SRI LANKA ACCREDITATION BOARD
for CONFORMITY ASSESSMENT

QUESTIONNAIRE
for RECOGNITION *of*
GOOD LABORATORY PRACTICE

Instructions to the Applicant:

1. Please fill the questionnaire on your own judgment of activities related to GLP.
2. Procedures need not always to be documented and may be in the form of Guidelines and Formats.

SLAB RECOGNITION PROGRAMME OF GOOD LABORATORY PRACTICE

QUESTIONNAIRE

This questionnaire is a self-assessment check list to assess the readiness of your laboratory or test facility for an assessment by SLAB.

Questionnaire Completed By

Name: _____

Position: _____

Name of the laboratory/test facility: _____

Signature: _____ Date: _____

1. Test Facility Management System

Does your Laboratory have a GLP Manual and relevant Procedures **Yes** ☐ **No** ☐

** (See Page 8 for the contents of a GLP Manual)*

Does the manual contain / refer to?

Scope of test system/ studies	Yes/ No
GLP Statement with Chief Executive/Study Director's Endorsement	Yes/ No
Document Control Procedure (Internal and External)	Yes/ No
Procedure for Control of Records	Yes/ No
Corrective Action Procedure	Yes/ No
Preventive Action Procedure	Yes/ No
Procedure for Review of study requests	Yes/ No
Procedure for Handling of Complaints	Yes/ No
Procedure for Control of Non-conforming Work	Yes/ No
Internal Auditing Procedure	Yes/ No
Management Review Procedure	Yes/ No
Quality Assurance Programme	Yes/No
Procedure for Training	Yes/ No
Procedure for safe Handling of Test Equipment	Yes/ No
Procedure for Calibration of Test Equipment	Yes/ No
Procedure for Handling of Test Items	Yes/ No
Job Descriptions	Yes/ No

Please enclose a copy of the GLP manual

Does the Laboratory maintain Records for

Records of Review of Requests	Yes/ No
Records related to maintenance of Equipment	Yes/ No
Records of Quality Assurance	Yes/ No
Training Records	Yes/ No
Records related to Competence Development	Yes/ No

2. Accommodation

Brief Description of the Testing Facility

(Please include number of rooms, approximate size of them and any special features)

Please enclose a sketch of the testing facility layout.

Is Environmental Control Necessary? Yes ☐ No ☐

If so, is the testing facility air conditioned? Yes ☐ No ☐

Control achieved by:

Temperature range = ^{0}C

Relative Humidity Range = %

Temperature is monitored :

☐ Continually

☐ Occasionally

☐ Not at all

Relative humidity is monitored :

☐ Continually

☐ Occasionally

☐ Not at all

3. Equipment and Reference Materials/Items

Equipment Inventory

Is there an up-to-date inventory of all items of equipment? Yes ☐ No ☐

Calibration

Are items of measuring and testing equipment/items calibrated regularly? Yes ☐ No ☐

Are records kept of these calibrations? Yes ☐ No ☐

Is there a well-defined system for scheduling future calibrations? Yes ☐ No ☐

Are reference materials or Standard controls verified/calibrated? Yes ☐ No ☐

In-house Checks

Is ancillary equipment checked regularly? Yes ☐ No ☐

Are records kept of these checks? Yes ☐ No ☐

Is there a well-defined system for scheduling future checks? Yes ☐ No ☐

4. Standard Operating Procedures

Are Standard Operating procedures technically validated? Yes ☐ No ☐

Is there a procedure for method validation? Yes ☐ No ☐

Please enclose the copies of standard operating procedures.

5 . Sampling

Is sampling relevant to the scope performed in the test facility? Yes ☐ No ☐

Are there documented procedures for sampling? Yes ☐ No ☐

5.1 Sampling Procedures

Are procedures for receipt, identification, stabilization, storage and retention of samples documented?

Receipts Yes ☐ No ☐

Identification Yes ☐ No ☐

Stabilization and preservation Yes ☐ No ☐

Storage Yes ☐ No ☐

Retention Yes ☐ No ☐

Are procedures for preparing standards solutions and materials documented? Yes ☐ No ☐

6. Quality Assurance Programme

Has the laboratory developed a Quality Assurance Programme Yes ☐ No ☐

Does the laboratory participate in PT or inter laboratory comparison programmes Yes ☐ No ☐

What internal procedures are used to monitor the validity of Standard Operating Procedures?

☐ Intra-laboratory programs? Details:

☐ True blanks ☐ Replicates

☐ Check samples ☐ Standard additions

☐ Standard reference materials

Have precision data and limits of detection (Where relevant) been Calculated for all methods based on internal quality control data? Yes ☐ No ☐

Are these recorded? Yes ☐ No ☐

6.1 Uncertainty of Measurement

Has the laboratory estimated uncertainty of measurement for the studies applied? Yes ☐ No ☐

6. Records of Study Data and Reporting

How is Study Data Recorded?

☐ In workbooks ☐ Ink or ball pen

☐ Proforma worksheets ☐ Pencil

☐ Plain paper

How Frequency are Calculations & Data Transfers Checked?

☐ Full check on all calculations and transfers

☐ Regular partial check %
(Enclose statistical justification for partial checks)

☐ Occasional checks (Not acceptable)

☐ No regular check (Not acceptable)

How is Test Data Stored?

☐ In workbooks ☐ Pro-forma worksheets

☐ In files ☐ On computer

☐ Other (details please)

Is There a validated computerized system? Yes ☐ No ☐

Can Test Data be readily retrieved starting from?

☐ Client name ☐ Project name

☐ Date of study ☐ Report Issued

☐ Other (specify)

6.1 Reporting

Is a Report issued for each study? Yes ☐ No ☐

7. Miscellaneous

Have you enclosed copies of?

☐ Application for recognition

☐ Measurements/Tests for which recognition is sought.

☐ Laboratory's GLP Manual & Procedures Manual.

☐ Examples of job descriptions and training records.

☐ An organizational chart.

☐ A sketch of the layout.

☐ Equipment list.

☐ Standard Operating Procedures and test methods.

☐ Examples of quality assurance data.

☐ Examples of sample register page and relevant test records.

☐ Copy of a final study report.

☐ Internal audit report and corrective action records.

☐ Management review records.

8. Contents of GLP Manual

The contents of a GLP Manual will include but may not be limited to the following. Reference should be given to the procedures or other references, where ever necessary.

- Introduction to Test Facility/Organization
- References
- Definitions of Terms
- Scope of Study and GLP
- GLP Statement
- Organization and management
- Staff responsibilities and Authorities
- Review of Study
- Sampling
- Quality Assurance Programme
- Facilities
- Apparatus, Materials and reagents
- Test systems
- Test and reference standards/items
- Standard Operating Procedures
- Study planning and management
- Performance of Study
- Reporting of Study
- Storage and retention of records, materials and reports