Medicines & Healthcare products Regulatory Agency

MHRA

Guidance on Responding to a GLP & GCP Laboratories Inspection Report

This guide has been provided to assist in preparing responses to Inspection Reports. This format is not mandatory but is the inspectorate's preferred method for providing responses and should help to reduce the time taken to reach a compliance decision after the inspection. The guidance is presented in the same format as the deficiency annex to a GLP & GCP Laboratories inspection report.

1.0 CRITICAL DEFICIENCIES

Critical deficiencies may be more complex in nature and responses may take different formats depending on the issues cited. Specific guidance is therefore not provided, but the general principles below apply.

Please note responses to critical deficiencies will be reviewed at IAG2 (GCP) or by the head of the GLPMA and compliance management team (GLP)

2.0 MAJOR DEFICIENCIES

2.1 This is a Major deficiency.

2.1.1 There may be a number of examples provided on a deficiency.

Initial Site Response

- Choose a new colour for your first set of responses.
- Answer the deficiencies raised directly underneath, preferably using the Word version of the inspection report provided.
- Responses should be clear and concise. Responses with information not directly relevant to the remediation actions may be returned without review with a request to rewrite and simplify (these types of responses are not an efficient use of the inspectors' or the company's time).
- If you do not believe a deficiency should be raised, please contact the lead inspector.
- State clearly what you are going to do and when you are going to do it (DDMMYYYY). If your response is a commitment to 'review a system', then state when the review will be complete and what will happen with the output of the review, the inspector may request that the output be provided.
- As part of the response the root cause should be determined and the wider (systemic) impact considered. This is likely to include other sites in the organisation and studies conducted. Please do not just respond with a correction to the single identified point.
- If you have reviewed all similar areas to find other examples of the deficiency, but no others were found, clearly state this and include a description of how the system review was performed.
- Choose appropriate timelines that are realistic (do not give extended times for simple actions).
- Where timelines are long due to the complexity of the solution, but operations are continued,
    - provide the supporting rationale e.g. facility planned to undergo major refurbishment and provision of new equipment in Q3, SOP to be updated as part of facility recommissioning.
    - consider interim actions designed to control the deficiency taking into account the potential impact to public safety and the environment until the longer-term action is complete. Where this option is followed please briefly describe the interim actions to be taken and how they will be managed and the supporting rationale

e.g. facility planned to undergo major refurbishment and provision of new equipment in Q3, SOP to be updated as part of facility recommissioning.

- Do not provide evidence of what you have done, unless specifically asked to.
- Provide your response in an editable Word document to allow the inspector to respond (if required).
- Hard copies are not required and will not be reviewed.

MHRA requests for further information

- If the inspector requires further information, they will be in red font and the request will be directly below the point that they require information for.
- Each request for further information will be dated to clearly identify which points require further response.

Site Second Response

- The site should choose a new colour for all sets of responses and reply underneath the further request.
- Each new response should be dated
- The whole record of all responses will therefore be in a single document.
- Do not change previous response text when you are providing additional information or further responses.

3 OTHER DEFICIENCIES

3.1 This is a deficiency that is classed as an 'Other'.

Initial Site Response

- Follow the same format for responses as outlined above.

Completion of CAPA

Please be aware that you are required to communicate with the inspector(s) if you are unable to meet a timeline commitment. This communication should take place before you go beyond the due date. The post-inspection compliance decisions are based on the acceptance of the remediation actions and their associated timescales for completion. Delays in completing remedial actions have historically resulted in significant compliance issues for facilities and studies therefore senior management should commit adequate resources to ensure the timely completion of the CAPA.

Next Inspection

The implementation of CAPA will be reviewed at the next inspection to determine if the organisation has done what they said they would. If CAPA were not adequately addressed or failed to meet the agreed timelines the findings may be upgraded, for example, if previous major findings have not been addressed, then a critical finding may be given.

Change Notification

Use the gxplabs@mhra.gov.uk to inform the MHRA of any significant changes at your test facility. For GLP facilities please complete notification of change form to inform the GLPMA of the details of the change.