

Types of Contamination

by Jason Kelly

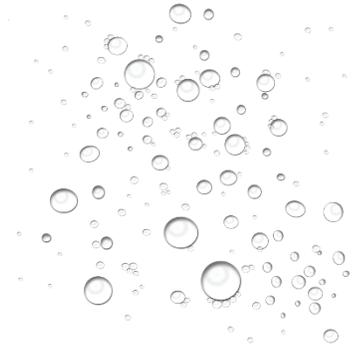
Types of Contamination

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Contamination in the cleanroom can lead to product quality and safety issues and must always be controlled. What are the most common types of contamination you can find in a cleanroom?

Water Contamination

Biological contaminants - Include human fecal matters that introduce disease-causing bacteria like E. coli and many other deadly pathogens. For example contaminated water used for drinking, bathing, washing and food preparation results to various infections, with diarrheal diseases being the most common. The WHO estimates about 1.8 million deaths annually from waterborne diseases. Water droplets in the cleanroom provide an avenue for bacterial growth.

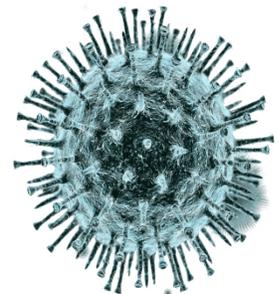


Surface and Airborne Contamination

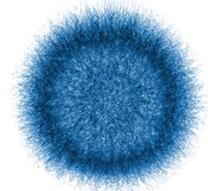
Bacteria - Represent the most important group of pathogens within the context of microbiological contamination. They are either “commensal” bacteria or “pathogenic” bacteria. Commensal bacteria are part of our natural flora and are usually harmless. They even act as protection from the colonization of pathogenic microorganisms



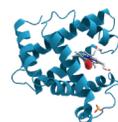
Viruses – These are genetic entities that exist somewhere between living and non-living states, first observed in 1898 by Paul Frosch and Friedrich Loeffler to be smaller than any known bacteria. Viruses exist as capsid or a protein coat (sometimes within a membrane) when found outside of host cells. When they come into contact with host cells, viruses insert their genetic material into the host, where they multiply and literally take over the host’s functions.



Fungi -These are either single or multi-celled organisms found in any habitat, mostly on plant material and in soil. They cause skin diseases in humans that include ringworm, athlete’s foot and thrush. Yeasts and molds are types of fungi.



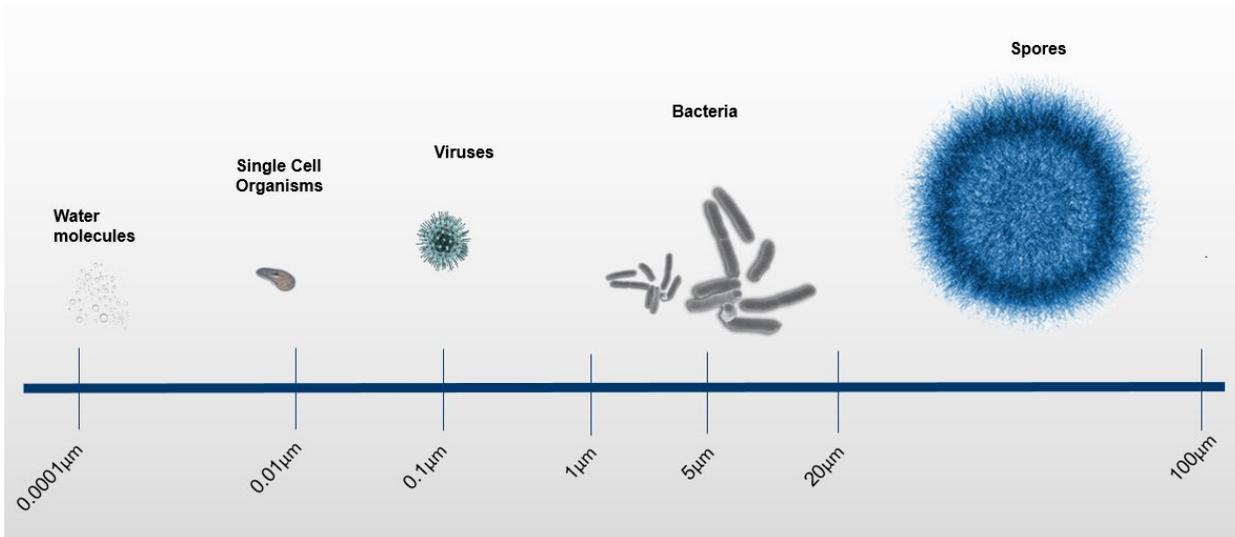
Prions -These are infectious agents made up entirely of protein material. They cause diseases similar to a viral infection.



Protozoa - These are single-celled organisms that thrive in moist habitats like soil, marine environments and even fresh water.



Sizes of Cleanroom Contamination sources



Where does cleanroom contamination come from?

One of the most common sources of contamination in the cleanroom is the actual personnel working in the cleanroom environment. The best way to avoid contamination in the cleanroom is to provide proper GMP training on aseptic gowning and to validate each person entering the cleanroom. Anything else that is brought into the cleanroom must be properly cleaned and wiped down. A robust Environmental Monitoring plan should continuously check the cleanroom environment for any signals of high particle concentrations that has shifted from a control baseline.

HEPA filters will need routine testing to ensure performance. Process equipment will need to be checked for excessive particle generation of any moving parts and airflow pressure curtains to ensure clean air is flowing over critical zones must be validated with smoke studies to ensure that there are not any erroneous flows or unwanted air currents that could cause contamination of the zone instead of preventing it.

HVAC system air change rates must be checked and air velocities maintained as well as operator comfort with temperature and humidity properly controlled and monitored. Sweaty operators equate to much more particle contamination generation and shedding in the cleanroom.

Understanding how to control the contamination in your cleanroom is critical to a healthy and contamination free cleanroom environment.