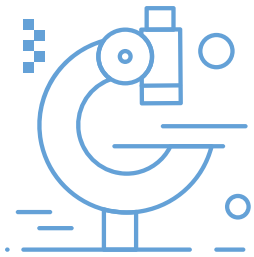
WHAT IS A CLEANROOM AND WHAT IS IT USED FOR?

As you read this, you are surrounded by millions of microscopic airborne particles. In fact, there are around one million particles larger than one-half micrometer in every cubic foot of air in an average room. While you might not notice this particulate matter until you get sick or feel an allergic reaction, certain items are much more sensitive to these contaminants than humans are.

To prevent microbes, dust particles, and other airborne contaminants from entering high-purity or sensitive small products, the air where these items are produced must be controlled. Cleanrooms are spaces that provide a suitable environment for the safe and consistent development of these products. Below you can find information on what cleanrooms are, what they are used for, and how our cleanroom at Fresh Water Systems benefits our production of high-purity water filters.

WHAT IS A CLEANROOM?



A cleanroom is a controlled space that maintains low levels of airborne particles via HEPA (high-efficiency particulate air) filtration. By lowering levels of contaminants in the air, HEPA filters reduce the risk of product contamination during assembly.

Cleanrooms are used for a variety of applications, such as pharmaceuticals, electronics, and, in our case, high-purity water filter assembly. In addition to reducing airborne particles, cleanrooms regulate temperature, humidity, airflow, and air pressure to ensure the safest and most consistent environment for production.

HOW IS A CLEANROOM USED?

A cleanroom is used in industries where contamination lowers the quality of a product. These applications include medicine development, where contamination can alter a drug's effect on the body, nanotechnology, where dust and other particulate matter can cause massive problems for semiconductors, and the food and beverage industry, where fewer germs provide safer and cleaner products for buyers to consume. Industries that incorporate cleanrooms in production include:

- Manufacturing companies
- Research facilities
- Pharmaceutical companies
- Electronics manufacturers
- Medicine development
- Battery production

The human body harbors over thirty million bacteria, sheds 500 million skin cells per day, and releases microorganism-tainted particles through the mouth and nose. Consequently, humans greatly disturb the cleanroom environment without proper precautions. To maintain cleanroom standards, operators must wear proper gowns, gloves, masks, and caps to minimize contamination by the human body. Operators are also encouraged to avoid large, exaggerated movements that can stir particulate matter in the air. Any spills in the space or unsealed items entering the room must be sprayed and wiped with a 70% IPA (Isopropyl Alcohol) solution.

The items that can be manufactured in a specific cleanroom depend on the cleanroom's classification. The number of particles per cubic meter or cubic foot of air determines the classification of a cleanroom. For example, for a cleanroom to be suitable for manufacturing surgical masks, it must meet the requirements for at least an ISO 5 or Class 100 cleanroom.

These rooms allow for 100,000 particles over 0.1 micrometers (µm) in size per cubic meter of air and only 100 particles over 0.5 µm per cubic foot of air. Each classification type has particle level requirements for particles of 0.1, 0.2, 0.3, 0.5, 1, and 5 micrometers in size. You can find specific information about each cleanroom classification below.

CLEANROOM CLASSIFICATIONS

Cleanrooms are classified by their ISO (International Standards Organization) and FS 209E (Federal Standard) classes. ISO classifications are determined by air contamination per cubic meter of air, while FS 209E classes are measured by contamination per cubic foot of air. Each classification reduces particles by 90% of the previous class. Below are listed all ISO and FS 209E classifications from ISO 1 (cleanest) to ISO 9 (typical room levels).

Cleanrooms must also meet standards for airflow. These are measured in air changes per hour

ISO Class	FS 209E Class	Particle Limit Per Cubic Meter (µm³)						Particle Limit/ft³
		≥0.1 µm	≥0.2 µm	≥0.3 µm	≥0.5 µm	≥1 µm	≥5 µm	≥0.5 µm
ISO 1		10						
ISO 2		100	24	10				
ISO 3	Class 1	1,000	237	102	35			1
ISO 4	Class 10	10,000	2,370	1,020	352	83		10
ISO 5	Class 100	100,000	23,700	10,200	3,520	832	29	100
ISO 6	Class 1,000	1,000,000	237,000	102,000	35,200	8,320	293	1,000
ISO 7	Class 10,000				352,000	83,200	2,930	10,000
ISO 8	Class 100,000				3,520,000	832,000	29,300	100,000
ISO 9					35,200,000	8,320,000	293,000	

and the ceiling coverage of fan filter units (FFU). FFUs are stand-alone modules with a HEPA filter, fan, and control system. Below are the air changes and ceiling coverage required for each ISO class.

ISO CLASS	AIR CHANGES PER HOUR	CEILING COVERAGE
ISO 1	500-750	80-100%
ISO 2	500-750	80-100%
ISO 3	500-750	60-100%
ISO 4	400-750	50-90%
ISO 5	240-600	35-70%
ISO 6	150-240	25-40%
ISO 7	60-150	15-25%
ISO 8	5-60	5-15%

WHY DO CLEANROOMS MATTER?

Cleanrooms provide high-level quality control for a variety of products. The cleanest of cleanrooms (ISO 1) are required for nanotechnology production and life sciences. These provide an optimal environment to protect electronic components, such as semiconductors and digital displays, from hardware damage caused by airborne particles and temperature and humidity changes. Particle contamination has become an increasing concern in technology as components become smaller, particularly screens with LCD panels. High-resolution displays contain smaller parts than their lower-resolution counterparts, meaning contamination from even tiny airborne particles can damage a portion of the device.

Cleanrooms also play their part in the production of water filters. At Fresh Water Systems, manufacturing high-purity water filters in our cleanroom ensures the highest possible product quality and efficacy. We strictly adhere to cleanroom standards to deliver consistent and dependable water filters for your applications.

OUR CLEANROOM AT FRESH WATER SYSTEMS

Our cleanroom at Fresh Water Systems is an ISO 7 (Class 10,000) manufacturing space for ourhigh-purity filtration products. This room allows us to make your filter purchase custom to order in a controlled environment, providing you with uncompromised premier quality.. In our cleanroom, we offer a variety of filter media, including Polyethersulfone (PES), Polysulfone (PS), and Polypropylene (PP). Additionally, we offer multiple high purity filter customization options for end cap configuration, O-ring and gasket material, filter length, and micron rating. We can assemble all media, length, micron, seal material, and end cap options offered in our

High-Purity Filter productguides. These filters are shipped individually bagged and boxed to ensure filter integrity is maintained. We recertify our cleanroom annually to maintain the production quality that our customers expect and deserve.

In addition to being manufactured in a cleanroom, all of the high-purity filter components and materials of construction comply with the FDA's regulations for food and beverage contact use as detailed in the US Code of Federal Regulations 21CFR. The filter components and materials used to produce filter media and hardware meet the specifications for biological safety per USP Class VI-121C for plastics. The filter cartridges have also passed the European Commission Directives (EU10/2011).

OUR CLEANROOM SPECIFICATIONS

Our cleanroom features the following specifications:

- ISO 7 (Class 10,000) level contamination control
- Maximum 10,000 particles larger than 0.5 µm per cubic foot of air
- 60 air changes per hour
- Controlled temperature and humidity
- Pass-through window for sealed products entering and exiting the cleanroom
- Sticky mats for footwear

Our cleanroom contains about one percent of the airborne particles of an average room. Humans are the greatest threat to the air quality in a cleanroom, so proper precautions must be taken to maintain air quality standards. All filter components are sealed before both entering and exiting the space via the pass-through window, ensuring the filters are never exposed to air outside the cleanroom.

All operators entering the room must equip a proper gown, cap, mask, and gloves to reduce the risk of human-caused contamination. Sticky mats must also be used for all footwear prior to entry to reduce the number of foreign objects introduced to the room. These features grant peace of mind knowing that our high-purity filters can operate at optimal performance with a very low risk of contamination or inefficiency. We are proud to be able to provide you with industry-trusted high purity filtration components from our meticulously maintained cleanroom facility. Our variety of filter configurations offers you customized filtration solutions and ensures that quality or purity is uncompromised.