Good Laboratory Practice (GLP) Compliance Programme

GLP01 - Procedures and Conditions for GLP Registration

GLP 01 – 18 April 2018
The GLP compliance Programme is managed by Enterprise Singapore

CONTENTS **Page**

1. Introduction

1.1 The GLP compliance programme was launched in November 2007. The programme aims to support research work in Singapore for generation of high quality and reliable test data related to the safety of chemical substances and preparations.

1.2 The GLP Compliance Programme is available to any facility undertaking non-clinical health and environmental safety studies. The Programme will support studies that are required by local or overseas regulations for the purpose of registering or licensing for use of pharmaceuticals, pesticides, food & feed additives, cosmetics, veterinary drug products, industrial chemicals and similar products.

1.3 Having peer-evaluated by an evaluation ream from the Organisation for Economic Cooperation and Development (OECD) in 2009 and demonstrated full adherent to the OECD requirements, Singapore became a full member of OECD Mutual Acceptance of Data (MAD) system in January 2010.

SECTION A : REGISTRATION PROCEDURES

2. Organisation Structure

2.1 Enterprise Singapore has been appointed by the Ministry of Trade and Industry as the national GLP Monitoring Authority (GLP MA).

2.2 As the GLP Monitoring Authority, Enterprise Singapore will administer the GLP Compliance Programme and register facilities that meet the OECD Principles of Good Laboratory Practice and represent Singapore internationally in OECD committees and working groups.

2.3 The Singapore Accreditation Council (SAC) has been appointed by Enterprise Singapore to administer the Singapore GLP Compliance Programme.

2.4 SAC has established a Council Committee for Good Laboratory Practice (CCGLP) comprising of various stakeholders such as regulator, industry association, tertiary and research institution, and GLP practitioner to provide guidance on the operation of the Programme.

2.5 SAC will maintain a pool of inspectors for inspection of facilities. They hold appropriate qualifications in various disciplines in science and technology, and are experienced in quality system operation and inspection. Where required, technical experts may be appointed to the team to assist with the inspection of facility's compliance with the GLP criteria. Technical experts are chosen for their expert knowledge and experience, and they may be drawn from the government laboratories, academic and research institutions, and industrial organisations in Singapore and overseas.

3 Operational Standards

3.1 The GLP Compliance Programme is administered in accordance with the relevant requirements of ISO/IEC 17011*: 2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies* and the following OECD Series of documents :

- **Number 2** : Guidance for GLP Monitoring Authorities – Revised Guidelines for Compliance Monitoring Procedures for Good Laboratory Practice (Monograph no. 110)
- **Number 3** : Guidance for GLP Monitoring Authorities – Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (Monographs 111)
- **Number 9** : Guidance for GLP Monitoring Authorities – Guidance for the Preparation of GLP Inspection Reports (Monograph No. 115)
- And any other documents published by OECD from time to time

3.2 Testing facilities registered as being GLP compliant are assessed directly against the requirements of the following OECD Environmental Health and Safety Publications from the Series on Principles of Good Laboratory Practice and Compliance Monitoring:

- **Number 1**: The OECD Principles of Good Laboratory Practice (1998)
- **Number 4**: GLP Consensus Document: Quality Assurance and GLP (1999)
- **Number 5:** GLP Consensus Document: Compliance of Laboratory Suppliers with GLP Principles (1999)
- **Number 6**: GLP Consensus Document: The Application of the GLP Principles to Field Studies(1999)
- **Number 7**: GLP Consensus Document: The Application of the GLP Principles to Short-Term Studies (1999)
- **Number 8**: GLP Consensus Document: The Role and Responsibilities of the Study Director in GLP Studies (1999)
- **Number 10**: GLP Consensus Document: The Application of the Principles of GLP to Computerised Systems (1995).
- **Number 13**: GLP Consensus Document : The Application of the OECD Principles to the Organisation and Management of Multi-site Studies (2002)
- **Number 14**: GLP Advisory Document : The Application of the Principles of GLP to In-vitro Studies (2004)

- **Number 15**: GLP Advisory Document : The Establishment and Control of Archives that operate in compliance with the Principles of GLP (2007)
- **Number 16**: GLP Advisory Document : GLP Requirements for Peer Review of Histopathology
- And any other documents published by OECD from time to time.

Document Number 1 is the primary criteria document against which all GLP compliant test facilities are inspected.

These publications are available at no charge at the OECD's World Wide Web site at: http://www.oecd.org/ehs

Alternatively they can be obtained from:

OECD Environment Directorate
Environmental Health and Safety Division
Andre-Pascal
75775 Paris Cedex 16
France
Fax : 33 1 4524 1675

4 Registration Process

4.1 Scope

4.1.1 The Singapore GLP Compliance Programme is voluntary. Any facility that wishes to conduct studies, for submission on behalf of their sponsors, on environmental safety studies that are in compliant with the requirements of OECD Principles of Good Laboratory Practice may apply. A facility may also apply on the request by a Receiving Authority either from Singapore or overseas.

4.1.2 Any facility interested to obtain registration as a GLP compliant facility is encouraged to study in detail the documents specified in clause 3.2. The facility is encouraged to have an ISO/IEC 17025 accreditation for the testing component associated with the GLP activities. This is, however, not mandatory.

4.1.3 The scope of application for the OECD Principles is restricted to non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs, food additives, feed additives and industrial chemicals. The testing of these items is for the purpose of obtaining data on their properties and/or safety with respect to human health and/or the environment.

4.1.4 These non-clinical health and environment safety studies are intended to be submitted to regulatory or receiving authorities for the purpose of registering

or licensing the pharmaceutical, pesticide, food or feed additive, cosmetic or veterinary drug product or for regulating the industrial chemical.

4.1.5 SAC will grant a GLP compliance registration only for the types of studies and for the purposes indicated in clause 4.1.3. Other types of trials on test items (such as clinical trials) related to non-safety testing (eg efficacy) are outside the scope of the Programme.

4.1.6 Once a test facility is satisfied that the OECD Principles of GLP are applicable to the scope of studies it conducts, and has documented its technical and quality systems to comply with the OECD Principles of Good Laboratory Practice and associated consensus documents, an application for registration can be made to SAC. A schematic overview of the registration procedure is shown in flowchart in Annex 1.

4.2 Application

4.2.1 All applications shall be made through SACiNet (online platform for accreditation process). All applications are to be supported with documents or other information necessary or requested by SAC from time to time for the assessment of the facility. Some of the important information required in the form include :

a. The type of non-clinical safety studies conducted at the facility for which GLP registration is sought. In accordance with OECD recommendations, these can be detailed under the following groupings :
   i. Physical- Chemical Testing
   ii. Toxicity Studies
   iii. Mutagenicity Studies
   iv. Environmental Toxicity Studies on Aquatic and Terrestrial Organisms
   v. Studies on Behaviour in Water, Soil and Air, Bioaccumulation
   vi. Residue Studies
   vii. Studies on the Effects of Mesocosms and Natural Ecosystems
   viii. Analytical and Clinical Chemistry Testing
   ix. Other Studies

   In addition, further detail on the scope of capability within these groupings for which the facility is seeking GLP compliance should be submitted to the Secretariat.

b. Key technical staff within the organisation such as CEO, Test Facility Management), Quality Assurance Personnel, Study Directors/ Principal Investigators, Pathologist, Veterinarian, Section Managers, etc

c. Key standard operating procedures (SOPs) providing the framework for the GLP quality system.

d. Information on the physical facilities for which GLP compliance is sought, including any remote test sites

e. A copy of the master schedule of studies.

4.2.2 Once an application is received, a Lead Inspector will be appointed for the facility. This Inspector will review the SOPs against the OECD Principles of Good Laboratory Practice to confirm the readiness for an initial inspection. A document review report will be issued to the facility identifying any gaps so that the facility can rectify the discrepancies. A suitable date will be arranged for the on-site inspection.

4.3 Preliminary Inspection

4.3.1 The facility may request for an advisory visit (prior to a formal initial inspection) by a SAC Staff officer to review the existing systems and procedures. The objective of the visit is to advise on the readiness for the initial inspection and also on any aspects of the GLP quality system that need further development. A man-day charge is levied for such visit. Information on the various inspection fees can be found in the GLP Fee Schedule.

4.4 Management Representative

4.4.1 Each applicant and registered facility is required to nominate a senior staff member to represent it in all dealings with SAC. This person will be the point of contact between SAC and the facility and is known as the Management Representative. All correspondences and invoices will be addressed to the Management Representative.

4.4.2 The Management Representative may be a senior technical or managerial staff who holds an appropriate position in the organisation with the authority to ensure their facility complies with the criteria for registration at all times. The facility is obliged to inform SAC immediately whenever there is a change of responsibilities or resignation of the Management Representative. The Management Representative is expected to be present at entry and exit meetings for the GLP inspection.

4.5 Documentation Review

4.5.1 Before initial inspection and routine inspection of the facility, the facility's SOPs and supporting documents making up the framework of the GLP system will be reviewed to ensure compliance with the OECD Principles of Good Laboratory Practice and applicable consensus and advisory documents.

4.6 Inspection Procedure

4.6.1 The facility should approach a GLP inspection as an opportunity for professional, technical and quality management information exchange. The inspection is not to find fault, but rather to evaluate the system and to provide

helpful, constructive comment and suggestions to enable the facility to maintain an effective GLP system.

4.6.2 The inspection is a fact-finding exercise undertaken by SAC inspector(s), and where necessary, by one or more technical experts. Where technical experts are appointed, they are acting on behalf of SAC for the GLP Programme and do not represent any other organisation with which they may be associated.

4.6.3 The facility has a right to veto once the use of any particular inspector or technical expert proposed for the inspection provided there are valid reasons such as conflict of interest.

4.6.4 The objective of inspection is to confirm that the facility is implementing what it has documented in its SOPs and that its system is in accordance with the OECD Principles of Good Laboratory Practice. For an inspection to take place, the prospective facility shall have completed at least one study that has been conducted in compliance with the Principles. During the on-site visit, the inspector(s) will focus on the operation of the GLP system. Information gathered will include, but is not limited to, review of records, discussions with management and key GLP personnel, and observation of relevant activities. A significant element of the inspection will involve study audits - of studies in progress and/or completed studies from the archive.

4.6.5 The time to conduct an on-site inspection will depend on the size of the facility, the number of test sites and the scope of registration. It may range from 1 to 5 days.

4.6.6 The on-site inspection starts with an entry meeting between the SAC inspector(s) and senior / key staff of the facility. The entry meeting provides an opportunity for:

- introductions between the key GLP personnel and the inspection team
- confirmation of the scope of inspection (considering both studies conducted and test sites) and the timetable for inspection.
- clarification of any queries that the inspector(s) or staff may have.

4.6.7 The facility will be asked to provide appropriate guide(s)/ escort(s) for each phase of the inspection. These escorts should be senior staff of the organisation who have sufficient authority to ensure the inspector(s) have access to all documents, personnel and activities they may wish to see.

4.7 Classification of Deficiencies

4.7.1 Observations made during the inspection will be recorded on a checklist. These will include observations of compliance as well as any deficiencies.

4.7.2 Following the information gathering, the inspector(s) will meet in private to review their notes and summarise their findings.

4.7.3 The on-site inspection will end with an exit meeting where the facility representatives are given a summary report including any deficiencies that have been found. All findings will be fully discussed with the facility representatives before the departure of the team.

4.7.4 Within seven working days of the visit, a written report on the inspection findings will be sent to the facility. The findings will be placed into four categories:-

a. **Critical deficiency** - A *critical* deficiency is one which seriously threatens the credibility of the Singapore GLP Compliance Programme. It includes gross lack of technical competence, persistent violation of Procedures and Conditions, regulations, gross lack of commitment of the organisation to quality or compliance with OECD GLP Principles and existence of serious doubt on the integrity and impartiality of the organisation. A management system breakdown, as indicated by a series of *significant deficiences* which seriously threaten the quality of all activities under the system, warrants a *critical* deficiency.

Note:
Gross lack of competence may arise from lack of competent staff for critical activities, inappropriate environment for critical activities, lack of critical equipment, lack of critical traceability, totally invalid raw data test, calibration or inspection method, total breakdown of the record or documentation system, lack of or totally ineffective quality assurance procedures or other causes.

b. **Significant deficiency** - A *significant* deficiency has serious adverse effect on the validity of an activity, its results or the competence of the organisation or a violation of SAC Procedures & Conditions for registration.

The existence of a serious doubt on the technical validity of an activity or its raw data, reported studies, as indicated by a series of related *minor* deficiencies is a *significant* deficiency. Furthermore, persistence of a *minor* deficiency for an extended period of time and without any plausible explanation may be a violation of SAC Procedures & Conditions for registration, warrants is a *significant* deficiency.

c. **Minor deficiency** - A *minor* deficiency has no serious adverse effect on the validity of the activity, its results or the competence of the organisation.

Note:
Minor deficiencies have a tendency to grow into significant deficiencies if not addressed appropriately at the time.

d. **Observation** - An inspection finding that does not warrant non-conformity but is identified by the inspection team as an opportunity for improvement.

4.7.5 The test facility will be informed at the Exit Meeting of the possible outcomes. These outcomes may be :

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

b. **Pending** – A partial compliance with GLP with some significant deficiencies noted. These deficiencies do not affect the validity of the studies, however clearance of these deficiencies is required. An on-site inspection by a SAC staff may be conducted to verify for effective implementation. The charges for such follow-up visit are based on the rate in the GLP Fee Schedule.

c. **Not in Compliance with GLP** - The test facility is unable to meet the Principles of Good Laboratory Practice and it is required that a full re-inspection be conducted after it has addressed the deficiencies.

4.7.6 The lead inspector will monitor the progress of the test facility in carrying out the required corrective actions. Once satisfied that all conditions for registration have been met, a recommendation for registration will be made. A Certificate of Registration will be issued to the applicant facility. In addition, the name of the test facility together with details of its scope of GLP compliance will be posted in the SAC website for the Programme.

4.7.7 For an existing registered facility, an inspection team may find some deficiencies from time to time (in study audits or GLP compliance of the facility) that are classified as “significant”. From the time the deficiency is cited till satisfactory corrective actions, the registration status of the facility will be denoted as “Pending”.

4.8 Scope of Registration

4.8.1 In addition to the Certificate of Registration, a Schedule will be issued, which detailed the scope or types of non-clinical safety studies for which GLP compliance can be claimed under the Programme.

4.8.2 This scope will be presented under the classification detailed in clause 4.2.1 above, but will include further details to describe the types of studies that the facility is properly equipped and sufficiently experienced to conduct.

4.9 Surveillance Inspection

4.9.1 Once the test facility is registered, it will be subjected to surveillance inspection. The surveillance programme is designed to ensure that the GLP systems continues to meet the criteria for registration and continues to work effectively. SAC reserves the right, however, to undertake additional inspection at any time to investigate complaints of any nature.

4.9.2 At the first anniversary of the initial on-site inspection, a routine study audit will be conducted on-site by inspector(s). In order to ensure that the GLP systems are operating effectively, SAC considers a routine study audit as necessary. The scope of a routine study audit is normally to follow up on the findings of the initial inspection and to conduct one or more study audits on completed studies from the archive or studies in progress. Some other elements of the GLP system may be examined at these visits, particularly if there are changes in personnel or in other key areas.

4.9.3 At the second anniversary of the initial on-site inspection, and every two years thereafter, a full inspection will be carried out. The full inspections are similar in scope, duration and procedures to the initial inspection.

4.9.4 For both the routine study audit and full inspections, the reporting procedures are similar to those at initial inspections. Once the facility is registered, there is a limit on the time required to carry out any corrective actions. Once compliance has been demonstrated within the agreed time, SAC will continue registration of the facility.

4.9.5 A registered facility can submit a written request for a change in the scope of registration to the SAC at any time. If the request to extend the range or types of studies that the facility can undertake does not coincide with the scheduled inspection visit, SAC will have to carry out a special inspection to confirm compliance with the OECD Principles for these types of studies. Such an inspection will be chargeable.

4.9.6 If the routine study audits, full inspections or any special inspections conducted reveal that the test facility's systems no longer meet SAC's criteria for registration or the GLP Principles, or if the organisation refuses to carry out requested corrective actions either at all, or in the specified time, then registration may be suspended or withdrawn.

4.10 Special Inspection Activities

4.10.1 In addition to the circumstance indicated in clause 4.9.5 where the test facility can request a special inspection at any time to consider an extension to its scope of registration, the following are other circumstances that may require additional special inspections :

a. The facility has had a physical change in accommodation that necessitates an on-site inspection to verify registration criteria are being maintained.

b. Information is brought to SAC's attention which strongly suggests the registered facility is no longer operating in compliance with the GLP Principles.

c. Following a formal request from a regulatory or receiving authority either in Singapore or from another OECD country. Such requests to SAC would normally arise from a particular study conducted or to be

conducted at the facility, and which are intended to or have been submitted to the requesting authority. The scope of such inspection would likely be restricted to an audit of the particular study in question.

d. SAC has been requested to conduct an inspection of a particular test facility or test site by another GLP compliance monitoring authority. This would normally apply to multi-site studies where the main test facility is overseas, with a particular test site in Singapore

SECTION B: RIGHTS AND DUTIES OF APPLICANT & REGISTERED FACILITIES

5 Conditions for Registration

5.1 Duties of Applicant and Registered Facilities

5.1.1 The facility must have a written quality management system that states how the facility meets all of the requirements of the OECD Principles of Good Laboratory Practice, applicable consensus and advisory documents and applicable registration criteria. The quality system of the facility must operate in the way it is documented.

5.1.2 The facility must allow inspector(s) and observers reasonable access to the premises, facilities, resources, operations, procedures, records and staff so that the inspector(s) can effectively assess the GLP systems and activities.

5.1.3 The facility must agree to allow inspector(s) the right to take samples, inspect records and produce copies and photographs on site, if it is necessary for reasons of perpetuation of evidence.

5.1.4 The facility must promptly pay all fees, charges and expenses relating to the initial inspection, registration of facility and any subsequent activities by SAC regardless of the outcome of these activities. Failure to do so may result in suspension or withdrawal of the registration, and a requirement for any future fees to be paid in advance. The prevailing rates are detailed in the GLP Fee Schedule. SAC reserves the right to change the fees as and when necessary.

5.1.5 The facility must maintain impartiality and integrity in its dealings with clients and all interested parties involved in the registered activity.

5.1.6 The facility may claim to be a registered GLP compliant facility (or make reference to the registration in any advertising or communication medium) only for work covered by the scope of study types which the facility has been registered by SAC and only if that work has been carried out in accordance with the SAC criteria. The facility must not make any statement about its registration that SAC considers misleading or which is not authorised. The facility must not use the registration in such a way as to bring SAC into disrepute.

5.1.7 The facility must not use the registration to imply approval by SAC of any

product or item the facility has tested.

5.1.8 The facility must ensure that the study reports are issued (or parts of them) are not used in a way that could mislead sponsors or others.

5.1.9 The facility must notify SAC promptly of changes in the facility's status or operations such as:

- loss of key GLP personnel, particularly the GLP management
- changes in senior personnel duties and responsibilities (including change of Management Representative)
- significant changes in accommodation and/or equipment
- changes in legal, commercial or organisational status
- changes in policies and procedures.

5.1.10 The facility must not vary the technical operations or facilities covered in the scope of registration during the period between inspections, unless notice has been given in writing and a confirmation in writing have been made that such changes do not invalid a registration.

5.1.11 The facility must conduct at least one completed study within two inspection cycle. The reference to GLP compliant study in any study final report shall adhere strictly to the terms stated in clause 5.1.1.

5.1.12 The registration may be withdrawn either by the facility or by SAC. The 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. The Certificates of Registration and Schedules must be returned to SAC or destroyed.

5.1.13 If the facility is temporarily unable to meet the registration conditions, SAC may request the facility to stop making any reference to SAC registration. The facility may also be asked not to claim compliance with the criteria for registration until SAC is satisfied that the facility is meeting the conditions, or pending the result of any appeal made by the facility.

5.1.14 If the facility fails to comply with such a request, SAC may:

- suspend registration, or
- withdraw registration, or
- decline to continue or extend the scope of registration, or
- reduce the scope of registration.

Such decisions and the grounds for them will be communicated to the facility in writing.

5.1.15 The facility's compliance with these decisions will be reviewed at a non routine inspection.

5.1.16 SAC may withdraw or decline to grant or continue registration if the facility

becomes bankrupt or makes any arrangements with its creditors, or enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purpose of reconstruction), or has a receiver appointed, or is sold or is taken over. Such decisions and the grounds for them will be communicated to the facility in writing. In addition, SAC may require the facility to stop displaying the registration certificate during this period and to refrain from any reference to itself as registered under the GLP Compliance Programme.

5.1.17 The facility whose registration that has been terminated may re-apply after one year from the anniversary date as stated on the letter of termination. The registration process follows clause 4.6 of this document.

5.2 Rights of Applicant and Registered Facilities

5.2.1 Application under the GLP Compliance Programme is open to all organisations that come within the scope detailed in Clause 4.8 above, regardless of size or professional affiliations.

5.2.2 SAC will confine its requirements, inspections and registration decisions to the scope of registration requested.

5.2.3 The application will normally be acknowledged within 1 working day of receipt and a tax invoice for the application fee paid will be provided.

5.2.4 An estimate of time required, fees and expenses (where relevant) for inspection activity will be provided.

5.2.5 A report with the results of each inspection will be sent to the facility within 7 working days from the completion of the on-site inspection.

5.2.6 Upon the granting of registration, SAC will issue facility with a Certificate of Registration and will include registration details of the facility in the website.

5.2.7 SAC will notify the facility of any changes in the criteria for registration and give the facility reasonable time to adjust its procedures to meet the new requirements.

5.2.8 Registration is continued once a facility is registered in the Programme. A series of inspections comprising surveillances will be conducted annually.

5.2.9 A facility has the right to veto any proposed inspector or technical expert whom the facility considers may have a conflict of interest when conducting the inspection.

5.2.10 Complaints or appeals can be made to SAC.

5.2.11 The facility must allow inspector(s) and observers reasonable access to the premises, facilities, resources, operations, procedures, records and staff so that the inspector(s) can effectively assess the GLP systems and activities.

5.3 Confidentiality

5.3.1 SAC requires its inspectors, staff and technical experts to abide by a code of ethics, professional standards and confidentiality. They agree in writing to keep information about the facility confidential and to declare any conflicts of interest.

5.3.2 All inspectors, observers (such as members of Mutual Joint Visit teams from OECD), committee members and members of SAC Staff sign undertakings of confidentiality and independence. For inspectors and technical experts, an additional undertaking has to be signed prior to the initial appointment as inspectors.

5.3.3 All applications will be treated as confidential until the facility is registered.

5.3.4 From time to time, SAC may be asked to submit reports of inspections or study audits to regulatory authorities. In addition, compliance statements or summaries of inspections or reports of study audits may be made by SAC to the requesting authority. SAC will evaluate such request and if it has been determined that there is a need, the request will be acceded. In such cases, the facility's consent for the issuance of the inspection report to external authorities will be sought.

6. Appeals and Complaints

6.1 Appeals and complaints fall into three categories:

- appeals on registration decisions
- complaints on registered facilities
- complaints on registration and inspection activities.

6.2 Appeals and complaints are to send to SAC in writing.

6.3 Appeals on Registration Decisions

6.3.1 An appeal may be made about a registration activity, such as:

- suspension of registration or part of the registration scope
- withdrawal of registration.

6.3.2 For disagreements related to inspector procedure, decision or activities, the facility should attempt to resolve any technical issues with the Lead Inspector.

6.3.3 For formal appeal on registration decisions, it should be made in writing and should be send to the Director of Accreditation. An appropriate person will be appointed by the Director to investigate it. The Director, in consultation with the SAC Chair will appoint an independent appeal committee to look into the appeal. The appeal will consider whether:

- current SAC policies and procedures have been properly followed
- current SAC policies and procedures are adequate and appropriate
- registration decisions have been soundly based on objective evidence.

6.3.4 An Appeal Committee will set up as in accordance with SAC 01 Terms and Conditions document. The relevant section of the SAC 01 Terms and Conditions is attached in Annex 2.

6.3.5 The decision of the appeal and the proposed actions if any, will be sent to the facility.

6.4 Complaints on Registered Facilities

6.4.1 Registered facilities are responsible for the quality of their own services. They should deal appropriately through their own complaint procedures for complaints from customers or public.

6.4.2 When a formal complaint about a registered facility is received, the Director of Accreditation will appoint an appropriate person to investigate it. If the complaint is not relating to the compliance to GLP Principles, SAC will facilitate the complainant and the registered facility to negotiate a satisfactory outcome. However, if the complaint relates to the compliance of the facility to the GLP Principles, SAC will investigate the legitimacy of the complaint and conduct an on-site inspection, if required.

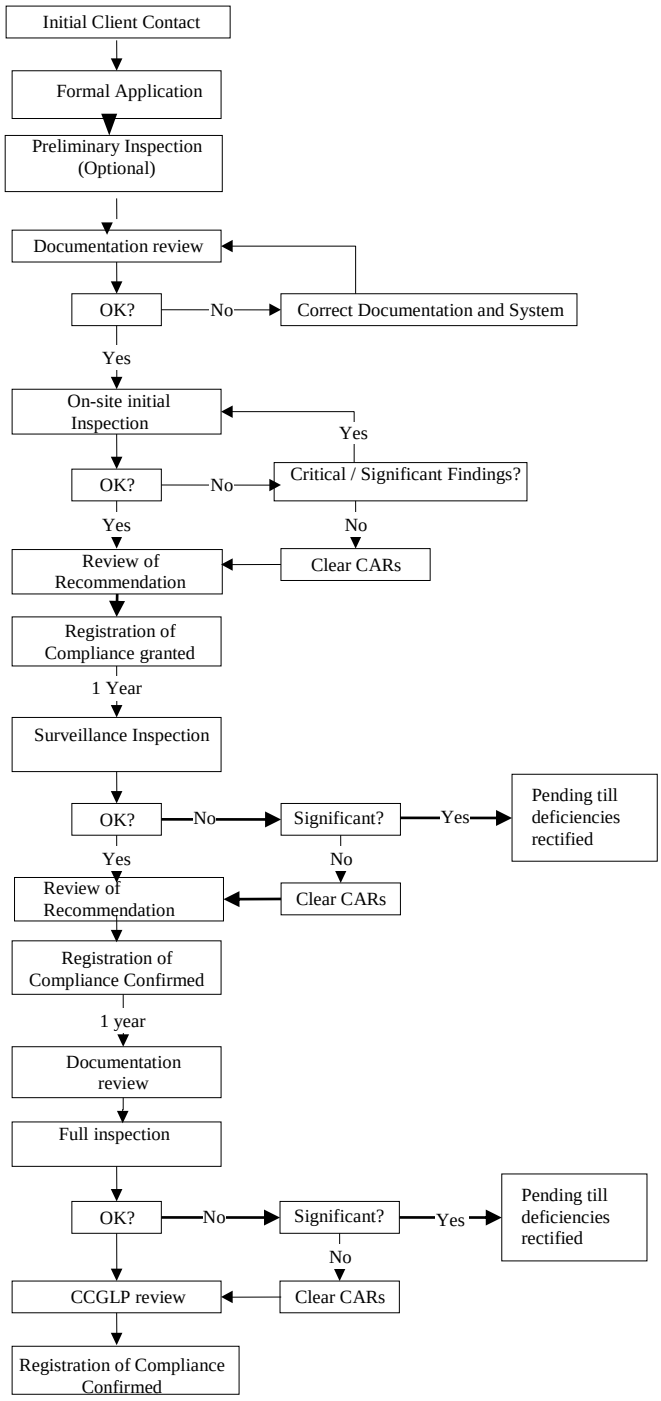
6.4.3 The results of SAC investigations, and the proposed actions if any, will be feedback to the registered facility and to the complainant accordingly.

6.5 Complaints on Registration Activities

6.5.1 Any complaints about the performance of SAC services or staff or inspectors will be investigated by the Deputy Director (GLP) or an appropriate person appointed by the Director of Accreditation in accordance to the SAC complaints procedure. The facility will be advised of the result of the investigation and of corrective action taken.

Annex 1

Registration Procedure Chart



Annex 2

Appeal Procedures (as stated in SAC 01 Terms and Conditions)

1. Appeals made in writing against any decision for refusal or withdrawal of accreditation or any disputes concerning the interpretation of criteria must be made no later than one month from the date of refusal, withdrawal or disputes. Such appeal, which shall be submitted to Director, will be considered by the Council acting on the advice of an Appeal Committee. The Committee appointed in respect of each appeal shall consist of a Chairman and at least two members of the Council or Council Committee, none of which shall have any direct commercial interest in the subject of appeal. The Committee may co-opt technical experts as and when required.

2. The decision of the Appeal Committee shall be final and shall not be called into question or subject to review or appeal by any court of law.