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Advisory Document of the Panel on Good Laboratory Practice

The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP

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Environment Directorate

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No. 2, *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice* (1995)

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This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

Foreword

In the framework of the Revision of the OECD Principles on Good Laboratory Practice, the Expert Group was not able to reach consensus on whether and how to deal with the role and responsibilities of the sponsor of chemical safety studies in the Principles. The revised Principles of GLP* contain several explicit references to the sponsor, and the issue is implicit in several other principles. However, there was no agreement on the need for and content of a separate section in the Principles on this matter.

On the recommendation of the Chairman of the Expert Group, the Panel on GLP therefore agreed to develop a document which could advise the testing industry as far as possible on current practice in Member countries and the interpretation of Panel of the GLP Principles related to this issue. At its ninth meeting in March 1997, the panel endorsed a document drafted by a Task Group on the role and responsibilities of the sponsor. The Task Group had met in Lisbon on 8th and 9th January 1997, was chaired by Theo Helder (Netherlands), and comprised Panel Members or their representatives from Canada, Finland, France, Germany, Portugal, Sweden, and Switzerland.

The Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals at its 26th Meeting endorsed the document and recommended that it be derestricted under the authority of the Secretary-General. The Joint Meeting recommended that it be published alongside the Guidance Documents for GLP Monitoring Authorities and the Consensus Documents in the OECD Series on GLP and Compliance Monitoring as the first “Advisory Document”.

*. See No. 1 of the Series in GLP and Compliance Monitoring, OECD, Paris, 1998

Advisory Document of the Panel on GLP

THE ROLE AND RESPONSIBILITIES OF THE SPONSOR

IN THE APPLICATION OF THE PRINCIPLES OF GLP

Introduction

1. Although the revised Principles of Good Laboratory Practice only explicitly assign a few responsibilities to the sponsor of a study, the sponsor has other implicit responsibilities. These arise from the fact that the sponsor is often the party who initiates one or more studies and directly submits the results thereof to regulatory authorities. The sponsor must therefore assume an active role in confirming that all non-clinical health and environmental safety studies were conducted in compliance with GLP. Sponsors cannot rely solely on the assurances of test facilities they may have contracted to arrange or perform such studies. The guidance given below attempts to outline both the explicit and implicit responsibilities of a sponsor necessary to fulfil his obligations.

Definition

2. "Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study." (See revised OECD Principles of GLP, para. 2.2, point no. 5.)

Note: Sponsor can include:

- an entity[1] who initiates and support, by provision of financial or other resources, non-clinical health and environmental safety studies;

- an entity who submits non-clinical health and environmental safety studies to regulatory authorities in support of a product registration or other application for which GLP compliance is required.

Responsibilities of the Sponsor

3. The sponsor should understand the requirements of the Principles of Good Laboratory Practice, in particular those related to the responsibilities of the test facility management and the Study Director/Principal Investigator.

Note: If parts of the study are contracted out to subcontractors by the sponsor, the sponsor should be aware that the responsibility for the whole study remains with the Study Director, including the validity of the raw data and the report.

1. "Entity" may include an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organisational unit thereof, or any other legally identifiable body.

4. When commissioning a non-clinical health and environmental safety study, the sponsor should ensure that the test facility is able to conduct the study in compliance with GLP and that it is aware that the study is to be performed under GLP.

Note: There are various tools for assessing the ability of a test facility to conduct a study in compliance with GLP. It can be useful for the sponsor to monitor contracted laboratories prior to the initiation of as well as during the study in accordance with its nature, length and complexity to ensure that its facilities, equipment, SOPs and personnel are according to GLP. If the test facility is in the national GLP compliance monitoring programme, the national monitoring authority[2] may also be contacted to determine the current GLP compliance status of the test facility.

5. Where several studies are presented to a regulatory authority in a single package, the responsibility for the integrity of the assembled package of unaltered final reports lies with the sponsor. It is necessary that the sponsor ensures that adequate communication links exist between his representatives and all parties conducting a study, such as the Study Director, Quality Assurance unit and test facility management.

6. The sponsor is explicitly mentioned in several of the requirements of the revised OECD Principles of GLP:

Characterisation of Test Item: "In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study." (See revised Principles, para. 6.2, point no. 3.)

Note: This requirement has been added to the revised GLP Principles in order to ensure that there is no mix-up of test items.

Study Plan: "The study plan should also be approved by the test facility management and the sponsor if required by national regulation or legislation in the country where the study is being performed." (See revised Principles, para. 8.1, point no. 1.)

Note: Some Member countries require approval of study plans by sponsors due to legal considerations related to responsibility for validity of test data.

Content of the Study Plan: "The Study Plan should contain...information concerning the sponsor and the test facility ...the name and address of the sponsor" (See revised Principles, para. 8.2, point no. 2 a.)

"The Study Plan should contain... (the) date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed." (See revised Principles, para. 8.2, point no. 3a.)

2. Sponsors should be aware that, notwithstanding any contractual requirements for confidentiality, national GLP monitoring authorities have access to all data produced by a GLP compliance facility.

Content of the Final Report: "The final report should include...information concerning the sponsor and the test facility...name and address of the sponsor." (See revised Principles, para. 9.2, point no. 2 a.)

Storage and Retention of Records and Materials: "If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s)." (See revised Principles, para. 10.4.)

Note: In this case, the sponsor is expected to arrange for an archive for the appropriate storage and retrieval of study plans, raw data, specimens, samples of test and reference items and final reports in accordance with the Principles of GLP.

Other Issues

Provision of chemical safety information:

7. The sponsor should inform the test facility of any known potential risks of the test item to human health or the environment as well as any protective measures which should be taken by test facility staff.

Characterisation of the test item:

8. The revised OECD Principles of GLP include several requirements related to the characterisation of the test item (e.g. para. 6.2, point nos. 1 and 2; para. 9.2, point no. 1 d). These requirements call for careful identification of the test item and description of its characteristics. This characterisation is carried out either by the contracted test facility or by the sponsor. If the characterisation is indeed conducted by the sponsor, this fact should be explicitly mentioned in the final report. Sponsors should be aware that failure to conduct characterisation in accordance with GLP case could lead to rejection of a study by a regulatory authority in some Member countries.

9. If characterisation data are not disclosed by the sponsor to the contracted test facility, this fact should also be explicitly mentioned in the final report.

Submission of data to regulatory authorities:

10. The ultimate responsibility for the scientific validity of a study lies with the Study Director, and not with the sponsor, whose responsibility is to make the decision, based on the outcome of the studies, whether or not to submit a chemical for registration to a regulatory authority.