Information for GLP Study Sponsors

GLP COMPLIANCE MONITORING IN AUSTRALIA

What is GLP?

- GLP is a quality system concerned with the organisational processes and conditions under which a non-clinical health and environmental safety study are planned, performed, monitored, recorded, archived and reported.
- The OECD Principles of Good Laboratory Practice were developed in the late 1970s to promote the development of quality test data associated with non-clinical studies and to form a basis for the mutual acceptance of such data amongst OECD countries.
- Adopted by the OECD Council in 1981 and revised in 1997.
- The Principles should be applied to **NON-CLINICAL SAFETY TESTING** of test items in pharmaceuticals, pesticides, cosmetics, veterinary drugs, food additives, feed additives and industrial chemicals.

GLP in Australia

- The assessment, regulation and management of chemicals in Australia are the responsibility of various Australian regulatory agencies. These are:

  Therapeutics Goods Administration (TGA) → Pharmaceuticals

  Australian Pesticides and Veterinary Medicines Authority (APVMA)
  (formerly the National Registration Authority (NRA)) → Veterinary & agricultural chemicals

  National Industrial Chemicals Notification and Assessment Scheme (NICNAS) → Industrial Chemicals

- In January 2003 the APVMA mandated that all residue studies must be done in accordance with the OECD Principles of GLP. Further details, including exemptions to this requirement, can be found in the NRA Gazette No 3, 5 March 2002. A number of organisations in Australia have also initiated studies in compliance with GLP to meet client demands and overseas requirements.

GLP and NATA

- NATA is recognised by the Australian government, by a Memorandum of Understanding, as the national GLP compliance monitoring authority and as the organisation to represent Australian on the OECD Working Group on GLP.

- Only those facilities recognised by NATA for GLP compliance can claim to be GLP compliant under the Australian compliance monitoring.

- Mutual Acceptance of data (as defined by the OECD Council Directives) for Australian GLP facilities applies only for data from those GLP recognised facilities.

- NATA provides an annual report to foreign GLP compliance monitoring authorities that lists facilities that are in the Australian program and their current GLP status.

- NATA notifies all members of the OECD GLP Working Group and Australian regulators of any studies or any facilities found to be GLP non-compliant.

GLP and Clinical Studies

- The Principles only apply to non-clinical health and environmental safety studies required for the purpose of registering or licensing various products.

- They **do not** apply to clinical studies.

- This is stated in the introduction to the OECD Principles of GLP and also in the introduction to the USFDA GLP code (in the US Central Federal Register).

- The USFDA has also advised that it does not require GLP for any aspect of clinical studies. It looks for an assurance of the quality of the test data associated with clinical studies. In the US this is most often by means of a certification under the Clinical Laboratory Improvement Act (CLIA). In Australia this is most appropriately shown by a NATA ISO/IEC 15189 accreditation in the field of Medical Testing.
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- There is no requirement within EC countries for GLP to be applied to the analytical component of clinical studies.

- A NATA technical (i.e. ISO/IEC 17025-based) accreditation is a demonstration of adherence to “good laboratory practices” in a clinical testing laboratory.

Roles and Responsibilities of the Sponsor

- The sponsor is the entity that commissions, supports and /or submits a non-clinical health and environmental safety study.

- The sponsor should understand the requirements of the OECD Principles of Good Laboratory Practice, in particular, those related to the responsibilities of test facility management and the Study Director/Principal Investigator. For example, it is the responsibility of the test facility management (not the sponsor) to appoint the Study Director.

- The Principles explicitly state that
  - A mechanism should be developed, in co-operation with the test facility and the sponsor, to verify the identity of the test item used in the study.
  - The name and address of the sponsor must be detailed in the study plan and the final report.
  - If the test facility goes out of business that the archived study data should be transferred to the sponsor.

- The Study Director is responsible for the content and approval of the study plan. A sponsor supplied study plan must be checked by the Study Director for GLP compliance and must be signed by her/him.

- The Study Director is responsible for the content and conclusion described in the study report. The sponsor cannot require changes to be made to the report unless they are formatting changes required by the registration authority.

- Further information on the role of the Sponsor is detailed in Document No 11 of the OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring: Advisory Document of the Panel on Good Laboratory Practice – *The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP.*

Contact Details

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