

Summary - Alternatives Methods to Formaldehyde Fogging of Clean Rooms

There are regulatory expectations for the periodic sanitization of clean rooms to ensure conformance to expected environmental bioburden levels though none of these explicitly require the use of fogging (2), (3), (4).

For biological facilities where viral contamination is a concern, there may be regulatory reasons to sanitize via fogging with some frequency as both Annex 2 of the European Commission and the World Health Organization's GMPs for biological products mention the terms "shall" and "should" with regards to fumigation (4), (5).

Many non-biologics facilities successfully meet the general regulatory expectations for sanitization through the use of only liquid sanitizers, disinfectants, and sterilants. However, fogging can be very effective and may offer advantages over the use of liquid sanitizers in certain situations (e.g. very high ceilings, inaccessible surfaces that require sanitization, etc).

Fortunately there are other chemicals that can be used to fog clean rooms. Although there are others, three potential replacement options are listed below along with some advantages and disadvantages of each. It should be noted that what is considered an advantage is highly dependent on the specific application. These chemicals are all considered sterilants under certain conditions though the concentration of the agent that is required to achieve destruction of bacterial endospores varies greatly. With proper design and validation, all can have good distribution throughout the clean room on a consistent basis. Labor costs are still typically lower than with liquid sanitizers because the chemical can be distributed by airflow instead of by personnel.

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