SOURCES OF CLEANROOM CONTAMINATION

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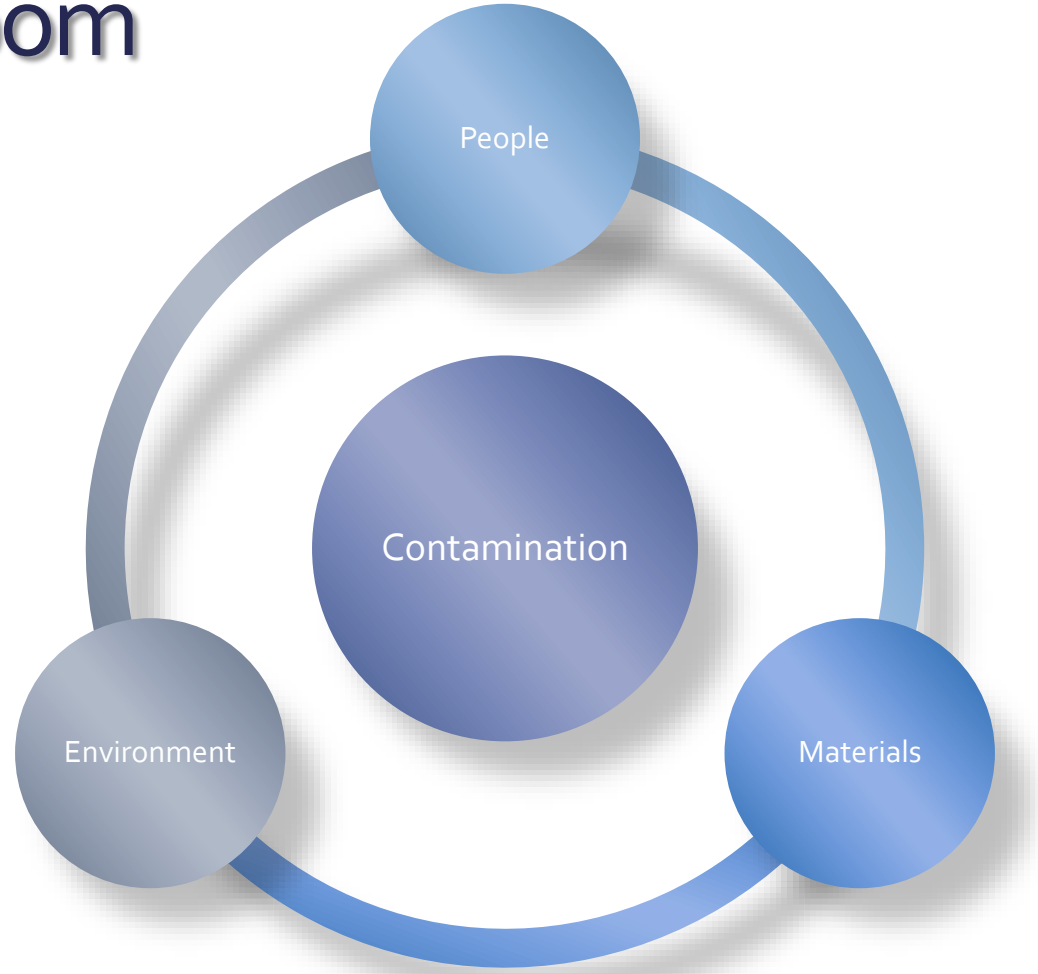
Sources of Contamination in the Cleanroom



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People

People are a major source of contamination in the cleanroom.

Notice the number of particles produced per minute during these activities.

ACTIVITY	PARTICLES/MINUTE (0.3 microns and larger)
Motionless (Standing or Seated)	100,000
Walking about 2 mph	5,000,000
Walking about 3.5 mph	7,000,000
Walking about 5 mph	10,000,000
Horseplay	100,000,000

*** A Basic Introduction to Clean Rooms By Roger McFadden, Technical Director, Coastwide Laboratories**

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People

Makeup, jewelry, excessive clothing, open toe or open back shoes, heels, artificial nails, long hair, cleanliness of personnel can all be contributing factors in cleanroom contamination.

All makeup, jewelry and excessive clothing must be removed. Long hair should be secured before entering the cleanroom.

Prevent personnel from entering if they have sunburn, skin irritations, open sores, or respiratory infections, these personnel should be reassigned to non-cleanroom duties.

Gowning

Proper gowning is critical in reducing contamination in the cleanroom.

Proper fitting gowning materials are essential. Gowning materials that are too large or too small are unable to contain the microbes within the gown.

Gowns should not be reused throughout the day or week. Once a gown is removed it should be disposed of or sent to be cleaned.

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Gowning

Proper fitting gowning materials are essential. Gowning materials that are too large or too small are unable to contain the microbes within the gown.

Gowns should not be reused throughout the day or week. Once a gown is removed it should be disposed of or sent to be cleaned.

The extent of gowning will depend on the required cleanliness level of the cleanroom.

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Gowning

Dedicated shoes for use only in the cleanroom can help prevent contamination from the outside being brought into the cleanroom.

Smokers should not be allowed to enter the cleanroom for a minimum of 30 minutes after smoking.

No personal items such as cell phones, keys, food, drinks, gum or mints are permitted in the cleanroom.

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Proper Behavior

- Slow Purposeful Movements
- Avoid Certain Mannerisms
- Be Aware of Attire

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Cleanroom Behavior

Millions of viable and non-viable particles are produced when moving in the cleanroom. Therefore, it is imperative to limit talking and actions in the cleanroom to only those required for the manufacturing of the product or compounding of a drug.

Avoid touching any exposed skin.

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Cleanroom Behavior

Radios should not be allowed in the cleanroom. It encourages excessive movement and singing.

Running, horseplay and other non-professional activities are not permitted. All movements are to be slow and purposeful.

Personnel must not lean against walls, equipment or tables.

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Physical Conditions

The cleanroom design along with other conditions have an impact on the cleanliness of the cleanroom.

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Temperature and Humidity

Temperature must be set at a temperature which will be comfortable when personnel are completely gowned.

If it is too warm personnel will sweat which will deposit some of the deeper skin flora into the cleanroom.

If it is too cold personnel will make unnecessary movements to keep warm such as shivering.

Humidity must be maintained at a comfortable level for personnel and not allow for microbial growth.

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Surrounding Conditions

Surrounding conditions, which are usually out of the company's control, can have a large impact on the contamination within the cleanroom.

Construction, heavy rain and other outside conditions will increase the amount of microbes in the outside air and personnel will be more likely bring into the cleanroom on their clothing and hair.

This goes hand in hand with proper gowning.

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Cleanroom Design

Proper cleanroom design and function is essential.

The facility size must be appropriate for the number of people working. Too many people will increase the burden on the clean room which will make it difficult for it to flush out all the particles that are generated.

The busier the personnel are the less likely they will adhere to slow movements and aseptic techniques.

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Cleanroom Design

The room's class is important in determining the appropriate number of room changes. Even though the number of room changes may be sufficient for a static state, it is important to ensure that the number of room changes is appropriate for the dynamic activity of the room.

All materials used in the clean room, and ideally the gown room, should be non porous so they are able to be cleaned and if necessary, sterilized. Stainless steel is ideal. Wood and particle board are to be avoided.

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Seasons

Seasons can impact the types of microbial flora found in the cleanroom.

Farming and landscaping activities can increase the microbes in the outside air.

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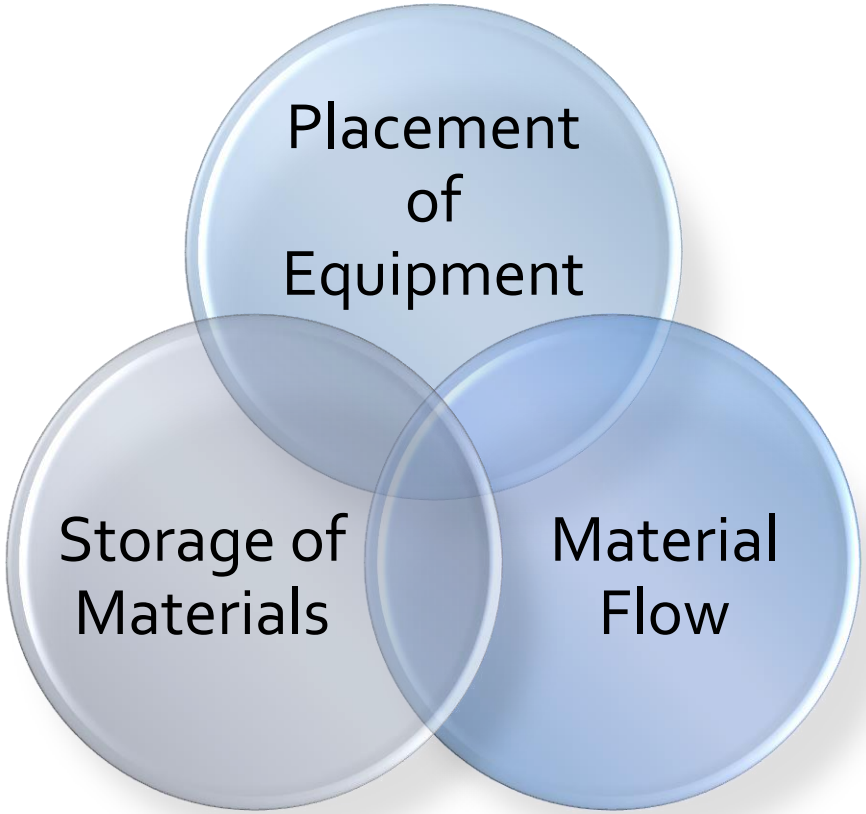
Materials and Equipment

How materials are stored and transferred into the cleanroom can impact contamination in the room.



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Materials and Equipment

Placement of equipment, exhaust, pumps etc. can impact the airflow of the room and cause contamination.

Equipment must be positioned in a manner that allows cleaning of the equipment as well as the cleanroom walls, floor etc.

Smoke pattern studies can be helpful in determining proper positioning of equipment in the cleanroom.

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Materials and Equipment

Packaging materials can carry a large number of bacteria and mold spores and must be removed prior to materials being placed in the cleanroom.

Be cognizant and draft an SOP that describes the flow of materials into the cleanroom.

All materials must be disinfected before being moved into the cleanroom.

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Materials and Equipment

Limit the amount of supplies allowed in the cleanroom.

There should be an SOP describing how to clean the equipment in the cleanroom, in order to ensure that the equipment is not harboring and microorganisms.

Avoid bringing in the following materials, if possible: wood pulp-based products, Styrofoam products, powders, erasers, pencils, felt tipped pens and anything that shreds or aerosolizes.

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