



# STERILITY TEST AUDIT SITUATIONS & FINDINGS – CASE STUDY

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## Introduction

### Case

Your firm has not thoroughly investigated the failure of a batch or any of its components to meet its specifications whether or not the batch has already been distributed [21 C.F.R. § 211.192]. For example, the inspection documented that X Injection, batch # XX, failed the sterility test. Your quality control unit repeated the test on a new sample to confirm the original result prior to initiating an investigation. The quality control unit's decision to perform a retest without a conclusive assignable laboratory cause is not in accord with USP <71> and is an unacceptable practice. The retest again revealed non-sterility, and the lot was eventually rejected."

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## Instructions to the group

1. As auditors, in 15-20 minutes, discuss and prepare an audit checklist and the associated documentation. Draw conclusions, categorize findings and justify!
2. Briefly, write in bullet-point format in your flipchart.
3. Make a 5 minute presentation to the class justifying the points to be audited.



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### Summary/Justification (Comments of FDA Auditor)

Although the lot was eventually rejected, there is no assurance that other lots manufactured and filled in the same production line were not contaminated.

The inspection found that the results were valid and that no laboratory error was identified. However, no investigation of the manufacturing process and facility controls was performed to identify the root cause of the sterility failure. This information from the failure investigation also helps determine how many additional other batches may be affected.

Note that when microbial growth is observed, a lot should be considered non-sterile and an investigation conducted. An initial positive test would be invalid only in an instance in which microbial growth can be unequivocally ascribed to laboratory error. Only if conclusive and documented evidence clearly shows that the contamination occurred as part of testing should a new test be performed.

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## Summary/Justification

When available evidence is inconclusive, batches should be rejected as not conforming to sterility requirements. After considering all relevant factors concerning the manufacture of the product and testing of the samples, the comprehensive written investigation should include specific conclusions and identified corrective actions.



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### Summary/Justification (Cont.)

Please include in the response to this letter a copy of your final sterility failure investigation report for XX Injection, batch # XX, including a detailed explanation of your root cause analysis and the corrective actions implemented to prevent recurrence of the event that led to the contamination. Also indicate if a media was conducted as part of your sterility failure evaluation. Also include a list of all of sterile drug products manufactured at your facility that initially failed the sterility test, and that were released based on a passing re-sample or re-test result. Provide the product name, original test and re-test date, and microorganism isolated.