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Good Housekeeping: The Art Of Contamination Controls

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It took Dr. Joseph Lister a while to convince physicians that something invisible had to be protected against, but since the concept took hold, cleanliness has been a major concern in life sciences. Now there are numerous standards defining "clean" in hospitals, pharmaceutical manufacturers, biotech labs, and other life sciences areas, plus numerous options for meeting those standards.

Cleaning The Cleanroom
Anyone not clear about the importance of fighting contaminants just needs to review the statement of Roger McFadden, technical director of Coastwide Laboratories, based in Wilsonville, OR. In his paper, "A Basic Introduction to Cleanrooms," McFadden noted: "A human hair is about 75-100 microns in diameter. A particle 200 times smaller (0.5 micron) can cause major disaster in a cleanroom. In fact, the Hubble Space Telescope was damaged and did not perform as designed because of a particle smaller than 0.5 micron."

According to Rich Hill, president/COO of Data Clean Corp. in Des Plaines, IL (www.dataclean.com), which has been sanitizing cleanrooms since 1979, "There's a distinct difference between cleanrooms for life sciences and pharma, versus cleanrooms in nonsterile environments like electronics. In my view, environments processing high-end electronics tend to be cleaner in terms of ferreting out particulates, whatever their sterility. In pharma and life sciences, you're more concerned about sterility," he says. However, he adds, "If you're manufacturing acetaminophen, then aspirin dust from the lab next door is a dangerous cross-contaminant."

Though no one would talk specific dollars, it's acknowledged that establishing a cleanroom can be expensive. One option that's developed over the years is modular, softwall cleanrooms that are easily set up and broken down. "Softwall cleanrooms work well within an already controlled environment. If you have an existing temperature-controlled room with cleanroom compatible surfaces [i.e. epoxy painted walls, nonshedding ceiling tiles, sheet vinyl flooring, or epoxy painted floors], softwall cleanrooms are very cost-effective," says Kathie Kalafatis, president/CEO of CleanAir Solutions (www.cleanroomspecialists.com), a designer of cleanrooms. "With our options, we can help a facility isolate an area to meet anything up to Class 100 [Class 100 guards against those 0.5 micron particulates] applications." She stresses modular cleanrooms are not designed to be constructed in easily contaminated open environments, and they won't work where a pressure-controlled environment is needed.

Fighting With Filters
Advances in HEPA filters have been a boon for minimizing airborne impurities, whatever the environment. In manufacturing, metal contaminants offer another challenge for companies creating tablets and capsules.

"Compression machines that form such vessels use a lot of force, which can embed some of that metal in tablets and capsules. Also, the die used to form the capsule can break off and become another contaminant," says Ray Spurgeon, product manager of the X-ray division of Eriez Magnetics (www.eriez.com). Both X-rays and magnetic separation devices are two of the options the company manufactures for detecting and culling out such particulates.

Chemical Choices
Hydrogen peroxide is being discussed more as a cleaning agent, partly due to speed, especially when compared to formaldehyde. The latter has been used as an agent for sanitizing cleanrooms, especially in Europe, but it's fallen out of favor since a 2004 panel of international scientists run by the World Health Organization found it to be a carcinogen.

"In pharmaceutical companies where 'the faster the better' is the motto, good evaporation of the cleaning agent is always key," says Claire Fritz, marketing manager for the VHP cleaning systems manufactured by STERIS Corp. (www.steris.com). "Formaldehyde can take up to 24 hours before your personnel get back within the area," she says. Peroxide dissipates faster, so personnel can be readmitted in as little as 3 hours. However, it also can easily creep into

areas you're not trying to affect. "You have to make sure doors and other areas that could provide cracks are sealed properly," says Fritz. "Many strides have been made to minimize joints where micro-organisms can thrive [e.g. modular walls and ceilings]," Kalafatis adds.

Dry ice is another chemical choice for fighting contaminants. "Dry ice just disappears on impact, so you have minimal or no disassembly. If there's a rubber mold, you can clean the mold hot; in fact, dry ice works even better then. We're seeing dry ice used a lot in the medical device industry," says Tyson Marlowe, director of global development at ColdJet.com. "It also cleans in place, so you can reduce expenses from shutdowns."

More Eco-Friendly Options?

"I kind of smile when I hear everyone talk about eco-friendly now, since I feel we've been eco-friendly from the beginning," says Hill. "Most of our cleaners are alcohol- and citrus-based, so although they're chemicals, generally they're pretty benign. They're not caustic or very aggressive — they can't be, considering the environments we work in," he points out.

UV radiation is an option being explored for more eco-friendly cleaning, but in the meantime, disposable items are already being touted as a way to cut down on cleaning solutions. "Using disposables means lower investments need to be made in cleaning and sterilizing facilities, at least for small and midsize volumes," says Hans Engels, CEO of DSM Pharmaceutical's (www.dsm.com) business group. "The higher use of raw materials [plastic] is compensated by significantly reduced use of water for cleaning," says Engels.

On the other hand, what might the actual costs be if reusing sterilized glass bottles and tubes instead of simply disposing of plastics? Also, what happens to the outside environment while disposables make internal environments cleaner? "It's important to scratch below the surface as to what's green vs. eco-friendly. If we use disposable wipes for cleaning a surface, they become landfill," Hill points out.

Energy consumption is another environmental concern. "Cleanrooms must be kept running at all times, even off hours," says Kalafatis. Unfortunately, she says the airflow rate standards (which are what affect costs) come from an antiquated, decades-old FDA chart that tracks the airflow rate, known as the ACH. "Astonishingly, little attention has been paid to changing these charts, although it is the most important aspect of cleanroom design," Kalafatis says. For now, the industry is focusing on upgrading filters to be more energy-efficient. "Fan filters, air handlers, and lighting systems have become the focus of the green effort," she says.

Don't Forget The Personnel Factor

Don't assume higher education assures protocols will be observed. Bud Williams, manager of cleanroom certification for Salus in Waukegan, IL (www.salustech.net), tells the following story: "We were doing particle counts at one company, gowned up head to toe. Suddenly, in walks a fellow in street clothes. No booties, nothing. He just strolls in, grabs something off a shelf — and walks back out."

As you might imagine, that is not a good way to get cleanroom certification — or even to maintain less stringent in-house cleaning standards. "Lots of people don't understand why a room on one side of the wall is different on the other side," Hill says.

Williams agrees. "Your staff needs to be made aware of cleanroom procedure even if they're not working there. They could compromise the efficiency and cleanliness, the whole certification, if they don't understand the consequences of their lack of care," he says. He recommends simply keeping nonessential personnel out of areas. "There's probably no reason the accountants need access to such an environment."

Finally, always consider what it is you're trying to protect. "When mixing IVs, you're protecting the product from contamination. If you're working with biohazards, you're trying to protect the personnel," says Williams.

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