

Good Laboratory Practice (GLP)

IS-2

INAB is the statutory GLP Compliance Monitoring Authority with responsibility for the inspection and verification of Good Laboratory Practice (GLP) under S.I No 4 of 1991 European Communities (Good Laboratory Practice) Regulations implementing EU Directive 88/320.

Non-clinical health and environmental safety studies of all chemical products (for example medicinal products, cosmetics, veterinary products, feed additives and pesticides) are required by legislation to be conducted to the EU/OECD Principles of Good Laboratory Practice. These Principles address the organisational process and the conditions under which studies are planned, performed, monitored, recorded, reported and archived. The data generated by these studies is required by regulatory authorities responsible for the licensing of such products.

INAB is responsible for:

- Planning and conducting all GLP inspections and study audits of test facilities in the National GLP Programme and reporting the outcome of these inspections to the OECD, the European Commission and all GLP Compliance Monitoring Authorities.
- Processing all queries concerning GLP between Ireland and other member states and being the Irish point of contact for information on all test facilities in the EU and OECD GLP compliance programmes.
- Representing Irish interests during the development of GLP related policy issues through participation at meetings of both the EU and the OECD GLP Expert Working Groups.

More detailed information on the INAB National GLP Compliance Programme can be found at www.inab.ie and in INAB's Good Laboratory Practice (GLP) Compliance Monitoring Programme Manual, and guidelines on GLP Principles are available at www.oecd.org/ehs

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