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COMPLIANCE OF LABORATORY SUPPLIERS WITH GLP PRINCIPLES

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GLP Consensus Document

COMPLIANCE OF LABORATORY SUPPLIERS WITH GLP PRINCIPLES

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 1999

FOREWORD

In the framework of the OECD Consensus Workshop on Good Laboratory Practice, held 16th-18th October 1990 in Bad Dürkheim, Germany, a Working Group met to discuss and arrive at consensus on the compliance of laboratory suppliers with Principles of GLP. The Working Group was chaired by Dr. David Moore (Head, GLP Compliance Monitoring Authority, United Kingdom). Participants in the Working Group represented GLP compliance monitoring units and test facilities in Austria, Finland, France, Germany, Japan, Sweden and the United Kingdom.

The Working Group established the context of this consensus document, and made recommendations related to the role of suppliers vis-à-vis GLP Principles including the role of accreditation as a complementary tool to GLP compliance. It reached consensus and provided guidance on issues related to several specific categories of supplies. These issues are set out in the document.

The draft consensus document developed by the Working Group was circulated to Member countries and revised, based on the comments received. It was subsequently endorsed by the OECD Panel on GLP and the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals. The Environment Committee then recommended that this document be derestricted under the authority of the Secretary-General.

In light of the adoption of the Revised OECD Principles of GLP in 1997, this Consensus Document was reviewed by the Working Group on GLP and revised to make it consistent with modifications made to the Principles. It was endorsed by the Working Group in April 1999 and, subsequently by the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology in August 1999. It too is declassified under the authority of the Secretary-General.

GLP CONSENSUS DOCUMENT

COMPLIANCE OF LABORATORY SUPPLIERS WITH GLP PRINCIPLES

Background

The responsibilities of the management of test facilities are defined in the OECD Principles of Good Laboratory Practice[1] under the heading of Test Facility Organisation and Personnel (Section II.1). Test facility management should ensure that the GLP Principles are complied with at the test facility and that a sufficient number of qualified personnel, appropriate facilities, equipment and materials are available for the timely and proper conduct of the study. They also should ensure that test facility suppliers meet requirements appropriate to their use in a study. On the basis of these requirements, suppliers of materials used in studies submitted to regulatory authorities need not be included in national GLP compliance programmes but they do play a definite role relating to the responsibilities of the management of test facilities.

As by definition in the GLP Principles, the responsibility for the quality and fitness for use of equipment and materials rests entirely with the management of the test facility. The acceptability of equipment and materials in GLP-compliant laboratories should therefore be guaranteed to any regulatory authority to whom studies are submitted. The main purpose of this document is to offer advice to both test facility management and suppliers as to how they might meet GLP requirements through national accreditation schemes and/or working to formal national or international standards, or by adopting other measures which may be appropriate to a particular product. National or international standards, which may be set by an accreditation organisation, may be applied whenever they are acceptable to the test facility's management. The management of facilities, individually or in co-operation with each other, should thus maintain close contacts with suppliers and with their accreditation organisations.

Standards and accreditation schemes

Laboratories use various supplied materials in studies conducted in compliance with the GLP Principles. Suppliers have attempted to produce products which satisfy users' obligations as set out in the GLP Principles. Many suppliers have adopted manufacturing practices which comply with formal national or international standards, or have become accredited within various national schemes. These initiatives have been taken in the anticipation that supplied products will therefore be acceptable to regulatory authorities who require studies to be conducted in compliance with GLP Principles.

Suppliers are recommended to implement International Standard ISO 9001, and particularly Part 1 - Specification for Design/Development, Production, Installation and Servicing. This International Standard can be supported with European Standard EN 45001; the importance of Paragraph 5.4.7 of the latter, which refers to subcontracting, is emphasized.

Where appropriate, accreditation can be especially useful to suppliers. Accreditation schemes frequently monitor members' implementation of national and international standards; thus a supplier or

1 See The OECD Principles of Good Laboratory Practice (as revised in 1997), No. 1 in this OECD series on Principles of GLP and Compliance Monitoring.

manufacturer's accreditation certificate may signify to the customer the satisfactory implementation of a standard in addition to other aspects of accreditation. It is recommended that suppliers seek membership, where feasible and/or appropriate, in national accreditation schemes.

Although accreditation is a useful complementary tool to support compliance with the GLP Principles, it is not an acceptable alternative to GLP compliance nor will it lead to international recognition in the context of meeting the requirements for the mutual acceptance of data as set out in the OECD Council Acts.[2]

Test systems

The Revised Principles of GLP [Section II.8.2(5b)] require that the characterisation of test systems (animals, plants and other organisms) should be given in the study plan. This is the requirement that can be directly fulfilled by information from the supplier. In some countries where GLP has been implemented, suppliers belong to national regulatory or voluntary accreditation schemes (for example, for laboratory animals) which can provide users with additional documentary evidence that they are using a test system of a defined quality.

Animal feed, bedding and water

Although not specifically indicated in the Revised GLP Principles, animal feed should be analysed at regular intervals to establish its composition in order to avoid any potential interference with the test system. Water and bedding should also be analysed to ensure that contaminants are not present at levels capable of influencing the results of a study. Certificates of analysis are routinely provided by suppliers, including water authorities. Suppliers should provide appropriate documentary evidence to ensure the reliability of the analyses carried out.

Radio-labeled chemicals

Commercial pressure has forced suppliers of radio-labeled chemicals to seek formal GLP compliance by inclusion in national GLP compliance programmes. In many instances these suppliers produce labeled test items which are required to be fully characterised by procedures which comply with the GLP Principles. Suppliers of radio-labeled chemicals may need to be covered through national GLP compliance monitoring programmes.

Computer systems, applications software

All computer software, including that obtained from an external supplier, should normally be acceptance-tested before being put into service by a laboratory. From this requirement it can be inferred that it is acceptable for formal validation of applications software to be carried out by the supplier on behalf of the user, provided that the user undertakes the formal acceptance tests.

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2 Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)], adopted 12th May 1981, and Council Decision-Recommendation on Compliance with the Principles of Good Laboratory Practice [C(89)87(Final)], adopted 2nd October 1989. For the texts of both Council Acts, see The OECD Principles of Good Laboratory Practice (as revised in 1997), No. 1 in this OECD series on Principles of GLP and Compliance Monitoring.

The user should ensure that all software obtained externally has been provided by a recognised supplier. Many suppliers have endeavoured to meet users' requirements by implementing ISO 9001. This is considered to be useful.

The Revised Principles of GLP (Section II.1.2.2g) place the responsibility to ensure that software programmes have been validated with the Study Director. The validation may be undertaken by the user or the supplier, but full documentation of the process must be available and should be retained in the archives. In cases where the validation is performed by the user, Standard Operating Procedures should be available [Section II.7.4(2b)].

It is the responsibility of the user to undertake an acceptance test before use of the software programme. The acceptance test should be fully documented.

[See OECD Consensus Document No. 10, The Application of the Principles of GLP to Computerised Systems, 1995.]

Reference items

It is the responsibility of test facility management to ensure that all manufactured reference items meet the GLP requirements for identity, composition, purity and stability for each batch of material (Sections II.6.2.2 and II.6.2.4 of the Revised Principles of GLP).

Certificates provided by suppliers should cover data on identity, purity and stability (under specified conditions if needed) and any other characteristics to define each batch appropriately. In special cases the supplier may need to provide further information on, for example, methods of analysis, and should be prepared to demonstrate national/international measures of quality control, for example by reference to Good Manufacturing Practice or a national/international pharmacopoeia.

Apparatus

It is the responsibility of test facility management to ensure that instruments are adequate and functioning according to their intended use. Test facility management should also ensure that instruments are inspected and calibrated at prescribed intervals. Calibration should be traceable to national or international standards of measurement as appropriate. If reference standards are kept by the user they should be calibrated by a competent body at prescribed intervals.

Suppliers are expected to provide all information necessary for the correct performance of the instruments. For certain types of instruments, for example balances and reference thermometers, calibration certificates should also be provided.

Sterilised materials

It is the responsibility of test facility management to ensure that materials which should be free from sources of infection have been properly sterilised with appropriate control procedures. Suppliers should be able to provide proper evidence, for example through certificates or reference to national standards, that

materials sterilised by irradiation or other means or agents are free from sources of infection or undesirable residues from sterilisation agents.

General reagents

The user should ensure that reagents are obtained only from an accredited supplier. The supplier should provide documentary evidence of any accreditation status. Where there is no national accreditation scheme the user should ensure receipt of a certificate of analysis from the supplier which guarantees that the reagent is as described by the label.

The user should be responsible for ensuring, by arrangement with the supplier, that all reagents are labeled with sufficient detail to comply with the specific requirements of GLP.

Detergents and disinfectants

The user should be aware of all active constituents to enable a suitable choice for use and to remove the potential for any contamination or interference which could be said to affect the integrity of a study.

Products required for microbiological testing

The user should be responsible for ensuring by arrangement with the supplier that all such products are labeled with at least the following information: source, identity, date of production, shelf life, storage conditions.

The supplier should ensure that documentation is available giving evidence of any accreditation status. Where there is no national accreditation scheme the supplier should provide the user with a validation document which gives evidence of the fact that the product is as described by its label.