

# Cost Considerations When Controlling Air Quality

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The options when designing a clean room or controlled environment are numerous. The advantages and disadvantages of designs and recommendations on cost-effectiveness are outlined.

## Clean-rooms defined

It is generally accepted that a controlled environment, that is, a clean room in which particles of dust and microbial growth are controlled is the most suitable environment for the production of medical devices. Table I shows the definition of a clean room.

The most common method used to control the airborne particulate is to introduce high-efficiency particulate air (HEPA) filtered air through the room on a repeated basis, therefore, diluting any contaminated air within the room. The introduction of the additional air and restriction of the

airflow from the room creates a pressure differential between the inside and the external contaminated area. Ingress is therefore difficult and the main source of contamination within the area is through personnel movement and equipment. Procedures to control this should be in place.

Classification of the room is performed by assessing the cleanliness of the air in the room using ISO 14644-1.<sup>1</sup> Various levels are applied in a range from one to eight. Class one has the lowest level of particulate (Table II) and the most common levels of classification used in the device industry range from Class five to Class eight.

## Design options

Clean-room design can vary greatly, however, adherence to a specification should always be considered. There are basically three structural designs

for rooms and three air-handling designs to consider for the medical device industry (Table III). There is no specific rule that specifies the correct combination of airflow and structural design. This decision depends on the intended use and budget requirements.

## Playing hard wall

Hard-wall designs generally feature a recirculating airflow through a central air-handling unit in any of the airflow designs shown in Table III and Figure 1. The room is constructed from a solid wall or steel, double-skinned partition panel and a sealed nonshedding floor and a grid ceiling or panelled ceiling. Lights, ducting and services of air and power can be fitted on the ceiling or suspended from steel work above the room. Entrance to the room would be via a double-entry system to reduce the risk of contaminated air entering the clean

**Table I:** Definition of clean room according to ISO 14644-1, Cleanrooms and associated controlled environments, Part 1: Classification of air cleanliness.

"A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimise the introduction, generation and retention of particles inside the room and in which other relevant parameters, for example, temperature, humidity, and pressure are controlled as necessary."

**Table II:** Room classifications and particulate level.

Classification System	Class					
	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8
ISO 14644-1						
Federal Standard 209E	1	10	100	1000	10000	100000
European Union Guide to Good Manufacturing Practice	-	-	A/B	-	C	D

**Table III:** The variation of structural and air-flow designs.

Structural designs	Air-flow design
■ Hard wall	■ Conventional
■ Soft wall	■ Unidirectional (formerly laminar flow)
■ Mini environment	■ Mixed flow

room. The design of the room tends to dictate that it has a fixed position and further expansion is disruptive to production. The design of the room usually makes this the most expensive form of installation and any planned expansion can cause production downtime. Levels five to eight can be achieved with this design although the most common levels for this set up are six to eight. Installation times

start at just a few weeks and increase subject to complexity and size.

**Soft-wall alternative**

Soft-wall designs typically feature single-pass airflow and can also be with any of the airflow designs listed in Table III and Figure 1. Construction usually consists of a tubular steel frame with side walls constructed of strips of poly(vinyl) chloride that are

overlapped to create a semisolid wall. Air handling is introduced through a single or a series of filter fan units (FFUs) that pull air through a pre-filter and then force it through a HEPA filter.

These rooms can be mounted on castors, which allows them to be used in various areas or fixed in a single position over a work area or piece of equipment. Their versatile construction materials and modular design allow rapid installation. Some suppliers offer delivery within a week. The modular design can also reduce disruption when expanding the area. The installation time tends to be 5% of the time taken to install a hard wall. The simplicity of the design also helps to keep capital costs low: approximately 30–50% less than those for a hard-wall construction. The disadvantage of this design means it is not suited to being positioned near external doors, because strong draughts can disrupt the integrity of the side walls. Table IV lists the positives and negatives of hard-wall versus soft-wall clean rooms.

**Mini environment, maximum economy**

Mini-environment design takes a specific view of the area that needs to be controlled. It is most commonly used within isolators, flow booths or an automated piece of machinery. By dealing with a small area, costs can be kept low. Because of the small area, minimal consideration needs to be given to contamination generated from personnel, if they are generally located outside the mini environment but still within the general clean-room area. High levels of classification can be achieved and vary from one to five. Typically, a mini environment is placed within a hard wall or soft wall room/area, therefore, reducing the risk of contamination when placing product or removing product from the cleaner zone.

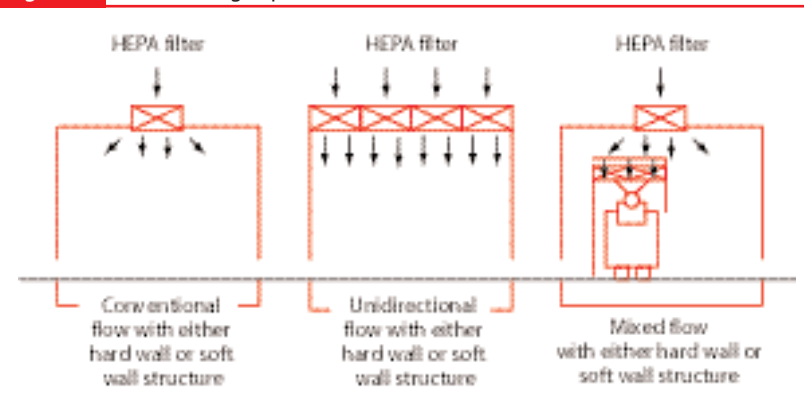
**Clinical trials**

The clean-room requirement when producing a new device for clinical trials is to replicate the type of envi-

**Table IV:** Positives and negatives of hard wall versus soft wall clean rooms.

Soft wall Positives	Negatives
Lower capital cost	Lower pressure differential
Short installation time	Can be disrupted by strong external draughts
Can be validated to ISO 14644-1 from Class 5 to Class 8	Aesthetically not as pleasing as a hard-wall design
Can be mobile	Room integrity can be breached from nontrained personnel or by poor operating procedures
Can be expanded without disrupting production	Prefilters need to be changed or cleaned quarterly
Can be relocated to alternative area or new building	
Higher rate of air change	
Equipment can be moved in and out easily	
No building control or planning permission required	
Can have transfer and change areas	
Clear ceiling panels allow lighting from external area	
Hardwall Positives	Negatives
Aesthetically pleasing	Higher capital
Room integrity harder to breach	Longer installation times (10–15 times longer)
Not affected by external draughts required	Building regulations planning permission
More life to prefilters because of reprocessed air. Annual change.	Disruptive and expensive to expand
	Not practical to increase level of classification

**Figure 1:** Air-flow design options.



ronment and level of clean-room classification that would be used in large-scale manufacturing. The trend, therefore, is to use a clean room of modular design, which can offer a high standard of environment, but has the ability to rapidly expand with the growth of manufacturing output. Limited budgets at the development stage for the clean room mean that a soft-wall room offers the required flexibility and can expand from just a few square metres up to 100 m<sup>2</sup> plus. One of the major technological advancements that has helped to produce the soft wall clean room is the improved design of the FFU. The combined sealed unit incorporates prefiltration, a motorised fan and a HEPA filter. The low-profile design with integral power and control features enable these units to be added to an existing room without having to alter any previous installation. These advancements allow a company or individual to develop his/her medical device within a classified clean-room area for a budget of less than £10 000 (€14 164). The room can then be installed within premises without altering the fabrication of the building and prevents a company from breaching any lease restrictions. As demand grows on the clean room and the need arises to expand the room or relocate the clean room to new premises, this can be achieved without losing the initial investment.

The flexibility of the soft-wall room together with using combined FFUs make this design an extremely attractive option.

#### Reference

1. ISO 14644-1 Cleanrooms and Associated Controlled Environments, Part 1: Classification of air cleanliness. ISO 14644-1: 1999.

#### Recommended reading

W. Whyte, *Cleanroom Design*, John Wiley and Sons, Chichester, UK, 1999, ISBN 0-471-94204-9.



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