

The Moldy Nightmare: Q&As, Part 1

Q&As breakfast session from the PDA Pharmaceutical Microbiology Conference "Mold Contamination and Remediation – A Moldy Nightmare." Published in The Moldy Nightmare: Q&As, Part 1, in the PDA electronic journal, mycologist Ziva Abraham has more than 35 years of academic, research, and experience in microbiology and quality assurance.

Q1 If you see low-level recovery (1 or 2 CFU) on an airlock gowning bench every three months or so, with no other recoveries in the airlock, would you suspect inadequate cleaning practices?

A1 Low recovery in gowning areas is a common phenomenon, as this is the entry point into the controlled areas from the uncontrolled areas. Having said that, it is important to have a science-based cleaning program to address all mold that can be tracked through foot-borne traffic. The cleaning and disinfection program should include use of a general-purpose disinfectant with a surfactant that helps break surface tension and aids in cleaning as well as periodic use of a sporicidal agent to address bacterial and fungal spores.

Q2 If mold is found only in air sampling (not on surface), what should be the action plan?

A2 Mold recovery in air samples may be due to multiple reasons. Surface contaminants can become airborne, so the source could be foot- or wheel-borne contamination brought in. Inadequate storage of monitoring equipment and inadequate wipe-down procedures can be another reason. Monitoring equipment without a HEPA-filtered exhaust is known to be a contamination source. Growth of mold in walls after leaks, compromised HEPA filters, or mold growing on seals can cause airborne mold recovery. It is also important to track the mold to its source and map the transport into the area where it was recovered. Often dead spaces (e.g., in cleanrooms where the air is not cleared due to the location of HEPA filters), returns, and cleanroom and barrier system integration may allow the contaminants to linger for a long time.

If the mold is found in filling areas, especially RABs, the area between the HEPAs without a diffuser membrane is hard to clean and can hold contaminants that can become airborne.

Finally, depending upon the mold species recovered, especially the deuteromycotous fungi, which proliferate very fast, an abiotic factor such as moisture, carbon source, mineral oil, etc., should be looked at.

In summary, the investigation should be based on the genus recovered and the source, and the remedial action should be based on the above-mentioned points.

Once the source has been determined, increasing use of sporicidal agent, especially where the mold source is found, and trending monitoring data to assess the effectiveness of remedial measures is recommended. If a decision for using fogging is made, as the root cause is undetermined, the chemistry of the fog, the fog size, and the number of foggers to be used to cover the area in question should be considered. The smaller the fog particle size, the more buoyant, allowing it to stay in the air for longer periods of time.

Q3 What mold genus should be included in disinfection efficacy studies?

A3 It is beneficial to use a USP-recommended *Aspergillus* strain along with the one or two predominant mold isolates recovered from the environment or product testing. Per the recent European standard, EN 13697, it is recommended to use the mature *Aspergillus* spores for disinfectant qualification.

Q4 Why do some molds fail during disinfectant qualification studies?

A4 Disinfectant label claim testing is performed using colorless deuteromycotous fungi *Aspergillus* and *Trichophyton*. Disinfectants with fungicidal claims, while using this testing method, may not be able to kill some colored Deuteromycota, most Ascomycota, and some Zygomycota.

It is recommended to understand the structures of the mold recovered in the cleanroom against those tested for fungicidal label claim. In some cases, increasing the contact time may help with the required kill, while in other cases prevention is the best strategy.

Q5 Is rotation of cleaning agent essential? Is it true that microbes grow resistant to the cleaning agent?

A5 There is no documented evidence of resistance, but to address all types of bacterial and mold contamination a rotation program utilizing a general-purpose disinfectant with surfactant, as well as a sporicidal agent, is effective at eliminating vegetative forms and spores.

Q6 Can you comment on the degree of disinfectant resistance between fungi and bacterial spores?

A6 Among the bacteria, the spore formers are harder to eliminate. For example, *Bacillus cereus* has the least kill even with sporicidal agents. It is hard for the disinfectant to penetrate the spore structure. As for ascomycotous mold, whose sexual spores are protected by two layers as compared to one layer in bacterial spores, it is harder to eliminate these fungi. Hence, preventing the entry of hard-to-kill bacterial spores and ascomycotous fungi that are soil or cellulosic material-borne respectively is a winning strategy.

Source: [潔淨室滋生黴菌 · 為什麼有些聲稱可以殺滅黴菌的消毒劑沒有效果? \(qq.com\)](#)