



GLPMA GUIDANCE ON STUDY REPORTING

GUIDANCE FOLLOWING EARLY TERMINATION OF A GLP STUDY.

In situations where termination of a GLP study occurs a study plan amendment must be produced to provide an explanation as to why the study was terminated. This amendment must be verified by QA.

The following is required for a terminated study in which data has been generated before assessment or incorporation of the data into the final report.

- A summary report must be written summarising the study activities and data generated during the course of the study. The report should also include details of the early termination and the rationale for this decision.
- The data and any study material (for example samples and supporting records) must be archived.
- The study must remain on the regulatory master schedule, clearly indicating that it was terminated early as detailed in OECD Position Paper Number 21 Regarding Possible Influence of Sponsors on Conclusions of GLP Studies.

For facilities wishing to maintain a claim of GLP compliance for the work performed then Quality Assurance (QA) must audit the summary report.

For studies in which the study plan has been signed but no data has been generated, there is no requirement to produce a summary report.

INTERIM REPORTS

A clear distinction should be made between an interim report which details the findings of a study up to a particular date and a final report which details the findings of a study which has been performed in its entirety and in accordance with the study plan. It is not acceptable for a Study Director to make a claim of GLP compliance for an interim report except when requested by the regulatory receiving authority.

Written confirmation of the requirement to submit an interim report with a GLP claim of compliance should be obtained from the requesting receiving authority and retained in the study file. When an interim report is issued the GLP claim of compliance should be

transparent on the activities it covers and the report should detail the activities still to be performed to achieve the objectives of the full study.

In these situations, QA should always perform an audit of the interim report.

In situations in which interim reports without a claim of compliance are issued, it will be the responsibility of the test facility to define the requirements and procedures for the production of the report. As such it would be appropriate to include such guidance and instruction in a standard operating procedure.

GUIDANCE ON THE TIMING OF SIGNATURES IN A STUDY REPORT

Schedule 1 Part II 2.- (f) and Schedule 1 Part IX 2.- (d) of the UK GLP Regulations requires a quality assurance statement to be included in the final report and that the statement should be signed. Consequently, for the Study Director's statement of compliance to be valid when it is signed, the QA Statement should already be in place.

GUIDANCE ON THE USE OF GLP STUDY REPORT AMENDMENTS

Schedule 1 Part IX 1.- (4) of the UK Good Laboratory Practice regulations states that corrections and additions (of already generated experimental data) to a final report should be in the form of report amendments. Amendments should clearly specify the reason for the corrections or additions to the study report and should be signed and dated by the Study Director.

Circumstances for report amendments may include requests from receiving authorities to reopen a GLP study. A Test Facility must contact the UK GLPMA to request to re-open a study to perform additional experimental work and must retain written confirmation of the request from the receiving authority (if applicable). All requests will be reviewed on a case-by-case basis.

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

- No changes are made to the detailed information presented and that the narrative text of the final report remains identical.
- Any changes in wording relate only to those required for formal statements
- Any reformatted reports are identified as such.

STUDY DIRECTOR AND QUALITY ASSURANCE RESPONSIBILITIES

The responsibilities of the Study Director and QA apply to a final report amendment in the same manner that 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, an appropriate replacement Study Director should be appointed by study plan amendment. If the appointment of an appropriate Study Director is no longer possible for example the relevant department no longer exists, and therefore no suitably qualified Study Director can be appointed this should be stated, and the amendment signed by Test Facility Management.
- Be inspected by QA and contain a signed statement detailing the inspections conducted in relation to the study (for example, relevant critical phases, process inspections as well as review of the amended final report and data pertinent to it) and confirmation that the amendment reflects the raw data. The MHRA guidance on content of the QA statement should be followed.
- Be retained in the facility archive.
- Be reflected on the Master Schedule.

FORMAT

The format of the amendment itself is not dictated by the Regulations although it/they must be sequentially numbered. Two options for report amendment format 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.
- An updated signed compliance statement by the Study Director.
- An updated signed QA statement.

FULL FORM

Should the amendment affect multiple sections of the final report, 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 compliance statement by the Study Director.
- Include an updated QA statement.

Other options may also be acceptable if 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 of a change to a study/submission. Test Facilities should request confirmation from the sponsor that the amended final report has been received. This confirmation should be retained in the study package.

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 and assess whether any other reports may be similarly affected.