



Good Laboratory Practice (GLP) Compliance Programme

GLP 02 - Fee Schedule for the Registration of GLP Facilities

GLP 02 – 11 October 2019

The GLP compliance Programme is managed by Enterprise Singapore

© All rights reserved

1. Fee Structure

1.1 The fee structure of the GLP programme comprises the following:

- a. Application Fee
- b. Preliminary Inspection Fee
- c. Document Review Fee
- d. Field Inspection Fee
- e. Facility Inspection Fee
- f. Verification / Non-Routine Inspection Fee
- g. Surveillance Inspection Fee
- h. Technical Expertise Fee
- i. Annual Fee

1.2 The different categories of fees listed are explained in the following paragraphs. All fees (except the application and annual fees) are charged based on the inspection of the facility per man-day.

2. Application Fee

2.1 The facility applying for GLP Registration shall pay an application fee of \$1,000. The fee is payable to the Enterprise Singapore upon submission of application form for registration to the SAC Secretariat. The application fee is non-refundable. The application fee will cover the cost of processing the application. The application fee will lapse after one year. If the facility fails to achieve GLP registration during this period, the facility is required to re-apply.

3. Preliminary Inspection Fee

3.1 Upon receipt of the application form and related documents from the facility, the Secretariat will conduct a preliminary inspection if it is requested by the facility. The provision of technical expertise is decided by the Secretariat in consultation with the facility. This inspection is optional and it will cover document review and on-site inspection. A \$1,000 per man-day rate will apply.

4. Document Review Fee

4.1 Submission of documentation for GLP Registration involves provision of information (as a minimum) on the facility's management, operation, quality manual, standard operating procedures, quality assurance manual, facility layout, study plan, data and study audits records. A \$1,000 per man-day rate will apply.

5. Field Inspection Fee

5.1 Where much of the data is derived from the field studies, a visit by the inspector to field will be made. A man-day rate of \$1,000 for the inspection will apply. In addition, the facility is expected to cover the travel, accommodation and other related costs in traveling to the field.

6. Facility Inspection Fee

- 6.1 The facility will be quoted for the facility inspection fee that is computed based on per man-day that is required to complete the inspection for its intended scope of registration. After the initial GLP registration has been granted, surveillance inspection will be conducted annually to ensure GLP compliance has been maintained. A man-day rate of \$1,000 for the inspection will apply.

7. Verification / Non Routine Inspection Fee

- 7.1 Where verification visits are conducted, the fee is \$1,000 per man-day. Non Routine visits are performed as and when required. This may be due to changes in key personnel within the facility, changes in scope of registration, major changes to the operating and/or quality system etc. Other instances include possible study audits by special request from regulatory authorities of member countries of OECD requirements or suspected fraud or collusion in the facility considered.

8. Surveillance Inspection Fee

- 8.1 After the initial inspection has been carried out, surveillance inspections may be conducted at the completion of the whole study. In other instances, study audits are conducted yearly to ensure continuing compliance. A man-day rate of \$1,000 applies.

9. Technical Expertise Fee

- 9.1 Technical Expertise will be called upon by the SAC Secretariat to provide advice to ensure that specific requirements and good practices are adhered to by the facility. The Lead Inspector will seek the agreement from the facility prior to bringing in this expertise. A man-day rate of \$1,000 applies.

10. Annual Fee

- 10.1 A fee of \$3,000 is charged annually for the Certificate of Registration. For issue of duplicate copy of the Certificate, an administrative charge of \$200 will be levied.

11. Cancellation Policy

- 11.1 The Council may make a charge of up to 10% of the value of the fee in respect of visits which are cancelled other than by the Council, at short notices (less than 7 working days).

12. Revision of Fees

- 12.1 The SAC reserves the right to review the above fees as and when necessary.

13. Goods and Services Tax (GST)

13.1 All fees are in Singapore dollars and are subject to GST.

14. Payment Terms

14.1 All payment terms are 30 days from the date of the invoice. SAC reserves the right to withdraw credit, (for example in cases of bad credit or payment history) in which payment is required in advance of any assessment work being undertaken.

14.2 All fees up to and including initial inspection and any associated supplementary fees must be paid before registration is granted.

Summary of Fee Structure

Fee Schedule	S\$ (per man-day rate)
Application Fee	1,000
Inspection Fee (Preliminary Inspection, Document Review, Field Inspection, Facility Inspection, Surveillance Inspection, Verification Inspection, Non-routine Inspection)	1,000 (per inspector/ technical expert day)
Annual Fee	3,000
Typical GLP Registration Cost (inclusive of Application, 1 day documentation review, 1 day facility inspection with 1 officer, and annual fee)	6,000