

Cleanroom Manufacturing: Why It's Important

Patient safety is critical in the medical device and pharmaceutical industries. From medical device manufacturers to the doctors performing often life-saving operations, everyone plays a crucial role in ensuring patient safety. One simple way to impact that is by using cleaner devices and products.

There are many factors that affect how 'clean' a product is, and one of them is cleanroom manufacturing.

What is a cleanroom?

A cleanroom is essentially a room with a controlled environment that has lower levels of contaminants such as airborne microbes, dust, aerosol particles and more.

Cleanrooms are classified according to the number and size of particles permitted per volume of air. The International Standards Organization (ISO) has 9 ratings for cleanrooms with ISO 1 being the most stringent.

There are strict standards governing the cleanliness of a cleanroom, and failure to comply with these standards can lead to any number of negative outcomes, including compromised patient health.

The FDA and ISO 13485 certification standards require all cleanrooms to follow written procedures.

The ISO 13485 certification standards, adopted by many medical device manufacturers as part of their quality management systems, make it mandatory for all manufacturers to have formal written procedures regarding control on documents and records, controls for non-conformance, internal auditing procedures, corrective and preventative actions, process and design controls, record retention, and accountability and traceability.

How are cleanrooms kept clean?

All ISO-certified cleanrooms are positive-pressure rooms, which means the pressure within the room is greater than the pressure in the surrounding environment. The pressure in a positive pressure room, together with the suction of air into the cleanroom through a series of High-Efficiency Particle Air (HEPA) filters, keep the air within the cleanroom uncontaminated.

Sources of contamination

Contamination threatens the quality of the technical processes, production activities, and the products. There are many sources of contamination in a cleanroom and a major culprit is personnel.

As part of the protocol to control the contamination, a procedure to inspect and monitor the working conditions must be developed. In medical device manufacturing, this includes having a list of all personnel—with information on their health, cleanliness, and clothing requirements—who affect the quality of these medical devices.

Contamination control can also be strengthened with proper gowning protocol and adopting best behavior practices inside the cleanroom, on top of having a robust training and qualification program in place to educate all operators on the basics of microbiology principles. An example of contamination control is minimizing contamination sources like pallets, corrugate, raw material outer wraps, equipment and more in the clean room.