The Ratings Game

A game of objectivity & evaluation for any auditor!

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Introduction

An audit scenario from the archives of the MHRA.

Your team will have 2 minutes per scenario to evaluate all the objective evidence presented to you.

At the end of the 2 minutes you must write down the nonconformity rating.

Scenario 1

During an audit of Internal Audit system, you notice that four audits from a total of twelve from the annual programme were not performed in the previous year (Micro Lab, QA, Donor Services and Processing).

The Quality Manager states that due to pressure of work these audits have not been completed as they were not ‘critical’ business processes. The audits have been included on this years programme and will be performed in the next 3-6 months.

Time Up!

Please write down your answer

Answer

Other

Scenario 2

In the Quality Department, you notice that section 9.3.1 of Corrective Action procedure (QP 04 issue 3) had been hand amended to remove the requirement for the Quality Manager to sign off the close out of all corrective actions.

The deletion had been initialled WGP and dated four weeks ago.

Time Up!

Please write down your answer

More Information

- Check document control procedure - are hand amendments are permitted?
- If they are not, there is a non-conformity
- If hand amendments are permitted:
  - Who is WGP? Is WGP authorised to amend quality procedures? Are there other copies?

- Interview WGP to establish the reason for the amendment.
- Is there a plan to formalise the change? If so, when?
- Is there a problem with the document approval procedure?
- Check how often the informal change process is utilised
- Sample other procedural hand amendments for conformity

Scenario 3

During an audit of the stores extension/refurbishment project, you notice that despite the project leader having identified that the project had been started without the change control procedure having been followed, an incident report had not been raised to investigate this failure.

Although the lack of change control was identified on 4th September the project was not halted until a formal change control and assessment of the project could be raised. The subsequent retrospective change control was not authorised until the 2nd October.

There has been no formal assessments of the risks presented by the project to adjacent GMP areas

Time Up!

Please write down your answer

Answer

Major

Scenario 4

During an audit of the hospital blood bank, you notice that a member of staff transforms a unit of blood (component) to being confirmed as being cross matched and creates a new status label.

You notice that there is no results of the unit being cross matched.

On questioning the member of staff they confirm that the cross matching process had not yet been performed, but they were going on previous requests for that person.

Time Up!

Please write down your answer

Answer

Major