

## Layout of a Cleanroom Air Handling Unit

An excerpt from the [GMP Compliance Adviser](#), Chapter [3.1 Air Handling Technology](#)



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The specific concept and design for an air handling system result from the requirements and local conditions placed on the cleanroom.

When selecting the type of system to be utilized, each of the following criteria can play a role:

- Influence of the ambient air
- Climatic conditions of the site
- Operating costs of the various systems, especially the costs of energy consumption: electricity, heat, cooling (cooling and dehumidification) and humidification
- Life-cycle cost assessment
- Cleanliness requirements
- Flexibility

For the manufacture of pharmaceuticals, the following types of air handling units (AHUs) are most commonly used:

- 100% fresh air units
- Centralized re-circulation and mixed air units
- Decentralized re-circulation and mixed air units with centralized fresh air conditioning
- 100% re-circulating air units

The selection of the type of system to be used is often based on risk assessments of potential paths of airborne contamination. The introduction of contaminants by air is then only given and represents a risk if a stable aerosol is generated which can be carried by the air.

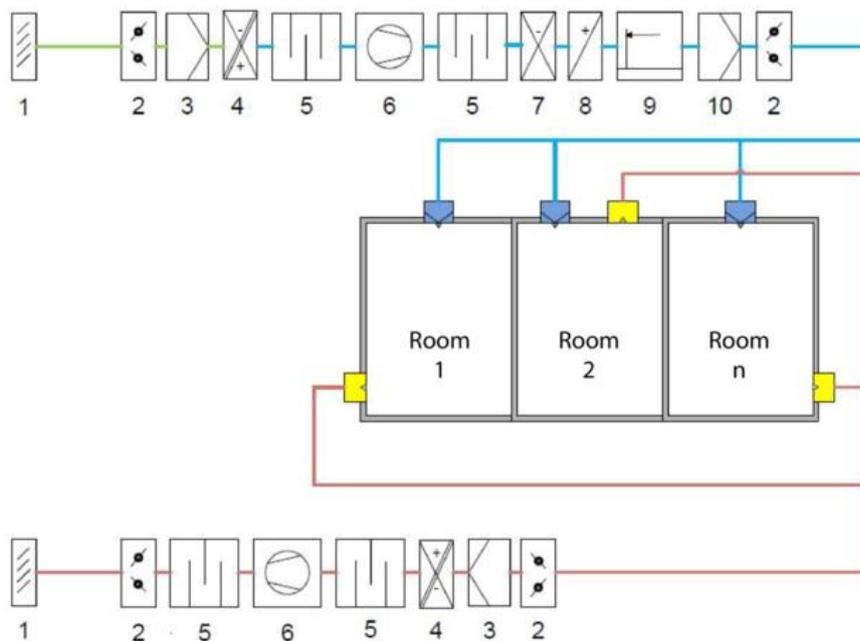
The AHU has the task to condition the air according to the calculated design requirements. An AHU system is comprised of the following main components:

- Conditioning
  - AHU with the appropriate configuration
- Distribution

- Air ducts with internal components such as heaters or coolers for zone-based conditioning, flow regulators, etc.
- Air ducts are to be constructed with the appropriate seal quality in order to minimize energy waste. Recommendation: seal grade C for rectangular ducts acc. to EN 1507 for round ducts acc. to EN 12237
- Orifices
  - Inlet air diffusers – with or without filter,
  - exhaust grills – with or without filter

Following the direction of the airflow, the system has the following layout, whereby the components shown can be varied as required (see Figure 1).

Figure 1 Layout of an air handling system (example with 100% fresh air)



The diagram legend is to be understood as follows:

- (1) Protective grating for drawing in outside fresh air or discharging exhaust air (may be equipped with bird or insect proofing grating and/or coarse dust filter. See 3.1.6 Particle Filters for Air for the definition of filter classes.)
- Fresh air duct
- **Supply air handling unit**  
These can be comprised of the following components, e.g.:
  - (2) fresh air louver flaps
  - (3) 1st filter stage (depending on location of the fresh air inlet and climatic conditions, a pre-heater may be necessary to protect the filter material from moisture)

(4) Heat recovery system for fresh air handling units with re-cycle composite systems, regenerative heat exchanger (also called a heat exchanger wheel) or cross-flow plate heat exchanger. For mixed-air systems, a mixing chamber for the addition of fresh air to the room air is installed if the recycled air is reused.

not shown: pre-heater – can be excluded in most cases for mixed air systems (mixing of recycled with fresh air)

(5) Silencer (to minimize the size of the AHU, a silencer with non-particle emitting design can also be installed directly within the duct system)

(6) Variable speed fan (to meet the demands at the actual design operating point or to control a constant or variable air flow rate using a frequency converter)

(5) Silencer

(7) Chiller with demister and fully draining condensate pan with adequate space for cleaning. At low air speeds the demister can be eliminated – this reduces the pressure loss in the AHU.

(8) Main heater with adequate space for cleaning

(9) Humidifier with fully draining condensate pan

(10) 2nd filter stage (for filters representing the final stage of the supply air treatment, these can be situated before the humidifier)

(2) louver flaps

- Air supply duct system
  - Zone-based final conditioning units for temperature and humidity control
  - Flow rate controllers – variable or constant depending on requirements
  - Measuring orifice
- Inlet diffuser with or without final filter (EPA, HEPA, ULPA depending on requirements)
- **Supplied area, room or group of rooms**
- Return air grill with or without coarse filter (in gowning airlocks a coarse dust filter is used to keep the return air duct clean – ISO-coarse as per ISO 16890 – or a lint remover is recommended)
- Return air duct system
  - Volume flow rate controller – if active room pressure control is utilized an active controller is required
  - Measurement orifices
- **Return/exhaust air handling unit**
  - (2) return air louver flaps
  - (3) optional filter stage for protection of heat recovery exchanger

- (4) heat recovery system – coupled with feed air system
- (5) silencer
- (6) variable speed fan (to meet the demands for the actual operating point or to control a constant or variable air flow rate using a frequency converter)
- (5) silencer (to minimize the size of the AHU, a silencer with non-particle emitting design can also be installed directly within the duct system)
- (2) exhaust louver flaps
- Exhaust duct system
- (1) exhaust weather guard grill

As part of a risk assessment, it is evident that the “cleanroom” (production, process) lies between the inlet and return air grills. This means that the cleanliness of the inlet air as well as the air currents or flows within the clean/production room may have an influence on the product. The components within the cleanroom are thus to be ranked as less critical.

A potential influence from the surrounding air is given if the product is exposed to the ambient air. The potential contamination depends upon the extent of the “contamination surface area”, the duration of the exposure and the following process steps (e.g. subsequent sterile filtration or sterilization).

To ensure the necessary air quality according to the clean room requirements of a pharmaceutical production facility, the acknowledged standard components are used for configuration of the air handling units.

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