

While development of resistance to sanitization agents is not scientifically supported, differences in innate resistance is a factor to consider in a sanitization program<sup>[1]</sup>, including rotation of sanitization agents.

Of primary importance in any sanitization program is the proper selection of a chemical agent to reduce microbial bioburden. Selection should be based upon the number and specific microorganisms present in the area where the sanitizing agent is to be routinely applied. In addition, effective cleaning should precede any application of sanitant. The condition of the surfaces that are to be sanitized require proper conditioning through cleaning, since deposits can prevent proper sanitizer contact with target microorganisms. Furthermore, residues on the surface to be sanitized have been found to inactivate or reduce the effectiveness of some types of sanitizers (e.g. hypochlorites) rendering the sanitization procedure ineffective”.

### **When is Sanitant Rotation Beneficial?**

There are conditions when the rotation of sanitizing agents should be considered. Standard Operating Procedures (SOP) shall describe, but not be limited to, the following ... Cleaning schedule and disinfectant rotation”.

The following are some useful points when considering rotation as part of a routine aseptic processing area environmental control program:

1. *Seasonal Variation:* in locations, which have significant seasonal changes, the environmental microflora can fluctuate from season to season. As a result, the anticipated bioburden that may be introduced into an area that is part of a routine sanitization program can change. This necessitates the need to assess the best chemical sanitizer to control the anticipated contaminants during each seasonal period.
2. *Microbial Variation:* it is well known that there is no single sanitant that is universally effective for all potential microbial contaminants. As a result, sanitant rotation can be a viable option to ensure that all potential environmental contaminants are controlled and not allowed to selectively proliferate in an area that is part of a routine sanitization program. The use of a single type of sanitizer may allow for selection and persistence of resistant strains. Therefore, the rotation of sanitant agents should be based on “good sense of using a medium level maintenance sanitant/cleaner with some frequent application of a sporicide that is based upon environmental data” of the varying types of micro-organisms identified.
3. *Compatibility:* the varying nature of microorganisms and their intrinsic differences may warrant the use of sanitants at some frequency that may not be compatible to area surfaces and associated equipment. By rotating sanitizing agents, the potential damage to these surfaces is reduced, while still ensuring that microbial contaminants are not allowed to proliferate to an unacceptable level.
4. *Ineffective Use:* A poorly executed sanitization program or procedure that consistently results in improper application with the sanitizer (e.g. at less than manufacturers recommended concentration or insufficient contact time) can