Barbara Kanegsberg and Ed Kanegsberg

Keeping Product Clean In and Out of the Cleanroom, Part 1: The Interface

With Kevina O'Donoghue

Are you aware that incorrect materials transfer could pose one of the biggest potential sources of contamination within a cleanroom? How many of you can say that while performing the transfer of materials into the cleanroom environment you are fully aware of your actions, practices, and methods?

KEEP THE PRODUCT CLEAN

Paperwork, raw materials for manufacturing the product, tools, and equipment must be successfully transferred to the cleanroom. The goal of a materials transfer program is to keep contamination from the outside world from entering the cleanroom. Benefits of investing effort in a materials transfer program include higher quality product, lower costs, and an enhanced competitive position.

Some materials are double bagged, some single bagged, and may be stored for long periods of time in cardboard boxes in warehouse environments. Other materials such as tools may not be bagged at all and are likely to have come from an uncontrolled environment.

Contamination control protocols for material transfer are vital. Materials brought into the cleanroom that have not been cleaned effectively during the transfer process are an immense source of particulate and thin film contamination. Inadequately cleaned materials can be a huge source of spore forming bacteria, extremely resistant bugs that are very difficult to eradicate from a cleanroom environment. Manufacturers of all critical product should be concerned about the impact of biological contamination, not just those producing medical devices and pharmaceuticals. Many people are not aware that biological contamination will dramatically affect particulate counts which are required in every cleanroom industry. At the same time, sterility is not enough; "dead dirt" can wreck havoc with critical devices. Water soluble lubricants and near-neutral pH processes can provide water, warmth, and nutrients, a favourable environment for biological contamination.

Figure 1. When utilized properly, a hatch is one option for materials transfer. (Photo courtesy of Sealed Air Nelipak®, Galway, Ireland)

ROOM DESIGN

Materials transfer may be through a hatch leading directly from an unmonitored manufacturing area to a cleanroom or a transfer hatch between two cleanrooms. Is this an optimal arrangement for your process? With a hatch, employees are tempted to stand on either side, engaging in lively conversation, even enjoying their morning coffee. Such behaviour increases the likelihood of contamination. For new construction, consider a material transfer room.

Material transfer rooms should function like gowning rooms with a 'clean' side and a 'dirty' side. Very often a line of tape separates these areas. In practice, a "line in the sand," does not keep personnel from crossing over to the 'clean' side inadequately gowned or in street clothes. Too often we see issues with high levels of contamination on the 'clean' side of the material transfer room where the root cause is the 'dirty' side.

Rather than a strip of tape, consider an "étagère," a physical barrier such as racking or cabinets that allows expedited transfer of materials while discouraging personnel movement to the clean side. If racking or

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SOIL IDENTIFICATION

Perhaps the main value of the device which is the embodiment of this suggestion is identification of soil components. It is that which eNoses most often supply computerized identification or recognition of specific aroma components. One can imagine use of a secondary computer algorithm to select the appropriate cleaning fluid based on analysis of soil components and a database of HSP values.

NO CONTACT, NO FOUL!

This device for recognition of surface contamination doesn't have to contact the surface. Further the response time of the current generation of eNoses is around one or so minutes. So the device could provide on-line output that would be time-sensitive and independent of surface roughness.

SUMMARY

ENoses are not expensive and not used in cleaning operations at any level of surface soil content. My question, why not? Critical cleaning, any cleaning, requires knowledge of chemical content and that's what an eNose provides.

Note: A patent application has been filed for the device when used to detect surface cleanliness.

Reference

1. Image courtesy of NASA's JPL.

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cabinets are on wheels, it is simple to move them to allow access of large equipment or bulky materials. Of course, because such barriers are not physically distinct rooms, the dirty side of the transfer room should also be fairly clean.

CONVENIENCE

Cleaning materials within the transfer area must be convenient. A wipe down station should always be visible in the material transfer room with a low-residue cleaning agent such as isopropyl alcohol (IPA) and low-lint wipes readily accessible. If there is a hatch rather than a room, consider wipe down stations immediately before and immediately after transfer. If no wipe down station is present, there is the temptation for personnel to pass material in without cleaning it.

TRANSFER VERSUS GOWNING

The changing/gowning areas should not be used for wiping down and transferring materials to avoid potential contamination of personnel and cleanroom clothing. Good practice within a cleanroom should generally allow clean materials to come in one way and used materials to exit by another area.

STAY TUNED

In Part 2, we will discuss techniques for cleaning during transfer, managing bulky materials, and automation.

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