizing. Maintaining proper pressurization gradient between adjacent spaces is important to prevent infiltration and cross-contamination. Air filtration techniques and air conditioning components are constantly monitored and upgraded in order to improve the finished product and reduce energy consumption asunder, overstate quality requirements and tolerances which may result in unnecessary costs. Higher air flows and pressures require more HVAC capacity. Since most engineering decisions will have an impact on HVAC systems, it is important to recognize opportunities to seek the best engineering solutions.

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[11] Pharmaceutical buildings as a rule are totally enclosed without any fenestrations, Continuing education and development Inc. HVAC design for pharmaceutical facilities.

[12] The HVAC industry is a worldwide enterprise, Continuing education and development Inc. HVAC design for pharmaceutical facilities.