Cleanroom management: Using filters in the cleanroom

A cleanroom is one of the mainstays of pharma production. Ken Sutherland gives a brief review of the characteristics and classification of cleanroom systems, and looks at the use of filters in the provision of ultra-clean working spaces.

A cleanroom is an enclosed working space in which work is done that is delicate, and needs protecting from contamination by impurities in the ambient air. The air quality (i.e. the amount of suspended material in the air), the temperature and the humidity are regulated in order to protect the contents of the room from the dust and bacteriologically contaminated particles that exist naturally in the atmosphere and in the ambient air around the cleanroom, and also those that might be generated within the cleanroom itself.

A formal definition of a cleanroom is given in the international cleanroom standard (ISO 14644: Cleanrooms and Associated Controlled Environments) as: "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, e.g. temperature, humidity, and pressure, are controlled as necessary."

The need for, and use of, cleanrooms as places for manufacture mainly sprang out of the space race of the 1960s. Nowadays, a wide variety of industries utilise clean room manufacture, most obviously the micro-electronics sector (including silicon chip fabrication, especially using surface-mount technology, disk drives, and so on) and pharmaceutical processing (including biochemical and biomedical products), but also including fine chemicals manufacture, silk screening, photographic and optical systems, aerospace and satellite technology, and nuclear systems. Almost all industries are aware of cleanroom principles because laboratory practice has been employing them, or something similar, since long before 1960.

Why use a cleanroom?

Natural, "fresh" air contains about 35 million particles of 0.5 µm in diameter, or larger, per cubic metre (which is 1 million per cubic foot). Even if the factory is built in as rural a surrounding area as the planning regulations will allow, the chances are that other nearby emissions will pollute the ambient air to a poorer quality than this.

With the air in a typical office building, after conditioning for comfortable human occupation, still containing between 15 and 35 million particles per cubic metre, it should be noticed that a particle 200 times smaller than a human hair (which is approximately 75-100 µm in diameter) can cause major damage to sensitive equipment. Without the availability of cleanrooms, the creation of structures and devices with feature sizes that are equal to or less than that of a dust particle would be impossible. One oversize particle settling at a critical point of a circuit board can cause the whole board to fail.

Thus cleanroom manufacturers pay strict attention to air particles, with most cleanroom design and manufacturing companies targeting the elimination of air particles 0.5 µm in size or larger, which has been generally the function of cleanroom air filters. However, some industries are now imposing even smaller air particle standards.

Where does the dust come from?

The dust in a cleanroom could primarily come from the ambient air at the working site, drawn in to the whole factory or institution. However, this is very likely to have been conditioned to a level that is comfortable for the general office and factory workers, and this level may be suitable for non-critical work in a clean area.

To this background level of suspended solids must be added the contamination that can come from just about anywhere in the working area, with the people in the room as potentially the largest source of contamination, as a human being sheds *one billion* flakes of skin in a 24 hour period. So, just standing still, one person loses about 100,000 particles per minute, while walking around the room at only 3 km/h releases 5 million particles per minute.

Other sources of cleanroom contamination are the facility itself (e.g. paint and other surface coatings, air conditioning debris, materials of construction of the room and its contents), particles generated by tools (e.g. lubricants and machining residues), and working and cleaning fluids (e.g. floor finishes or coatings and cleaning chemicals). Cosmetics, perfume, hair care products and clothing debris are other sources of cleanroom contamination.

Material released by human bodies can, to a large extent, be kept out of the working atmosphere by the wearing of suitable protective clothing over as much of the body as possible (and is comfortable) – but some particles will always work their way through, to add to those arising from all of the other sources. The cleanroom system must thus reduce the contamination entering with the air drawn in to the room, and also remove that produced within the room to a suitable level to match the requirements of the processes being undertaken.

Cleanroom classification

Cleanrooms vary enormously in size, at the smaller end being no more than an enclosed

cabinet on legs (a glove box) fitted with pairs of gloves on the ends of sleeves long enough to enable the operator to reach all parts of the box and with windows and access ports, all the way to very large rooms (called ballrooms) or suites of rooms, in which a series of operations each perhaps needing different conditions can be carried out. Cleanrooms may be divided into two areas: the critical area, which is that part of the cleanroom where contamination can gain direct access to the production area, and the general area, which consists of the rest of the clean room. The critical area can then be provided with its own mini-environment. Cleanrooms are generally classified by the cleanliness of the air achieved within the room, and the classification is determined in the "at rest" state, i.e. when no one is in the clean room.

There have been a variety of national standards used in the classification of clean working spaces, one of the most widely encountered being the US Federal Standard 209 Revision E, but this standard, and the others, are being superseded by the new International Standards Organisation (ISO) 14664-1. Some key figures from this ISO standard are given in the accompanying Table 1, which shows for each ISO Class, the maximum number of particles of the stated size (or larger) per cubic metre of cleanroom air. [Note – the lower the ISO Class number, the better the air quality.]

ISO 14664 actually has eight parts, with 14664-1 carrying the above classification, and the other seven parts being concerned with test methods and so on. The intended owner of the cleanroom will specify the level of cleanliness required, from which specification will come the required ISI Class, to which standard (or, perhaps, better) the room will be built.

Use is still made of the USFed 209E standard, in which Class 100,000 corresponds with ISO Class 8, Class 10,000 with ISO Class 7, Class 1000 with ISO Class 6, Class 100 with ISO Class 5, and Class 10 with ISO Class 4. The Fed Class number is the maximum number of 0.5 µm particles in a cubic foot of room air.

The old British standard (BS 5295) is also still used. In this one, the Classes are marked by capital letters, with C corresponding to ISO Class3, D to Class 4, E and F to Class 5, G and H to Class 6, J to Class 7 and K to Class 8.

An important parallel standard is BS/EN 12469:2000 relating to biotechnology, giving the performance criteria for microbiological safety cabinets.

Cleanroom characteristics

The main components of a cleanroom include:

- an airtight enclosure;

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- a worker entry and exit door, usually in the form of an airlock;
- probably a separate entry and exit port for work in progress, raw materials and any waste products, also as airlocks;
- an inlet point for fresh, purified air;
- an exit point, or series of vents, for discharge of contaminated air; and
- piped services, such as water, compressed air, gas and electricity as appropriate.

If any material being handled in the cleanroom is toxic to humans, then the workers may wear respirator hoods, needing connection to a breathing air source. Other similar protective apparel may be provided.

The cleanroom should obviously be well-lit and have nonslip floors. Its interior surfaces should be easily cleaned, with a finish that is relatively resistant to abrasion, while the whole construction should essentially be free from nooks and crannies.

Under some circumstances, the room may be maintained at an air pressure slightly above ambient, so that any untoward leakage will be outwards, rather than carrying unpurified air into the room.

In many pharmaceutical and biochemical applications toxic materials are used, and if these escape into the cleanroom atmosphere then the area outside the cleanroom must be protected from them. In this case, the room air pressure may be slightly below atmospheric, to prevent outward leakage. Any vents in the room structure would then normally be protected by an activated carbon filter.

Air flow and purification

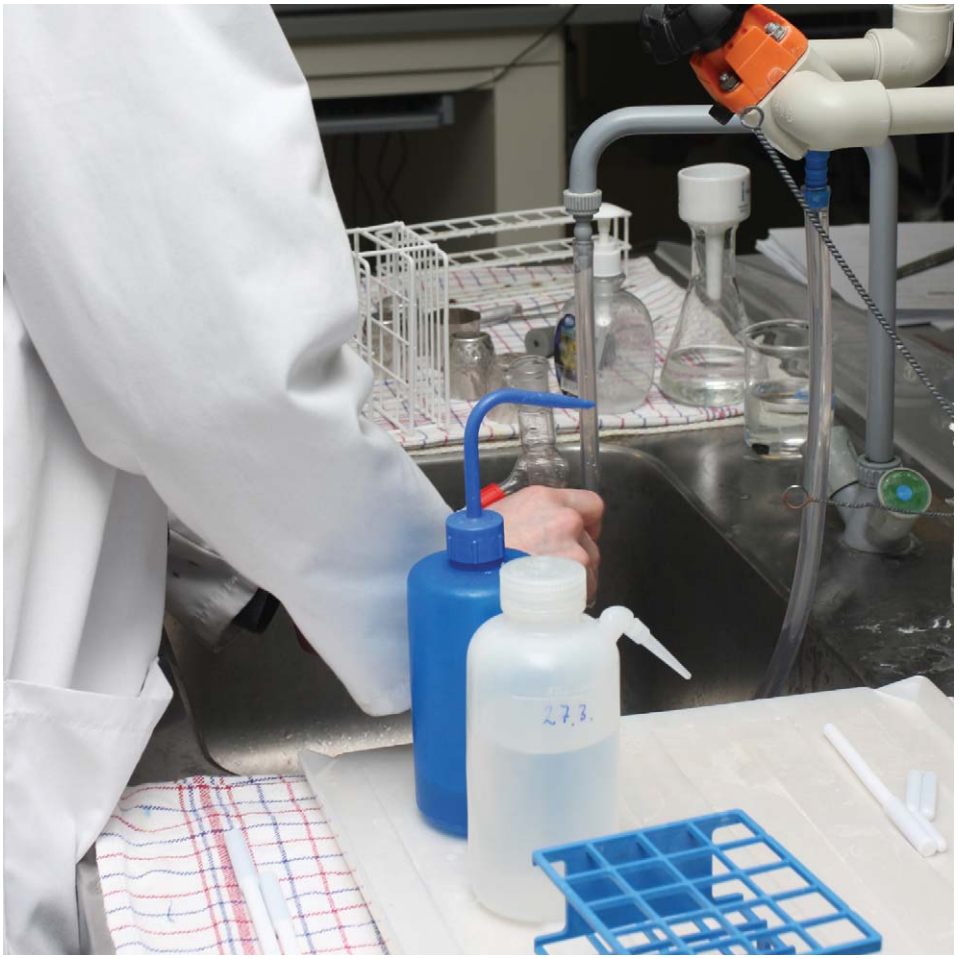
The air flow pattern in a clean room will need to be matched to the main purpose of the cleanroom itself. The main difference in flow pattern is between whole-room circulation and point of use ventilation. The latter requires an airflow within a small zone where the air quality must be particularly high, or where the flow is required to carry away any emissions from the local process.

The air feed to the cleanroom will, almost certainly, come from a central air conditioning plant treating air for the whole factory and

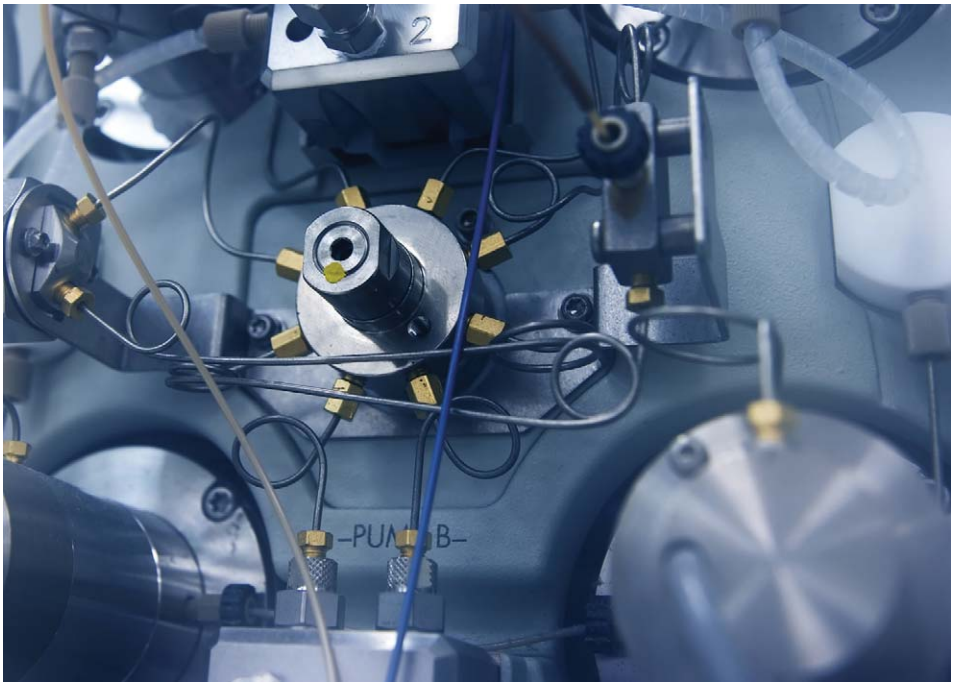
Table 1: Standards for the maximum number of particles per m³ of cleanroom air

ISO Class	0.1 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
1	10				
2	100	10	4	8	29
3	1,000	102	35	83	293
4	10,000	1,020	352	832	2,930
5	100,000	10,200	3,520	8,320	29,300
6	1,000,000	102,000	35,200	83,200	293,000
7			352,000	832,000	
8			3.52 m	8.32 m	
9			35.2 m		

associated offices. On the rare occasion where there is no such plant, then the inlet air will have to be conditioned – in either case by means of a similar plant, consisting first of a coarse or fine dust filter, acting as a pre-filter, mainly to protect the remaining equipment in the air conditioner. The pre-filter is followed by a heat exchanger, for temperature control, and a humidifier, for control of relative humidity. The circulating fan usually comes next, followed by the main air quality control filter, consisting of a pre-filter to take out any debris produced in the preceding equipment, and then a HEPA or ULPA filter of a fineness that will match the required cleanroom conditions.



Preparing for the cleanroom. Other sources of cleanroom contamination are the facility itself, particles generated by tools and working and cleaning fluids (e.g. floor finishes or coatings and cleaning chemicals).



Continued cleanliness of the interior air is ensured by the provision of auxiliary filtration systems, each consisting of one or more ducts leading to a collection manifold, a fan and high-efficiency filter system and a return duct.

The final filter can be sited outside the cleanroom, which enables easier filter maintenance, or inside the room, perhaps with several filters each at the delivery end of a clean air duct, so that air may be delivered directly to any sensitive working zone inside the cleanroom.

This air conditioning plant, with the right choice of final filter, will ensure the entry of clean air into the cleanroom, but will do nothing about the particles generated inside the room. Continued cleanliness of the interior air is ensured by the provision of auxiliary filtration systems, each consisting of one or more ducts leading to a collection manifold, a fan and high-efficiency filter system and a return duct. This enables the removal of impurities from their point of generation (as, for example, in an air bench, where air is drawn down through holes in the working surface, with clean air flowing over the work and the operator, and dirty air leaving from below the bench). The return points, with the filter as near to the discharge point as possible, can also be directed at the most sensitive regions.

Flow rates in cleanroom systems can be derived from recommended velocities for vertical flow of 0.3 m/s, with 0.45 m/s recommended for horizontal flow. This is equivalent to an air flow rate of 1000-1500 m^3/hr per m^2 of room area – higher than a typical air conditioning system.

The filters used to achieve the required cleanroom conditions are mainly of the standard HEPA and ULPA panel type, with media pleated to the depth of the panel. Where absolute laminar flow is not required, then the more effective V-block panels, using mini-pleated media can be used. It is normal for a pre-filter to be used upstream of the high efficiency filter, and for the cleanest rooms this will often need a HEPA grade as pre-filter to an ULPA panel. ●

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