



# SUFFERING FROM MOLDS?

by Martin Lush

## FACT FILE

- > Molds are the second most common contaminant of controlled environments. Although for some of you, they are probably the first!
- > Primary sources of mold contamination can be many and varied. Vegetation, soil, paper, wood, cardboard and exposed pipework lagging or insulation can all act as contamination sources
- > Molds can produce thousands of individual spores. Although less resistant than their bacterial counterparts, these spores make it easy for contamination to spread fast, either by direct contact with surfaces or via people
- > Most don't need a lot of food and water to survive



## WHAT MUST YOU DO WHEN YOU FIND THEM?

Make sure you get as much data and information as possible. Without really understanding the problem, you can't deal with it. Additional cleaning will not work in isolation. Questions you want answers to will include:

- > Is it an isolated occurrence or is there an adverse trend relating to:
  - Sample location (room, corridor)?
  - Sample type (settle plate, active air, and surface or personnel samples)?
  - Type of mold isolated?
  - Time of year. There are lots more spores in the general environment during harvesting of crops and in areas of high humidity. This can lead to contaminants getting into your controlled environments via people and/or material transfer
- > What is the general level of control like for your classified areas? Good or not so good?
  - Bacterial isolates?
  - Non-viable particulates?
  - Temperature and relative humidity?
  - Differential pressure alarms and excursions?
  - Air change rates/room recovery rates?
  - Air flow patterns?
- > What has changed? When adverse trends are experienced something has changed. You just need to find out what and when. Look at your change control log and, more importantly, talk to the people who really know, like the operators and engineers. Poor environmental control is the symptom, not the cause, so start digging:
  - Have you changed anything to do with the HVAC system that will compromise room clean-up (removal of environmental contaminants)?
  - Have you done any building work recently...or even had a plant shutdown?
  - Any major engineering interventions?
  - Any new operators who have inadequate or variable aseptic and gowning techniques?



- Any increase in production output which could compromise good aseptic practice?
  - Changes to sanitization agents, frequency or methods?
- > Organize the data and information so you can understand it! Investigations of this type, when done well, generate a great deal of information and data. Make sure you create a simple and visual way to present the information to prevent confusion. For example:
- Use cusum trends to find out when the adverse trend started
  - Mark positive locations on the facility map or schematic. Any pattern?
  - Create a timeline of events
- > Remember poor environmental control is usually due to multiple factors, some of which could be months old. Go back at least six to eight months and start linking events together.

## MOLD CONTAMINATION: YOUR CALL TO ACTION

- > Make routine plant inspections (at least weekly). Confirm all surfaces are intact and cleanable and that standards of GMP remain high. The higher these standards are, the better the environmental control. Spot potential contamination sources and remove them
- > If you're unsure of the contamination source(s), attempt to re-establish control by doing a deep clean of the facility with a suitable sanitizing agent and sporicide. Remember, not all are equally effective against molds
- > Work hard to establish what has changed (remember everything happens for a reason). Adverse trends are usually due to multiple causes (changes), not just one singular event
- > Remember that good environmental control requires continuous vigilance 24/7. It's a war, not a battle

Get better educated. To defeat molds and bacteria, you need to better understand them. We can provide you with customized on-site training courses like Contamination Control, Pharmaceutical Microbiology or Microbiological Risk Assessment and Decision Making. Our experts are some of the best in the business... and they could save you a fortune. After all, poor environmental control is always a distraction and can be very costly.



### ABOUT THE AUTHOR

Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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