

Swedac GLP Compliance Programme

Good Laboratory Practice Standards

The purpose of performing GLP inspection is to evaluate the degree of conformity of test facility and studies with OECD Principles of GLP as well as the integrity of the data to assure that the resulting data are of adequate quality for assessment and decision making by regulators.

The general regulations (STAFS 2008:4) of the Swedish Board for Accreditation and Conformity Assessment (Swedac) apply for the OECD Good Laboratory Practice (GLP) Compliance Monitoring Programme for facilities conducting non-clinical health and environmental safety studies on for example; industrial chemicals including pesticides and biocides, pharmaceuticals, veterinary medicines, food and feed additives and cosmetic products. These general regulations for GLP are adapted to national conditions and harmonised with the OECD Principles of GLP as expressed in current editions of the OECD series on principles of GLP and Compliance Monitoring.

GLP Compliance Statement

In their reports, the test facility shall for each non-clinical safety study declare that the study in question has been performed according to the OECD Principles of GLP. Also, in study reports it shall be clearly stated when a laboratory study, or part of it, has not been performed in compliance with the OECD Principles of GLP. Any deviations from the OECD Principles of GLP shall be specified.

The Inspection Programme

Swedac is appointed as the inspecting GLP authority in Sweden by the ministry of Foreign affairs, regulation implementing the OECD principles of Good Laboratory Practice (Förordning (1991:93) om införande av OECD:s principer om god laboratoriesed).

The European legal framework is described in EU directives 2004/9/EG and 2004/10/EG. Swedac shall monitor compliance with Swedac's GLP rules (STAFS 2008:4). Such monitoring will be performed during Laboratory Inspections and Study Audits.

The procedures employed by Swedac for monitoring GLP compliance are based on OECD recommendations.

How to be included in the Inspection Programme

All Swedish facilities that perform non-clinical safety studies can apply at Swedac to be included in the GLP Inspection Programme.

Frequency of inspections

Regular Inspections are performed at all test facilities included in the GLP Inspection Programme approximately every second year. If it is necessary follow-up inspections could be performed with shorter time intervals.

Directed Inspections/Study Audits may be performed at the request by a Regulatory Authority e. g. prompted by a query arising from the submission of data to a Regulatory Authority. Requests on an inspection/study audit can also be made from a Monitoring Authority from another Member country in the case of Multi-site Studies.

Confidentiality

Confidentiality regulations and professional secrecy according to the Official Secrets Act (Offentlighets- och sekretesslag 2009:400) are applied to persons executing supervisory control.

Non-compliance

Non-compliance with Swedac's GLP rules may result in removal of test facilities from the GLP Inspection Programme and rejection by Swedac of documentation from individual laboratory studies, of all reports from an individual test laboratory or in rejection of an application.

Inspection and Study Audit Procedures

The Inspection Programme established by Swedac for monitoring GLP compliance of test facilities inside the country permits assessment of current laboratory operations as well as audit of data from ongoing and completed studies.

- Inspections and/or Study Audits may be either regular or directed/ requested.
- The test facility to be inspected should usually be notified in advance of the scheduled visit.
- Before the inspections and/or Study Audits the inspector should become familiar with any existing information (e. g. previous inspection reports, study reports etc.) relevant to the subject.

The Inspector shall briefly discuss the purpose and the nature of the visit with the authorised representatives of the test facility and shall request access to any relevant documents, or other information, that are required to complete the Inspection and/or Study Audit.

The management of the test facility is responsible for keeping all raw data, material etc. from laboratory studies accessible to Swedac and shall on request supply samples, copies of documents or other material relevant to the samples and considered necessary for execution of the supervision.

A complete facility inspection and study audit is performed according to the OECD Principles of GLP and shall cover the following specific items:

Item 1 Organisation and Personnel

Purpose: To check that the test facility organisation complies with Swedac's GLP rules (STAFS 2008:4) and to determine whether the laboratory has an adequate number of qualified personnel.

Item 2 Quality Assurance Function

Purpose: To assess the mechanism by which the test facility management is assured that the GLP studies are conducted in accordance with Swedac's GLP rules (STAFS 2008:4).

Item 3 Facilities

Purpose: To determine whether the facilities are suitable for the studies to be conducted in accordance with Swedac's GLP rules (STAFS 2008:4).

Item 4 Apparatus, Materials and Reagents

Purpose: To assess whether the test facility has suitably located and properly functioning apparatus with a sufficient and adequate capacity; and to check that it is maintained and operated in a manner meeting the requirements of the tests conducted. To check that materials and reagents are properly labelled, used and stored, and that the materials used do not interfere with the test system.

Item 5 Test System

Purpose: To check that the test system (animals, plants, microbes, cellular conditions, subcellular conditions, chemical conditions or physical conditions) is adequately accommodated and controlled. In cases where the test system includes animals, adequate animal care and housing to minimise the risk of uncontrolled influences that could interfere with the results of the study is checked.

Item 6 Test and Reference Items

Purpose: To check procedures designed to ensure that the identity, quantity and composition of test and reference items administered to the test systems are known and are in accordance with the Study Plan and amendments to it.

Item 7 Operating Procedures

Purpose: To check that the test laboratory has written Standard Operating Procedures (SOPs) that are relevant to the studies conducted.

Item 8 Performance of a Study

Purpose: To check that written Study Plans and the studies are performed in conformance with the Study Plans and in compliance with Swedac's GLP rules (STAFS 2008:4).

Item 9 Reporting of Study Results

Purpose: To assess whether the Study Report has been prepared in accordance with Swedac's GLP rules (STAFS 2008:4) and to assess the consistency between raw data and the Study Report.

Item 10 Storage and Retention of Records

Purpose: To check that proper provision is made for storage and retention of records and materials.

Results of an inspection

Inspections and Study Audits are concluded with a consultation with the responsible persons of the test facility concerning the deviations from OECD Principles of GLP found, if any, and results in a written report.

The names of the laboratories subject to Laboratory Inspections within the GLP Inspection Programme, their GLP-status (in compliance, pending or not in compliance) and the date(s) when the inspections were conducted are kept in a record and annually reported to the European Commission and to the secretariat of OECD.

Finally Swedac issues a Statement of GLP-Compliance to the laboratories that are found to conform to the requirements. The statement is only a verification of what is annually reported to the European Commission and the GLP Authorities in the OECD member countries, and only confirms that the facility was in compliance with OECD GLP principles at the time of inspection.



Besöksadress: Österlånggatan 9, 503 31 Borås
Postadress: Box 878, 501 15 Borås



0771-99 09 00



registrator@swedac.se



www.swedac.se