Particles on Surfaces

This article is based on an original publication by Berkshire.

Filtered air, workers dressed head-to-toe in protective gear, spotless steel and plastic surfaces, no signs of paper or cardboard— by all appearances a germ-, dust- and static-free environment.

In a cleanroom environment, "clean" to the eye isn't good enough. Microscopic saboteurs remain and compromise product integrity. To combat them, semiconductor and pharmaceutical manufacturers, among others, utilize several processes to detect, count and remove the tiniest of intruders.

Companies employ laser scanning to measure particles per unit area and incubation to count the number of colony forming units (CFUs) of bacteria. Since even in the cleanest cleanrooms utilizing the latest air filtering technology will have unwanted particles, the focus is on why and how these particles affix themselves to the surfaces of sensitive equipment, contaminating them and compromising their functionality, so the most effective approach to minimize their presence can be used.

Through accumulated data derived from testing, we know microscopic particles do not bounce after striking a hard surface; rather, through inelastic collisions with the surface, they bind to them and remain there because of various binding forces acting on them. The primary forces involved here are capillary binding forces that originate from surface tension within the thin liquid layer between particles and surfaces. The goal is to "clean" the surface by reducing this layer's surface tension while providing a mechanical means of removing and capturing the particles. Is wiping the answer?

Isopropyl alcohol (IPA) is an excellent solvent to use when cleaning both particles and bacteria. However, simply applying IPA to a surface and letting it do its job is not enough. While the surface tension will be reduced as long as the IPA is present, the particles will not leave the surface. Mechanical removal must be done with a cleanroom wiper to both remove the unwanted material and contain it on the wiper for removal from the room.

How best to wipe?

- 1. Wipe gloves before wiping surfaces, and then discard the wiper.
- 2. Use linear strokes whenever possible.
- 3. Start at known clean areas and go to known dirty areas.
- 4. Go from dry areas to wet areas.
- 5. Each wiping stroke should be done with a clean wiper surface (there are eight clean surfaces on a quarter-folded wiper when both sides are used).

Once counter surfaces have been cleaned, it's time to tidy up the walls and the floors. Approach cleaning them as you did when you used the five steps above—but be sure to use larger wiping cloths.

To clean the floors, pre-wetted mop covers ("booties") are most effective and are the easiest to use. Simply use linear wiping strokes from clean to dirty and replace the cover when it shows visible dirt or after a specific area has been cleaned.

Walls do not need to be cleaned as frequently since they do not encounter particles at near the same frequency as floors and other horizontal flat surfaces. To clean walls, the same mop used for cleaning floors will work fine. Again, work from clean to dirty (the clean areas of the walls are usually near the HEPA filters while the dirtiest areas will be closer to the floor), using a vertical motion from top to bottom. A horizontal motion also works, but in either case immediately change a soiled wipe.

The next step is determining when your cleanroom has been sufficiently cleaned. First, perform an overall visual inspection. Do the cleaned surfaces look clean? If not, repeat the cleaning process in problem areas until no dirt appears on the wipes (using a black wipe at this point allows the cleaner to inspect for light-colored particles). Keep in mind the human eye can only register particles as small as 50 μ m (approximately 0.002 inches). Surface illumination using bright light/UV light can aid in detecting smaller particles for removal.

Pharmaceutical companies are especially conscious of needing a manufacturing environment that is as close to 100% clean as possible. Injectable (parenteral) materials must be manufactured in a totally clean and sterile environment because there is no opportunity to sterilize them after packaging. The work area must not only be free of unwanted particles but also of the recently manufactured drug AND any cleaning material used to remove it.

But just how clean is "clean enough" for parenteral drug manufacturers? While no environment can ever be totally free of particles, steps can be taken to minimize their presence. Two requirements must be met for "no lingering traces" standard to be met:

- 1. Wipe until there are no visible traces of soil on either the surface or the wipe
- 2. Examine the surface with a bright light/UV light to reveal trace residues and remove them

Also, be sure to spot check surfaces with swabs and analyze them with UV-visible spectrophotometers (for active drugs) or Total Organic Carbon (TOC) analyzers (for cleaning agents) for the presence of residue. If the swabs' contaminant levels are below established criteria, the risk of future cross-contamination is diminished and the area can be considered clean.

For microelectronic companies, specifically semiconductor manufacturers, cleanliness is also paramount. Even submicron-sized particles ($< 1\mu m$) can wreak havoc on the delicate integrated circuitry contained on these silicone-based circuit board wafers.

To keep delicate wafers as clean as possible, start with the machines used to create them. Physical and chemical treatments specially designed to clean the equipment should be done periodically so that, as the wafers move through the process cycle, residues and accompanying particles do not attach themselves to the circuitry. Thanks to a basic property of surface particles—light is scattered when it is impinged on them— identifying them in the equipment is relatively easy.

A prime wafer (one with no circuitry on it) is placed into a computer-controlled, laser scanning instrument that maps the entire surface, recording particles as they scatter the laser beam. These particles show up as dots on the map. The wafer is then sent to clean processing equipment and the particles are measured again. The net increase in these particles (called "adders") establishes whether or not the equipment is clean enough to be used during the cycling activity.

While there is no environment that is completely germ- and particle-free, scientific advancements have made it possible to drastically reduce harmful materials. Taking the time and the effort to thoroughly inspect and clean equipment may cost time, but it will save money in the long run.