CASE STUDY
Non-Sterile API Manufacturer

Carmelo Rosa, M.S., Psy.D.

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Case Study

Background

1. Large site manufacturing non-sterile API by chemical synthesis. There are a total of 10 individual non-dedicated manufacturing plots/units, each operating near full capacity.
2. A total of 90 different APIs are manufactured on-site.
3. The firm has 3 testing chemistry labs and 2 micro labs
4. QC Laboratory No. 1, with 30 analysts performs all chemistry testing for raw materials, in-process, and finished API product. Fifteen HPLC and GC were not connected to the network.
5. QC Laboratory No. 2, with 15 employees performing stability testing
6. QC Laboratory No. 3 is responsible for all R&D testing
7. Over 250 OOS investigations related to impurities and assay were generated.
8. Trial injections, unreported OOS/OOT results were found in 7 of the HPLCs that were not connected to the network.
9. One of the laboratories was found with the audit trail function disable and found employees that appear testing the stability samples were not on site at the time of the activities.
10. Operators were found altering the batch records and also not on site at the time of the mixing operation
11. At least 10 analysts were sharing the administrator's
12. Microbiological sheets for on-going microbial testing reported 14 "Nil" (negative) results when the auditor visit the incubator found the incubator with 20 of 45 plates with microbial growth
13. The auditor found that in 5 instances the HPLC integration parameters was manipulated and the HPLC-computer clock was altered to make it seem as if the passing result was obtained on the date the trial injection OOS was obtained.
14. Six trial injection OOS were overwritten by the retest sample injections

QUESTIONS/ASSIGNMENT

1. What would you do if you were the person from corporate QA or a Regulator Inspecting the facility?
2. What would be your audit approach?
3. Where, and how do you start, and justify your approach
4. How do you assess the extent of the problem?
5. Who do you contact and inform the findings to?
6. What SOPs will need to be revised
7. What Changes in the management structure are needed

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6. What short and long term goals would you consider?
7. Explain your risk assessment?
8. At what point would you implement a CAPA, and how?
9. Prepare a risk assessment
10. Prepare a mitigation plan

How and where to start ?

1. Systems impacted
2. Assessment/Evaluation/Mitigation Plan
3. Rick Assessment
4. SOP
5. Training
6. Changes Needed
7. Personnel
8. Application/Marketing Authorization/Recalls