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Minncare® Dry Fog Technology Research Report:

Environmentally Friendly Disinfection of a Pharmaceutical Cleanroom

Introduction

With the growing need for microbiological clean environments, room disinfection is a critical part of maintaining a microbiologically clean environment for a variety of purposes: manufacturing, employee safety in research environments, patient safety in hospitals, and contamination control.

Cleanroom disinfection is a routine procedure in many pharmaceutical, biotech, cosmetic, and other microbiology industries. These industries are dependent on microbiologically clean areas primarily for production and R&D. Additionally, some industries are governed by regulatory bodies that impose standards for microbiological cleanliness and set requirements for regular, certified biodecontamination of certain areas. Pharmaceutical facilities have a number of areas that require regular disinfection procedures in order to provide a microbiologically clean environment. Typical biodecontamination procedures include:

- Annual shutdown biodecontamination
- Commissioning biodecontamination
- Decommissioning biodecontamination of areas used for pathogen work
- Eradication of problematic microorganisms from production lines and laboratory areas
- Emergency biodecontamination for accidental release or spillage of microorganisms
- Regular cleanroom biodecontamination
- Isolator and pass-through biodecontamination

A large pharmaceutical plant in the Midwest was investigating ways to achieve a higher level of system automation and integrity, as well as, improve the level of spores killed during a disinfection procedure. The plant had used two different types of disinfection, H2O2 (hydrogen peroxide) and formaldehyde, and was not satisfied with either approach. Operating personnel decided to explore alternatives in order to achieve their requirements more effectively.

Dry Fog Technology

After researching the available alternatives, the plant decided to investigate a dry fogging approach. The technology selected — the Minncare Dry Fog (DF) System — produces very fine droplets of disinfectant that are dispersed throughout a room. The disinfectant used by this system is a proprietary cold sterilant solution consisting of a stable mixture of peracetic acid and H2O2 that is bactericidal, fungicidal, virucidal, and sporicidal. Table 1 compares the activity levels of peracetic acid, H2O2, and other biocides in treating common contaminants.

During the DF process, the humidity level of the room to be treated is first raised to 80%. Then the dry fog solution is evenly and completely dispersed in the room. A single DF unit can disinfect rooms up to 35,000 cubic feet (1,000 cubic meters) in size. Figure 1 shows a sample DF system setup for a 8,500- cubic-foot room.

The disinfectant droplets are only 7.5 microns in diameter, so they bounce off solid surfaces and resist the excessive condensation, possible corrosion, and surface wetting commonly associated with other fogging or manual cleaning procedures. The droplets eventually evaporate and the vapor penetrates normally in accessible areas resulting in a more thorough disinfection process. The chemical is fully biodegradable, requires a extremely short process time, and is much less corrosive than aldehyde-based materials.

Auto-San Room Test

The immediate area of concern for the pharmaceutical plant was the auto-san (automatic sanitization) room, a staging area for disinfection of nonproduct contact parts and large equipment heading into the clean room. The plant was using a solution of H2O2 sprayed via wet/fogging nozzles for sanitization in the auto-san room. The solution feed was set up in the staging chamber just outside the room with a line penetrating the wall to the nozzle. While the system was consistently achieving a 3-log or greater reduction of bacterial spores with the H2O2 method, having to wet all of the surfaces led to concerns over the potential for corrosion and material compatibility issues. Also, handling the low-pH active H2O2 required extensive safety precautions, and the overall method's efficiency in terms of total dispense, exposure, and exhaust timing was less than desirable. A test procedure was arranged for the auto-san room, which was 27 cubic meters in size. Two sets of tests were run using two different levels of DF exposure time.

Table 1: Activities of the most important biocides (Guyader, 1996)

Biocides	Bacteria		Myco-bacteria	Spores	Moulds	Yeasts	Virus
	Gram -	Gram +					
Peracetic acid	+++	+++		++	++	++	++
Alcohols	++	++		0	++	++	+
Alcohol (70°)	++	++	0	+	+	++	+
Glutaraldehyde	+++	+++	++	+	+++	++	++
Quat Ammonium	+++	+*	0	0	+	+	+
Chlorine	+++	+++	++	++	++	++	++
Hydrogen Peroxyde	+++	+++		+	+	+	0
Iodine	+++	+++	++	++	++	++	++
* Not active on Pseudomonas							

The goal of the plan was to demonstrate a point at which the DF achieved a 4- to 6 log reduction on biologic indicator (BI) spore strips. The use of bacterial endospores, typically Geobacillus stearo-

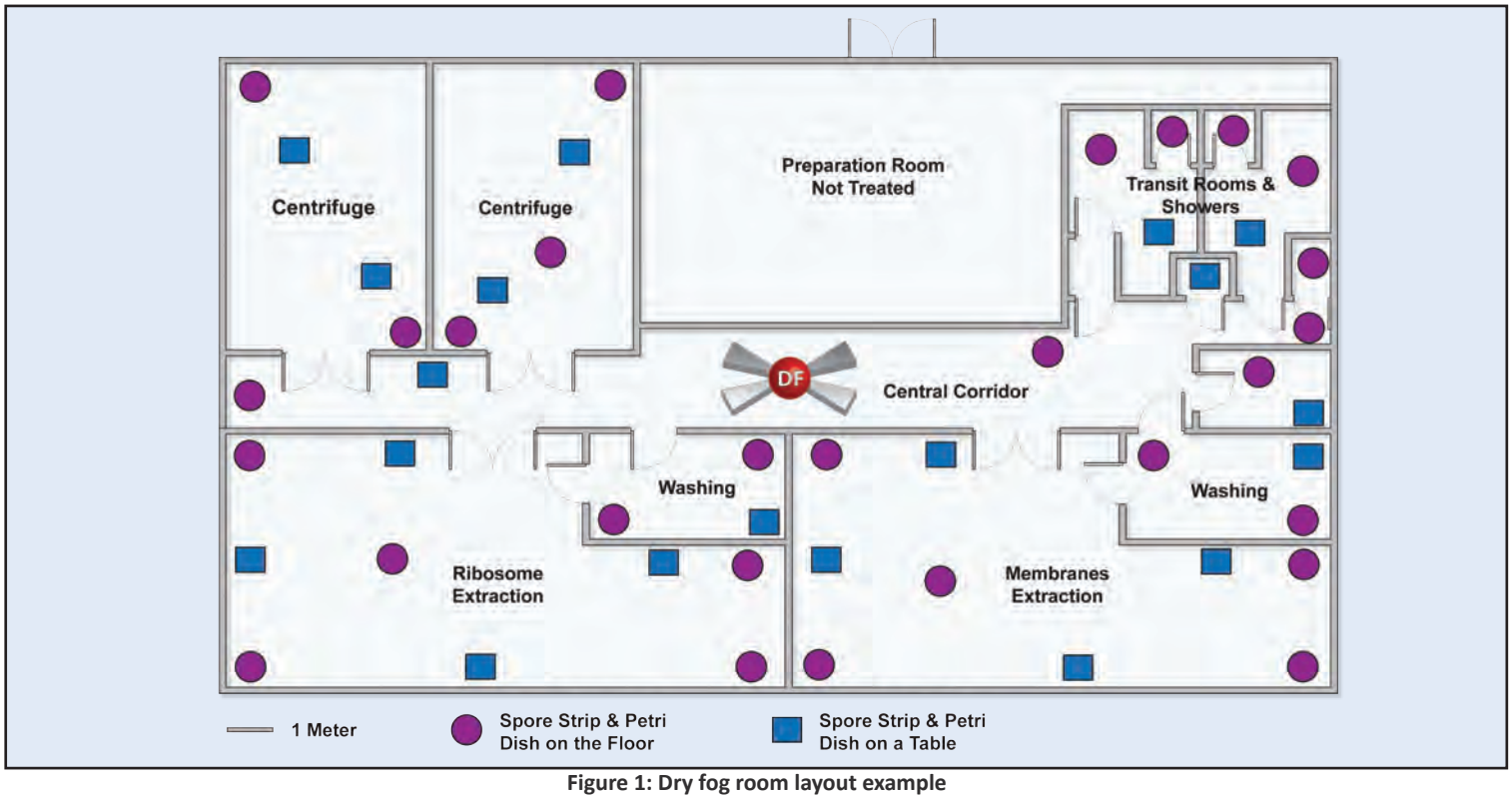

Figure 1: Dry fog room layout example

thermophilus, as a BI to measure the success of decontamination is a common standard. Overall results of testing showed that regardless of the concentration of the dry fog disinfectant and in as low as 15 minutes of contact time, a >6-log reduction was achieved on all BI indicators. Further, even with a reduced exhaust time versus the preexisting process, issues with corrosion and residual cleanup were eliminated. Based on the results of the DF test in the auto-san room, the plant decided to investigate using it in active pharmaceutical ingredient

API Production Area Test

(API) production areas. Previously, these areas were being disinfected — when returned to an aseptic state after facility shutdown — using a formaldehyde fog/spray. The procedure involved evacuating the building, remotely initiating spraying, and quarantining the building for several hours. Afterward, ventilation would be reintroduced and an additional one to two days were required to bring the formaldehyde concentrations back to the very low levels required by procedure, finally allowing reentry. Furthermore, after the building was deemed safe for reentry, extensive personnel protective equipment and significant monitoring were required to ensure that operators were not exposed to detectable levels of formaldehyde during subsequent manual cleaning and sanitization activities.

The test procedure with dry fog consisted of disinfecting a two story area of the building that included a stairwell and elevator shaft. The DF unit (see Figure 2) was positioned on the floor near the center of the room. Twelve 3-log BIs and 12 6-log BIs were placed around the room and on the ceiling. After a standard diffusion time and a hold time of 1 hour, the HVAC was reintroduced. The disinfectant level dropped to a safe reentry point in less than 15 minutes, saving one to two days that would have been lost using formaldehyde treatment. Subsequent BI results showed an overall spore reduction of 6 logs at the monitored locations, a level of sanitization which easily surpassed the protocol requirements.

Conclusion

As a result of the demonstrations, the plant decided to use the DF technology for disinfection procedures going forward. Some of the benefits noted by the company were:

- More reliable and better efficacy (6 log reduction)
- Replacement of a hazardous chemical previously used (formaldehyde)
- Reduced downtime during the treatment procedure (typically 3 hours or less)
- Greatly reduced downtime for venting (compared to formaldehyde)
- Reduced procedure costs (compared to either H2O2 or formaldehyde)
- Significantly reduced corrosion
- Fewer material compatibility issues
- Elimination of sanitization agent residue
- Elimination of post-sanitization manual cleanup

Those benefits ultimately translated into a better, faster, safer, and more environmentally friendly process that reduced labor and lowered operational costs.

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