In the case of sterility testing, if an assignable cause associated with laboratory error is identified, an invalid sterility test may only be repeated once.

Microbiological repeat testing is very similar to repeat testing conducted during analytical laboratory investigations. If an assignable cause is clearly identified, the initial OOS test result is invalidated and the original testing is repeated to generate a valid result

Unlike microbiological testing, some analytical test methods consist of multiple analyses per test sample. In such cases, a single repeat test of only one analysis may be acceptable to replace a single initial OOS result. It is important to recognize that this option is not available in microbiological repeat testing because multiple analyses per test sample are not performed.

Retesting

Microbiological retesting is an investigational tool that may be used as part of the Investigational Measurements Protocol. The number of retests to be performed on a sample should be specified in advance and should prescribe a point when to end testing and begin evaluating the product/material.

According to the FDA OOS Draft Guidance, repeat testing until a passing result is obtained (i.e., testing into compliance) is objectionable under the cGMPs.

If the compendia do not define retest criteria, the decision to retest shall be made by Q.A. management and must be based on a sound scientific rationale. A retesting protocol should be created and approved by laboratory supervision prior to any retesting.

The retest protocol must be based on the specific problem identified, the history of the product, the method, the batch/lot used, and any applicable compendial requirements.

The retest protocol must also delineate the number of retests to be performed. The number of retests to be performed may vary, but this number should be based upon sound scientific reasoning. When sufficient sample is available, retesting must be executed using the same sample set that was the source of the original OOS test result, unless there is scientific rationale for not using this sample.

The retest plan must also include a control lot to be used to verify the accuracy of the analyses and the acceptance criteria for the control lot must be specified.

Microbial limit retests may use up to a maximum amount of 25 grams for a solid sample or 25 ml for a liquid sample.

The value of retesting during a microbiological OOS investigation is fairly limited in scope. Retesting may be performed only to corroborate or confirm the original OOS test result. If the retest results *do confirm* the initial OOS test result, this data can be used to support the case that the initial OOS test result is valid and not due to laboratory contamination. A confirmed OOS test result will cause the rejection of the test article (unless approved for reprocessing).

