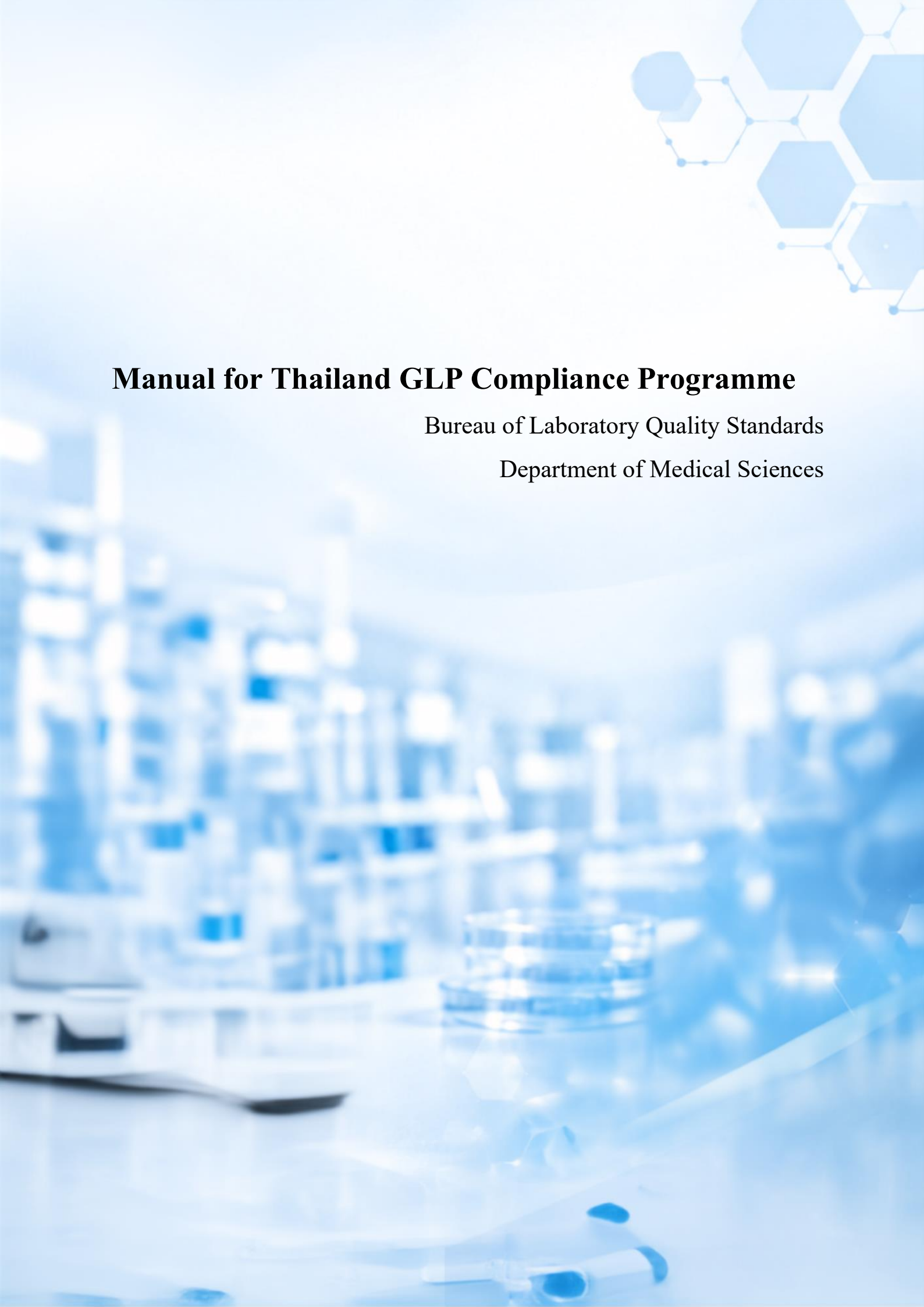
Manual for
Thailand GLP
Compliance Programme

Bureau of Laboratory Quality Standards
Department of Medical Sciences

กรมวิทยาศาสตร์การแพทย์
Department of Medical Sciences



Manual for Thailand GLP Compliance Programme

Bureau of Laboratory Quality Standards

Department of Medical Sciences

Manual for Thailand GLP Compliance Programme

Editor

Ms. Sarinee Lenapun

Ms. Thunyarat Sooksomboon

Mr. Wannaprach Ruengdet

Consultant

Mr. Surasak Muenphon

Publisher

Bureau of Laboratory Quality Standards

Department of Medical Sciences

Ministry of Public Health

Policy for GLP Monitoring Authority

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 to implement the following policy:

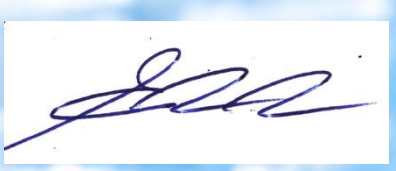
(a) Administer the GLP Compliance Programme (GLP CP) and register facilities that meet the OECD Principles of Good Laboratory Practice and the Thai legal and official requirements.

(b) Provide valuable resources to develop the capability of inspector and personnel support the organization.

(c) Cooperate with the Thai regulatory bodies such as FDA and others.

(d) Facilitate international liaison and the continuing exchange of information between GLP Monitoring Authority from other member countries.

(e) Work towards achieving the full membership of the OECD Mutual Acceptance of Data (MAD) in the assessment of chemicals.



(Mr. Surasak Muenphon)

Director

Bureau of Laboratory Quality Standards

Contents

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, DMSc has been appointed as the National OECD GLP Compliance Monitoring Authority (CMA) by the National Standardization Council (NSC) which is chaired by the Prime Minister (letter No. MOI 0714/31429) dated 29th August 2018. BLQS has been appointed by the Director General of the DMSc as the National OECD GLP CMA by letter no. 2703/2561 dated 6th September 2018.

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 and may comprise of 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 Non-clinical health and environmental safety study should be referred to OECD Test Guideline or other test guideline or other method.

2.4 The top management of the Test Facility or the authorized representative shall sign the application.

2.5 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 OECD GLP TF registration at all times. The authorized representative is expected to be present at staring and closing conference.

2.6 The application shall be submitted with the detail of the GLP management system and the implementation documents, which can fulfill the requirements of the BLQS CMA as mentioned in 3.2.

2.7 The test facilities shall comply with the registration procedure and shall pay fees as listed in Annex 1.

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

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

2.8.2 Prepare the evidences (e.g. SOPs, test items, references item, test system) during on-site inspection according to the request of the Inspectors, including hand-on analysis.

2.8.3 Provide the room for document reviews, meeting of Inspector team and other activities.

2.9 Test Facility Management is also reminded that legislation exists which controls the use of animals in experiments. Test Facilities should follow the up-to-date of Animal for Scientific Purpose Act.

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 categories of inspection of the GLP Compliance Programme includes pre-inspection, full inspection (facility inspection and study audit), and extra ordinary inspections. The procedure for carrying out all category of inspection and study audit should be performed according to *OECD No.3: The Revised Guidance for the Conduct of Laboratory Inspections and Study Audits.* The criteria described in the OECD Consensus and Advisory Documents shall also be taken into consideration during the test facility inspections and study audits (where appropriate).

The BLQS CMA will conduct routine inspection (full inspection) in the first year after granting date and subsequently every two years. The inspection process is demonstrated in the flow chart as in Annex 2.

The BLQS CMA shall maintain a Master Register containing the name of test facility, the date of inspection, scope, the area of studies/expertise, compliance status and remarks. The Master Register is prepared by designated personnel, reviewed by GLP Manager and approved by Director of BLQS.

3.2 Test Facility Registration Process

The National GLP Compliance Programme is voluntary. The 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 the Test Facility claiming compliance with GLP.

The Test Facility shall submit documents as follows:

1. Application form no.5 (F 07 15 025): Applications form for GLP compliance test facility.
2. Application form no.6 (F 07 15 026): Detail of specific information for GLP compliance test facility.
3. Application 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 other names.
15. Study plan and Final report.
16. List of personnel and Curriculum vitae.
17. OECD Test Guidelines or other test guideline or method.

Test Facility shall provide original documents no. 1 – 3, two hard copies and two removable drives containing documents no. 1 - 17. All documents must be properly sorted and labelled according to the *List of documents submit to BLQS for inspection (F 07 15 198)*. The documents 1 – 3 and *List of documents submit to BLQS for inspection (F 07 15 198)* can be downloaded from http://blqs.dmsc.moph.go.th. The controlled release of all documents is the responsibility of the Test Facility.

All documents will be completely checked by GLP officer using *WS 07 15 021/01: GLP application review* within 10 working days. GLP officer will inform the Test Facility if the documents are not completed and the Test Facility will have to submit additional documents as requested within 20 working days. The BLQS will terminate the application of the Test Facility if the request cannot be done. For the first entry to the programme, the Test Facility shall have at least **one completed study and one on-going study*** that has been conducted in compliance with the OECD GLP principles. GLP officer will assign test facility code number as described in *SOP 07 15 030: Assignment test facility registration and code number*. GLP officer will then

request the Test Facility to pay the fees. The registration fees are categorised as mentioned in Annex 1.

After payment, the BLQS will prepare an invitation letter to a lead inspector, inspector (s), and expert (s) where necessary, to conduct inspection. If the invitation is accepted, he/she will be requested to sign on *Consent of acceptance as inspectors Form (F 07 15 022)* and *Confidential, Financial and Conflict of Interest Statement Form (F 07 15 023)* will be delivered to the inspector team. Meanwhile, The BLQS will subsequently request acceptance of the proposed inspector team from the test facility via email or letter. If there is any objection, an official letter from the test facility should be summited to BLQS within 15 working days. A new inspector team will be assigned only when reasons are accepted by BLQS's director.

The BLQS will appoint the inspector team according to *SOP 07 15 024: Appointment of inspector.* GLP officer will discuss with the GLP manager on an inspection schedule. The final agenda *(F 07 15 082: Agenda and Notification of GLP pre-inspection/F 07 15 078: Agenda and Notification of GLP inspection*) will be delivered to the test facility at least 10 working days prior to the inspection date.

4. Category of Inspection

4.1 Pre-inspection

Pre-inspection is carried out when the Test Facility firstly registers to the programme. Pre-inspection will be conducted within 90 working days upon receiving completed application document including payment. The pre-inspection schedule *(F 07 15 082: Agenda and Notification of GLP pre-inspection)* will be officially informed to the test facility for at least 10 working days before inspection date. A pre-inspection is normally carried out within one day to assess the establishment of the OECD Principles of Good Laboratory Practice as well as policy, requirements and conditions of BLQS CMA in the test facility. The detail of Pre-inspection process is described in *SOP 07 15 027: Pre-inspection*. Prior to inspection date, the inspector team should have a meeting to review documents and plan for inspection.

At the starting conference, it is necessary that Test Facility Management (TFM) or Authorized Representative, Study Director, Archivist and QA staffs should be present during the pre-inspection, especially at starting and closing conference. All participants have to sign on the form: *F 07 15 051: Starting and closing conference for GLP inspection*. Lead inspector should describe the purpose and scope of the visit. The Lead inspector should also inform that the normal work could be slightly disturbed and additional documents and records may be requested during pre-inspection. TFM should be requested to make a presentation concerning the organisation and the activities of the test facility.

The inspector team should at least observe the environmental conditions, the identification and storage of apparatus, test systems, test and reference items and archives in order to familiarize facility management. The result of pre-inspection will be verbally given at the closing conference. The BLQS shall send the official pre-inspection report (*WS 07 15 027/01: GLP Pre-Inspection Report)* to test facility within 15 working days. Test facility should take appropriate actions and should summit to BLQS within 6 months after pre-inspection date. If not, the BLQS will consider to remove from the programme. The Test Facility can, however, reapply to the programme as a new registrant.

4.2 Full Inspection

The full inspection is involved for both facility inspection and study audit. The inspection should be conducted for at least 2 – 5 working days depending on number of studies conducted by test facility. The duration of the inspection can be extended during the inspection with one or more days depending upon the size of the Test Facility and the numbers of studies to be audited or unforeseen situations. All details of conducting test facility inspection and study audit were mentioned in *SOP 07 15 031: The conduct of test facility inspections and study audit.*

The inspector team consists of a lead inspector and inspector(s) or expert(s) (where necessary). The inspection agenda (*F 07 15 078: Agenda and Notification of GLP inspection*) will be officially informed to the test facility for at least 10 working days before inspection date. Prior to inspection date, the inspector team should have a meeting to select the studies for auditing. The numbers of the completed studies should be randomly selected depending on (1) If the test facility has less than eight completed studies, all studies will be audited (2) If the test facility has more than eight completed studies, at least eight studies will be randomly selected. The Test Facility should have at least one ongoing study to be audited for performance during full inspection.

At the starting conference, it is necessary that TFM or Authorized Representative, Study Director, Archivist and QA staffs should be present during the full inspection, especially at starting and closing conference. All participants have to sign on the form: *F 07 15 051: Starting and closing conference for GLP inspection*. Lead inspector should describe the purpose, confirm the scope and area of expertise for inspection, and identify the test facilities areas, study selected for audit, documents and personnel involve in inspection process. The Lead inspector should also inform that the normal work could be slightly disturbed and additional documents and records may be requested during full inspection. TFM should be requested to make a presentation concerning the organisation and the activities of the test facility. A meeting room for reviewing documents and other activities should be provided throughout the inspection. TFM should assign appropriate personnel to accompany the inspectors.

The facilities inspection should be conducted on the first day. During the full inspection, inspectors may interview TFM, QA, Study Director, Study Personnel and Archivist of the test facility. The inspection team will not be concerned with the scientific design of the study or the interpretation of the findings of the studies.

Any deviations and observations are found; each inspector should record in *F 07 15 034: Record of inspection*. The inspector team should discuss, summarize their findings and prepare a draft inspection report in *F 07 15 036: On-site Report of Inspection/Study Audit*. The findings are classified as follows *(Refer to OECD No. 2 Page 13 - classification of findings):*

- **Deviation,** the evidence which is not in compliance with the principles of GLP. The deficiency seriously influences the good functioning of the GLP quality system or the integrity of study data (Refer to 5 Approval of inspection)

- **Observation,** the evidence which does not have serious impact on the functioning of the GLP quality of the integrity of data.

The inspector should discuss their findings with representative of the test facility at a closing conference. If there is no objection on the findings, The test facility will be informed of the possible outcomes (a) In Compliance or (b) Not In Compliance. The on-site report (*F 07 15 036: On-site Report of Inspection/Study Audit*) will then be finalized and signed. The test facility

shall describe actions taken with evidences in regard to all deviations and observations using the signed on-site report form within the timeframe for deviation according to clause 5.

The inspection team will prepare a final report on inspection using *WS 07 15 023/01: Report on inspection of test facility* as described in *SOP 07 15 023*: *Preparation of inspection report* based on OECD document *No.9, Guidance for the Preparation of GLP Inspection Report, (1995)*. The final report should be completely done with sign and date by the inspector team within 15 working days after the corrective actions are satisfied.

Note:

1. Routine inspection is the full inspection of certified test facility to ensure and monitor its GLP compliance for certificate renewal. It will be conducted at the first year within validity of each TF and inspected every two years onward approximately on the last inspection date. Prior to the valid date, test facility shall apply for routine inspection at least 120 working days. The inspection will subsequently be conducted within 60 working days before the valid date.
2. The certified test facility shall have at least one new completed study in every area of expertise for each year.
3. In case of serious or major deviations from the GLP Principles are observed, the lead inspector can decide to stop the inspection earlier than planned and should report back to the CMA within 5 working days.

4.3 Extra Ordinary Inspection

The following are other circumstances that may require facility inspections and/or study audits as listed below but not limited to:

- **An extension of area of expertise:** Where an area of expertise is extended before the next round of routine inspection, the test facility may request to apply for full inspection.
- **A follow up inspection:** Where corrective actions taken by the test facility are not completely satisfied, the inspector may propose to on-site verification of those corrective actions.
- **A significant change:** Where relocation, major renovation, TF name changes or new TFM occurs in the facility, the test facility shall immediately address to BLQS CMA. The director of BLQS CMA will consider whether the full inspection is required.
- **A request from Regulatory Authority and/or Compliance Monitoring Authority:** Specific Study Audits may be requested by other CMAs or local Regulatory Authorities. Such requests may sometimes involve Test Facility Inspections.
- **Others** where necessary.

5. Approval of inspection

Findings that are not in compliance with the OECD Principles of GLP, BLQS GLP CP and Test Facility's procedure, the inspector team should classify as deviation or observation.

Deviation:

Deviation is defined as deviation from the GLP Principles, BLQS GLP CP and Test Facility's procedure that threatens the integrity of quality system and/or study data.

When deviation is observed appropriate corrective action shall be taken by the test facility within 45 working days from the date signed on the on-site report. If corrective action is not submitted within the timeframe, the GLP manager will make recommendation to Director of BLQS for consideration to remove the test facility from the programme.

If corrective action is submitted within the timeframe, the inspector team will review the corrective actions within 10 working days. When corrective actions of all deviations are satisfied, the inspector team will make the inspection report *(WS 07 15 023/01: Report on inspection of test facility)* and submit it, including the on-site report (*F 07 15 036: On-site Report of Inspection/Study Audit*), to the BLQS CMA within 15 working days.

The GLP manager will check all documents, prepare the recommendation *(WS 07 15 031: Recommendation for GLP registration by BLQS)* and submit to the Director of BLQS for final decision within 10 working days. For test facility found to be in compliance, the Director of BLQS will issue Certificate of Compliance to OECD GLP and a letter of Statement of Compliance *(F 07 15 083: Letter of Statement of Compliance)*.

Note: If the inspector team requests more evidences of corrective actions taken, the test facility should submit within 10 working days. Follow up inspection will be considered where corrective actions taken remain dissatisfied. If the follow up inspection is still not satisfied, then the GLP manager will be recommended to remove the test facility from the programme.

Where serious deviations are found, the action taken by BLQS CMA will depend upon the particular circumstances of each case and the legal or administrative provisions under which Thailand GLP Compliance Programme has been established. 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 validity of studies conducted in the test facility;

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

- Suspension of Test Facility Inspections or Study Audits of a test facility and, for example and where administratively possible, removal of the test facility from the Thailand GLP Compliance Programme or from any existing list or register of test facilities subject to GLP Test Facility Inspections;

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

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

Observation:

During the inspection, findings which are not recorded as not in compliance with the OECD Principles of GLP. The BLQS GLP CP and test facility's procedure, are raised as observation for the reasons as follows:

a) An area of concern but no effect(s) on validity and integrity of data.

b) An opportunity for test facility to consider possible improvement.

6. Status of GLP Compliance

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

(a) In Compliance with GLP (ic): No deficiency was identified and registration will be granted/continued following satisfactory provision of documented objective evidence for other deficiencies (if any).

(b) Not In Compliance with GLP (nic): The test facility is unable to meet the Principles of GLP and it is required that a follow-up inspection be conducted after it has addressed the deficiencies.

(c) Pending (pen): The test facility is under an appeal process.

7. Removal of test facility

The BLQS CMA may also remove test facilities from the National GLP Compliance Programme in the right of:

a) Failure to comply with National GLP Compliance Programme requirements as stated in this manual;

b) Failure to provide cooperation or facilities for BLQS, its inspectors and/or its authorized representatives to perform 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 facility 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.

Once the test facility is removed from the programme, the test facility can re-enter into the programme by submitting a new application. The BLQS will consider whether it is necessary to conduct pre-inspection or a full inspection can be conducted directly.

8. Withdrawal of the registration

The test facility will officially inform withdrawal the registration to BLQS CMA under the following circumstances.

8.1 The test facility is declared bankrupt from courts.

8.2 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.

8.3 Test facility discontinues its functions.

9. Appeals

The test facility has the right to file an appeal in writing to the Director General of DMSc under the categories below;

9.1 Registration decision: Problems or differences of opinion between inspectors and test facility management will normally be resolved during the inspection or at the exit meeting. However, where problems persist and agreement on differences cannot be reached during the inspection process, the test facility management may appeal the findings received from the GLP Inspector.

9.2 Removal of test facility: as described in clause 7.

10. Complaints on registration and inspection activities

Complaints from Test Facility is defined as expression (written, or by electronic media), of discontent or accusation addressed to the BLQS CMA. The discontent or accusation can be aimed at the BLQS staffs, inspectors or experts acting on behalf of the authority and which is relevant to performance or behavior of BLQS CMA service. The complaint is managed by GLP manager within 60 days. In case of the complicate one, more than 60 days may be needed. The complaints will be recorded on Complaint Log Form. The result of the complaint(s) will be reported to the complainant.

11. Actions for registered Test Facility

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

11.2 The test facility must promptly pay all fees, charges and expenses relating to the initial inspection, registration of facility and any subsequent activities by BLQS CMA regardless of the outcome of these activities. Any failure may result in the withdrawal of the registration.

11.3 The Test Facility must not use GLP - compliant status to imply approval of any products or substances by BLQS CMA.

11.4 The test facility must not make any statement about its GLP - compliant status to mislead the public as well as to bring BLQS CMA into disrepute.

11.5 The test facility must immediately stop making reference to terms "GLP – compliant facility" or "GLP - registered facility" on all advertising materials which contains the terms or refers to them when the test facility is withdrawn from National GLP Compliance Programme.

11.6 If loss of key personnel, particularly the Test Facility Management and the infrastructure of the test facility, or the areas of expertise conducted is significantly extended or changed, the test facility has the obligation to inform these changes to BLQS CMA within 15 working days.

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

12. Miscellaneous

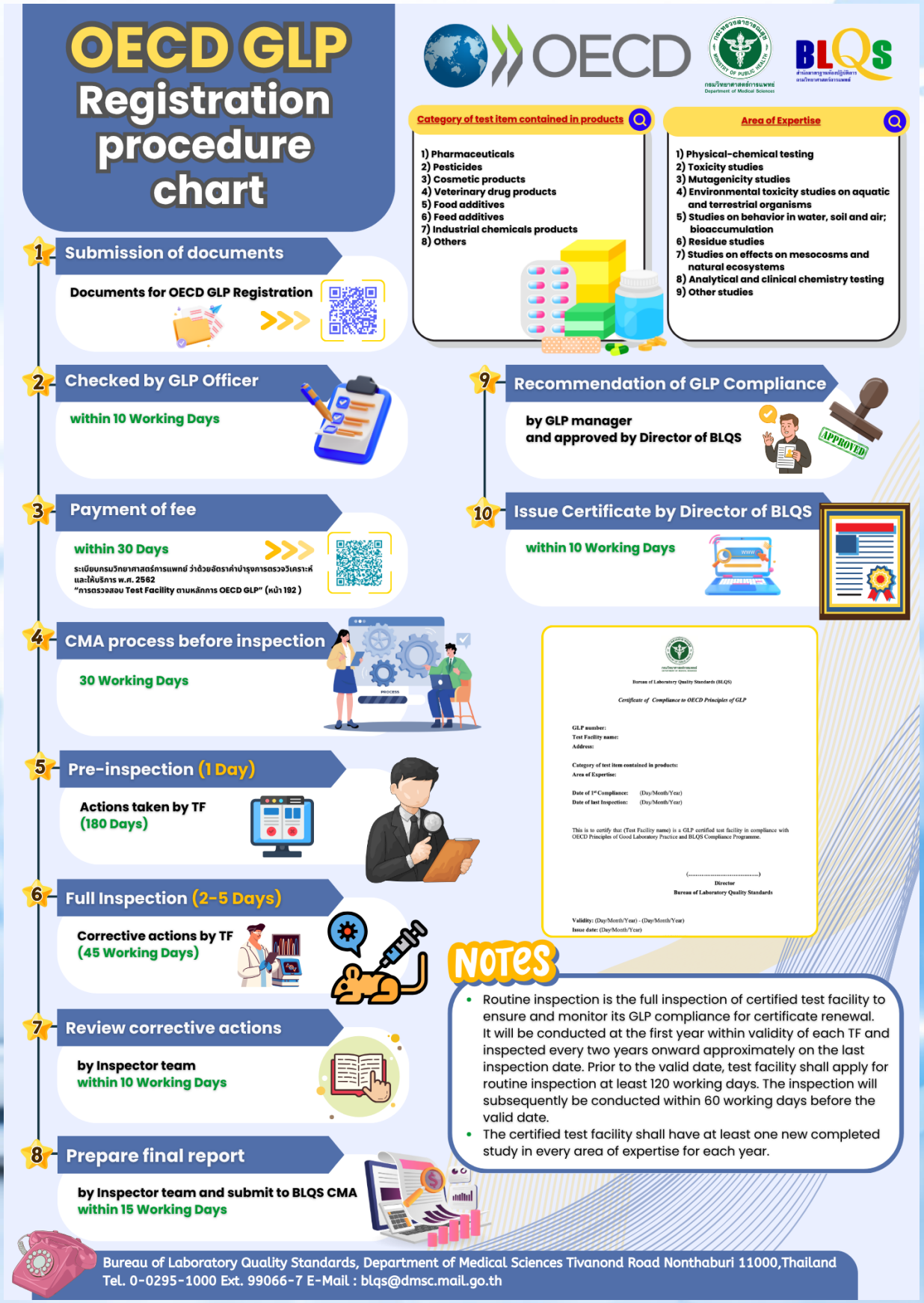
12.1 In case of any amendment or any change of the criteria of registration the BLQS CMA shall inform registered test facilities. The registered Test Facilities shall commit to follow any changes in the criteria and shall adjust its procedures to meet the new requirements within the time frame.

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

12.3 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., https://blqs.dmsc.moph.go.th/page-view/129

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

Annex 1: Registration Procedure Chart



Annex 2: Standard Form of a GLP Compliance statement

Bureau of Laboratory Quality Standards (BLQS)

Certificate of Compliance to OECD Principles of GLP

GLP number:

Test Facility name:

Address:

Category of test item contained in products:

Area of Expertise:

Date of 1st Compliance:

Date of last Inspection:

This is to certify that (Test Facility name) is a GLP certified test facility in compliance with OECD Principles of Good Laboratory Practice and BLQS Compliance Programme.

(……..……)

Director

Bureau of Laboratory Quality Standards

Validity:

Issued date: