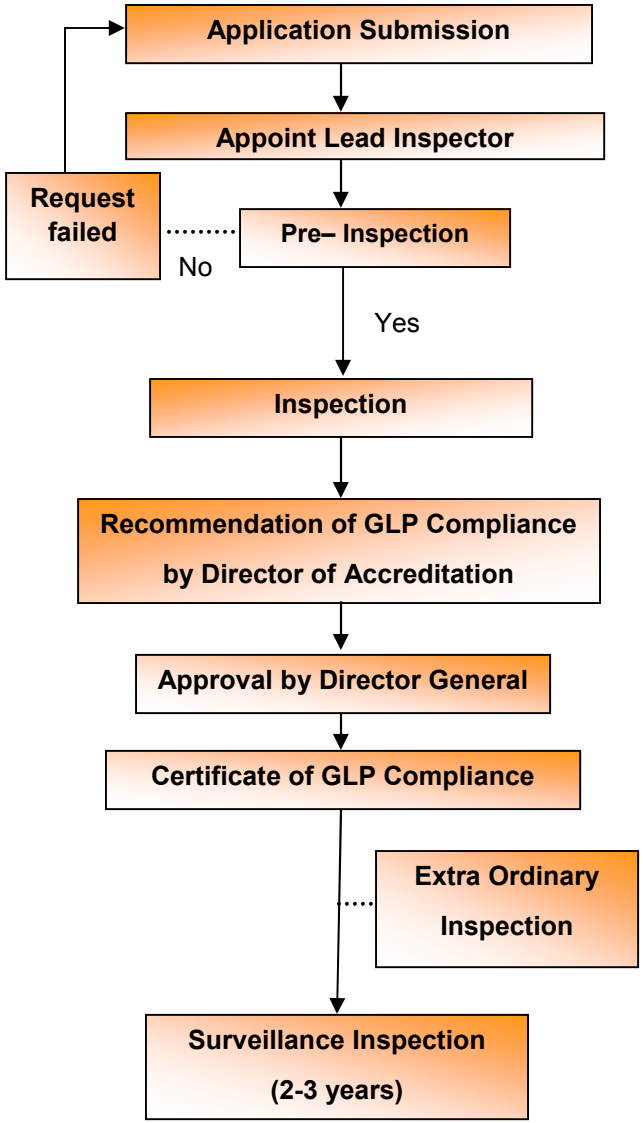
Inspection Process In STANDARDS MALAYSIA GLP CP



SCOPE FOR STANDARDS MALAYSIA GLP CP

Category of Test Item:

i) Industrial Chemicals
ii) Pesticides
iii) Feed Additives
iv) Biotechnology (non-pharmaceutical products)

Type of Studies/ Area of Expertise on Test Item:

i) Physical-chemical testing
ii) Toxicity studies
iii) Mutagenicity studies
iv) Environmental toxicity studies on aquatic and terrestrial organisms
v) Studies on behavior in water, soil and air; bio-accumulation
vi) Residue studies
vii) Studies on effects on mesocosms and natural ecosystems
viii) Analytical and clinical chemistry testing
ix) Others

For futher information, kindly contact:

Department of Standards Malaysia
Century Square
Level 1 & 2, Block 2300, Jalan Usahawan,
63000 Cyberjaya, Selangor

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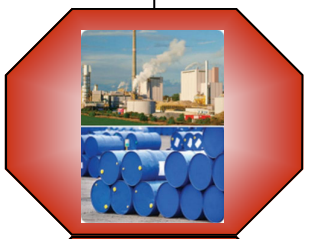
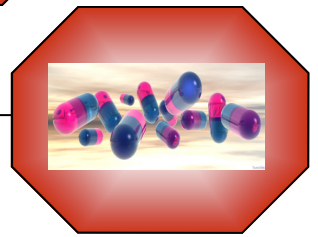
STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (OECD GLP)





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STANDARDS MALAYSIA

About Us

The Department of Standards Malaysia (STANDARDS MALAYSIA) was set up by the Government on 28 August 1996 under the Standards of Malaysia Act 1996 (Act 549). Governed by the Ministry of Science, Technology and Innovation (MOSTI), STANDARDS MALAYSIA operates as the sole national standards and accreditation body in the country.

GLP Compliance Monitoring Authority (CMA)

STANDARDS MALAYSIA and National Pharmaceutical Control Bureau, Ministry of Health (NPCB, MoH) have been appointed by the Government of Malaysia on 13 February 2008 as the Compliance Monitoring Authority (CMA) for monitoring compliance with the Organisation for Economic Co-operation and Development Principles of Good Laboratory Practice (OECD GLP).

STANDARDS MALAYSIA Good Laboratory Practice Compliance Programme (GLP CP)

STANDARDS MALAYSIA GLP CP is intended to ascertain whether test facilities have implemented requirements as described in documents of OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring.

STANDARDS MALAYSIA will inspect, register and monitor test facility on regular basis of approximately two year's cycle in accordance with the Master Register of GLP CP. The programme includes Pre-inspection, Inspection, Surveillance Inspection and Extra Ordinary Inspection.

OECD GLP

Good Laboratory Practice is a quality system concern with the organisational process and the condition for non-clinical health and environment safety studies are planned, performed, monitored , recorded, archived, and reported in accordance with OECD criteria.

The studies are undertaken to generate safety studies data to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, pesticide, cosmetics, veterinary drugs as well as food and feed additives and industrial chemicals.

The application of GLP to studies assures the quality and integrity of the data generated and allows the data to be used with confidence by relevant Regulatory Authorities and users.

The OECD Series on Principles of Good Laboratory Practice have been developed to promote the quality and validity of test data used for determining the safety of chemicals and chemicals product.

OECD Series on Principles of Good Laboratory Practice and STANDARDS MALAYSIA GLP CP Manual

1. Doc. No. 1: OECD Principles of Good Laboratory Practice.
2. Doc. No. 2: Guidance for the GLP Monitoring Authorities Procedures for GLP.
3. Doc. No. 3: Guidance for the conduct of Laboratory Inspections and Study Audit Quality Assurance and GLP.
4. Doc. No. 4 Quality Assurance and GLP.
5. Doc. No. 5: Compliance of Laboratory Suppliers with GLP principles.
6. Doc. No. 6: The application of the GLP principles in the field studies.
7. Doc. No. 7: The application of the GLP principles to short term studies.
8. Doc. No. 8: The role and Responsibilities of the Study Director in GLP studies.
9. Doc. No. 9: Guidance for the preparation of GLP Inspection Reports.
10. Doc. No. 10: The application of the Principles of GLP to Computerized Systems.
11. Doc. No. 11: Advisory document of the Working Group on GLP: The role and responsibility of the Sponsor in the Application of the Principle of GLP.
12. Doc. No. 12: Advisory document of the Working Group on GLP: Requesting & Carrying out Inspection and Study Audit in Another Country.
13. Doc. No. 13: Advisory document of the Working Group on GLP: The application of the OECD GLP to the Organizational and Management of Multi-Site Studies
14. Doc. No. 14: Advisory document of the Working Group on GLP: The application of the OECD Principles of GLP to in vitro studies.
15. Doc. No. 15: Advisory document of the Working Group on GLP: Establishment & Control of Archives that Operate in Compliance with the Principles of GLP.
16. STANDARDS MALAYSIA GLP Compliance Programme Manual.