Cleaning & Maintenance Management online
www.cmmonline.com

What The Cleaning Industry Can Learn From Cleanrooms

Standardized, consistent cleaning lends itself to various applications in the JanSan industry.

Author: Dr. Jay Glasel

For many years, I have been teaching a course on cleanroom design, operations and maintenance to classes chiefly composed of professionals from the pharmaceutical industry.

At the beginning of the curriculum that deals with maintaining a cleanroom, I present a slide that states: "Almost all the aspects of running and using a cleanroom are basically the same ones we use to keep a clean private home or commercial working space, except they're formalized and more rigorous."

Modern industrial cleanrooms developed from their origins in the 1960s when a requirement for dust-free working environments became necessary in a variety of situations that ranged from assembling military gyroscopes to the National Aeronautics and Space Administration (NASA) moon landing project.

The first standard for cleanrooms was published by the U.S. Air Force (USAF) in 1961 (Technical Manual TO 00-25-203) and the first U.S. federal standard for cleanroom air quality (Federal Standard 209) was developed in 1963 from work at Sandia Laboratories where nuclear weapons were assembled.

Since the '60s, cleanroom technology and methods have been adapted by many industries where contamination by particles, chemicals and microbials must be avoided.

At present, the standards of airborne, surface particle and microbial contamination cleanliness for pharmaceutical cleanrooms in the U.S., Europe and Asia are developed and set by international non-governmental organizations but are accepted and enforced — with varying degrees of effectiveness — by governmental regulatory agencies like the Food and Drug Administration (FDA) in the U.S.

Effectiveness Of Cleanrooms

Cleanrooms are classified by the cleanliness of the air in their interiors expressed as the number of airborne particles per cubic meter, known as the "airborne particle density."

Typical town air that surrounds us in everyday life has a particle density of around 100 trillion particles per cubic meter.

Contrast this with a typical pharmaceutical cleanroom that has an airborne particle density of 1,000 particles per cubic meter or a typical semiconductor industry cleanroom, which has an airborne particle density of 2 particles per cubic meter, and it's apparent that the technology and expertise exists to maintain a high degree of cleanliness in working spaces.

The reason cleanrooms are classified according to the density of airborne particles present is that, unless these particles are removed quickly and efficiently from the air in the workspace, a large number of them will inevitably settle on vertical and horizontal objects.

From these objects, the contamination can be transferred to everything else in the workspace.

The same problem with particle contamination exists in non-cleanroom working spaces: Airborne contamination settles on surfaces and can be transferred from there to other objects or from person to person.

The fundamental strategies for reducing airborne contamination in a cleanroom are:

1. Special design of cleanrooms, including airtightness, airlock entrances, special interior surface coatings, etc.
2. The extensive use of high-efficiency particulate air (HEPA) filters and recirculation/filtering of a significant percentage of room air
3. The use of special garments for personnel working in the cleanroom
4. Rigorous and regular cleaning of surfaces in the cleanroom
5. Rigorous and regular monitoring of airborne particle densities and surface contamination within the cleanroom.

Of these five strategies, numbers one and three are not practical in an existing commercial setting; numbers one, two and three are not practical in schools.

All of these five strategies are possible in a hospital setting, although some or all of them are frequently not implemented even in modern surgical operating theaters.

On the other hand, with modifications and simplifications, strategies number four and five, cleaning surfaces and monitoring for contamination, are possible to implement in all non-cleanroom settings with the objective to decrease surface and airborne particle contamination.

Sources Of Particle Contamination

A question that cleaning and maintenance professionals may not ask themselves — because the answer may seem obvious — is: Where does most of the particle contamination come from?

Most people believe contamination is tracked into work areas from the outside environment by personnel and, in addition, enters through unfiltered heating, ventilation and air conditioning (HVAC) systems from the surrounding atmosphere.

Undoubtedly, these sources do contribute to airborne contamination in most working spaces.

However, cleanroom professionals have long known that a major source of airborne and surface contamination in cleanrooms is the cleanroom personnel themselves.

Specifically, skin particles that are shed by all humans.

Consider these simple facts:

- Each human being sheds approximately a billion skin cells per day — about 1 outermost layer of epithelial cells per day
- A skin cell is about 33 micrometers by 44 micrometers — a size just under the ability to be easily seen by the naked eye
- About one in 10 skin cells carry bacteria
- Some species of bacteria deposited on surfaces via skin particles can remain viable for months and even years.

Consequently, major contributors to both particle and bacterial contamination are the workers themselves going about their normal tasks.

And, as long as human beings are in workspaces, there is nothing that can be done about their being sources of this contamination.

Unless airborne skin particles are removed by a HEPA-filtered HVAC system, they will eventually settle on vertical and horizontal surfaces.

Once settled on these surfaces, the skin and other particles must be removed by efficient cleaning methods or the contamination, along with contamination from other sources, will spread through a whole facility by normal human-surface contacts.

In cleanrooms, this particle contamination is reduced by HEPA filtering of the air within the room, by garments — including face and hair masks and shoe coverings — worn by the workers and by rigorous cleaning routines all governed by protocols written for each individual facility to conform with international specifications.

In pharmaceutical cleanrooms, an independent quality control (QC) department is often tasked with monitoring the cleanroom, which means testing the level of airborne and surface contamination for both particle and bacterial content.

Airborne particle and bacterial densities are usually checked both in the presence and absence of workers, while surface contamination monitoring is done both before and after cleaning.

The success of this system of maintenance for pharmaceutical and semiconductor cleanrooms is demonstrated by the low particle density levels in cleanrooms.

Learning From Cleanrooms

As mentioned, some technologies, such as HEPA-filtered HVAC systems, are not practical for non-hospital settings due to installation expense and upkeep.

Likewise, the use of special garments is not practical outside of a hospital environment.

Conversely, practical steps within the capabilities of almost any facility interested in using the principles for keeping cleanrooms clean include:

- An understanding of the major sources of particle/microbial contamination in an individual workplace
- The development of written specifications for cleaning performance and rigorous monitoring of the actual performance.

Handheld airborne particle counters, also called optical particle counters (OPC), are easy to operate, stable and useful tools for determining the magnitude of airborne contamination problems in working spaces.

Remembering that airborne contamination rapidly becomes surface contamination, OPCs can be used to determine amounts of contamination coming from existing HVAC systems: That is, OPCs can be used to determine where some basic air filtering could reduce major amounts of airborne contamination entering the workspace.

OPCs can also be used to determine what portions of workspaces are major sources of particle contamination — equipment, unusual human activity, etc. — that could therefore be sealed off or otherwise contained.

Thus, using OPCs could save money and increase cleaning efficiency by showing where airborne contamination that eventually settles on surfaces can be reduced.

As far as cleaning operations go, a realization of the basic "laws" of cleaning should be understood by groups in charge of maintenance.

These laws are:

1. Whenever a surface becomes clean, something else becomes dirty
2. Cleaning just moves soil from where it is to where we want it to be
3. Soil is never destroyed, always created and often relocated.

It follows from these laws that:

- Since soil isn't destroyed by a cleaning solution, when you mix rinse solutions with a cleaning agent, you're just recycling soil
- One can never get surfaces completely clean: If a perfectly clean surface meets a cleaning agent containing even one molecule of soil, that soil molecule can be transferred back to the clean surface and contaminate it.

As an example of the practical application of these laws in cleanrooms, moistened cleaning wipes used to clean surfaces are refolded after a set number of wipes to expose a clean wiping area to the surface.

And, after a set number of foldings, the wiper is replaced by a clean wetted wipe.

The operations are done according to rules established for each working area.

Another example is that if mop cleaning is used for cleanroom floors, it has been found that the three-bucket system is preferable to the two-bucket system; rules are established for how many changes of cleaning and rinsing solution must be done for a given floor surface area.

Also, the wiping parts of the mops themselves are subject to being discarded after a set number of uses and are made of materials that optimize absorption of contamination.

In addition, some facilities are finding that eliminating mopping altogether by adopting spray-and-vacuum technology solves many cleaning problems.

Finally, there is a point that even some cleanroom maintenance professionals neglect: Cleaning a surface without rinsing it leaves residues that may not only lead to further contamination sticking to the surface, but may also damage the surface.

Using OPCs judicially, using wipes correctly and mopping or otherwise removing soil in optimized ways are just a few of the many procedures used in all well-maintained cleanrooms that could be adapted to commercial cleaning environments to improve cleaning efficiency and reduce contamination.

Dr. Jay Glasel is the managing member and founder of Global Scientific Consulting LLC. He is a professor emeritus in the Department of Microbial, Molecular and Structural Biology at the University of Connecticut Medical/Dental School in Farmington, Connecticut. Glasel has lectured in many countries in Europe and Asia, and his scientific research has been in the fields of structural biochemistry, molecular immunology, pharmacology and cell biology. Glasel is co-editor and an author for the Academic Press textbook "Introduction to Biophysical Methods for Protein and Nucleic Acid Research" and many other contributed book chapters and original scientific research articles.