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Keeping Product Clean In and Out of the Cleanroom, Part 2: The Program

With Kevina O'Donoghue

The first step in developing an effective precision cleaning process for the product is to determine where cleaning can be avoided. Keeping the product clean, particularly during transfer and storage, is an important part of your contamination control program.

Much effort is expended in keeping the cleanroom clean, in monitoring the cleanroom. Much effort is expended in developing, validating, and monitoring cleaning processes for both so-called "high-end" products and for industrial applications. It is critical to manage three major sources of contamination for products fabricated within the cleanroom. These contamination sources are:

- People
- Equipment
- Transfer

EFFECTIVE TRANSFER

Many items such as raw materials for use in the manufacturing of the product are supplied double bagged or triple bagged depending on the manufacturing process. The outer packaging could potentially be highly contaminated so careful removal of this packaging is of utmost importance.

Sometimes pallet trucks of cardboard boxes are loaded into the transfer area. How do you remove contamination from those parts when going from the dirty side to the clean side? How do you avoid particle generation? In general, it is wise to remove all cardboard packaging outside of the controlled environment. As we explained in the previous column,¹ the material transfer room is a controlled environment that includes a 'dirty' side and a 'clean side.' However, contamination must be minimized even in the 'dirty side.' Therefore, remove the cardboard in an area outside of but proximal to the transfer area; then immediately move materials to the transfer area.

CLEANING

Set a cleaning protocol for surfaces, packaging, and product during transfer. We have observed people spraying isopropyl alcohol (IPA) on a part, then transferring it into the cleanroom. Simply anointing the material with IPA may not be adequate. Remember that effective cleaning typically involves both physical and chemical action. A more effective, but still convenient cleaning protocol is to use an alcohol spray, such as IPA, in conjunction with non-linting wipes. The IPA must be of high quality and free of residue. Large storage containers and benchtop dispensers must be made of materials that do not leach residue. While there is no perfect cleanroom wipe, the selected wipe must be optimal for the application.²

In the transfer room or area, first clean the benchtop and racking. As soon as material is transferred to the dirty side of the transfer room,¹ clean the outer bag. Very often this outer bag is removed and not cleaned down. The risk of this technique is that contamination from this outer bag can get onto the inside bag and onto the gloves of the material handler who wipes the inside bag.

STORAGE

Once cleaned, the outer bag can be removed. The inside bag should then be wiped down and left on the pre-cleaned benchtop or racking fixture for cleanroom personnel to collect. If the material is left on this racking for a long period of time, then cleanroom personnel should wipe it again as a precautionary measure, before bringing it into the cleanroom environment. The definition of "a long time," analogous to a Clean Hold Time in pharmaceutical validation, is specific to the fabrication process and facility; you should determine and document a reasonable policy.

Sometimes material is stored within the material

transfer area or cleanroom environment itself until ready for use. In this case, the benchtop/racking surface and outer bag is wiped down thoroughly as described above and left on the surface for entry into the storage area. All materials stored for long periods of time within the material transfer or cleanroom should be left double bagged. It should be noted that if materials are stored within a cleanroom in totes or on racking, then these should be cleaned on a regular basis as part of the cleanroom cleaning schedule. When the material is required for use, then the outer bag should be cleaned again and removed and the inner bag cleaned before opening. Final packaging should be removed only just prior to use of the material.

CONTAMINANTS DEAD AND ALIVE

It is important to understand the source of particulate contamination, both viable and non-viable. If sterility is the only concern, then sterile materials, double or triple bagged, may not need to go through such rigorous cleaning of the packaging as each layer of packaging is sterile. However, care should be taken when removing the outer packaging to ensure it does not pose a threat to the inner packaging. Be aware that particle counts include both viable and non-viable particles.

LARGE ITEMS

Transferring bulky materials is particularly difficult. Sometimes, only parts of the assembly can be cleaned prior to transfer. In medical and pharmaceutical applications, cleanliness of large, bulky objects is typically determined by swabbing and testing for microbial contamination. Aside from the time factor in microbial analysis (perhaps three to five days), the absence of significant microbial contamination does not necessarily rule out non-viable contamination, particulate, and thin film. Sampling followed by particulate counting and/or non-volatile residue testing may be required.

Some items may have to be wheeled into the cleanroom on trolleys due to the weight or size of the material. These trolleys should be thoroughly cleaned before entering the cleanroom, in particular the wheels. Sticky mats may help to remove excess contamination

from the floor area but this alone is not a good enough clean for entry into the cleanroom; the hubs and axles can also be contaminated. To minimize entry of contamination to the cleanroom, one trolley can be used to transfer the material from the warehouse to the 'dirty' side of the material transfer room and another trolley that is dedicated for cleanroom use can be used to transfer the material into cleanroom from the 'clean' side. This method however does involve an extra handling step. Unfortunately, more often than not, this extra desirable transfer step is judged to be consumption of

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valuable time. Setting up written justified policies for such activities may be helpful.

ACCOUNTABILITY

With larger assemblies there is also the issue of responsibility and accountability. The people in the warehouse may move materials into the transfer area without cleaning them, on the assumption that cleanroom technicians will take care of cleaning issues. Those in the cleanroom may assume that the parts have been pre-cleaned. Even worse, in the interest of supposed efficiency, management may tacitly support or even mandate an unwise policy of bringing materials into the cleanroom without cleaning them. If you are faced with such fallacious cost-cutting measures, and if logic does not prevail, tracking the failure rate may be the most compelling approach.

IS AUTOMATION THE ANSWER?

Not always. The assumption is made that people are the problem and that if you remove the people, there will be no contamination problems associated with materials transfer. Automation simply does things the same way each time; you may be automating a process that inherently generates particles.



Figure 1: Transfer equipment can be configured to minimize contamination transport.

The equipment itself can generate particles. We have observed transfer equipment, moving materials into a cleanroom, that had both particulate and non-particulate contamination on the "tracks." The design and maintenance of transfer and process equipment must be considered, because equipment and fixturing can degrade. Sometimes, the same racks or trays are used in both early stages of production and in the cleanroom. It is important to separate and segregate the processes (Figure 1). People need to be involved in design, oversight, and monitoring of transfer processes.

KEY PROGRAM

The material transfer process should be a key element in the cleanroom contamination control program. Too often, the process of materials transfer is not given a huge amount of time, if any, in employees training programs. It is vital that personnel performing the material transfer process understand the responsibility and importance of their role and are fully aware of the impacts of their methods and practices. They must also understand the impact of their behaviors, particularly the negative impact of incorrect behaviours. Personnel awareness and understanding is crucial for this process to be performed effectively; for this to happen, there must be management support and understanding.

References:

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2. Siegerman, H., "Wiping Surfaces Clean," Vicon Publishing, 2004.

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