



Good Laboratory Practice (GLP) Compliance Programme

Fee Schedule for the Registration of GLP Facilities

GLP Fee structure

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

3. Application Fee

- 3.1 The facility applying for GLP Registration shall pay an application fee of \$ 1000 (excluding GST). The fee is payable to the Standards, Productivity and Innovation Board upon submission of application form for registration to the GLP Secretariat. The application fee is non-refundable. The application fee will cover the cost of processing the application. The application fee shall lapse after one year. If the facility fails to achieve GLP registration during this period, the facility is required to re-apply.

4. Preliminary Inspection Fee

- 4.1 Upon receipt of the application form and related documents from the facility, the Secretariat will conduct a preliminary inspection if it is the request from the facility to do so. This visit is optional. For facilities that have opted for a preliminary inspection, the visit covers one day of document review and another day of on-site inspection. The preliminary inspection fee is \$ 3000, if no technical expertise is involved. If technical expertise is necessary and / or on-site inspection needs more than one day, there will be additional fee of \$ 1500 per man-day or \$ 750 per half man-day. The provision of technical expertise is decided by the Secretariat in consultation with the facility.

5. Document Review Fee

- 5.1 Submission of documentation for submission 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. As a

minimum, a one-day document review will be conducted by the inspector prior to the site visit. A \$ 1,500 per man-day rate will apply.

6. Field Inspection Fee

Where much of the data is derived from the field studies, a visit by the inspector to field will be made. The facility is expected to cover the travel, accommodation and other related costs in traveling to the field. The typical man-day rates for the inspection, \$ 1500 per man-day will apply.

7. Facility Inspection Fee

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, the facility will be visited annually to ensure GLP compliance has been maintained.

8. Verification / Non Routine Inspection Fee

8.1 Where verification visits are conducted, the fee is \$ 1500 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.

9. Surveillance Inspection Fee

9.1 After the initial inspection has been carried, surveillance inspections may be conducted at the completion of the whole study. In other instances, study audits are conducted at the anniversary month yearly to ensure continuing compliance. A typical man-day rate of \$ 1500 applies.

10. Technical Expertise Fee

10.1 Technical Expertise will be called upon by the GLP 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 typical man-day rate of \$ 1,500 applies.

11. Annual Certificate Fee

11.1 A fee of \$ 1500 is charged annually for the Certificate of Registration. For issue of duplicate copies of the Certificate, an administrative charge of \$ 500 will be levied initially.

Fee Schedule	
Application Fee	1000
Fee Component	S\$ (per man-day rate)
Preliminary Inspection Fee	3000
Documentation Review Fee	1500
Field Inspection Fee	1500
Facility Inspection Fee	1500
Verification Inspection Fee	1500
Non Routine Inspection Fee	1500
Surveillance Inspection Fee	1500
Technical Expertise Fee	1500
Annual Certificate Fee	1500
Typical GLP Registration Cost (inclusive of Application, 1 day documentation review, 1 day facility inspection with 1 officer, and annual certificate fee)	5500