GOOD MANUFACTURING PRACTICES (GMP) PRODUCT CERTIFICATION SCHEME

Sri Lanka Standards GMP Certified Institution

RULES AND PROCEDURES

SRI LANKA STANDARDS INSTITUTION
No. 17, Victoria Place, Elvitigala Mawatha, Colombo 08
Tel Fax: +94 11 2672613, e-mail: dsc@slsi.lk, website: www.slsi.lk

SRI LANKA STANDARDS INSTITUTION

GOOD MANUFACTURING PRACTICES (GMP) PRODUCT CERTIFICATION SCHEME

RULES AND PROCEDURES

POLICY AND OBJECTIVES

Sri Lanka Standards Institution (SLSI) being the National Standards Body, as one of its national obligations will carry out the assessment and certification of Good Manufacturing Practices (GMP) system operated by organization in accordance with recognized Good Manufacturing Practices Standards. This objective is achieved by having an open, independent and competent Good Manufacturing Practices certification scheme operated in the most cost-effective manner. While achieving the above objective SLSI will strictly adhere to the following policies.

- Use most modern methods, procedures and recognized standards/ Codes of Practice.
- Employ competent and impartial auditors acceptable to clients.
- The Product Certification Scheme is open to any organization operating in the world.

PROCEDURE

The proceeding part of this document will outline the procedures of the Good Manufacturing Practices Product Certification Scheme operated by the SLSI.

1 APPLICATION

1.1 The application form and the other necessary documents such as Guidelines for Applicants, Rules & Procedures, the current Fee Schedule, the conditions for the use of the Good Manufacturing Practices Mark and the Certification Agreement are enclosed in the brochure, which is available at the SLSI, No. 17, Victoria Place, ElvitigalaMawatha, Colombo 08.

1.2 Duly completed application form shall be addressed to the **Director General, Sri Lanka Standards Institution, No. 17, Victoria Place, Elvitigala Mawatha, Colombo 08.**

1.3 The application shall accompany the following.

- Documented information of the applicant
- Application Processing Fee

1.4 Application processing fee is nonrefundable

1.5 Applicants (Clients) who produce similar products or provide similar services at different locations, each with its own autonomous management, shall submit separate applications in respect of each location.

1.6 In case of identical products are manufactured in different manufacturing units or provide identical services, one application shall be produced detailing out the manufacturing/service sites.

1.7 The SLSI shall review the application and documented information submitted by the client, and if those documents are in order, a letter of acknowledgement is sent requesting the client to propose a date for the Stage-I audit. If those documents are not in order, the client is informed regarding the inadequacies.

1.8 The client shall enter into a Certification agreement with the Sri Lanka Standards Institution

2 SCOPE

In determining the scope of the certification, the products and/or services specified by the client and information gathered during the Stage-I audit are considered.

3 AUDIT OBJECTIVES

3.1 Determination of the extent of conformity of the GMP system to be audited, or parts of it, with audit criteria.

3.2 Determination of the extent of conformity of activities, processes and products with the requirements and procedures of the management system.

3.3 Evaluation of the capability of the management system to ensure compliance with legal and contractual requirements and other requirements to which the organization is committed.

3.4 Evaluation of the effectiveness of the management system in meeting its specified objectives.

3.5 Identification of areas for potential improvement of the management system.

4 INITIAL AUDIT

4.1 STAGE-I AUDIT

4.1.1 Once the client requests to conduct a Stage-I audit, SLSI shall nominate an impartial & competent audit team to conduct the Stage-I audit taking into consideration of the size of the organization. If the client fails to get the Stage-I audit conducted within a period not exceeding six months, the client shall submit a fresh application for reconsideration of GMP certification.

4.1.2 SLSI shall ensure that the duration of the Stage-I audit does not exceed the 1/3 of the total number of auditor man-days of the initial audit.

4.1.3 SLSI shall send a letter indicating the charges and other details to the client before the Stage-I audit.

4.1.4 Auditor(s) shall visit the auditee's premises on an agreed date(s) and the whole Management System of the client is examined for.

a. Revision issue and authorization

b. Applicable Departments/ Processes

c. Availability in locations, and

d. Scope clarification

4.1.5 The Stage-I audit has the following objectives.

a. To audit the client’s management system documentation.

b. To evaluate the client’s location and site-specific conditions and to undertake discussions with the client’s personnel to determine the preparedness for the Stage-II audit.

c. To review the client’s status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes objectives and operation of the management system.

d. To collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance.

e. To review the allocation of resources for Stage-II audit and agree with the client on the details of the Stage-II audit.

f. To provide a focus for planning the Stage-II audit by gaining a sufficient understanding of the client’s management system and site operations.

g. To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the Stage-II audit.

4.1.6 The Auditee has the following Responsibilities with respect to the Stage-I audit

a. Furnish the documentation covering the relevant scope (for which certification is sought) to the audit team.

b. Furnish all records relating to the implementation of Management System to the audit team.

4.1.7 A detailed report on Stage-I audit is prepared covering the information required for the Stage-II audit and indicating any areas need to be further improved and is sent to the client. SLSI shall

ensure that all deficiencies highlighted during the audit are recorded in the Stage-I audit report. The results of the Stage-I audit shall be used for planning of the Stage-II audit.

4.2 STAGE-II AUDIT

4.2.1 The purpose of the Stage-II audit is to evaluate the implementation, including effectiveness, of the client's management system. The Stage-II audit shall take place at the site(s) of the client.

4.2.2 The decision for the conduct of Stage-II audit is taken only when the client confirms in writing that all the deficiencies highlighted during the Stage-I audit had been rectified and the client is ready for the Stage-II audit.

4.2.3 Once the client requests to conduct a Stage-II audit after closing the deficiencies highlighted in the Stage-I audit report, SLSI shall nominate an impartial & competent audit team to conduct the Stage-II audit taking into consideration of the size of the organization. The duration of the Stage-II audit shall be the 2/3 of the total number of auditor man-days of the initial audit.

4.2.4 The Stage-II audit is conducted on mutually agreed date(s) between the client and the SLSI. The date of Stage-II audit should be at least two weeks from the Stage-I audit subject to a maximum period of six months. If it exceeds six months period to rectify the deficiencies highlighted during the Stage-I audit, a fresh application shall be submitted by the client, and it shall be treated as new application.

4.2.5 The audit plan and the letter indicating the charges of the Stage-II audit are sent to the client and his written approval is obtained before the commencement of the audit. The client has the right to raise objections to the audit plan as well as the composition of the audit team.

4.2.6 The leader of the audit team shall ensure that his team strictly adheres to the audit plan and complete the audit right on time.

4.2.7 The Stage-II audit shall include at least the following.

a. Information and evidence about conformity to all requirements of the applicable standards or other normative document.

b. Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectation in the applicable standards or other normative document).

c. The client's management system and performance as regards legal compliance.

d. Operational control of the client's processes.

e. Internal auditing and management system meeting.

f. Management responsibility for the client's policies.

g. Links between the normative requirement, policy, performance objectives and targets (consistent with the expectation in the applicable standards or other normative documents), any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit findings and conclusions

4.2.8 The Stage-II audit shall have the following broad activities.

a. **Opening Meeting**

- Management of the company and those responsible for the functions or processes to be audited shall be available for the opening meeting.
- The purpose of the opening meeting, which shall usually be conducted by the audit team leader, is to provide a short explanation of how the audit activities will be undertaken and shall include the following elements.
  - Introduction of the participants, including an outline of their roles.

- Confirmation of the scope of certification.
- Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes, and other relevant arrangements with the client, such as the date and time for the closing meeting, interim meetings between the audit team and the client's management.
- Confirmation of formal communication channels between the audit team and the client.
- Confirmation that the resources and facilities needed by the audit team are available.
- Confirmation of matters relating to confidentiality.
- Confirmation of relevant work safety, emergency and security procedures for the audit team.
- Confirmation of the availability, roles and identities of any guides and observers.
- The method of reporting, including any grading of audit findings including nonconformities.
- Information about the conditions under which the audit may be prematurely terminated.
- Confirmation that the audit team leader and audit team representing the Certification Body is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails.
- Confirmation of the status of findings of the previous review or audit, if applicable.
- Methods and procedures to be used to conduct the audit based on sampling;
- Confirmation of the language to be used during the audit.
- Confirmation that, during the audit, the client will be kept informed of audit progress and any concerns.
- Opportunity for the client to ask questions.

b. Individual audit assignments by auditors

- ❖ Involve in-depth appraisal of all levels of documentation for adequacy, availability, and compliance.
- ❖ Investigation of the employees understanding on documents by interviewing.
- ❖ Look for compliance by observation, data, records, cross checking, and interviews.
- ❖ Draw attention of the escorting officer on any non-conformance detected and record them.
- ❖ Start and finish assignments on time.

c. Auditors' meeting

- ❖ The Team Leader with the members of the audit team shall:
  - review the audit findings, and any other appropriate information obtained during the audit, against the audit objectives and audit criteria and classify the nonconformities.
  - agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process.
  - agree with any necessary follow-up actions.
  - confirm the appropriateness of the audit programme or identify any modification required for future audits.
- ❖ Discuss about the findings with the Team Leader and take a decision.
- ❖ Clarify any doubtful areas from the Team Leader.

- ❖ Take decision on any changes required.
- ❖ Raise Non-Conformity Reports (NCRs) and hand over them to the Team Leader.
- ❖ Ensure that an internal audit of the complete Management System and a management system meeting have been done effectively.
- ❖ Make the final decision.

d. Team Leader's meeting with the Chief Executive Officer (CEO) towards the end of the day

- ❖ Inform the CEO or management representative in advance the day's progress, (non-conformities detected so far) so that he may not be taken by surprise at the closing meeting.
- ❖ To give the CEO or management representative a chance to correct minor non-conformities before the completion of the audit.
- ❖ CEO is prepared ahead for the closing meeting and both parties could agree on a time frame to close the audit.

e. Closing meeting at the end of the audit

- ❖ The management of the organization and those responsible for the functions or processes to be audited shall be available for the closing meeting.
- ❖ The purpose of the closing meeting, which shall normally be conducted by the audit team leader, is to present the audit conclusions, including the recommendation regarding certification. Any non-conformity shall be presented in such a manner that they are understood, and the timeframe for responding shall be agreed. The closing meeting shall also include the following elements.
  - Advising the client that the audit evidence collected was based on a sample of the information, thereby introducing an element of uncertainty.
  - The method and timeframe of reporting, including any grading of audit findings.
  - The Certification Body's process for handling nonconformities including any consequences relating to the status of the client's certification.
  - The timeframe *(not exceeding 03 months)* for the client to submit completed correction and corrective action for any nonconformities identified during the audit.
  - The Certification Body's post audit activities.
  - Information about the complaint handling and appeal processes.
- ❖ The client shall be given the opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the certification body

5 NONCONFORMITY

5.1 MAJOR NONCONFORMITY

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

5.2 MINOR NONCONFORMITY

An isolated incident of a failure to fulfil one or more requirements of the Management System Standards and/or other related requirements of the Management System certification scheme.

6 REPORT ON STAGE-II AUDIT

The SLSI shall prepare a formal report in detail commenting on the client's Management System. The report also accompanies a list of non-conformities detected giving cross-reference to the section of the client's Management System and to the corresponding requirements of the applicable standard(s).

The personnel who take the decision on granting, refusing, maintaining, renewing, suspending, restoring, or withdrawing certification, or on expanding or reducing the scope of certification, shall understand the applicable standard(s) and certification requirements, and shall have demonstrated competence to evaluate the outcomes of the audit processes including related recommendations of the audit team.

6.1 In the case of certification is recommended, a copy of the report with a recommendation from Director (Systems Certification) is sent to the SLSI to grant certification.

6.2 In case of certification is not recommended, a mutually agreed time limit not exceeding three months shall be given for corrective actions to be completed by the client.

6.3 Once the client confirms the completion of corrective actions the audit team may carry out a follow-up audit or accept the written evidence from the auditee (sometimes for further clarification during surveillance audit) and recommended for certification.

6.4 In case of non-certification due to major nonconformities, the client may agree with the audit team a time frame, not exceeding three months, to implement corrective actions, but the certification is recommended only after verifying the effectiveness of the actions taken by the client through a follow-up audit of the Management System.

6.5 If the SLSI not able to verify the implementation of corrections and corrective actions of any major nonconformity within six months after the last day of Stage II audit, the SLSI shall conduct another Stage II audit prior to recommending certification.

7 GRANTING/ REFUSING OF CERTIFICATION

7.1 The decision to grant or refuse the certification shall be taken by the certifying authority based on the audit report and the recommendations made as given under clause 6.

7.2 When certification is granted, a certificate shall be issued to the client. Before awarding the certificate, the client is expected to sign a Certification Agreement with the SLSI, if the client has not signed those Agreements initially when the SLSI had decided to process the application.

7.3 The certificate shall apply only to the specific process(es) and the product(s), or the service(s) stipulated in the schedule.

7.4 When the client has lodged a number of applications in respect of the number of locations, he will be issued separate certificates in respect of each location.

7.5 The certificate shall be printed as per the details given below.

7.5.1 The name and geographical location of each certified client (or the geographical location of the headquarters and any sites within the scope of a multi-site certification).

7.5.2 the effective date of granting, expanding or reducing of the scope of certification, or renewing certification which shall not be before the date of the relevant certification decision.

The original certification date on the certificate when a certificate lapses for a period of time provided that:

- the current certification cycle starts, and expiry date are clearly indicated.
- The last certification cycle expiry date be indicated along with the date of recertification audit.

7.5.3 The expiry date or recertification due date is consistent with the recertification cycle.

7.5.4 a unique identification code.

7.5.5 the management system standard and/or other normative document, including indication of issue status (e.g. revision date or number) used for audit of the certified client.

7.5.6 the scope of certification with respect to the type of activities, products and services as applicable at each site without being misleading or ambiguous.

7.5.7 the name, address and certification mark of the certification body; other marks (e.g. accreditation symbol, client's logo) may be used provided they are not misleading or ambiguous).

7.6 If an organization certified for HACCP/ ISO 22000 and ISO 9001(nonfood products), the GMP certificate can be issued on request of the client.

7.7 The printed certificate shall be issued after completing it properly, under the signature of DG/ CEO of SLSI.

8 SURVEILLANCE AUDIT

8.1 The surveillance audits shall be conducted by the SLSI at twelve months intervals counted from the last date of the stage-II/ recertification audit.

8.2 A surveillance audit schedule shall be prepared incorporating the representative areas and functions covered by the scope and surveillance activities may include.

a. Enquiries from the SLSI to the certified client on aspects of certification

b. Reviewing any client's statements with respect to its operations

c. Requests to the clients to provide documents and records and

d. Other means of monitoring the certified client's performance

8.3 Surveillance audit programme shall include at least

a. internal audits and management system meeting

b. A review of actions taken on non-conformities identified during the previous audit

c. treatment of complaints

d. effectiveness of the management system with regard to achieving the certified client's objectives

e. progress of plan activities aimed at continual improvement

f. continuing operational control

g. review of any changes, and

h. use of marks and/or any other reference to certifications

8.4 The dates in the surveillance audit schedule are flexible and can be agreed to between the certificate holder and the SLSI.

8.5 As with Stage-II audit for the certification to remain valid any audit findings must be subject to agreed and implemented corrective action.

9 RECERTIFICATION

9.1 Application for the recertification shall be sent to the certificate holder at least 06 months before the expiry date of the certificate to reapply for the recertification.

9.2 The recertification may involve all the steps except stage-I audit as given under the initial audit (clause 5).

9.3 Stage-I audit shall be carried out.

a. When the recertification process cannot be completed before the expiration of the certificate.

b. In situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g. changes to legislation).

9.4 The required fee for renewal shall be necessary to be paid by the certificate holder.

9.5 SLSI shall make decisions on renewing certification based on the results of the recertification audit as well as the results of the review of the system over the period of certification and complaints received from users of certification.

10 SPECIAL AUDIT

10.1 EXTENSIONS TO SCOPE

In response to an application of a certification already granted, SLSI shall review the application and decide whether any audit activities necessary to be carried out to decide whether the extension can be granted

10.2 SHORT NOTICE AUDITS/ UNANNOUNCED AUDITS

These types of audits are carried out to investigate complaints, or in response to changes, or as follow up on suspended clients.

It may be necessary for SLSI to conduct audits of certified clients at short notice or unannounced to investigate complaints, or in response to changes, or as follow up on suspended clients. In such cases:

- SLSI shall describe and make known in advance to the certified clients the conditions under which such audits will be conducted.
- SLSI shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

The fee for these audits shall be based on number of man days required to conduct the audit.

11 ADDITIONAL AUDIT / FOLLOW UP AUDIT

These types of audits are carried out to verify effective correction and corrective actions. This may be an additional full audit, an additional limited audit, or documented evidence *(to be confirmed during future surveillance audits)*. Considering the nature of the nonconformity *(either it is major or minor)*, the 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.

12 AUDIT TEAM AND AUDIT TEAM TASKS

12.1 The SLSI shall use qualified, impartial and competent auditors to conduct audits.

12.2 The size of the audit team will be decided in accordance with the GMP Guidelines (GMP G 6.2 – 01).

12.3 The SLSI shall provide the name of and, when requested, make available background information on each member of the audit team, with sufficient time for the client to object to the appointment of any particular auditor and for the SLSI to reconstitute the team in response to any valid objection.

12.4 The audit plan shall be communicated, and the dates of the audit shall be agreed upon, in advance, with the client organization.

12.5 The audit team shall.

12.5.1 Examine and verify the structure, policies, processes, procedures, records and related documents of the client organization relevant to the management system.

12.5.2 Determine that these meet all the requirements relevant to the intended scope of certification.

12.5.3 Determine that the processes and procedures are established, implemented and maintained effectively, to provide a basis for confidence in the client's management system.

12.5.4 Communicate to the client, for its action, any inconsistencies between the client's policy, objectives and targets *(consistent with the expectations in the relevant management system standard(s) or other normative documents)* and the results.

13 SELECTION OF AUDITORS

13.1 Special care shall be taken not to include any auditor who has some interest in the auditing organization to maintain impartiality of the audit.

13.2 Auditors' academic background and experience in the subject area to be audited is considered in selecting an auditor to carry out an audit.

14 FEES

14.1 The fees payable by the client are determined by the SLSI and shall be revised from time to time without prior notice.

14.2 The current fee structure is enclosed in the brochure separately.

14.3 All fees as determined and intimated to the company by the SLSI shall be paid in advance.

15 CONFIDENTIALITY

15.1 The SLSI shall, through legally enforceable agreements, have a policy and arrangements to safeguard the confidentiality of the information obtained or created during the performance of certification activities at all levels of its structure, including committees and External Bodies or individuals acting on its behalf.

15.2 The SLSI shall inform the client, in advance, of the information it intends to place in the public domain. All other information, except for information that is made publicly accessible by the client, shall be considered confidential.

15.3 Other than the information given in the public domain, information about a particular client or individual shall not be disclosed to a third party without the written consent of the client or individual concerned. Where the SLSI is required by law to release confidential information to a third party, the client or individual concerned shall, unless regulated by law, be notified in advance of the information provided

15.4 Information about the client from sources other than the client (e.g. complainant, regulators) shall be treated as confidential, consistent with the policy of SLSI.

15.5 Personnel, including any committee members, contractors, personnel of External Bodies or individuals acting on the Certification Body's behalf, shall keep confidential all information obtained or created during the performance of certification activities of SLSI.

15.6 The SLSI shall make available and use equipment and facilities that ensure the secure handling of confidential information *(e.g. documents, records).*

15.7 When confidential information is made available to other bodies *(e.g. Accreditation Body, agreement group of a peer assessment scheme)*, the SLSI shall inform its client of this action.

16 IMPARTIALITY

16.1 The SLSI shall undertake assessment activities impartially and shall be responsible for the impartiality of its conformity assessment activities, and it shall not allow commercial, financial or other pressures to compromise impartiality.

17 USE OF THE GMP CERTIFICATION AND GMP CERTIFICATION MARKS

17.1 The organization shall use the Good Manufacturing Practices Certification Marks subject to the "*Conditions for the Use of the Good Manufacturing Practices Certification Mark*" issued by SLSI.

17.2 GMP certification mark may be displayed on the product or product packaging

The certification mark may contain:

a) identification of the object of conformity assessment (e.g., process, product or services);

b) The name of the owner and/or issuer of mark (certification body);

c) the standard or normative document under which product, process, service has been certified or conformity assessment body has been accredited;

d) unique identification, which is traceable to the statement of conformity.

17.3 A reference to GMP certification mark of conformity may also to be used on other media such as letterheads, business cards, company vehicles, promotional materials, internet web sites, social media

17.4 The organization shall not use the GMP Certification Mark in a misleading manner and not state its certification in a manner as to be considered misleading or unauthorized and bring disrepute on SLSI.

17.5 The organization shall conform to the requirements of the SLSI when making reference to its certification status in communication media such as the internet, brochures or an advertising, or other documents

17.6 The organization shall not make or permit any misleading statement regarding its certification

17.7 The organization shall not use or permit the use of a certification document or any part thereof in a misleading manner

17.8 The organization shall discontinue the use of all advertising matters that contain a reference to certification, as directed by the SLSI

17.9 The organization shall amend all advertising matter when the scope of certification has been reduced.

17.10 The organization shall not imply that the certification applies to activities that are outside the scope of certification.

17.11 The organization shall not use its certification in such a manner that would bring the SLSI and/or certification system into disrepute and lose public trust.

18 MISUSE OF CERTIFICATION

An organization whose certificate has lapsed, suspended, or cancelled shall not display, advertise, or otherwise use the certificate or the certifying authorities' symbol or any other material purporting to indicate the validity of the certification. In the case of reduce the scope of certification the company shall display or advertise only the amended scope.

19 SUSPENSION OF CERTIFICATION

19.1 Certification shall be suspended under the following circumstances

a. The client's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system.

Examples.

1. *If the client has not taken effective corrective actions within the agreed time period for the major non-conformities raised during the surveillance audits*
2. *Improper use of certification, certification document or certification mark and if it is not rectified to the satisfaction of the SLSI within an agreed time period.*

b. The certified client does not allow surveillance or recertification audits to be conducted at the required frequencies.

c. The certified client has voluntarily requested a suspension.

19.2 A suspension of certification shall be confirmed by a registered letter.

19.3 The suspension shall be removed, and the organization is notified accordingly upon fulfillment of corrective action within the specified period.

19.4 The certification is cancelled, and the certification document is withdrawn if the stipulated condition of suspension is not rectified within the specified period of time.

19.5 In the case of suspension, the client shall refrain from further promotion of its certification.

20 EXPANDING AND REDUCING THE SCOPE /CANCELLATION/WITHDRAWAL/RESTORING OF CERTIFICATION

20.1 SLSI shall cancel the certification and withdraw the certification document and cancel any agreement for the use of Good Manufacturing Practices Certification Mark in the following circumstances.

a. Under the provision in clause 18.

b. A surveillance audit confirms that non-conformities of serious nature are present.

c. At the formal request of the organization.

d. If the system rules are changed and the organization either will not or cannot ensure conformance to the new requirements.

e. If the organization ceases to supply the product, process or services stated in the certificate for a period exceeding six months.

f. If the certified organization fails to meet financial obligations to the SLSI.

g. Failure to comply with any other requirements stipulated by the certifying authority under this scheme.

20.2 The cancellation shall be notified by the organization by a registered letter and the SLSI shall publish the notification of the cancellation.

20.3 SLSI shall reduce the client's scope of certification to exclude the parts not meeting the requirement, when the client has persistently or seriously failed to meet the certification requirement for those parts of the scope of certification.

20.4 Failure to resolve the issues that have resulted in the suspension in a time established by the SLSI shall result in the reduction of the scope of certification.

20.5 Upon cancellation of the certificate, once the client rectifies the failures and achieves the status of consistency of the GMP and informs the SLSI, action will be taken to restore the certificate.

20.6 SLSI shall restore the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established by the SLSI shall result in withdrawal or reduction of the scope of certification (The suspension would not exceed six months)

21 CORRECTIVE ACTION

A certified organization shall be responsible for taking prompt and adequate action to correct any contravention of the system rules, and for formally notifying the certifying authority of the corrective action proposed or taken.

22 CHANGES TO THE REQUIREMENTS FOR MANAGEMENT SYSTEM CERTIFICATION

In the event of the changes being required to the requirements of the Management System Certification, the SLSI shall.

a. Give its certified organizations due notice of any changes to its requirements for certification.

b. Provide opportunity for the affected organizations to submit comments on the proposed changes.

c. Verify that each certified organization complies with the new requirements.

d. Effective dates for the implementation of these new requirements shall be fixed by a contractual arrangement with a certified organization.

23 PUBLICITY

23.1 SLSI shall publish a directory of certified companies.

23.2 A certified organization is entitled to:

- ❖ Inform potential customers, purchasers or purchasing authorities of the full and exact details of the certification.
- ❖ Display the certification document.
- ❖ Use of the GMP Certification Mark as specifically authorized.

24 APPEALS

24.1 If the certificate holder is not satisfied with the decision taken by the SLSI, the certificate holder is eligible to appeal in writing to the council of the SLSI within 14 days of receipt of such a decision.

24.2 The decision of the council on any such appeal shall be final and conclusive.

25 OBLIGATIONS

25.1 The certificate holder shall co-operate with the SLSI in all activities related to the scheme. The organization shall also ensure that the auditors of SLSI are permitted and assisted to undertake the audit of the Management System.

25.2 The certificate holder shall pay all relevant fees as specified by the SLSI.

25.3 Any changes to the certified scope of the client shall communicate to the SLSI immediately.

25.4 The certificate holder shall permit them to conduct a witness audit by the Accreditation Body at any stage of the certification cycle when a request is made by the institution.

25.5 Where appropriate, certificate holder may permit the participation of trainee auditors in the audit team.

26 COMMUNICATION

All communication relating to the Good Manufacturing Practices Certification Scheme shall be addressed to the Director (Systems Certification) except for appeals. In case of an appeal, such details shall be sent to the Director General/ CEO of the SLSI.