

Frequently Asked Questions on GLP

1. What is GLP?

The principles of Good Laboratory Practice (GLP) define a set of rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

The GLP principles have been developed to promote the quality and validity of data generated in the testing of chemicals in order to facilitate their recognition for purposes of assessment and other uses relating to the protection of human health and the environment. Although not limited to authorities, the recognition of data becomes most important in the context of regulatory processes where authorities have to assess the possible effects of chemicals on human health and the environment, often as part of an authorisation procedure.

The recognition of test data generated in accordance with the principles of GLP by the authorities in several countries avoids duplicative testing, is beneficial to animal welfare and reduces costs for industry and governments. Moreover, common principles for GLP facilitate the exchange of information and prevent the emergence of non-tariff barriers to trade, while contributing to the protection of human health and environment.

Further information on GLP can be found on the European Commission's website: <http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/laboratory-practice/>

2. What are the legal tools used to regulate GLP?

Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) was transposed into national legislation by legal notice 371 of 2004.

Disclaimer: This document has been produced for information purposes only and is not in any respect a legal interpretation of the GLP regulations.