

What is This Thing Called GLP?

Every laboratory interested in producing quality results is interested in maintaining sound laboratory management practices. Sometimes these practices are referred to, in general terms, as good laboratory practice (“lower case glp”). ISO/IEC 17025, the standard used by NATA to accredit laboratories, is an example of a code of good laboratory practice. NATA has, therefore, been working with codes of good laboratory practice for over 60 years. There is, however, another set of initials, GLP (“upper case GLP”).

This article sets out to explain this latter GLP and its applicability to Australian laboratories. The basic document dealing with GLP is the OECD Principles of Good Laboratory Practice, published by the OECD’s Environment Directorate, and most recently revised in 1998. This document was produced by the OECD GLP Working Group, on which Australia is represented by NATA. Some countries issue their own versions of the GLP Principles, often as part of national legislation, but the foundation of these documents are the OECD Principles of GLP.

In the US the equivalent legislation is:

US (FDA) CFR 21: Part 58 – Good Laboratory Practice for Nonclinical Laboratories studies

US (EPA) CFR 40 Vol 7 Part 160 – Good Laboratory Practice Standards (Pesticides Programs)

CFR 40 Part 28 Part 792 Toxic Substance Control Act

In EU countries the equivalent legislation is:

Directive 2004/10/EC

There is a misconception in some quarters that GLP is required for the conduct of clinical studies. The introduction to the OECD Principles of GLP (and the introduction to the USFDA GLPs) make clear that they apply only to non-clinical (pre-clinical) studies. The relevant documents for clinical studies are the various codes of GCP (e.g. ICH) and are most often developed by regulators.

Regulators (including those in the US) do require a demonstration of the quality of test data from clinical studies. This could include accreditation of a laboratory to ISO/IEC 17025:2005. In the US, this may well be by means of conformance with CLIA (Clinical Laboratories Improvement Act). In Australia, this can be demonstrated by the testing laboratory’s NATA accreditation (in Medical Testing, Chemical Testing, etc).

The basis for the development of GLP was to provide assurance regarding test data related to the hazard assessment of chemicals (pharmaceuticals, veterinary and agricultural chemicals, industrial chemicals) when manufacturers are seeking to register products for use. In Australia the relevant registration authorities are TGA (pharmaceuticals), APVMA (veterinary and agricultural chemicals), and NICNAS (industrial chemicals).

The Principles of GLP are applied to the conduct of non-clinical health and environmental safety studies of test items contained in various chemical products. A study covers work done in a laboratory, in animal houses, in greenhouses, and in the field. The Principles of GLP do not apply to clinical studies. Non-clinical studies include physico-chemical testing, toxicity, mutagenicity, environmental toxicity, bioaccumulation and residue studies; studies of effect on mesocosms and ecosystems, and the analytical chemistry associated with such studies.

The OECD Principles of GLP describe a quality system concerned with the organisational process and the conditions under which non-clinical studies are planned, performed, recorded, archived and reported. It does not concern itself with the technical validity of the studies themselves. The Principles can be quite prescriptive about some aspects of the conduct of the studies, especially in relation to the role of the Study Director (and any Principal Investigators), the role of the Quality Assurance unit, the documenting of Standard Operating Procedures (SOPs), the content of study plans (protocols) and reports, and the way in which all data related to each study is archived.

The OECD Principles are an integral part of the OECD Council Directives on Mutual Acceptance of Data in the assessment of chemicals. Annex II of this document states that data generated in a facility that adheres to the OECD Principles of GLP and that is recognised as GLP compliant by a national GLP compliance monitoring authority must be accepted internationally. NATA, as the Australian GLP compliance monitoring authority, only inspects Australian facilities for compliance with the OECD Principles of Good Laboratory Practice (GLP). An inspection of an overseas facility by NATA would not mean that the data generated would be accepted by regulatory authorities. For data generated under GLP in another country to be accepted internationally under these directives, the relevant government would need to set up a compliance monitoring program and apply for provisional adherence to the Directives. Recognition of overseas facilities by NATA would not obligate overseas regulators to accept data from that country. For further information about can be obtain from Dr Dian Turnheim of the OECD Secretariat at Dian.Turnheim@oecd.org.