Disinfectant Efficacy Testing

Clean rooms and other classified areas in healthcare and pharmaceutical facilities must be kept in a state of microbiological control. This is accomplished by introducing and maintaining a sound cleaning and sanitization program within these controlled environments to prevent the microbial contamination of the products being manipulated. Disinfectant efficacy testing ensures that the agents routinely used in sterile manufacturing areas and laboratories are sufficiently effective in the inactivation of potential contaminants from surfaces. We have the experience necessary to successfully design and execute the appropriate disinfectant efficacy study to satisfy a client’s requirements.

Disinfectant Efficacy Testing Requirements

Our disinfectant efficacy testing is performed in accordance with USP chapter <1072>, AOAC Chapter 6, and other European standards (e.g., EN13704, EN13697, EN1276, EN1650, EN13704). Each study is designed to evaluate a disinfectant against a panel of clinically significant microorganisms, such as Gram-positive bacteria including spore forming organisms, Gram-negative bacteria, fungi, mold spores, and other environmental isolates supplied by the client (up to BSL Level 2), on the surfaces routinely disinfected.

Clients should implement a disinfectant efficacy program when:

- Qualifying a new chemical agent (e.g., sanitizer, fungicide, sporicide, bactericide)
- Environmental monitoring (EM) data suggests a drift in commonly recovered environmental flora
- Changes occur to facilities that could increase the bioburden challenge beyond normal operating levels
- Environmental monitoring data suggests that an organism is becoming evasive (e.g., biofilm formation) or resistant to current chemical disinfectants
A disinfectant efficacy program includes three main testing parameters:

- Chemical agent (e.g., sanitizer, fungicide, sporicide, bactericide)
- Test microorganism(s) (e.g., clinically significant reference or challenge cultures, environmental isolates, or both)
- Typical facility surfaces (e.g., tile, stainless steel, wall panels, glass, etc.)

**Pre-Studies for Disinfectant Efficacy Testing**

We perform the following two evaluations prior to the initiation of the disinfectant efficacy study in order to confirm that the study plan developed will provide relevant data:

- Neutralizing media study: A proper neutralizing media study will ensure that broth media can sufficiently neutralize chemical disinfectants while not being unduly toxic to organisms.
- Recovery study: A sound recovery study will ensure that organisms will not be overtly lost to desiccation and/or inadequate recovery methods, leading to the premature approval of a disinfectant that has not yet proven to be truly efficacious.

**Disinfectant Study Execution and Evaluation**

**Non-Porous Surfaces**

A disinfectant study incorporates the surface challenge method that best reflects the in-use conditions (i.e., contact time, in-use dilution, temperature, and surface type). Microbial contaminants are dried onto a coupon of the surface type and subjected to a chemical disinfectant for a predetermined period of time. Following the contact period, the chemical disinfectant will be neutralized and any remaining viable organisms will be recovered and enumerated.

Once enumerated, the recovered test population will then be compared to a viability control that was subjected to the same test method in the absence of a chemical disinfectant in order to establish log reduction of bioburden. A disinfectant is deemed acceptable and appropriate for use on each of the different surfaces evaluated following the specified contact period if this evaluation shows that each disinfectant, at the concentration tested, is able to demonstrate the appropriate log reduction as stipulated in the relevant standard or pharmacopoeia for the microorganisms used in the study.

**Suspension Tests**

Suspension tests are executed as above; however, the microorganisms are inoculated into separate in-use dilutions of the disinfectant for the appropriate contact time. Aliquots are then removed to a neutralizing broth and enumeration is performed as stated above for non-porous surfaces.

**Results Review and Consultation**

Following study execution, a detailed report is generated and sent to the client. This report provides evidence that the agents routinely used in sterile manufacturing areas and laboratories are sufficiently effective or ineffective in the inactivation of potential contaminants from the surfaces they were tested on. If questions arise, our staff is always available to speak with clients regarding the results of the study.