Guidance on the use of GLP Study Report Amendments

GLP Requirements

Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.

Study Director and Quality Assurance Responsibilities

The responsibilities of the study director and QA apply to a final report amendment in the same manner they would apply to a final report. Consequently, any amendment to a final report should:

- Contain a signed study director compliance statement (if the original study director is no longer available, this should be stated and the amendment signed by management).
- Be inspected by QA and contain a signed QA statement detailing the inspections conducted (for example, review of the amended final report and data pertinent to it) and confirming that the amendment reflects the raw data.
- Be retained in the facility archive.

Format

The form of the amendment itself is not dictated by the Regulations although it is advisable to sequentially number amendments. Two options for the amendment are detailed below,

Short Form

Should the amendment affect only a discrete part of the final report it is possible to issue a short document detailing the following:

- the correction to be made and/or the text to be added to a specific section
- the reason why the change is being made
- a signed statement by the study director
- a signed QA statement.

Full Form

Should the amendment affect multiple sections of the final report (for example, where amendment of a data point affects derived data, tabulated data and statistical analysis) it may be more appropriate to issue an amended final report that replaces the original final report in its entirety. In this instance, the amended final report should

- clearly state that it replaces the original version and detail the reason why the changes or additions have been made.
- Contain an updated signed statement by the study director
- Include an updated QA statement

Other options may also be acceptable as long as the requirements listed above are met.

Communication

Sponsors should be informed as soon as possible that a final report amendment or amended final report is required to ensure that any regulatory authorities that have received the original final report can be informed. Test facilities should request confirmation from the sponsor that the amended final report has been received and circulated appropriately.

If a final report is to be reformatted to meet the specific requirements of a regulatory authority, this is not considered to constitute either a correction or addition to the final report provided that:

- No changes are made to the detailed information presented and the narrative text of the final report remains identical
- Any changes in wording relate only to those required for formal statements (for example, addition of a statement of no data confidentiality within a final report reformatted for submission to the United States Environmental Protection Agency).

If the issue of a final report amendment is required to correct information within the original final report, test facility management should investigate the root cause of the error.