SCC

Good Laboratory Practice (GLP) Recognition Program

Program Overview

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Standards Council of Canada

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Good Laboratory Practice Recognition Program (GLP): Program Overview

The Standards Council of Canada (SCC) administers the Organization for Economic Co-operation and Development (OECD) initiative in Canada and is the only monitoring authority in Canada that grants OECD Good Laboratory Practices (GLP) recognition.

OECD GLP principles cover virtually all management aspects of non-clinical health and environmental safety studies, from planning experiments to archiving and reporting results. These principles apply to work done in laboratories, greenhouses and in the field.

Compliance with the OECD GLP principles helps ensure that non-clinical studies follow internationally accepted requirements. These studies are then more easily recognized by other OECD member countries.

1. Recognition Program Requirements

REQUIREMENTS
• OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring - OECD.

2. Program Scope

The Organization for Economic Co-operation and Development (OECD) Principles of Good Laboratory Practice (GLP) is a quality system covering the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived, and reported. Non-clinical health and environmental safety studies covered by the principles of GLP include work conducted in the laboratory, in greenhouses and in the field.

A 1989 OECD Council Decision-Recommendation [C(89)87(Final)] established that OECD Member countries, in which testing of chemicals for purposes of assessment related to the protection of human health and the environment being conducted pursuant to the principles of GLP, shall establish national procedures for monitoring compliance with GLP Principles, based upon facility inspections and study audits. To this end, in 1995, the SCC was established as a GLP Compliance Monitoring Authority (GLP MA) recognized by the OECD and functioning in accordance with the OECD document Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice.

Canadian Receiving Authorities have recognized SCC as the GLP MA of facilities submitting human health and environmental safety studies.

A comprehensive list of studies requiring compliance to the Principles of GLP is available from the respective receiving authorities. A 1981 OECD council decision [C(81)30(Final)] was made that data generated in an OECD Member country in accordance with the OECD Principles of GLP shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of human health and the environment; that is, the Mutual Acceptance of Data (MAD). SCC GLP MA in-compliance recognition of domestic test facilities and test sites (including field sites) involved in pre-market non-clinical human health and environmental safety studies on pesticide/biocide products, industrial chemicals, disinfectant efficacy studies, veterinary medical products, medical devices, tobacco products and pharmaceuticals meets the requirements of the OECD Decision on MAD, and facilitates acceptance of Canadian GLP studies submitted to receiving authorities in other OECD member countries.

This document describes SCC's policies and procedures in its role as the GLP MA with respect to granting GLP recognition. The GLP MA activities focus primarily on inspections and study audits of domestic facilities but can extend to foreign markets provided that they are not OECD member countries or full adherents. Facilities conducting other non-regulated GLP studies can apply for GLP compliance recognition and be inspected by SCC. SCC functions in accordance with the Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (No.2).

3. Personnel and Training

SCC maintains a roster of qualified GLP inspectors with practical experience. Inspectors are obtained from government Departments/Agencies or from contractors from the private sector. In all instances, SCC has in place conflict of interest protocols that will ensure the independence of the inspectors from the GLP facility, audited studies, and corresponding study sponsors.

SCC inspectors have no powers of access to facilities or study data; however, once on-site inspectors are tasked with conducting inspections, study audits, interviewing staff, and taking samples or documents as evidence of non-compliance. Any facility that refuses such access or does not permit copying of evidence will be declared Not-in-Compliance and will be removed from the program.

4. Inspection Cycle

Facilities are subject to a routine full inspection on a 2-year cycle with biennial inspections due on the anniversary date of the facility's first inspection date.

For organizations with multiple field sites in different geographical locations, initial GLP recognition is based on inspection of the headquarters site and typically at least one remote site provided that all such sites are functioning under the same management and operational procedures. Subsequent routine inspections are conducted in a manner that would permit a rotation through those sites yet to be inspected and in a manner whereby all the field test sites are seen over a four-year period.

Field sites will be inspected during the months which permit the inspection of all aspects of the field site. This includes the inspection of the actual field(s) where the crop will be planted and the inspection of field site equipment such as that used for the application of pesticides in the field. In the Canadian climate, this will typically mean that field site inspections cannot occur during the winter months or when weather is such that it would not allow the inspection of all aspects related to a field site.

5. Monitoring Authority Operation

The GLP MA operation is consistent with the *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (No.2)* with the recognition of GLP compliance based upon facility inspections and study audits conducted as per the *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (No.3)*.

5.1 Application

I.5.1.1 A facility applies to the GLP MA (SCC) for recognition by submitting the following:

a) A completed application form;
b) Facility information as described in the application form; and
c) The appropriate non-refundable application fee according to the current Fee Structure.

I.5.1.2 An SCC Account Manager is assigned to the file and acknowledges receipt of the application.

5.2 Pre-inspection Activities

I.5.2.1 The application and supporting documentation are reviewed by a qualified inspector and additional information is requested, if required. A standard list of materials will be requested to be provided prior to routine re-inspections for those already in the GLP monitoring program.
I.5.2.2 When the submitted documentation is deemed complete, a team of inspectors is assembled, and a mutually acceptable date is arranged for an inspection. The facility may object to the selection of the inspector(s) but must provide written rationale. SCC will review the rationale and determine if a change is required.

I.5.2.3 A facility is given appropriate advance notice of any impending inspection or specific study audit.

5.3 Facility Inspections and Study Audits

I.5.3.1 Inspections to assess GLP compliance fall into the following categories:

a) an initial full inspection, including a facility inspection and study audit(s) for facilities which have previously conducted GLP studies;
b) a facility-only inspection for facilities which have not conducted GLP studies. In this case, an inspection is performed to determine that the necessary infrastructure is in place (facilities, equipment, staff, SOPs, archives, etc.) to permit the facility to

successfully conduct GLP compliant studies. Once a complete study is available, it is subsequently audited to fully complete the recognition process.
A facility only inspection can also be performed for facilities that have already successfully completed a full inspection but have not performed a GLP study since the last inspection. Back-to-back facility only inspections are not permitted;

c) an extraordinary inspection to verify that identified GLP non-compliances from a previous inspection have been suitably addressed.
An extraordinary inspection can also be performed when an organization moves, has significant renovations/changes to the facility or when a facility wishes to increase their areas of expertise;
d) a regularly scheduled biennial full inspection targeted to be completed within 3-months of the anniversary date of compliance recognition; or
e) specific study audits requested by national or international receiving authorities.

I.5.3.2 Inspection costs are borne by the recipient facility. Costs associated with I.5.3.1 e are covered internally by the GLP MA unless it is performed as part of a regularly scheduled routine reinspection.

I.5.3.3 Inspection findings are discussed with facility representatives during a Closing Meeting in accordance with the *Revised Guidance for the Conduct of Test Facility Inspections and Study Audits (No. 3)*. During this meeting, a written findings report outlining all non-compliances (where applicable) is presented to the facility representatives. The report is then signed and dated by the inspector(s) and facility representative.

I.5.3.4 Following inspection and within ten (10) days, the facility may appeal any findings in the inspectors' report with which it disagrees.

I.5.3.5 In response to a request for a specific study audit, as per I.5.3.1 (e), SCC and the facility schedule a time agreeable to both parties to conduct the study audit. SCC provides the requesting authority with a detailed report which provides a summary of the activity and an outline of findings if applicable.

I.5.3.6 Onsite inspections are the preferred method of monitoring however remote inspections can be performed when deemed acceptable by SCC (for example, if it is not considered safe for the inspection team to travel to the facility).

5.4 Post-inspection Activities

I.5.4.1 Upon completion of all required actions, the inspector(s) review the facility's response and provided evidence of compliance to the GLP inspection findings. Depending upon the nature of the GLP non-compliances, an extraordinary inspection might be needed to verify that actions have been implemented as per clause I.5.3.1 (c).

If the inspector(s) cannot close the findings and does not believe that an extraordinary inspection will provide confidence in the data quality and integrity for the work that was done since the last inspection the facility may be deemed as not in compliance (not in compliance can

be for the whole facility or limited to specific studies), may be suspended and/or may be removed from the monitoring program.

I.5.4.2 The Lead Inspector provides a recommendation; the file is then assigned to an independent, qualified reviewer. If the independent reviewer cannot make a positive recommendation, the facility will be advised of further actions required for compliance. The facility may then either take appropriate action, terminate its application, withdraw from the monitoring program or appeal the GLP MA's decision.

5.5 Granting or Continuing Recognition of GLP Compliance

I.5.5.1 Continued recognition is based upon the results of regularly scheduled biennial full routine inspections (or as stated above for field sites).

I.5.5.2 SCC's Vice-President of Accreditation Services or their delegate grants a facility Recognition of GLP Compliance or continued in-compliance status.

I.5.5.3 If a facility is found as being not in compliance the facility is advised of the reason(s). The facility and may appeal the decision, following the procedures established by SCC for this purpose. For those facilities that are part of the GLP monitoring program when given a facility not in compliance decision, their GLP recognition is suspended until such time that a full re-inspection or extraordinary inspection are performed, and the facility is deemed as complying. Payment of a reinstatement fee is also required to remove the suspension. Facilities may reapply to the GLP monitoring program as needed.

I.5.5.4 GLP compliance is recognized by issuing formal documentation to compliant facilities: a certificate and formal letter granting recognition or continued recognition of GLP compliance. Applicant facilities inspected for facility-only are issued a letter acknowledging that the necessary infrastructure is in place (facilities, equipment, staff, SOPs, archives, etc.) to permit the facility to successfully conduct GLP compliant studies.

Additionally, a list of GLP compliant facilities, their dates of compliance and their areas of expertise is maintained on the SCC website.

I.5.5.5 A recognized GLP facility must continue to comply with the requirements and conditions of the OECD Principles on GLP and to cooperate with SCC in its performance as a GLP MA verifying such compliance. Specifically, the facility shall:

a) allow SCC to carry out routine inspections, typically conducted at approximately two-year intervals, to support continued compliance;
b) allow SCC to carry out specific study audits at the request of national or international receiving authorities; and
c) report immediately, to SCC, any change that could affect its GLP compliant status. This includes, but is not limited to, changes in studies conducted, personnel (particularly management, QA and Study Directors) or facility infrastructure.

5.6 Actions Resulting from GLP Noncompliance

I.5.6.1 Where only minor non-compliances have been found, such that the integrity of studies will not be compromised, SCC may grant or continue to grant GLP compliance (as per clause I.5.7.2) or, as appropriate, provide the Receiving Authority (RA) which requested a specific study audit with a detailed report of the findings.

I.5.6.2 Where major non-compliances are found, the action taken by the GLP MA is dependent upon the circumstances of each case. Actions may include:

a) requesting an extraordinary inspection to follow up on issues identified;
b) requesting that the facility amend the study final report(s) to indicate that it was not run in compliance with the OECD Principles on GLP;
c) suspending, refusing to grant or continue to grant recognition of GLP compliance.

Such action may include the removal of the facility from the program, a corresponding notation in the GLP MA list of inspected facilities described in clause I.5.8, notification to the applicable receiving authorities, and to the OECD secretariat.

5.7 Facility GLP Compliance Status

I.5.7.1 OECD GLP MAs must report facility compliance to each other. The status can be listed as: In-compliance; Pending; or Not-in-compliance. Being declared **"Not-in-compliance"** can have significant consequences to a facility as most receiving authorities throughout the world would reject submissions. SCC will use the category Not-in-compliance where required.

I.5.7.2 If a facility inspection or study audit identifies GLP non-compliances which will not significantly compromise the integrity of studies an in-compliance status is generally provided. After the inspection, the facility is given up to 90 days to resolve the findings. During this time and up until the final decision is made the facility is given a "Pending" status. Once a positive final decision is made the status is changed to "in compliance".

I.5.7.3 Each occasion where major deficiencies are noted are treated on a case-by-case approach. The criteria used to apply a not-in-compliance status:

- Major deviations from GLP requirements that have a negative impact on the quality or integrity of the raw data/report.
- Systemic non-compliances.
- Lack of appropriately trained qualified and experienced personnel in critical positions.
- Continuing non-compliance seen on consecutive inspections.
- Facility's inability to provide adequate evidence of conformity to close inspection findings within the prescribed period.

I.5.7.4 A facility that does not adhere to the requirements of clause I.5.5.5 shall be subject to a Not-in-compliance status and shall be withdrawn from the program.

5.8 Reporting Facility GLP Compliance

SCC, as the GLP MA maintains a list of inspected facilities including the identification of the facility, dates of inspection, nature of the inspection, area(s) of expertise and compliance status. The list is reported annually to all OECD member counties and full adherents, the European Commission, the OECD secretariat, and applicable domestic receiving authorities. The GLP MA immediately informs all parties of all changes to a facility's GLP compliance status.

6. GLP Recognition Publicity Guidelines

The following statement is recommended for use as a publicity statement by a recognised GLP facility:

"GLP compliance has been recognized by formal documentation issued on Yr/Mo/Day by the Standards Council of Canada, GLP Monitoring Authority based upon an inspection and study audits conducted Yr/Mo/Day - Yr/Mo/Day in the area(s) of [type of study(ies)]."

Should a facility request to be removed from the SCC GLP program, or should a facility be withdrawn by SCC from the SCC GLP monitoring program, the facility must immediately cease issuing all reference to its former GLP compliant status. Upon reinstatement a facility may resume such publicity.

Revision History

VERSION	DESCRIPTION OF CHANGE(S)	APPROVED DATE
1	• Initial Release • Separating program-specific content out of the ASB Program Overview • International recognition • Removed specific OECD requirements and referenced OECD Series	2024-03-26