



ENVIRONMENTAL MONITORING AUDIT SITUATIONS & FINDINGS – CASE STUDY

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Case (from an FDA investigator):

"Your environmental monitoring program does not give assurance that environmental contaminants are reliably detected. Your practice of manual identification, handling, processing and documenting results from agar plates reading is not reliable in terms of traceability and quality of the documentation (see example provided).

There is no assurance that results from all exposed and incubated plates are actually recorded, and the record forms used were not paginated and could be easily replaced.

There is no assurance that personnel have the right training, qualifications and oversight, and the necessary conditions (e.g. adequate lighting) to read and detect the possible difficult to detect growth on the plates".

Case study-1 :

Observations during audit

Your environmental monitoring (EM) and personnel monitoring (PM) data are not reliable because of the materials and procedures you use to conduct EM and PM tests. Multiple elements of these programs are scientifically unsound, including the following.

- Our investigators observed dried media plates you used for surface and personnel monitoring in the **(b)(4)** facility incubators. We documented that 36 of **(b)(4)** plates inside the Plant **(b)(4)** incubator showed signs of dryness and desiccation.
- EM records for active air monitoring of the aseptic filling area reported samples as being collected when they were not actually collected, and some records documented purported EM results of zero colony forming units (CFU) even when the samples for which those results were reported were not actually collected. Contemporaneous video recordings that FDA reviewed during the inspection showed that such EM samples had not been collected, even though your laboratory records reported results for those samples. Our investigators observed your firm's practice of falsifying EM results for samples that were not collected for multiple drugs, including **(b)(4)** injection USP lot **(b)(4)** and **(b)(4)** injection lot **(b)(4)**.

Case Study-2 :

Observations during audit

Our investigator(s) observed specific violations during the inspection, including, but not limited to, the following:

1. Your firm failed to establish adequate systems for monitoring environmental conditions and for cleaning and disinfecting the room and equipment in aseptic processing areas (21 CFR 211.42(c)(10)(iv) and (v)).

a. The aseptic processing environment is not adequately monitored. For example, there is no viable air monitoring inside of the Class 100 (ISO 5) filling barrier on the “**(b)(4) Line (b)(4).**” This is the critical area where drug product and pre-sterilized components are exposed and it is important that your firm collect air samples that adequately represent filling conditions.

Moreover, outside of the line **(b)(4)** filling area, **the three air samples taken in the Class 100 (ISO 5) area were not taken under dynamic conditions.** These active samples were instead taken after line set-up and before any filling.

We are concerned that the environmental monitoring (EM) program is not adequate to ensure the environment is suitable for aseptic processing of sterile product. The data generated does not sufficiently demonstrate that an ISO 5 environment is maintained.

Case Study-3 :

Observations during audit

Your firm failed to established an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(C)(10)(iv)).

- You have inadequate scientific justification for your environmental monitoring sampling plans in manufacturing areas for aseptically-filled injectable drug products. This include locations of viable airborne particulate sampling, settle plates and contact surface monitoring.
- We acknowledge your SOP/CB/QC/510, "Micorbiological Monitoring of Air, Surfaces and Personnel in Production areas." You use a chart contained in this SOP to justify your choice of environmental sampling locations, However, you did not supply data to support your current locations, In addition, neither your environmental monitoring procedures nor your sampling records clearly identify environmental monitoring sampler are taken.



Instructions to the group

1. Discuss and prepare an audit checklist with the associated documentation to request, plan who to interview and what activities to check. Review the E.M. data provided and categorize findings.
2. Briefly, complete in the table format provided in your flipchart, and make a brief presentation to the class.
3. Comment on the expectations of the group in terms of corrective actions to be implemented by the audited company.

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Nonconformity	Major / Minor (justify)	Documentation to request