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COMPLIANCE MONITORING**

NUMBER 9

GUIDANCE FOR GLP MONITORING AUTHORITIES

GUIDANCE FOR THE PREPARATION OF GLP INSPECTION REPORTS

ENVIRONMENT MONOGRAPH NO. 115

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1995

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FOREWORD

Under the auspices of the OECD Panel on Good Laboratory Practice, a working group met in Rockville, Maryland, from 21st through 23rd September 1994, to develop harmonised guidance for the preparation of GLP inspection reports. The working group was chaired by Mr. Paul Lepore of the United States Food and Drug Administration. Participants were from national GLP compliance monitoring authorities in the following countries: Canada, France, Germany, Norway, Sweden, Switzerland and the USA. The working group reached consensus on a draft document aimed at providing guidance for GLP monitoring authorities on the information on specific test facility inspections to be exchanged with their colleagues in other GLP monitoring authorities.

The Panel on GLP reviewed and amended the draft document prepared by the working group and subsequently forwarded the document to the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals, which, in turn, slightly amended the draft and recommended that it be considered by the Environment Policy Committee. The Environment Policy Committee subsequently recommended that this document be derestricted under the authority of the Secretary-General.

GUIDANCE FOR THE PREPARATION OF GLP INSPECTION REPORTS

One of the goals of the work of the OECD Panel on Good Laboratory Practice is to facilitate the sharing of information from GLP compliance monitoring programmes conducted by Member countries. This goal requires more than the promulgation of enforceable principles of GLP and the conduct of an inspection programme by the national monitoring authority. It is also necessary to have the reports of the inspections prepared in a useful and consistent manner. The Guidance for the Preparation of GLP Inspection Reports developed by the Panel on GLP set forth below suggests elements and/or concepts that can contribute to a useful report of a GLP inspection and study audit. It may be used by Member countries as a component of their compliance monitoring programme.

Report Headings

There are many acceptable ways to organise an inspection report, but the key is to make sure that it contains the required information and meets the requirements of the regulatory authority. Generally, report headings include a Summary, an Introduction, a Narrative, a Summary of the Exit Discussion, and Annexes. All of the information presented under these headings should portray an accurate picture of the adherence of the testing facility to the Principles of GLP and the quality of any study report that may have been audited.

The narrative headings may contain information as follows:

1. Summary

The summary section of the report should be presented first and should provide background information on the test facility, the type of inspection that was conducted, the deviations from the GLP Principles that were noted, and the responses of the test facility to the presented deviations. In accord with national practice, the report may include the compliance designation of the laboratory that was assigned by the inspectors.

2. Introduction

The introductory section should include some or all of the following elements:

- 2.1 The purpose and general description of the inspection, including the legal authority of the inspectors and the quality standards serving as the basis for the inspection.
- 2.2 An identification of the inspectors and the dates of inspection.
- 2.3 A description of the type of inspection (facility, study audit, etc.)
- 2.4 An identification of the test facility, including corporate identity, postal address, and contact person(s) [with telephone and telefax number(s)]
- 2.5 A description of the test facility identifying the categories of test substances and testing that is done and presenting information on the physical layout and the personnel.

- 2.6 The date of the previous GLP inspection, resulting GLP compliance status, and any relevant changes made by the test facility since that inspection.

3. Narrative

The Narrative portion of the report should contain a complete and factual description of the observations made and activities undertaken during the course of the inspection. Generally, the information recorded in this section should be reflected under the headings in the GLP Principles, as listed below:

- 3.1 Organisation and Personnel
- 3.2 Quality Assurance Programme
- 3.3 Facilities
- 3.4 Apparatus, Materials, Reagents and Specimens
- 3.5 Test Systems
- 3.6 Test and Reference Substances
- 3.7 Standard Operating Procedures
- 3.8 Performance of the Study
- 3.9 Reporting of Study Results
- 3.10 Storage and Retention of Records

Deviations from the GLP Principles should be supported by documentation (i.e., photocopies, photographs, test samples, etc.). All such documentation should be referenced and discussed in the Narrative and attached in the Annexes.

When a study has been selected for audit, the inspection report should describe the procedure for conducting the audit, including a description of the portion of the data or study that was actually examined. Any findings during the audit should be described in the Narrative and documented in the Annexes.

4. Exit Discussion

At the end of an inspection/study audit, an Exit Conference should be held between the inspection team and the responsible management of the test facility, at which GLP deviations found during the inspection/study audit may be discussed. During this Exit Conference, if allowed by national policy, a written list of observations should be presented describing the GLP deviations if any have been observed. The exit discussion should be summarized in this section.

The report should note the date and time of the Exit Conference; the names of attendees (inspection team, facility and others), with their affiliations. It should also give a brief summary of GLP deviations noted by the inspection team during the facility inspection and/or study audits. Responses of facility representatives to the inspection team's remarks should also be described.

In the case where a written list of observations has been made available, the test facility should acknowledge the inspectors' findings and make a commitment to take corrective action.

If a receipt of documents taken by the inspection team was prepared and signed by facility management, the person to whom the receipt for documents was provided should be identified. A copy of the receipt should be included in the Annexes.

5. Annexes

The Annexes should contain copies of documents that have been referenced in the report. Such documents may include:

- organisational charts of the facility;
- the agenda for the inspection;
- a listing of SOPs that have been demonstrated during the inspection;
- a listing of deviations that have been observed;
- photocopies that document observed deviations.

Other Information

In addition to the information described above, reports may contain other headings and information as appropriate or as required by a Member country's compliance monitoring programme. For example, the inspection report may address correction of deficiencies noted during previous inspections or any corrective action taken during the current inspection. Others may include a cover page which contains descriptive information that briefly identifies the inspection. Others find it useful to use a table of contents, especially when the inspection is of a large, complex facility to categorize, index, and identify information in the report. Some reports include a "conclusion" section which notifies the testing facility of the compliance status classification as judged by the inspection. Any, or all of these, are acceptable.

Approval

Reports should be signed and dated by the lead inspector and by other inspectors in accordance with their responsibilities.