NPRA GLP Compliance Programme – Frequently Asked Questions (FAQ)

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A. Introduction to GLP & Programme

1. Why should a test facility pursue GLP Certification from NPRA?

Obtaining GLP certification from NPRA signifies that a test facility operates in accordance with the OECD Principles of Good Laboratory Practice (GLP) and the requirements of the NPRA GLP Compliance Programme. This certification provides confidence in the reliability, integrity, and traceability of non-clinical safety data generated by the facility.

In addition, studies conducted at NPRA GLP-certified facilities are recognised under the OECD Mutual Acceptance of Data (MAD) system, enabling wider international acceptance of the data by other OECD member countries and adhering partners.

GLP certification also enhances the facility's credibility, promotes confidence among sponsors and regulatory authorities, and strengthens its competitiveness in the global market.

2. Is participation in the NPRA GLP Compliance Monitoring Programme mandatory for all test facilities performing non-clinical safety studies?

No. Participation in the NPRA GLP Compliance Programme is voluntary.

3. Can overseas test facilities apply for an inspection and be included under the NPRA GLP Compliance Programme?

No. The NPRA GLP Compliance Programme only covers test facilities located in Malaysia. Overseas test facilities are not eligible to be included.

However, NPRA may conduct study-specific inspections at foreign test facilities if requested by the regulatory authority (NPRA) to support product registration.

4. How do I apply for a Good Laboratory Practice (GLP) certificate?

Test facilities intending to participate in the NPRA GLP Compliance Programme shall follow the established application procedures. The application procedures and relevant forms can be accessed and downloaded from the NPRA GLP Compliance Programme webpage at www.npra.gov.my/en/glpgcp.html. Facilities are advised to review all requirements thoroughly before submitting an application.

B. Regulatory Acceptance & Compliance

5. Which non-clinical safety studies must be conducted in compliance with GLP for regulatory submission of New Chemical Entities (NCEs), biologics, and natural products with therapeutic claims?

Any non-clinical safety studies conducted to support the registration of the products above should be performed in compliance with the OECD Principles of Good Laboratory Practice (GLP). However, specific requirements may vary depending on the nature of the product and the intended regulatory use of the data.

The determination of which studies are required lies with the respective Regulatory Authorities to which the data are submitted for regulatory purposes.

6. Is GLP applied to non-clinical studies for the registration of cell and gene therapy products (CGTPs) in Malaysia?

According to the *Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia – Second Edition (September 2025),* pivotal pre-clinical safety studies for CGTPs are generally expected to be conducted in accordance with the OECD Principles of Good Laboratory Practice (GLP).

However, due to the unique characteristics of CGTPs, full compliance with GLP may not always be feasible. For example, certain technical expertise, unique animal care requirements, or specific endpoints may not be available at GLP-compliant test facilities.

In such cases, a scientific justification should be provided when pivotal pre-clinical safety studies are not conducted in full conformity with GLP. The justification must address the reasons for non-compliance and assess its potential impact on the reliability of the safety data.

7. Does GLP compliance of a study guarantee an approval by the Centre of Product and Cosmetic Evaluation, NPRA/Drug Control Authority (DCA)?

No. GLP compliance confirms that a study was conducted in accordance with the Principles of OECD GLP, ensuring the quality, integrity, and traceability of the data generated. However, approval by the Centre of Product and Cosmetic Evaluation/DCA also depends on whether the study design, results and overall product dossier meet the applicable regulatory guidelines and submission requirements.

8. Following a study-specific inspection by NPRA at a non-MAD overseas test facility, can the study be considered OECD GLP-compliant and accepted by other OECD or MAD-adhering countries?

No. The outcome of NPRA's study-specific inspection at an overseas test facility is only recognised for the purpose of supporting product registration in Malaysia and does not confer overall OECD GLP compliance status of the test facility. The acceptance of the inspection outcome by other OECD member or MAD-adhering countries shall depend on the respective country's policies.

9. What are the implications if NPRA withdraws a facility's GLP compliance status?

The test facility will be withdrawn from the NPRA GLP Compliance Programme, and the decision will be formally communicated to other OECD member countries and Mutual Acceptance of Data (MAD) adherent countries through the Secretariat of the OECD GLP Working Party. Consequently, non-clinical safety study data generated by the facility will no longer be accepted under the OECD MAD system.

A facility that has been removed from the Compliance Programme may reapply for inclusion by submitting a new application. NPRA will determine whether a pre-inspection is required or if the facility may proceed directly with a full inspection.

C. Study Conduct & QA Responsibilities

10. Can a test facility subcontract a part of a study under GLP?

Yes. Subcontracting a part of a study is permissible under GLP; however, it must be clearly described in the Study Plan, specifying which phase or activity of the study will be conducted at the test site(s).

Clear communication and defined responsibilities must be maintained between the Test Facility Management, Study Director, Principal Investigator(s), and Quality Assurance to ensure proper oversight and compliance with the OECD Principles of GLP.

11. What is the difference between an OECD GLP laboratory and a Quality Control (QC) laboratory?

An **OECD GLP laboratory** conducts non-clinical safety studies in accordance with the OECD Principles of Good Laboratory Practice (GLP) for **regulatory submissions purposes**. These laboratories operate under the OECD Mutual Acceptance of Data (MAD) framework, which ensures the integrity, traceability, and international acceptability of the data generated to support product registration. The final report issued upon completion of a non-clinical safety study forms part of the dossier submitted to regulatory authorities.

In contrast, a **QC laboratory** performs **routine analytical testing** (e.g., finished products, stability, batch release) usually under GMP requirements. QC laboratories focus on product quality and compliance, generating Certificates of Analysis (CoAs) rather than GLP study reports.

GLP Compliance Monitoring Authorities (CMAs) designated under the OECD GLP framework are responsible for inspecting, monitoring, and certifying test facilities that conduct non-clinical safety studies to ensure compliance with OECD GLP principles.

12. Is it sufficient for the QA statement to only include details of the study-based inspection?

According to the OECD Principles of GLP, the Quality Assurance (QA) statement included in the final study report must specify the types of inspections conducted and their respective dates. This includes identifying the specific phase(s) of the study inspected, as well as the dates when inspection findings were reported to the Test Facility Management (TFM), the Study Director, and, if applicable, the Principal Investigator(s).

A compliant QA statement should also reflect that the study has received adequate QA coverage. This entails not only study-based inspections but also consideration of

process-based and periodic facility-based inspections to ensure comprehensive oversight in accordance with GLP requirements.

13. Can Quality Control (QC) be performed by the Quality Assurance (QA) unit?

No. Quality Control (QC) and Quality Assurance (QA) are distinct functions under the Principles of GLP.

Under OECD GLP, Quality Assurance (QA) refers to an **independent** unit responsible for **verifying compliance with GLP** through inspections and audits. QA personnel do not perform QC activities.

Quality Control (QC) in the quality system refers to routine checking, measuring, and testing procedures built into study processes to ensure the accuracy and reliability of data.

If QC activities are incorporated into the test facility's processes, QA may take these into account when planning inspections. However, QC remains separate from QA responsibilities. As with all study activities, QC processes themselves are subject to QA inspection to confirm their proper implementation and compliance with GLP.

14. Can the Test Facility Management (TFM) and Quality Assurance (QA) functions be performed by the same individual?

No. The Test Facility Management (TFM) and Quality Assurance (QA) functions must remain separate and cannot be performed by the same individual. Since TFM is responsible for ensuring adequate resources for studies, it must be independent of QA activities to ensure proper oversight and compliance.

To ensure the independence of QA personnel, they should report directly to the TFM and must not assume any role in the studies they inspect (e.g. Study Director, study personnel, or TFM).

15. What actions should be taken if deviations from GLP are identified during a study?

Deviations from the study plan should be **described, explained, acknowledged** and dated in a timely manner by the Study Director and/or Principal Investigator(s), and maintained with the study raw data.

Deviations from Standard Operating Procedures (SOP) related to the study must be documented and acknowledged by the Study Director and the Principal Investigator(s), as applicable.

All deviations must be **assessed** for their potential impact on the study and reported in the final Study Report. Significant deviations may impact the regulatory acceptability of the study.

16. Can standard test guidelines (e.g., OECD Test Guidelines) be modified?

Modifications to OECD Test Guidelines or their test methods may be acceptable under Good Laboratory Practice (GLP) conditions. However, any modification must be scientifically justified, clearly described in the Study Plan, and reported in the Final Study Report.

The justification should demonstrate that the modified procedure remains scientifically valid, reliable, and relevant for its intended purpose.

D. Data, Records & Documentation

17. How long is the retention period for GLP records?

The OECD requires that GLP records be archived under controlled conditions, but does not prescribe a specific retention period. Test facilities must establish and document their own procedures for archiving and record retention.

In Malaysia, test facilities are required to retain these records and materials for a minimum of ten (10) years to ensure their availability for inspection and verification of compliance with the OECD Principles of GLP.

18. Can electronic-only archives replace traditional paper archives under GLP?

Yes. Electronic-only archives may replace paper archives provided that the electronic systems are fully validated, secure, and capable of ensuring long-term retrievability. The system must demonstrate equivalent integrity, authenticity, and accessibility to paper-based archives. Hybrid systems, comprising both paper and electronic records, are also acceptable under GLP requirements.

19. Who is responsible for maintaining CVs, job descriptions, and training records under GLP?

It is the responsibility of the Test Facility Management to ensure the maintenance of CVs, job descriptions, and training files for all relevant personnel. Superseded or outdated versions should be securely archived, and GLP inspectors must have access to these records during inspections.

20. Is a Quality Manual required under GLP?

No. Only Standard Operating Procedures (SOPs) are required.

21. Are electronic copies of Standard Operating Procedures (SOPs) and their electronic distribution permitted under GLP?

Yes. Electronic copies of SOPs and their electronic distribution are permitted under GLP, provided that document control procedures ensure authenticity, version control, and restricted access. Electronic SOPs must be approved by management and remain readily accessible at the workplace where the procedures are performed.

22. Are electronic signatures accepted under GLP?

Yes. Electronic signatures are generally accepted under GLP, provided that they are unique to the individual, securely maintained, and verifiably linked to the corresponding electronic records to prevent falsification or misuse. The electronic system must maintain audit trails for all data changes and ensure that records comply with GLP requirements for traceability, authenticity, and data integrity.

E. Facilities, Equipment & Systems

23. Should reference materials (e.g., standard weights, thermometers) be calibrated by accredited laboratories under GLP?

Yes. Reference materials used for verification purposes should be calibrated by a competent body, and must ensure traceability to national or international standards, with appropriate documentation to demonstrate compliance.

24. How should computerised systems be managed under GLP requirements?

Under GLP, computerised systems must be validated to demonstrate that they function as intended. These systems should be secure and reliable, with access restricted to authorised personnel only. Audit trails must be available and maintained to ensure traceability of all data entries, modifications, or deletions.

Regular data backup and recovery procedures should be implemented to ensure long-term protection of study records. In addition, all system configurations, updates, and changes must be documented to maintain data integrity and ensure compliance throughout the system's lifecycle.

F. Test Item Management

25. What aspects should be considered for the storage of a test item under GLP?

Storage of test items must ensure stability, integrity, and traceability. Key aspects include (but are not limited to):

- Storage Conditions: Maintain appropriate temperature, humidity, light protection, and segregation from incompatible materials.
- Identification & Labeling: Clearly label each test item with name/code, batch/lot number, expiry/re-test date, storage conditions, and relevant safety precautions.
- Segregation & Security: Store separately from other materials, restrict access to authorised personnel, and use quarantine areas where necessary.
- Stability Monitoring: Ensure that stability data support the defined storage duration and monitor for any signs of degradation.
- Documentation & Traceability: Maintain complete records of receipt, storage, use, and disposal to ensure full traceability throughout the test item's lifecycle.
- Inventory Management: Track quantities, usage, and expiry dates.
- Disposal Procedures: Dispose of expired or unused test items in accordance with approved SOPs and regulatory requirements, with all actions appropriately documented.

26. For test item transportation, is it solely the sponsor's responsibility to ensure required environmental conditions?

No. The responsibility is shared between the sponsor (or sender) and the test facility.

Prior to shipment, both parties should agree on the environmental conditions the test item may be exposed to during transportation and establish appropriate safeguards.

Special precautions are required if the test item is sensitive to temperature, light, or humidity. Monitoring devices such as data loggers, max/min thermometers, or dry ice checks (where applicable) should be used based on risk level.

Upon receipt, the test facility must assess and document the integrity of the test item. This includes reviewing the monitored shipping/environmental conditions, inspecting the physical condition of the item and its container, and recording the date of receipt.