IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
UBM A division of UBM Americas
Published on *IVT Network* (http://www.ivtnetwork.com)

Setting Environmental Limits for Mold Contamination

By **Jeanne Moldenhauer Jul 25, 2017 7:00 am PDT**

Abstract

Since the unfortunate mold contamination at the New England Compounding Pharmacy resulting in many deaths, there has been heightened focus on the presence of mold in manufacturing facilities. For some reason, rationale used for bacteria, i.e., commonly found on humans, is not an acceptable excuse for fungal isolates. While mold is not present on humans in the same amounts as bacteria are, they are present. (Akers and Lindsay, 2014). Additionally, many individuals come into contact with airborne mold on a daily basis. In some facilities, employees travel between buildings on a campus going through the environment and are exposed to airborne contaminants.

Mold has also been treated as an objectionable organism in cleanrooms, with many investigators considering the mold and/or Gram-negative contamination as a sign of poor housekeeping. The combination of these events has led to many establishing a zero-tolerance of mold. This has been effected by pharmaceutical companies, as well as some investigators, and company management. While this approach seems to address all of the concerns for potential mold contamination, it is not a practical limit, nor is it scientific. (Akers and Lindsay, 2014)

This paper discusses the how mold limits can be set and the scientific justification for allowing low level mold contaminants.