Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Guidance on responding to a GMP / GDP post inspection letter

This guidance has been provided to reduce regulatory burden when preparing responses to Post Inspection Letters. The 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 GMP/GDP post inspection letter.

1 CRITICAL

(*Critical deficiencies will 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)*.

2 MAJOR

2.1 **This is a Major deficiency.**

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

Reference: EU GMP Part I Chapter X, X.1, X.2 etc

Initial Site Response

- Choose a new colour for your first set of responses.
- Answer the deficiencies raised directly underneath, preferably on the same document provided.
- Verbose responses with information not directly relevant to the remediation actions may be returned without review with a request to rewrite and simplify (these type of responses are not an efficient use of the inspectors' or the company's time).
- State clearly what you are going to do and when you are going to do it. If your response is a commitment to "review a system", 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.
- Think about the wider (systemic) issue, including other sites in the organisation and 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 timeline 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, consider interim actions. These should be designed to protect the patient until the longer term action is complete.
- 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 first request for further information

- If the inspector requires further information, they will choose a different colour and put the request directly below the point that they require information for.
- The use of different colours for each set of responses allows each party 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.
- 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 OTHERS

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

Reference: EU GMP Part I Chapter Y, Y.1, Y.2 etc

Initial Site Response

- Follow the same format for responses as outlined above.

4 COMMENTS

4.1 **This is a comment, not a deficiency.**

Initial Site Response

- The site should respond to comments, even if it is just to acknowledge them.

Please be aware that you are required to communicate with the inspector(s) if you are going to miss 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. The interim compliance report can be used to notify of delays to commitment completion.

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