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CLEANROOM PRODUCTION SOLUTIONS

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Learning about Contamination Control - Part 1:

The Basics of a Cleanroom

Contents

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What is a Cleanroom?

The basics

A cleanroom is a controlled environment designed to minimise the presence of airborne particles, dust, contaminants and other impurities. It is commonly used in industries such as semiconductor manufacturing, pharmaceuticals, biotechnology, aerospace, and electronics, where even small particles or contaminants can have a significant impact on the production process or the final product. The use of cleanrooms helps ensure the quality, reliability, and performance of products that require a pristine environment for manufacturing, testing, or research.

Eliminating sub-micron airborne contamination is a process of control. Airborne contaminants are generated by:

- People
- Processes
- Facilities
- Equipment

Contaminants must be continually removed from the air in order to keep the area clean.

The amount of air particles permitted varies according to the standard to which your cleanroom has been certified. Cleanrooms are classified based on the maximum allowable particle count per cubic meter of air, according to international standards such as ISO 14644-1.

How big is a micron?

Pollen

Dust mite faeces

One micron

Ragweed

Strand of human hair
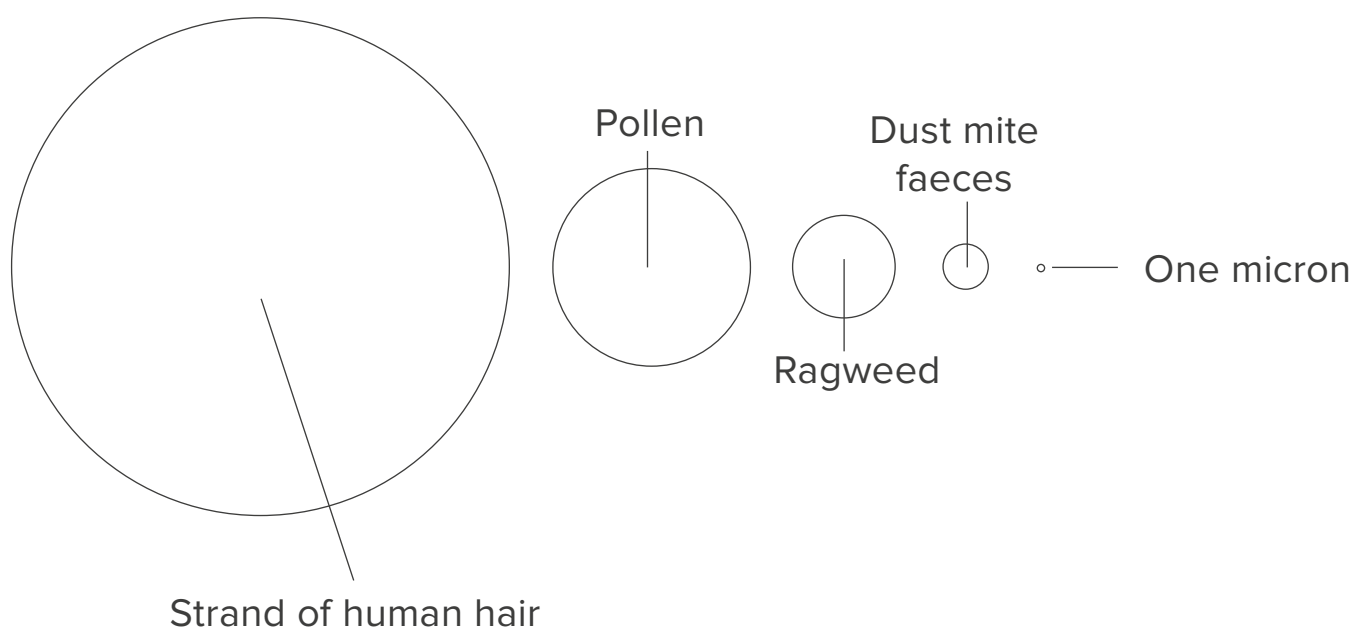
What is Cleanroom Contamination?

Types of contaminants
There are two types of contaminants:

1. Viable
Examples: Bacteria, viruses, fungal spores, moulds and yeast
Sources: People, outside air, water, equipment, tools, excipients, active ingredients

2. Non-viable
Examples: Metal specks or flakes, clothing fibres, dead skin, hairs
Sources: People, equipment and tools

Facts about contaminants

1. An adult human will lose about 6-14 grams of dead skin material every day, and lose a complete layer of skin about every four days, which is equivalent to 10,000,000 particles per day.
2. In a cleanroom, an adult will generate 100,000 particles per minute when motionless (fully gowned), and will generate 1,000,000 particles per minute when walking in the cleanroom.
3. According to several sources, approximately 75% to 80% of all particles generated in a cleanroom are from manufacturing personnel. About 15% comes from ventilation, and the remaining contamination comes from the room structure, equipment, and various other processes.

Important cleanroom reminders

- All materials entering the cleanroom should be wiped down before entering.
- If any of the materials going into the cleanroom are contained in a cardboard box, they should be removed from the box and placed either in a plastic bag or cleanroom tote box before entering the cleanroom.
- Trolleys/carts etc. if used beyond the cleanroom should be wiped down before entering the cleanroom – this includes castors.
- Individuals working in cleanrooms are required to follow strict protocols and wear special clothing such as coveralls, gloves, masks, and shoe covers.

Cleanroom classification comparison table

Cleanrooms are classified based on the maximum allowable particle count per cubic meter of air, according to international standards such as ISO 14644-1.

The table below shows a comparison of different classifications. The Federal Standard 209E classification of cleanrooms was replaced in 2001 by ISO 14644, however, is listed below as it is still widely used.

Different classifications are given within different countries; EU GMP (Good Manufacturing Practice) is mainly used within Europe while ISO and Federal Standard are used worldwide.

The classification ranges from ISO Class 1 (the cleanest) to ISO Class 9 (the least clean). Each class has specific requirements for airborne particle limits.

CLEANROOM STANDARD	CLEANROOM CLASSIFICATION GUIDELINES						
ISO 14644-1	ISO 1-2	ISO 3	ISO 4	ISO 5	ISO 6	ISO 7	ISO 8
EU GMP (at rest)*	-	-	-	A/B	-	C	D
Federal Standard 209E	-	1	10	100	1000	10,000	100,000

"at rest" corresponds to the maximum permitted number of particles when the cleanroom is not in operation.

Note: While ISO 9 does exist, it does not have specifications as found with other ISOs and so is not usually listed.

Cleanrooms are constructed to maintain a high level of cleanliness by controlling factors such as air quality, temperature, humidity, and pressure. They typically have specialised ventilation systems that filter the air to remove particles and maintain a positive or negative air pressure to prevent the entry of contaminants from outside.

HEPA (High Efficiency Particulate Air) filters required for all cleanrooms of ISO 5 and upwards.

ULPA (Ultra Low Penetration Air) filters required for ISO 3 and 4 upwards applications.

Recommended air velocity rates
ISO 14644-1 / FS209E

CLASS ISO 146144-1 (STANDARD 209E)	AVERAGE AIR FLOW VELOCITY (M/S)	AIR CHANGES PER HOUR
ISO 8	0.005 - 0.041	5 - 48
ISO 7	0.051 - 0.076	60 - 90
ISO 6	0.127 - 0.203	150 - 240
ISO 5	0.203 - 0.406	240 - 480
ISO 4	0.254 - 0.457	300 - 540
ISO 3	0.305 - 0.457	360 - 540
ISO 1-2	0.305 - 0.508	360 - 600

Recommended ceiling filter coverage
ISO 14644-1 / FS209E

CLASS	CEILING COVERAGE
ISO 8	5 - 15%
ISO 7	15 - 20%
ISO 6	25 - 40%
ISO 5	35 - 70%
ISO 4	50 - 90%
ISO 3	60 - 100%
ISO 1-2	80 - 100%

Note: Actual average velocity and air changes required may vary depending on the application and floor plan, including ceiling height.

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Notes:

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