Implementing a Contamination Control Process

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The rules and special procedures needed to clean a cleanroom, and how they differ from ordinary cleaning.

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A CLEANROOM CAN BE DEFINED as a high-tech, controlled environment where the concentration of airborne particles, humidity, and temperature are all controlled to parameters specified by the ISO 14644.

As science progresses, the demand for cleanrooms in bio-tech, pharmaceutical, medical device, semiconductor, and nanotechnology continue to grow. As the demand for these controlled environments increases, it becomes more and more critical to develop and implement effective contamination control programs. The purpose of these pro-grams is to ensure that any material, substance, or energy that adversely affects the product or process is eliminated, or at least, minimize to safe levels.

WHAT IS CONTAMINATION?

There are two broad categories of contamination; particulate and microbial. Non-viable particulate contamination is defined as a solid or liquid generally between .001 and 1000 microns in size. Examples of particulates are dust, fumes, smoke, fogs, and mists.

Viable particulate contamination can be defined as a particle that consists of, or supports one or more live microorganisms. Bacteria, viruses, and spores are all examples of viable particulate contamination.

SOURCES OF CONTAMINATION

By far, the human factor is the largest contributing factor to the amount of contamination inside a cleanroom. Skin cells are constantly shed from people. The entire epi-dermis or outer layer of skin is replaced approximately every four days. Oils from the skin are shed; hair is shed. And whatever is on a person's skin or hair is ultimately deposited into the cleanroom.

In addition to human beings, equipment transfer into the cleanroom can contribute greatly to the amount of particulate contamination inside the cleanroom, as can the tools, fluids, and the products that are manufactured.

With all of these external factors allowing damaging particulate contamination to enter the controlled environment, it is crucial to develop a contamination control program to combat such a barrage of potential contamination.

CONTAMINATION CONTROL METHODS

Since the human factor is the biggest contributor to the contamination problem, the first level of defense should be a comprehensive training program for all personnel who enter the cleanroom. The training should begin with the concept of a cleanroom and which elements from the out-side world need to stay in the outside world. A well-designed training program examines all elements of contamination and how to best prevent particulates from entering the environment in the first place. A Standard Operating Procedure (SOP) should be prepared and reviewed by all cleanroom staff. The SOP is a written document with specific action steps to be taken in the contamination control process.

Proper gowning or garment selection should be made in accordance with the class of cleanroom and product requirements. This may include hairnets, shoe covers, face covers, gloves, frocks, or full coveralls. The SOP will define the gowning procedures for entrance, work, and exit from the cleanroom.

It is also a good idea to implement a gowning certification program. This program will periodically assess the ability of each person entering the cleanroom to don gowning apparel without contaminating it, judged by a microbiological assessment of the gown itself at various points.

SHOULDN'T TRAINING AND GOWNING SOLVE EVERYTHING?

The personnel understand how a cleanroom works. Everybody knows that there are things from the outside environment that need to stay outside of the cleanroom. The staff is qualified and capable of donning gowning apparel. This should take care of all of the contamination, right? Wrong. No matter how well people are trained, and how well they follow gowning procedures, external contamination will always enter the cleanroom.

Because of this, a qualified engineer should examine air filtration. In order for the cleanroom to function properly, HEPA filters must be utilized and changed as needed. The best contamination control program in the world will be useless if the air inside the cleanroom is not clean. But clean air itself can not keep the cleanroom clean. If that were the case, you could leave a dirty car outside on a windy night and wake up to a clean, shiny car.

Particulates adhere to all surfaces in a cleanroom, and must be removed. There are physical properties by which particles adhere to a surface, and a surface will never be completely clean unless the proper techniques are utilized to break the bond or dissolve the particle itself.

Disinfection can be classified as the elimination of viable particulate on a surface. Typically a solution is applied to a surface to kill or inhibit the microorganisms. Disinfectant cleaners may or may not be sporicidal. Therefore it is recommended that a sporicidal cleaner be used periodically to eliminate endospores. Additionally, disinfectant cleaners used in the United States must be registered with the EPA.

Cleaning refers to the physical removal of soil, organic debris, and particulates from a surface. Proper cleaning requires the proper equipment, tools, and techniques.

As it is impossible to prevent all contaminates from entering the cleanroom, it is the goal of the cleaning program to remove as many of the contaminating particles as possible. Thus the first step in the cleaning process should be to vacuum all accessible surfaces from the cleanest part of the room to the dirtiest part of the room.

The cleanroom technician should always work towards the exit. A HEPA filtered vacuum, which filters 99.97% of all particles down to, and including 0.3 mi- must be used to guarantee particles that are collected are kept inside the vacuum and not reintroduced into the cleanroom.

Studies have shown that cleanrooms that use traditional wiping methods left twice as much contaminant in the cleanroom when compared to a vacuuming program with a HEPA vacuum.

The second step in the cleaning process is to wipe all surfaces with an approved cleaning solution. The cleaning should be done in a right to left or left to right manner. Never wipe in a circular motion, as this will contaminate areas, which have already been cleaned. The wipe should be inspected and refolded after each pass to make sure that the wipe is not soiled and a fresh surface of the wipe is always used on a new cleaning pass. Finally, the cleaning chemical should never be sprayed onto the surface that is being cleaned, rather sprayed directly on the wipe.

After the surfaces have been vacuumed and wiped, the final step in the cleaning process is mopping. The mopping done in a cleanroom is very different than mopping performed by a typical janitorial service. Lint free polyester or PVA mops attached to stainless steel handles are required. Additionally, a stainless steel or autoclaveable plastic two or three bucket mop system is standard equipment in contamination control. The two bucket system allows for the safe isolation of the contaminants that have been mopped from the surface of the cleanroom. In other words, the cleanroom technician will not re-mop an area with dirty or contaminated mop water.

Mopping should be done utilizing the pull and lift method, where the technician places the mop no more than three feet in front of the body, pulls the mop straight towards the body, lifts the mop and replaces slightly to the side, three feet in front of the body again. The strokes should overlap by at least four inches. This method, similarly to the wiping technique, prevents the dirty mop surface from

Figure 1: Lint free polyester or PVA mops attached to stainless steel handles are required for mopping.

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touching an area that has already been cleaned.

It is very important to change the water in the buckets frequently. In an ISO Class 7 and Class 8 cleanroom, the mop water should be changed after every 1000 square feet of surface cleaned. In an ISO Class 5 and Class 6 room, the water change should be more frequent, with a limit of 600 square feet of cleanable surface. Additionally, the water should be changed whenever a new room is cleaned, regardless of square footage cleaned.

A good contamination control pro-gram will document the number of water changes as well as the lot number of the cleaning chemical utilized and the length of time the cleaning chemical was allowed to dwell on the surfaces. Additionally, the documentation should note the specific tasks performed during each cleaning service and by whom. The documentation must be left inside the cleanroom itself and made available to quality and management personnel.

All three cleaning methods, HEPA vacuuming, unidirectional wiping, and pull and lift mopping have been validated at the ISO level. Therefore, the cleanroom operators do not have to validate the cleaning methods, only the ability to clean the cleanroom must be validated, which brings us to the next subject, environmental monitoring.

Figure 2: The first step in the cleaning process should be to vacuum all accessible surfaces.

As it relates to the contamination control program, the environmental monitoring within a cleanroom should be designed to provide an indication of the ability of the cleaning personnel and the ability of the designated cleaning protocols to keep the room clean.

Industry standards call for the following testing:

- Viable and nonviable airborne sampling under dynamic conditions
- Surface sampling before and after processing
- Surface sampling of critical or problematic areas
- Personnel sampling of gloves and gowns after exposure to aseptic processes

The results of the environmental tests will validate the efficiency of the contamination control program. Results outside the acceptable limits may suggest more frequent cleaning, more stringent gowning requirements, less foot-allowable human traffic inside the cleanroom, or a need for an improved air filtration or air flow.

Until there is no human traffic in a cleanroom, there will always be the need for a contamination control program. The contamination control program's goal is to keep the outside world from entering the cleanroom, and to efficiently remove whatever does enter the room. All contamination control programs will depend on the population of the room, the amount of air and air filtration, and the level of cleanliness that is desired. With proper training, cleaning equipment, and cleaning methodology, the desired level of cleanliness can be achieved and maintained to keep the outside world out.

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