FREQUENTLY ASKED QUESTIONS

1. How can I apply for a Good Laboratory Practice (GLP) certificate?

For all test facilities established in Organization for Economic Co-operation and Development (OECD) countries, you should contact the national GLP Monitoring Authority responsible for the scope of your studies.

For test facilities established in Malaysia, you should fill in the GLP Application Form (NPRA-433-10) which is available in our website. The application together with the supporting documents must be submitted to:

Deputy Director
Centre for Compliance and Quality Control,
National Pharmaceutical Regulatory Agency (NPRA),
Ministry of Health, Malaysia.
Lot 36, Jalan Profesor Diraja Ungku Aziz,
46200 Petaling Jaya,
Selangor, Malaysia.

2. Why should I get GLP Certification from NPRA?

Test facilities conducting non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives, medical devices and claimed to be compliant with the OECD Principles of GLP, under the Malaysian GLP Compliance Programme must be certified by NPRA.

The Malaysian Government through a Cabinet decision in February 2008 had agreed to appoint NPRA as Malaysian Compliance Monitoring Authority (CMA) in monitoring compliance to OECD Principles of Good Laboratory Practice for the non-clinical safety testing of chemicals (pharmaceutical products, cosmetic products, veterinary drugs, food additive etc.) and medical devices during marketing authorization submission. In October 2008, Malaysia has been accepted as a Provisional Member to the OECD Mutual Acceptance of Data (MAD) system. The Senior Director of Pharmaceutical Services Division has issued a Directive on 1 June 2009, in accordance to the Regulation 29 The Control of Drugs and Cosmetics Regulations 1984 (Amendment) 2006 on this matter. Therefore any test facilities conducting non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs, food additives and medical device, and claimed to be compliant with the OECD Principles of GLP, must be certified by NPRA.

In March 2013, Malaysia has been accepted as a non-member adherent to the OECD Mutual Acceptance of Data (MAD) system. The Senior Director of Pharmaceutical Services Division has issued a Directive on 1 July 2016 which was effective starting from 1 January 2018, in accordance to the Regulation 29 The Control of Drugs and Cosmetics Regulations 1984 (Amendment) 2006 on this matter. Therefore any test facilities conducting non-clinical safety testing of chemicals (pharmaceutical products, cosmetics products, veterinary drugs, food additives etc.) and medical device claimed to be compliant with the OECD Principles of GLP, must be certified by NPRA.

3. How do I get GLP Certification?

After submitting the application, test facilities will be inspected to determine compliance with the OECD GLP Principles. Pre-inspection will be conducted within 30 working days upon receiving a complete application. The test facility must have completed at least one GLP-compliant study before pre-inspection. This is then followed by full Inspection once corrective actions have been addressed. NPRA will issue Certificate of GLP Compliance if the test facility satisfies the OECD GLP Principles. The test facility will then be included in our GLP Compliance Monitoring Programme. The surveillance inspection will be conducted annually for the first two years and subsequent surveillance inspections in every two years after the date of the compliance certificate issued.

4. Is the NPRA GLP Compliance Monitoring Programme mandatory?

No. The NPRA GLP Compliance Programme is voluntary, however, in some countries, such as countries in OECD group, it is required by law that any non-clinical studies must to be conducted in compliance with the OECD Principles of GLP for products to be registered in their countries.

5. What are the non-clinical safety studies required to be conducted in GLP for regulatory submission of New Chemical Entity (NCE), biologic and herbals with high claims?

Any non-clinical safety studies conducted to support the safe use in human and safety evaluation for potential adverse effect(s) should be performed in compliance with GLP. However, requirement may vary depending on the nature of the product. Kindly consult Centre for Registration Product Department for further details.

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

Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) was released in 2015, it is currently on the basis of voluntary and expected to take full effect by 2021. For details on non-clinical studies, kindly also refer to EMA Guideline on human cell-based medicinal products and US FDA Preclinical Assessment of Investigational Cellular and Gene Therapy Products.

7. Is a Quality Manual required in GLP?

No, only Standard Operating Procedures are needed.

8. Can I subcontract a part of a study?

Yes, there are test facilities with one or more test sites. It should be very clearly mentioned in the Study Plan which part of the study is being carried out in the test sites. Clear communication lines between Management, Study Director, Principal Investigator(s) and Quality Assurance should exist.

9. Which main functions are required by the GLP principles?

Four main functions are required: Test Facility Management, Quality Assurance, Study Director and Archivist.

10. Can these functions be combined by the same person?

No. Quality Assurance and Study Director should always be two different persons. Even for other functions it is recommended to have different persons for each function.

11. Are electronic signatures and electronic raw data accepted?

Electronic raw data are allowed, if full reconstruction of the study is possible but the laboratories should pay attention to the stability of the data carriers. For example, is the software/hardware needed for reading of the electronic raw data still available after 10-20 years? Electronic signatures are generally accepted.

12. Are electronic copies of SOPs and the electronic distribution of these documents allowed?

Electronic SOPs are accepted, but they should always be available at the working place and should be approved by management.

13. Who should maintain CVs, job descriptions and training files?

There is no obligation in the GLP principles on where these documents have to be retained. Old versions of these documents should be stored in the archives. It is the responsibility of the management to organize the maintenance of these documents. GLP inspectors should always have access to these documents.

14. Should reference standards like weights, thermometers etc. be calibrated by accredited laboratories?

Yes, standards should be traceable to international or national standards, which can only be obtained by calibration of standards by a national meteorological institute or by an accredited laboratory.