Good Laboratory Practice (GLP) – Compliance Monitoring Programme

GLP Manual

Foreword

The Irish National Accreditation Board has the statutory responsibility for the European Union and the Organisation for Economic Co-operation and Development (EU/OECD GLP) scheme in Ireland. It is also the national Accreditation Body responsible for the accreditation of laboratories, certification bodies, inspection bodies and environmental verifiers in accordance with the relevant International Organisation for Standardisation (ISO) standards and guides.

The Irish National Accreditation Board has statutory responsibility for the enforcement of national legislation S.I. 18 of 2020 to give effect to Commission Directives 87/18/EEC, 88/320/EEC, 90/18/EEC, and Commission Directives 1999/11/EC and 1999/12/EC, which require certain testing on chemicals to be carried out in accordance with the annexed OECD Principles of Good Laboratory Practice and codified into Directives 2004/9/EC and 2004/10/EC on 11th February 2004.

INAB is noted under the Chemicals Act [No. 13 of 2008] to provide accreditation to ISO 17025 or GLP Compliance to laboratories testing detergents in support of the Detergents Regulation (EC) 648/2004 (Art. 8(2) and (3) only).

GLP applies to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

This publication presents the structure and operation of the National GLP Compliance Monitoring Programme in Ireland.

Relevant reference documentation:

- Good Laboratory Practice OECD Principles and Guidance for Compliance Monitoring ISBN 92-64-01282-6 OECD 2005
- S.I. No. 18 of 2020 European Communities (Good Laboratory Practice Amendment) Regulations, 2020
- Directive 2004/9/EC on the inspection and verification of good laboratory practice.
- Directive 2004/10/EC on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.

1. Introduction

Good Laboratory Practice (GLP) is concerned with the organisational process and the conditions under which laboratory studies are planned, performed, monitored, recorded and reported. The principles of GLP are designed to apply to test facilities carrying out health and environmental safety studies on chemical substances where the results are to be submitted to Receiving Authorities (national or international bodies with legal responsibility for the registration and licensing of chemical substances). The application of GLP to studies assures the quality and integrity of the data generated and allows this data to be used with confidence by relevant Receiving Authorities in hazard and risk assessment of chemicals.

The Irish Government designated the Irish National Accreditation Board (INAB) under Statutory Instrument *S.I. No. 4 of 1991 European Communities* (*Good Laboratory Practice*) *Regulations 1991*- see Annex 4) as the competent authority for verifying compliance with the OECD Principles of Good Laboratory Practice in order to give effect to European Council Directives 87/18/EEC, 88/320/EEC and European Commission Directive 90/18/EEC. The Regulations state that test facilities carrying out tests on chemical products in accordance with European Council Directive 67/548/EEC or any other Community provision providing for the application of Good Laboratory Practice in respect of tests on chemical products to evaluate their safety for man or the environment or both shall comply with the OECD Principles of Good Laboratory Practice.

Statutory Instrument S.I. No. 4 of 1991 requires test facilities carrying out tests on chemical products in accordance with Council Directives or any other Community provision providing for the application of Good Laboratory Practice to give a notice in writing to the person who commissioned the test and to INAB stating that the test has been carried out in conformity with the Principles of Good Laboratory Practice.

S.I. No.4 of 1991 was amended by S.I. No. 294 of 1999 to give effect to the Commission Directives 1999/11/EC and 1999/12/EC incorporating the revised OECD GLP principles (1997).

GLP related Directives are codified into Directives 2004/9/EC and 2004/10/EC.

In 2020 Statutory Instrument *S.I. 18 of 2020* was issued which revoked *S.I. 4 of 1991* and *294 of 1999*.

The purpose of the new 2020 Regulation is:

(i) to take account of the integration of the Irish National Accreditation Board (formerly a Committee of Forfás), in to the Health and Safety Authority (HSA), as a Committee thereof, with effect from 31st July 2014;

(ii) to clarify the powers of the Accreditation Board and the enforcement provisions available to the Accreditation Board; and

(iii) to revoke the above Regulations to reflect the codification of previous Good Laboratory Directives by –

(a) 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) (codified version); and

(b) Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version).

2. Administration

The Irish National Accreditation Board is located in the Department of Business, Enterprise and Innovation and is part of The Health & Safety Authority, a public agency under the aegis of the Department. All enquiries concerning GLP should be addressed to:

The Irish National Accreditation Board
Health and Safety Authority
Metropolitan Building
James Joyce Street
Dublin 1
Tel: 016147182
E-Mail: inab@inab.ie

The Irish National Accreditation Board has statutory responsibility for all matters relating to GLP including enquiries from Receiving Authorities, industry and GLP monitoring authorities in other countries. It conducts GLP inspections and study audits to monitor compliance with the OECD principles of GLP.

Since foreign monitoring authorities do not have any legal authority to carry out inspections in Ireland, the Irish National Accreditation Board co-operates fully with any requests from such monitoring authorities concerning the operation of GLP in Ireland.

In order to facilitate communications between sponsors of studies, test facilities and Receiving Authorities, INAB provides information on inspections to interested parties as follows:-

- An annual report of test facility inspections is provided to the European Commission in accordance with EU Directive 88/320/EEC and the OECD indicating the GLP compliance status of test facilities.

- An annual report is provided to the Health & Safety Authority (HSA) on the performance of INAB of its functions under the Act in the preceding year (Chemicals Act 2008 & 2010).

- A GLP Compliance Statement is issued by INAB to a test facility where an inspection has revealed an adequate compliance with GLP.

- Where a test facility does not comply with GLP to the extent that the integrity or authenticity of the studies it performs might be compromised, the European Commission is informed immediately (i.e. not later than seven days from the date of inspection). The Commission shall inform the other Member States.

The Irish National Accreditation Board is responsible for ensuring that an adequate team of inspectors having the necessary technical/scientific expertise is appointed to carry out inspections.
The Irish National Accreditation Board maintains records of studies audited, and records of test facilities inspected and their GLP Compliance status.

3. Confidentiality

Inspectors may have access to confidential and commercially valuable information whilst conducting inspections and audits and may even need to remove commercially sensitive documents from a test facility or to refer to them in detail in their reports. The following provisions apply for the maintenance of confidentiality not only for inspectors but also any other persons who gain access to confidential information as a result of GLP compliance monitoring activities:

- Inspectors are required by the Regulations to carry means of identification including authorisation by the Minister for Business, Enterprise and Employment, or the Chief Executive

Officer of the Irish National Accreditation Board and must produce this authorisation if so requested by any person affected by the Regulations.

- The disclosure of information, except in the exercise of their duties, obtained by any member of the INAB Board, or its staff, or any committee or consultative group appointed by it or by any person engaged by it, shall be prohibited.

- Copies of any documents removed from a facility by INAB are uniquely marked (Annex 1).

- Access to information and reports held by the Irish National Accreditation Board is restricted to the Irish National Accreditation Board staff and Board members, or applicable contractors acting on INAB's behalf.

- The Regulations make it an offence to disclose commercially sensitive or other confidential information (other than to the Commission of the European Communities or the Board) unless it is necessary to do so for the purpose of the enforcement of the Regulations.

- Reports of test facility inspections and study audits are made available only to Receiving Authority if so requested by a Receiving Authority, and where appropriate, to the test facilities inspected or concerned with the study audits and/or to study sponsors.

- Inspectors who are employed on contract by the Irish National Accreditation Board to perform test facility inspections or study audits are required to sign a contract incorporating appropriate confidentiality clauses.

4. Personnel and Training

The National GLP Monitoring Authority consists of a Chief Executive Officer and trained contracted inspectors scientifically qualified and having practical experience in a range of scientific disciplines relevant to the testing of chemicals.

Inspectors are required to be familiar with the GLP Principles and with the requirements necessary to comply with those Principles. Inspectors are required to undertake appropriate training having regard to their individual qualifications and experience. Training includes formal training courses for GLP inspectors. The Irish National Accreditation Board encourages consultations including joint training activities where necessary with the staff of other OECD member countries' national GLP Monitoring Authorities in order to promote international harmonisation in the interpretation and application of GLP Principles and in the monitoring of compliance with such Principles.

Inspectors that are on contract by the Irish National Accreditation Board are required to sign a contract that obliges them to disclose in advance any financial or other interests they might have in test facilities or firms sponsoring studies. The contract forbids inspectors to undertake work for the Irish National Accreditation Board where any such interest may arise.
The Irish National Accreditation Board has ultimate responsibility in all cases for determining the GLP compliance status of test facilities and the quality/acceptability of a study audit and for taking any action based on the results of test facility inspections or study audits that the Irish National Accreditation Board deems necessary.

The Chief Executive Officer signs each GLP Compliance statement issued by the Irish National Accreditation Board.

5. The National GLP Compliance Monitoring Programme

The National GLP Compliance Programme ascertains whether test facilities have implemented the OECD GLP Principles for the conduct of studies and are capable of assuring that the resulting data is of adequate quality and appropriately archived.

6. Scope and extent of the Programme

The scope and extent of the National GLP Compliance Programme is defined in Statutory Instrument *S.I. No. 18/2020 - European Communities (Good Laboratory Practice) Regulations, 2020*which designates the Irish National Accreditation Board as the Monitoring Authority.
The Programme applies to health and environmental non-clinical safety testing of all chemical substances (pharmaceutical products, pesticide products, cosmetic products, veterinary drugs, food additives, feed additives, biocides, medical devices and industrial chemicals) including physical, chemical, toxicological and ecotoxicological studies as well as field studies.

The wide diversity of facilities (in terms both of physical layout and management structure), together with the variety of types of studies encountered by Inspectors means that the Inspectors must use their own judgement when assessing the acceptability of the degree and extent of compliance with GLP Principles. The Principles of Good Laboratory Practice (GLP) are designed in the main to apply to test facilities carrying out comprehensive toxicological studies in connection with health and environmental safety testing of pharmaceuticals, agrochemicals, cosmetics, food additives, veterinary drugs, new industrial chemicals etc. Such studies in many instances involve animal testing that may be carried out over a period of months or even years. On the other hand, many of the chemical and physical tests used in characterisation of the above materials to provide data in support of a submission to a Receiving Authorityare relatively straightforward, of short duration and involve only small batches of samples. It is evident therefore that the Principles of GLP need to be interpreted sensibly to take account of the differences between a detailed toxicological study involving animal testing and the more routine nature of many chemical and physical tests.

Inspectors will not concern themselves with the scientific design of the study or the interpretation of the findings of studies with respect to risks for human and animal health or the environment. These aspects are the responsibility of those Receiving Authorities to which the data are submitted.

Test facility inspections are conducted to determine the degree of conformity of test facilities and studies with the GLP Principles and to confirm the quality and integrity of that data. A report, which describes the degree of adherence of a test facility to the GLP Principles, is prepared following each test facility inspection.

7. The Mechanisms by which test facilities enter the programme

A test facility can enter the national GLP Compliance Programme **either** at the request of the facility itself **or** by means of a notification to the Irish National Accreditation Board under *S.I. No. 18/2020 - European Communities (Good Laboratory Practice) Regulations, 2020*which obliges test facilities claiming compliance with GLP under the Regulations to notify the Irish National Accreditation Board in writing, of each and every claim of GLP compliance. This notification must be made to the Board within three months of making a claim of compliance with GLP. The test facility will be required to supply details of the facility such as *site plans, types of studies undertaken, number of staff, a facility organisation chart etc*. (Annex 2) following such a request or notification. A pre-inspection site visit may also be carried out to obtain further relevant information. The initial formal inspection of the test facility will normally be undertaken within six months of receiving the written request or notification from the test facility.

Test facilities carrying out GLP requiring studies on chemicals in the pharmaceutical, veterinary, agricultural, chemical areas etc., are obliged to carry them out in accordance with the OECD Principles of GLP and to notify INAB of these activities in writing.

Other test facilities may seek to enter the National Good Laboratory Practice Compliance Programme under one of the following categories:

(a) The test facility is seeking work in an area of testing which legislation requires the testing is carried out in accordance with GLP.

(b) Customers of the test facility require the test facility to have a National GLP Compliance statement even though it is not clear that legislation requires the testing is carried out in accordance with GLP.

Test facilities will be required to justify their reasons for wishing to enter the National GLP Compliance Monitoring Programme for categories (a) or (b) above. Test facilities allowed to enter the Programme *under* categories (a) or (b) will be subject to annual inspections or inspection of first study audits that will include reconsideration of the test facility's justification for requiring a GLP compliance statement.

In any event, all such test facilities will be required to undertake GLP requiring studies within an agreed timeframe, not exceeding two years. A test facility is removed from the National Compliance Monitoring Programme where no GLP requiring study has been carried out within any two-year period or where INAB concludes that the test facility's reasons for inclusion in the Programme are no longer justified.

A compliance statement is given only to those facilities, which are found to be operating in accordance with the OECD GLP principles, and compliance statements are renewed after each full routine biennial GLP inspection.

8. Categories of Test facility Inspections/Study Audits

The inspections and study audits fall into two main categories:

(i) A system of regular inspections of test facilities in its programme is undertaken by INAB at two-year intervals although special circumstances may lead to a higher frequency. These inspections will involve both a full inspection of the test facility and incorporate an audit of one or more of the ongoing or completed studies. A pre-inspection may be carried out for new applicants to familiarise the inspection team with the facility and obtain relevant information. A sample pre-inspection agenda is

(ii) in annex 3 and a sample inspection checklist and agenda is shown in annex 4 & 5.

(iii) Monitoring is also carried out at the specific request of national or foreign Receiving Authorities. Such requests are usually for study audits but may sometimes involve test facility inspections. In some instances, study audits may generate the need for a test facility inspection. In other instances, specific requests from a Receiving Authority may be provided from information derived from recently completed inspections and further visits to the test facility may not be necessary. The Receiving Authority is obliged to identify and justify the need for any inspection or study audit, which it has requested.

The test facility will usually be given advanced notice of a planned visit.

The Irish National Accreditation Board may occasionally invite, or upon request invite, official representatives of other authorities to participate in an inspection or study audit. Such invitations will be made known to the test facility/sponsor, as appropriate.

9. Powers of Inspectors

Statutory Instrument *S.I. No 18 of 2020* confers legal powers on authorised inspectors to enter test facilities, carry out inspections, and take samples and copies of documents and interview staff.

Inspectors will normally not wish to enter a test facility against the will of its management, however circumstances may arise where entry to the test facility and access to data are essential to protect public health or the environment.

10. **Test facility Inspection and Study Audit Procedures**

The procedures for carrying out test facility inspections and study audits for verification of GLP Compliance are in accordance with *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits,* N° 3 in the OECD series on Principles of GLP and Compliance Monitoring. In each section of these procedures there is a statement of purpose as well as an illustrative list of specific items, which could be considered during the course of a test facility inspection or study audit. These lists are not intended to be comprehensive and should not be taken as such.

The inspection or study audit concludes with an exit meeting during which management and other personnel are informed of the findings of the inspection. A list of observations are presented at that time, giving an overview of any observed major deviations or potential deviations from the GLP Principles.

The test facility is invited to give its comments on these observations, orally at the exit meeting and also later in writing (preferably within 2 weeks). Comments may concern agreement or disagreement with observations, but can also indicate follow-up or corrective actions taken or to be taken in the test facility. These comments are taken into account when drafting the final report on the inspection. The test facility will receive a copy of the full report.

11. **Follow-up to Test facility Inspections and Study Audits**

When a test facility inspection or study audit is completed, a written report of the findings is prepared and presented to management of the test facility. Management must confirm within four weeks their acceptance or otherwise of the report and detail any actions taken or being taken to rectify issues raised in the report.

If a test facility inspection or study audit reveals only minor deviations from the GLP Principles, the facility will be required to correct such minor deviations and to provide evidence to the GLP Monitoring Authority that these minor deviations have been corrected and where appropriate, that corrective action is being taken to prevent such deviations recurring. The Inspector may need, at an appropriate time, to return to the facility to verify that the proposed corrective actions have been effective.

Where no or where only minor deviations have been found, the National GLP Monitoring Authority may:-

- Issue a statement that the test facility has been inspected and found to be operating in compliance with GLP Principles. The date of the inspection, the period covered and, if appropriate, the categories of test inspected in the test facility at that time will be included. (See annex 5 - Test facility's GLP Activities). Such statements may be used to provide information to GLP Monitoring Authorities in other Member countries; **and/or**

- Provide the Receiving Authority that requested a study audit with a detailed report of the findings.

Where serious deviations are found, the action taken by the National GLP Monitoring Authority will depend upon the particular circumstances of each case and the legal or administrative provisions of the Regulations. Actions which may be taken include, but are not limited to, the following:

- Issuance of a statement giving details of the inadequacies or faults found which might affect the integrity of studies conducted in the test facility;

- Issuance of a recommendation to a Receiving Authority that a study be rejected;

- Suspension of test facility inspections or study audits of a test facility and/or, for example removal of the test facility from the National GLP Compliance Programme;

- Notification to the European Commission;

- Requiring that a statement detailing the deviations be attached to specific study reports;

- Action through the courts, where warranted by circumstances and where the legal/administrative procedures of the Regulations so permit.

The test facility will be informed before such actions are taken.

12. Payment of Fees and Charges

This section sets out INAB regulations on payment of fees for INAB services and schemes.

a. Payment of Fees

INAB charges fees for the operation of all its schemes. Fees are set annually and are subject to, at minimum, a yearly review. They are published in the 'Schedule of Fees' available at www.inab.ie

Note the invoice will be calculated based on the dates rates indicated at the time and include travel time. Inspection effort is calculated by time on site and off site work.

Charging arrangements between an organisation and its clients are in no way the responsibility of, and are not subject to the control of INAB.

b. Application Fee

An application fee is levied to offset costs involved in processing the application documents and appointing the inspection team.

The application fee is per organisation or group of organisations at a single location and listed at the time of application on the application form.

Subsequent applications for the inspection of related organisations not included in the original application may be subject to a further application fee.

c. Pre-Inspection Fee

A pre-inspection fee is levied to offset the costs involved in the onsite review of the implementation of the quality system.

d. Inspection/Study Audit Fee

The initial inspection fee is levied to offset the costs involved at the first inspection of the implementation of the quality system on site.

The initial inspection fee is dependent on the work to be undertaken by INAB and the number of inspectors and inspection days required for the inspection of an organisation.

e. Cancellation Fee

Where a confirmed visit has to be postponed by the organisation for any reason within 6 weeks of the confirmed date, a cancellation fee comprising the sum of expenses incurred for such a visit plus 50% of the fee applicable for the visit will be levied in addition to the inspection fee.

f. Fees for Additional Inspections

INAB reserves the right to levy fees if additional visits are found to be necessary, or if at any stage a failure to comply with INAB requirements imposes additional work on INAB or its inspectors.

A fee will be charged for an inspection arising from a change of premises.

g. Payments

Payments in full are expected within 30 days of issue of the invoice.

13. Appeals Procedure

Problems or differences of opinion between inspectors and test facility management will normally be resolved during the course of a test facility inspection or study audit. However, when problems persist and differences cannot be resolved at inspector level, the facility management may appeal the findings of the GLP inspectors. Appeals against the findings of the GLP inspectors and disputes concerning the interpretation of the OECD Principles of Good Laboratory Practice, should be submitted in writing to the Chief Executive Officer of the Irish National Accreditation Board, Metropolitan Building, James Joyce Street, Dublin 1. Such appeals shall be determined by the INAB Quality Manager, with suitable support expertise and representations as necessary.

14. International acceptance of data generated by test facilities in the GLP Compliance Monitoring Programme

The results of studies carried out by test facilities in the Irish GLP Compliance Monitoring Programme may be submitted to several Receiving Authorities for the purpose of registering and licensing of products in different countries. Since the Irish GLP Compliance Monitoring Programme is in accordance with the EU and OECD GLP principles and regulations, and data (i.e. statements of compliance and inspection reports) will be acceptable to most foreign Receiving Authorities.

Test facilities can expect this data to be acceptable to foreign Receiving Authorities that are members of the EU and OECD. In fact in the case of EU member states article 5 of DIRECTIVE 2004/9/EC states that "… *the results of laboratory inspections and study audits on GLP compliance carried out by a Member State shall be binding on the other Member States*".
In this regard, each year Member States draw up a report relating to the implementation of GLP within their territory. This report contains a list of the laboratories inspected, the date on which such inspections were carried out and a brief summary of the conclusions of the inspections. This report is forwarded to the Commission each year, not later that the 31st March.

INAB in implementing the EU directive DIRECTIVE 2004/9/EC is the national body responsible for handling all queries relating to GLP between Member States. Any requests by Irish Receiving Authorities for study audits in Ireland or overseas must be channelled through INAB. INAB is also the point of contact for any requests for information on the GLP compliance status of test facilities in Ireland and overseas.

Requests for study audits of Irish facilities from overseas authorities shall be managed by INAB. INAB is the point of contact in Ireland for information of the status of all EU and OECD test facilities and holds information on the status of all test facilities in the EU and OECD monitoring programmes.

If a GLP compliant test facility in the Irish GLP compliance programme experiences difficulties with the mutual acceptance of data by foreign authorities on grounds relating to GLP, they should immediately contact the Irish National Accreditation Board.

Mutual Acceptance of Data (MAD)
The MAD system helps to avoid conflicting or duplicative national requirements, provides a common basis for co-operation among national authorities and avoids creating non-tariff barriers to trade. OECD countries and full adherents have agreed that a safety test carried out in accordance with the OECD Test Guidelines and Principles of Good Laboratory Practice in one OECD country must be accepted by other OECD countries for assessment purposes. This is the concept of "tested once, accepted for assessment everywhere*". This saves the chemicals industry the expense of duplicate testing for products which are marketed in more than one country.

* While the receiving government must accept the study, how it interprets study results is its own prerogative.

15. **15) Documents relevant to the OECD Good laboratory Practice (GLP) Scheme**

The OECD series on Principles of Good laboratory Practice and Compliance Monitoring are available from:

OECD Publications Service
2 rue André Pascal
75775 Paris Cedex 16
France
Tel. ++33-1-45 24 8200 / Fax: ++33-1-45241675 E-mail: ehs.contact@oecd.org
https://www.oecd.org/chemicalsafety/testing/overview-of-good-laboratory-practice.htm

This series comprise multiple documents as follows:

OECD Principles of GLP
No 1: OECD Principles on Good Laboratory Practice (1997)

GLP Consensus and Advisory Documents

No 5: Compliance of Laboratory Suppliers with GLP Principles (revised in 1999)
No 6: The Application of the GLP Principles to Field Studies (revised in 1999)
No 7: The Application of the GLP Principles to Short Term Studies (revised in 1999
No 8: The Role and Responsibilities of the Study Director in GLP Studies (revised in 1999)
No 11: The Role and Responsibility of the Sponsor in the Application of the Principles of GLP (1998)
No 12: Requesting and Carrying Out Inspections and Study Audits in Another Country (2002)
No 13: The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies
No 14: The Application of the Principles of GLP to in vitro Studies (2004)
No 15: Establishment and Control of Archives that Operate in Compliance with the Principles of GLP (2007)
No 16: Guidance on the GLP Requirements for Peer Review of Histopathology (2014)
No 17: Application of GLP Principles to Computerised Systems (2016)
No. 19: Management, Characterisation and Use of Test Items (2018)
No. 22: GLP Data Integrity (2021)
No 23: Quality Assurance and GLP (2022)

Guidance Documents for Compliance Monitoring Authorities

No 2: Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995)
No 3: Revised Guidance for the Conduct of Laboratory Inspections and Study Audit (1995)
No 9: Guidance for the Preparation of GLP Inspection Reports (1995)

Position Papers

The Use of Laboratory Accreditation with reference to GLP Compliance Monitoring (1994)
Position Paper on 'Outsourcing' of Inspection Functions by GLP Compliance Monitoring Authorities (2006)
No. 18: OECD Position Paper Regarding the Relationship between the OECD Principles of GLP and ISO/IEC 17025 (2016)
No. 21: OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies (2020)
No. 24: Position Paper on Quality Improvement Tools and GLP (2022)

Guidance for Receiving Authorities

No. 20: Guidance for Receiving Authorities on the Review of the GLP Status of Non-Clinical Safety Studies (2019)

OECD publications can be downloaded from the OECD's website here

Statutory Instrument S.I. No.18 of 2020 is available at www.irishstatutebook.ie

Annex 1: National GLP Compliance Monitoring Authority Document Record Sheet – (if removed from Facility)

Facility:	Page:
Date:	Of:

Stamp Code:	Document Title:	Copies:	Scan:	Reviewed:	Comments:

Annex 2: Pre-Inspection/Inspection Material Request

In order to plan the programme for the visit the facility is requested to forward the following information:

1. Copy of the site plan;
2. List of all GLP-requiring studies undertaken since last visit, both completed and in progress;
3. Titles of all relevant S.O.Ps;
4. Organisation structure changes;
5. Staff changes (Management Organograms);
6. List of computerised systems;
7. Statement of compliance claims, if any.

Annex 3: Suggested Agendas

A. Pre-Inspection

STARTING CONFERENCE

- Introduction
- Outline of purpose and scope of visit
- Presentation by Test facility's management
- Designation of accompanying persons

DISCUSSION OF RANGE OF STUDIES

MANAGEMENT STRUCTURE OF THE TEST FACILITY

- Organisation Chart
- Documentation
- Master schedule studies
- Study plans
- SOPs
- Study reports
- Master schedule QA programme

LUNCH

VISIT TO TEST FACILITY

- Infrastructure
- Archives
- Equipment
- Test and reference substances
- Test systems

EXIT MEETING

B. Full Inspection/Study Audits

STARTING CONFERENCE

- Introduction
- Outline of purpose and scope of visit
- Approval of inspection/study audit programme
- Designation of accompanying persons

INSPECTION

- Organisation and personnel
- Documentation
- QA Programme
- Archives

INTERNAL DISCUSSION INSPECTION TEAM

LUNCH

INSPECTION (continued)

- Facilities
- Equipment
- Test and reference substances
- Test systems
- Performance

INTERNAL DISCUSSION INPSECTION TEAM

INTERIM EXIT MEETING WITH MANAGEMENT

STUDY AUDIT

INTERNAL DISUCSSION INSPECTION TEAM

LUNCH

STUDY AUDIT (Continue)

INTERNAL DISCUSSION INSPECTION TEAM

INTERIM EXIT MEETING WITH MANAGEMENT

STUDY AUDIT (Continue)

INTERNAL DISCUSSION INSPECTION TEAM

LUNCH

STUDY AUDIT (Continue)

INTERNAL DISCUSSION INSPECTION TEAM

PREPARATION EXIT MEETING

DISCUSSION INSPECTION TEAM

FINAL EXIT MEETING WITH MANAGEMENT

Annex 4: GLP Findings – Categories

- **A:** Compliance with the Principles of GLP
- **B:** Deficiency*:* A deficiency or a departure from the principles that do not present immediate risk to compliance. Corrective action is required
- **B*** Major: A deficiency is identified, that if not addressed may lead to serious problems in the future. Corrective action should be taken and justified by document evidence 30 days after the receipt of the provisional report
- **C** Critical: Had a direct effect on the integrity of data. This deviation is a non-compliance observation with regard to the GLP quality system of the Test facility and/or studies audited
- **D**: not applicable
- **Blank**: not verified, no judgement

Annex 5: Test facility's GLP Activities

Type of Studies	A	B	C	D	E	F	G
Physical-chemical test							
Toxicity studies							
Mutagenicity studies							
Environmental toxicity studies on aquatic and terrestrial organisms							
Studies on behaviour in water, soil, air, bioaccumulation							
Residue studies							
Studies on effects on mecocosms and natural ecosystems							
Analytical and clinical chemistry testing							
Other studies; specify							

A = Industrial Chemical
B = Pharmaceuticals
C = Veterinary Drugs
D = Phytopharmaceuticals
E = Food Additives
F = Feed Additives
G = Cosmetics
H = Biocides
I = Others (e.g. Medical devices)