Disinfection begins with proper selection

Deciding what type of disinfectant will provide the greatest efficacy for your application requires a back-to-basics approach

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It might not be too dramatic to state that bacteria, viruses, fungi, and spores represent a unique, insidious, and dangerous class of contaminants: unique in that under the right conditions the contaminant population can multiply over time; insidious in that these organisms can penetrate into small openings and crevices that can persist for long periods of time; and dangerous in that they can affect human health. So these contaminants must be destroyed and/or removed to achieve the desired cleanliness and aseptic condition. That's the role of disinfectants.

If there were only one chemical agent—i.e., one disinfectant—available to accomplish our objective, life would be simple. Unfortunately, there are many products to select from. So how do we choose? Do we base our decision on chemical structure? Personnel protection issues? Type of organisms to be destroyed? In this article, we'll focus our attention on these questions and others.

Chemical agents that destroy microorganisms can be termed "biocides"; it is useful to categorize them in terms of potency. Sanitizers, such as alcohols, can reduce microbial contamination by as much as 99.999 percent (known as a 5-log reduction) but are ineffective against spores. Disinfectants, such as phenolics and quaternary ammonium compounds, provide 100 percent kill of vegetative bacteria, some fungi, and viruses but are also ineffective against spores. To destroy spores and achieve 100 percent kill of all microorganisms requires sterilants—aldehydes or strong oxidants such as bleach or hydrogen peroxide.*

Finding the optimal chemistry for each environment is critical to removing these complex microorganisms.

The great bug hunt

Every facility must determine the resident micro flora unique to each environment. The United States Pharmacopeia (USP) provides guidance on microbial control and testing. Specifically, USP <1072>, "Disinfectants and Antiseptics"[1], and USP <797>, "Pharmaceutical Compounding—Sterile Preparations,"[2] provide guidance on identifying key organisms in critical areas. Testing to determine the organisms down to the genus and species level is crucial. Identifying the type of microorganisms and the number will provide the framework on which to build a microbial control program.

Now what?

Once the microorganisms have been identified, the cleanroom operator can select the proper biocide solution for the environmental isolates and surface materials. Things to consider:

- **Spores and surface sterilization.** Did you discover any spores in your testing? If so, it is critical that a surface sterilant be employed.
- **Personnel safety.** Many biocides are eye and skin irritants, unpleasant to use, and toxic. It is very important when choosing the application mode (fogging, spraying, wiping, mopping, or immersion) to be aware that these applications can create situations that are hazardous to personnel.
- **Surface contact time and material compatibility.** Dwell times can vary significantly depending on the particular biocide and the specific isolate to be destroyed. The effective contact time can be determined by following the biocide's label recommended claims or performing an in situ sanitization validation.
- **Chemical disinfectant media.** Several formats of chemical disinfectants are available for convenience: ready to use, concentrates, and pre-saturated wipers. Sterile solutions of biocides are commercially available as well. These solutions are aseptically sterile-filtered and/or gamma-irradiated to provide the requisite Sterility Assurance Level (SAL).

There are three important components to chemical selection: chemical effectiveness, compatibility with substrates, and safety to personnel. There are numerous biocides available that can offer a broad spectrum of activity to kill susceptible pathogenic species. Arranged alphabetically, and described more fully below, are some of the most commonly used biocides found in critical environments.[3,4]

Alcohols are sanitizers commonly used as a skin antiseptic. Of the available alcohols, isopropyl alcohol (IPA) is most often employed. Typical IPA concentrations vary between 60 and 85 percent. Most

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*These three classes conform, respectively, to low-level, intermediate-level, and high-level disinfectants as categorized by the Centers for Disease Control and Prevention (CDC). The reader is cautioned not to confuse the meaning of the word "disinfectant." In this article we will use it as defined above, not as a CDC descriptor.

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manner. Typical surfaces that are seen in critical environments include stainless steel, glass, vinyl (curtains), Plexiglas®, epoxy-coated gypsum (walls and ceilings), fiberglass-reinforced plastic (wall paneling), Tyvek®, and terrazzo floors. The effects of the biocides will vary depending on concentration and frequency of use. Stainless steel can pit and rust with the use of alcohols, aldehydes, chlorine compounds, and hydrogen peroxide/peracetic acid blends. The deterioration of the stainless steel may lead to "hot spots" of microbial growth. Alcohols, chlorine compounds, hydrogen peroxide, hydrogen peroxide/peracetic acid, and phenols can be absorbed by rubber compounds, which leads to brittleness and decomposition over time.[5]

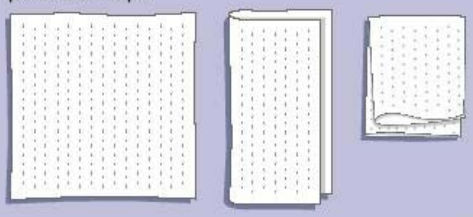
Safety

When creating a microbial control plan it is important that the biocidal objectives are aligned with concerns of personnel safety. Biocides are commonly eye and skin irritants, unpleasant to use, and highly toxic.

Table 2 outlines general biocide toxicity levels to personnel based on industry standard MSDS at the highest concentrations of commercially available products.[5]

Figure 1: Disinfection begins with proper wiper folding and use

Fold wiper in half, then in half again, creating a quarter-folded wiper.



Rotation

Rotation of disinfectants has received significant attention by researchers, parenteral manufacturers, and regulatory agencies. It is now generally accepted that microorganisms within cleanrooms do not develop resistance to disinfectants, as was believed[8,9] since the disinfectants are designed to provide 100 percent kill of these organisms. If there are no organisms left to mutate (as might occur, say, in the human body during antibiotic treatments), there is no resistance to be developed. Sutton[10] states it very explicitly: "The need for rotation of disinfectants in a pharmaceutical cleanroom sanitization program is unsupportable from a scientific basis." In principle there should be no need to rotate disinfectants, as long as the environmental isolates have been properly determined, the disinfectants have demonstrated the necessary kill capability, and the disinfectants have been used properly.

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