Good Laboratory Practice (GLP) IS-2

INAB Compliance Programme

INAB is the statutory GLP Compliance Monitoring Authority with responsibility for the inspection and verification of Good Laboratory Practice (GLP) under S.I No 18 of 2020 European Communities (Good Laboratory Practice) Regulations implementing EU Directives 2004/9/EC and 2004/10/EC.

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 processes and the conditions under which studies are planned, performed, monitored, recorded, reported and archived. Regulatory authorities responsible for the licensing of such products require the data generated by these studies.

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.

Good Laboratory Practice (GLP)

The principles of Good Laboratory Practice (GLP) promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices.
The principles have been developed in accordance with the Organisation for Economic Cooperation and Development (OECD) and the EU has adopted these principles and the revised OECD Guides for Compliance Monitoring Procedures for GLP as annexes to its two GLP Directives.
GLP underpins the mutual acceptance of test data between countries, which avoids duplicative testing, is beneficial to animal welfare, and reduces costs for industry and governments.
Common principles for GLP also facilitate the exchange of information and prevents the emergence of non-tariff barriers to trade, while contributing to the protection of human health and the environment.

INFORMATION

Further information on the national compliance programme can be found at www.inab.ie and in the Good Laboratory Practice (GLP) Compliance Monitoring Programme Manual.

OECD information available at
http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

European Commission information available at https://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en

The facilities in the INAB compliance programme may be found at https://www.inab.ie/Directory-of-Accredited-Bodies/Good-Laboratory-Practice/Compliant-Test-Facilities/

For further information, please contact INAB at inab@inab.ie