GOOD MANUFACTURING PRACTICES PRODUCT CERTIFICATION SCHEME

GMP Logo

GUIDELINES FOR APPLICANTS

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The Good Manufacturing Practices Certification Scheme is open to all manufacturing and service organizations operating in Sri Lanka and other parts of the world. This document delineates steps involved in the Good Manufacturing Practices Certification.

1. Application for Certification

1.1. Application

Applicants who produce similar products or provide similar services in different manufacturing/service units shall submit, one application detailing out the manufacturing/ service units.

Applicants who produce similar products or provide similar services in different manufacturing/service units, each with its own autonomous management shall submit separate applications in respect of each manufacturing/ service units.

1.2 Documented information

Documented information requested by the SLSI in the Application shall be submitted along with the Application.

2. Initial Audit

2.1. Stage-I Audit

This provides the opportunity for auditors to confirm the scope of certification. This visit also enables the auditors to assess the Good Manufacturing Practices System in totality including the degree of implementation and to determine the readiness for the stage-II audit. A report on stage-I audit shall be submitted to the client.

If the Team Leader of the audit team recommended the GMP certification to be granted to the organization, the certification will be granted based on the satisfactory evidences of the corrective actions taken to the stage I audit findings and this audit will be considered as the certification granting audit.

2.2. Stage-II Audit

The stage-II audit is arranged only; the applicant confirms their readiness for the stage-II audit.

Prior to the stage-II audit the audit plan and the list of members in the audit team will be sent to the applicant and approval is obtained. The applicant is given the freedom to raise objections to the audit schedule as well as to the inclusion of any member in the audit team.

Once the applicant has confirmed in writing that he is satisfied with the audit plan and the audit team, the SLSI will carry out the stage-II audit. Upon completion of the audit, SLSI will submit a detailed report covering nonconformities with reference to the requirements of the relevant GMP standard and the applicant's Good Manufacturing Practices documentation.

3. Nonconformity

Major Nonconformity

Failure to fulfil one or more requirements of the GMP Standard and/or other related requirements of the GMP certification scheme, which will affect seriously for system breakdown/product safety and quality.

Minor Nonconformity

An isolated incident of a failure to fulfil one or more requirements of the relevant GMP Standard and/or other related requirements of the Good Manufacturing Practices certification scheme.

4. Corrective Action and follow up audit

The applicant in response to the nonconformities highlighted in the audit report submits proposals for corrective action to all nonconformities found in the GMP System. Depending on the nature and the degree of the nonconformities some will be completed with an agreed time frame. After the implementation of corrective actions, the applicant will be requested to confirm that the agreed corrective actions are fully implemented. On receipt of confirmation SLSI will verify the corrective actions by a documentation review or follow up audit as appropriate. Considering the nature of the nonconformity *(either it is major or minor)*, audit team leader shall decide whether it is necessary to carry out a follow up audit to verify the effectiveness of the corrective action(s) taken. (The certificate will be issued for a period of one year, two years or three years based on the certification fee paid by the client).

5. Award of Certificate

On completion of a satisfactory stage-I or Stage II audit the System Certification Division of SLSI will submit the audit report to DDG/Team Leader for approval of granting certification. Upon approval by the DDG/Team Leader the applicant will receive a Good Manufacturing Practices certificate of conformity valid for three consecutive years subject to compliance with the following conditions.

a) Good Manufacturing Practices System

The SLSI shall be informed of any changes to the system, and consulted before any significant changes to the system are made during the validity period of the certificate.

b) Surveillance Audits

The holder of the certificate shall agree with the SLSI on a surveillance audit schedule. These audits are usually conducted once in twelve months interval. The auditors' findings at these audits shall also end up with the implementation of agreed corrective actions. The scope of the periodic audits is predetermined and usually covers a defined part of the GMP System and however precautions will be taken to ensure that the entire system is audited at least once during the period of validity of the certificate.

c) Special Audit

SLSI does not intend to make surprise visits to the premises of a certificate holder but reserves the right to do so with short notice in response to complaints or adverse information received.

If the holder of the certificate informs SLSI of a significant change in the certified GMP System, this may require and special audit. Details of which will be agreed between the holder and the SLSI. Fees for these audits will be charged at the prevailing rate for scheduled periodic audits.

d) Conditions for Use of the Good Manufacturing Practices Certification Marks

A certified organization shall use the GMP Certificate and the GMP certification Mark(s) for all purposes as specified in the "*Conditions for use of the Good Manufacturing Practices Certification Mark*".

e) Costs

The following fees are chargeable for GMP certification by the SLSI. The amounts chargeable are given separately in the GMP Certification Scheme - fee schedule.

- **Application processing fee**

  This includes the fee for processing of the Application.

- **Initial audit fee**

  This includes the charges with respect to the following

  - Stage-I audit
  - Stage-II audit

- **Annual fee**

  This includes charges for annual surveillance audits. This includes the certification fee charged annually.

- **Recertification audit fee**

  This includes the charges for recertification audit. Stage-I audit fee will be charged if the stage-I audit is carried out.

- **Additional fee**
  This includes charges for special/additional audits.

- **Sampling and testing fee**

  This includes charges for sampling and testing of product samples if required

6. Renewal of certificate

Certificate will be renewed every three years after conducting the recertification audit. The decision to renew will be taken based on the results of the recertification audit of the whole GMP System.

7. Complaints

Any interested party may lodge a complaint regarding the operation of the Good Manufacturing Practices certification scheme of SLSI. All complaints in writing shall be addressed to the Director General of the SLSI for consideration.

8. Impartiality and Confidentiality

Impartiality shall be maintained in the operation of the Good Manufacturing Practices certification scheme of SLSI. Confidentiality shall be assured to all applicants regarding information relating to the business, the Good Manufacturing Practices System and its operations. However, this information is required to be disclosed to the auditors, and they are required to sign a Statement of Impartiality & Confidentiality before each audit assignment.

HOW THE SCHEME OPERATES?

SLSI renews the certificate once in three years to ensure that the terms and conditions of the scheme are maintained

SLSI conducts annual surveillance audits to ensure that the GMP System is maintained and submits a report

SLSI grants certification based on the results of the stage I audit or stage-II audit

SLSI conducts the stage-II audit to evaluate the Organization's GMP and the effectiveness of its implementation and submit a report

SLSI arranges a stage-I audit to determine whether the documented system is adequate and submit a report

SLSI reviews the application

Any organization that wishes to obtain certification under this scheme, should submit a completed application along with the documented information requested by the application to the SLSI