Requirements and Conditions for GLP compliance test facility
Bureau of Laboratory Quality Standards, Department of Medical Sciences

Bureau of Laboratory Quality Standards (BLQS), Department of Medical Sciences (DMSc) is responsible for recognition of test facilities conducting safety studies for non-clinical health and environmental safety studies, for the purpose of registering and/or licensing pharmaceuticals, food and feed additives, cosmetics products, veterinary drug products and similar products, and for the regulation of industrial chemicals. This is in accordance with the situations and policy of the country to allow the government and private sectors to be able to issue the study results of health and environmental studies to meet the OECD Principles of Good Laboratory Practice which leads to export promotion and public health services throughout the country. The OECD Principles of Good Laboratory Practice are designed to apply to test facilities carrying out health and environmental safety studies on test items under scope of GLP where the results are to be submitted to Regulatory Authorities; national or international bodies with legal responsibility for the registration and licensing of chemicals. From this regard, the National Standardization Council (NSC) has appointed BLQS-DMSc as National Compliance Monitoring Authority since 29th August 2018 (letter No. MOI 0714/31429).

The BLQS is committed:

- To administer its policies and procedures in a non-discriminating manner.

- To enforce procedures to monitor the compliance of inspected test facilities in order to maintain impartiality and integrity.

- To assure its decision on inspection to those matters specifically related to the scope of the considered inspection.

- To assure that the BLQS employees and inspection are properly trained, exhibit public service at their best and are free from any commercial, financial and other under pressure, with might skew the inspection process.

- To assure that the BLQS shall maintain compliance, consistency, transparency and integrity in its daily conduct and when fulfilling its obligations.

- To assure maintenance of confidentiality when applicable.

- To assure allocation of resources to implement its quality related policies and procedures.

- To cooperate with the Thai regulatory bodies.

1. Scope

The BLQS GLP Compliance Programme is voluntary programme offer to test facilities conducting studies for non-clinical health and environmental safety studies on test item contained in products in the following categories:

1) Pharmaceuticals
2) Pesticides
3) Cosmetic products
4) Veterinary drug products
5) Food additives
6) Feed additives
7) Industrial chemicals products
8) Others

The testing of these items is for the purpose of the non-clinical safety testing of test items is to obtain data on their properties and/or their safety with respect to human health. Non-clinical health safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory. Type of studies/areas of expertise on test items subjected to the BLQS GLP CP are in the following categories:

1) Physical-chemical testing
2) Toxicity studies
3) Mutagenicity studies
4) Environmental toxicity studies on aquatic and terrestrial organisms
5) Studies on behavior in water, soil and air; bioaccumulation
6) Residue studies
7) Studies on effects on mesocosms and natural ecosystems
8) Analytical and clinical chemistry testing
9) Other studies

2. Requirements for Test Facility

2.1 The test facility must be legal identifiable. The test facility may comprises permanent test facilities, with or without sites away from its permanent.

2.2 The test facility shall implement the management system according to the OECD Principles of Good Laboratory Practice. Associated consensus and advisory documents should be implemented as applicable.

2.3 The top management of the test facility or the authorized representative shall sign the application.

2.4 Each applicant must nominate a senior staff member to represent it in dealing with BLQS, DMSc. The authorized representative may be a senior technical or managerial staff who holds an appropriate position in the organization with the authority to ensure their facility complies with the criteria for registration at all

times. The authorised representative is expected to be present at staring and closing conference.

2.5 The application shall be submitted with the detail of the GLP management system and the implementation document, which can fulfill the requirements of the BLQS. The controlled release of such documentation to BLQS is the responsibility of the test facility wishing to enter the BLQS GLP Compliance Programme. The BLQS will terminate the application if the documents are not completed within 180 days, after the date of submitting the application, where appropriate.

2.6 The test facilities shall comply with the registration procedure and shall pay fee schedule as scheduled and conditioned by the BLQS, DMSc.

2.7 The Test Facility shall obligate with the inspectors in the following;

2.7.1 Permit the access to the premises, facilities, resources, operations, procedures, records and staff.

2.7.2 Prepare for the evidences during on-site inspection according to the request of the Inspectors, including the hand on analysis for witness.

2.7.3 Prepare the test sample and evidence for the inspection.

2.7.4 Provide the room for examination of document, the meeting of Inspector team and other activities.

2.7.5 Assist and allow the use of the office stationary and the communication apparatus as necessary.

3. The National GLP Compliance Programme

3.1 General

The BLQS as a National GLP Compliance Programme 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 recommendation. The GLP Compliance Programme includes pre-inspection, full inspection/study audit, and extra ordinary inspections (where applicable). The inspection process is demonstrated in the registration procedure chart.

The BLQS will conduct Test Facilities Inspections/Study Audit for compliant test facilities for the first years after granted and then continue for routine inspection every two years in accordance with the GLP compliance programme. If no GLP study has been conducted within two years since the last inspection, a suspension for minimum 12 months will be given. Test facility should advise the BLQS as soon as possible that GLP study is to be performed. Hence, the BLQS will conduct Test Facility Inspection/Study Audit in order to reinstate the suspension status. If there is no action taken by test facilities within 6 months. The BLQS will remove the test facilities from GLP Compliance Programme. The BLQS may also remove test facilities from the GLP CP in the right of:

a) Failure to comply with GLP CP requirements as stated in this manual;

b) Failure to provide cooperation or facilities for BLQS, its inspectors and/or its Authorized representatives to discharge their official duties;

c) Fraudulent practices, which include but not limited to; deception of claims and alteration of GLP certificate;

d) An individual or sole proprietorship test facilities is declared bankrupt or enter into composition with his creditors; or

e) Compliant test facilities, being a company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction) or enters into receivership.

The BLQS CMA shall maintain a Master Register which containing information on the name of test facility, the date of inspection, scope, the area of studies/expertise, compliance status and remarks. These manual and relevant documents used in the programme are prepared by designated personnel, reviewed by GLP Manager and approved by Director of BLQS.

3.2 The Mechanisms by which Test Facilities enter the programme

The GLP Compliance Programme is voluntary. At Test Facility can enter the national GLP Compliance Programme either at the request of the facility itself or at the request of national or foreign Regulatory Authorities or at the request of foreign Monitoring Authorities or by means of a notification to the Receiving Authority which obliges Test Facilities claiming compliance with GLP.

The applicant shall pay for the registration fee. Fees are determined according to categories as mention in ☞ 4.4 The test facility wishing to enter the BLQS GLP Compliance Programme has to submit supporting documents containing background details on the organisation and the scope of its activities relevant to compliance facility with the OECD Principles of GLP as follows:

1. Form no.5 (F 07 15 025): Applications form for GLP compliance test facility.
2. Form no.6 (F 07 15 026): Detail of specific information for GLP compliance test facility.
3. Form no.7 (F 07 15 027): Self-evaluation complying with OECD Principles of Good Laboratory Practice
4. Location maps of the Test Facility and nearby landmark building.
5. Organogram.
6. Copy of the official company registration bored the authorized personnel names.
7. Copy of trade registration or the commercial license.
8. Power of attorney.
9. ☞ Nomination a GLP staff member as a coordinator to BLQS, DMSc.
10. ☞ Floor plan of the testing facilities.
11. Master schedules of all completed and on-going studies.
12. Full set of SOPs (include list of SOPs)
13. List of equipment.
14. Quality Manual or Site Master File or other names.
15. Study plan and ☞ Final report.
16. List of personnel and Curriculum vitae
17. ☞ One original document of information no. 1 – 3, two hard copies of all documents and three CDs or thumb drives contain all informations 1-16.

Application form can be download from http://blqs.dmsc.moph.go.th

The controlled release of such documentation to BLQS is the responsibility of the facility wishing to enter the BLQS GLP Compliance Programme. All documents will have complete check by GLP officer within 15 working days. The BLQS will terminate the application if the documents are not completed within 180 days after the date of submitting the application, where appropriate. Test facilities shall have at least **one completed study and one on-going study** that has been conducted in compliance with the OECD GLP principles.

4. Categories of Test Facility Inspection and Study Audit

4.1 Pre-inspection

Pre-inspections are carried out if the Test Facility has to be inspected for the first time. Pre-inspection will be conducted within 90 working days upon receiving completed application document. A pre-inspection is normally carried out within one day to familiarize the inspector team with the management structure, the physical layout of buildings, the documentation system and the ranges of studies of the test facility. The pre-inspection schedule will be informed to the test facility by letter at least 15 working days before date of inspection. Such documents shall provide information on:

- the type, size and layout of the test facility;
- the master schedule
- the management structure of the test facility including CVs, job description of key personnel
- at least one study plan/protocol for completed study

4.2 Full Inspection/Study Audit

The inspection process should be involved for both Test Facility Inspection and Study Audit. The procedure for carrying out all type of inspection and study audit according to *OECD No.3: The Revised Guidance for the Conduct of Laboratory Inspections and Study Audits.* Inspection and study audit of one or more on-going and at least one completed studies on a sampling basis should be conduct for at least 2-5 working days depending on number of studies conducted by test facility. The length of the inspection can be extended during the inspection with one or more days depending upon the size of the Test Facility and the number of study directors and GLP studies to be audited, or in case of unforeseen workload.

4.3 Extra Ordinary Inspection

The following are other circumstances that may require inspections as listed below but not limited to:

- **Follow up inspection**: If a Test Facility Inspection or Study Audit reveals deviations from the GLP Principles, the test facility will be required to correct deviations and provided written evidences to the BLQS GLP officer. The corrective action shall be submitted within 30 working days. The inspector may propose verification of corrective action on-site, when required. If the test facility cannot complete the corrective action on time, the BLQS shall decide to remove the facility from GLP Compliance Programme.
- conduct of inspection or study audits on the request of national or international authority: Specific Study Audits may also be requested by a foreign CMA or local/international Regulatory Authorities. Such requests may sometimes involve Test Facility Inspections. However, it is the responsibility of the Regulatory Authority or the foreign CMA to identify and justify the need of such Inspections and Study Audits.
- extension of new area of expertise
- significant changes in the test facility (e.g changes of address, relocation, renovation etc)
- others where necessary.

Note: Routine-inspection will be conducted at the first year after date of granted. The next inspection will be conducted every 2 years based on last granting date. Test facility shall apply for inspection at least 120 days before the expiry date. A full inspection will be carried out within 90 working days. ☞After the last granting date, the test facility shall have at least two new completed studies in every year.

☞ **4.4 Fees**

Registration attracts fees as follow:

Documentation Review Fee	
- Full inspection	Baht 10,000/ inspection
- Routine inspection	Baht 10,000/ inspection
- Extending scope	Baht 10,000/ inspection
Registration certificate fee	Baht 25,000/ application
Inspection Fee	
- Lead inspector	Baht 12,000/ application
- Inspector	Baht 9,000/ application
- Expert	Baht 6,000/ application
Annual fee	Baht 2,000/ year
Extra or replacement of registration certificate	Baht 2,000

5. Status of GLP Compliance

There will be two categories of compliance status given to test facilities namely;

(a) in compliance [ic] and

(b) not in compliance [nic]

The BLQS will issue a certificate with statement of GLP compliance to show the test facility has been inspected and found to be operating in compliance with Principles of GLP once inspection report completed.

6. Actions for registered Test Facility:

6.1 Keep on a management system in compliance with the OECD Principles of Good Laboratory Practice and BLQS's requirements at all time of registration.

6.2 Pays such fees as shall be determined by the BLQS. Failure to do so may result in the withdrawal of the registration.

6.3 Must not use the registration to imply approval by BLQS of any product or item from the Test Facility.

6.4 Must not make any statement about its registration to mislead the public.

6.5 Must not use the registration in such a way as to bring BLQS into disrepute.

6.6 If the registration is withdrawn, the Test Facility must immediately stop making reference to terms "GLP (compliant) facility/laboratory", "Registered facility/laboratory" or the like, and all advertising materials which contains the terms or refers to them.

6.7 If any change from the application forms which affect the performance of Test Facility occur, the BLQS shall be informed within 15 working days of the change in following contents:

6.7.1 Legal status or organization status and organization chart.
6.7.2 Loss of key GLP personnel, particularly the GLP management.
6.7.3 Changes in senior personnel duties and responsibilities (including change of Authorised Representative).
6.7.4 Significant changes in accommodation and/or equipments.
6.7.5 Policy and work procedures in the quality documents.
6.7.6 Others affecting that effect the competence of test facility due to the scope or registration conditions.

6.8 Collection and storage of all quality documents and study reports shall be archived as long as possible or where appropriate.

7. Withdrawal of the registration

The BLQS will withdraw the registration under the following circumstances.

7.1 The test facility is declared bankrupt from courts.

7.2 Functions of an organization do not fulfil GLP Compliant and/or the BLQS's requirements and conditions of the registration that have affected on the study results or the test facility service or the GLP Monitoring Units.

7.3 Test facility discontinues its functions.

7.4 Test facility could not complete a correction within a given time period.

7.5 An officially request by the test facility.

8. Use of the terms "GLP (compliant) facility/laboratory", "Registered facility, laboratory"

8.1 Test facility shall inform the BLQS of the term compliance statement exhibition.

8.2 The term compliance statement containing an endorsement form BLQS shall not be abused, misused, or misleading.

9. Miscellaneous

9.1 In case of any amendment or any change of the criteria of registration the BLQS shall inform registered test facilities. The registered Test Facilities shall commit to follow any changes in the criteria and shall adjust its procedures to meet the new requirements within the time frame.

9.2 The BLQS shall not take any responsibility of the test facility that is not conforming or not abided by the requirements of the BLQS.

9.3 The registered test facility names, typical product and area of expertise and registration number will be announced in the http://blqs.dmsc.moph.go.th.

9.4 Interested party shall submit the application to BLQS which located in the Ministry of Public Health, Nonthaburi.

☞ All information was derived from Manual for Thailand GLP Compliance Programme Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, Thailand, 5th Edition, Revision No.01 Dated issued 11 AUG 2021 which published on http://blqs.dmsc.moph.go.th

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88/7 Tiwanon rd, Nonthaburi, 11000, Thailand.
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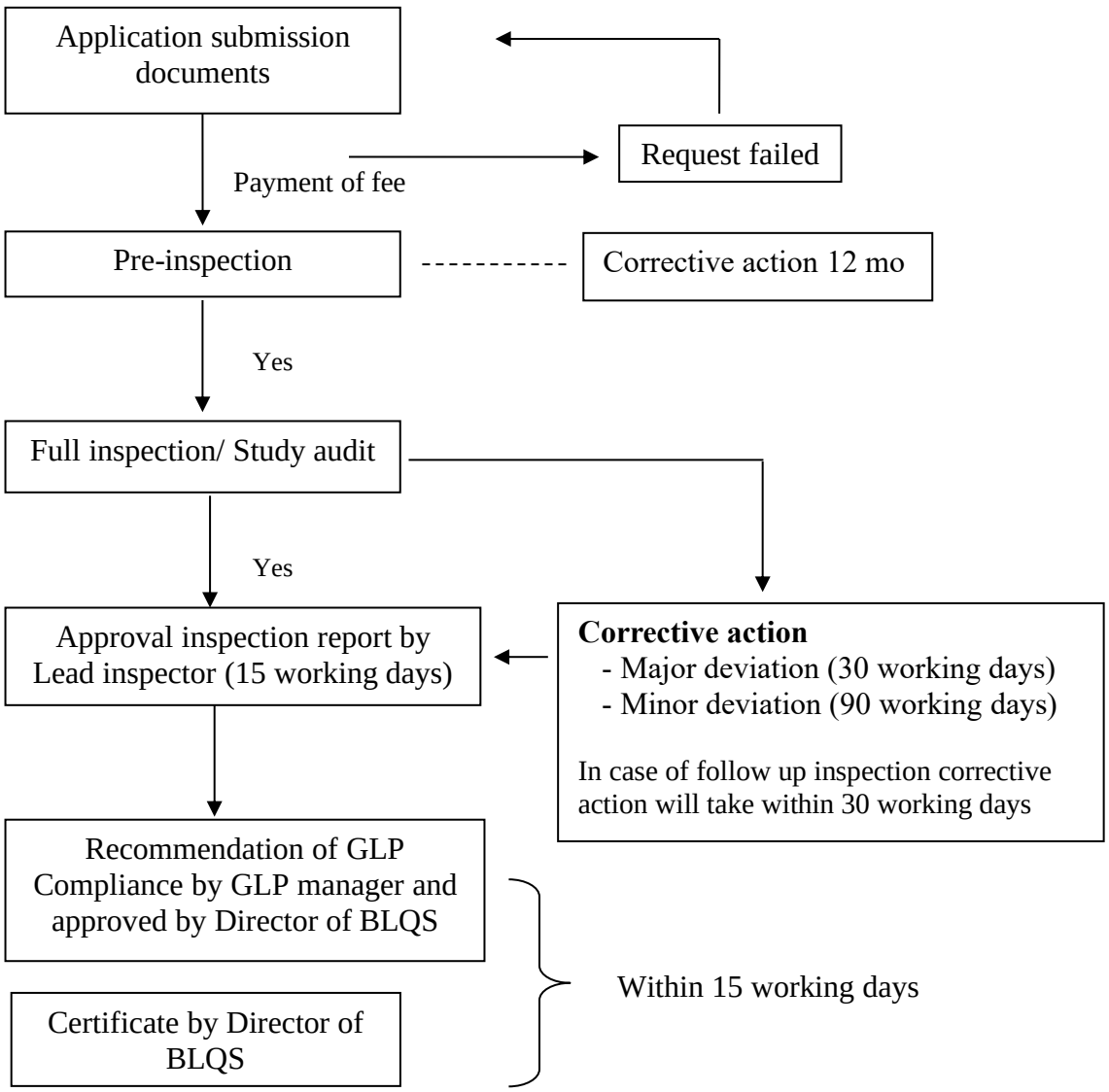
Registration Procedure Chart



Routine-inspection:

The 1st year after granting date for new applicant and then every two years subsequently.

Test facility shall apply for inspection at least 120 days before the expiry date. A full inspection will be carried out within 90 working days. ☞After the last granting date, the test facility shall have at least two new completed studies in every year.

Extra Ordinary Inspection

Extra ordinary inspection shall be carried out in situation as listed below but not limited to:

- Follow up inspection to verify corrective action
- On the request of national or international authority
- Extension of new area of expertise
- Significant changes in the test facility (e.g changes of address, relocation, renovation etc)
- Others where necessary.

Controlled copy list

Name	Position	Organization
1. Dr. Patravee Soisangwan	Director, High level	Bureau of Laboratory Quality Standards Department of Medical Sciences
2. Dr. Archawin Rojanawiwat	GLP manager	National Institute of Health of Thailand Department of Medical Sciences
3. Ms. Sarinee Lenapun	Head of OECD GLP Section	Bureau of Laboratory Quality Standards Department of Medical Sciences
4. Ms. Thunyarat Sooksomboon	Medical Scientist, Practitioner level and GLP officer	Bureau of Laboratory Quality Standards Department of Medical Sciences
5. Ms. Worranathsiri Kaewnaichit	Medical Scientist, Practitioner level and GLP officer	Bureau of Laboratory Quality Standards Department of Medical Sciences