Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
What are the expectations for industry for the inclusion of different sanitization agents within a routine sanitization program? Additionally, are there tangible benefits to routinely rotating sanitization agents? Finally, how is sanitant performance defined?

The definition of sanitant acceptability as stated in 40 CFR 156 indicates that sanitization products for use on non-food contact surfaces achieve at least a 99.9% (3-log) reduction in the number of test microorganisms over the parallel control count within 5 minutes. For the purpose of this discussion, the terms sanitization agent, sanitant, sanitizing agent, antiseptic, and disinfectant are used interchangeably as all of these agents are primarily designed to reduce microbiological bioburden on applied surfaces. The practice of rotating sanitization agents has primarily been based upon accepted wisdom that routine exposure to a single sanitization agent over time can promote the selection of microorganisms with increased resistance to antibiotic agents. This document discusses the current argument for sanitant rotation and provides points to consider in determining when the rotation of sanitants is beneficial as part of a routine sanitization program.

Sanitizers are defined by the Environmental Protection Agency as “pesticide products that are intended to disinfect or sanitize, reducing or mitigating growth or development of microbiological organisms including bacteria, fungi, or viruses on inanimate surfaces in the household, institutional, and/or commercial environment”.

Sanitizing agents have been used to reduce microorganisms on food and pharmaceutical processing equipment for nearly 100 years. Over this extended period of time, little data supporting the development of microbial resistance to such compounds have been observed.

The destruction and/or complete inactivation of microorganisms, accomplished by application of a sanitization agent, occur primarily through the disruption of physical properties of the bacterial cell rather than the interruption of a cellular metabolic process. Within a given microbial population, there are however natural differences in cell composition and physiology that can directly correlate to varying degrees of sensitivity to a given sanitizing agent. This “innate resistance” is a chromosomally controlled property that is naturally associated with a microorganism and is not subject to mutation as seen in acquired resistance to antibiotics[3]

While development of resistance to sanitization agents is not scientifically supported, differences in innate resistance is a factor to consider in a sanitization program, 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

