SUMMARY OF CHANGES (ISSUE 4, 14 APRIL 2016)

Name of Document: STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL			
Page No; Clause No; Line No.	**Amendment (Issue 4)**	**Page No; Clause No; Line No.**	**Previous Issue (Issue 3)**
	Amended 'STANDARDS MALAYSIA' to 'Standards Malaysia'.		
4	Additional new OECD series of documents – Doc. No. 16: Advisory document of the Working Group on GLP: Guidance on the GLP Requirements for Peer Review of Histopathology, 2014.		
	Deleted	10; 5.1	STANDARDS MALAYSIA should maintain records of test facilities inspected (and their GLP compliance status) and of studies audited for both national and international purposes.
14; 5.3.3	The Trainee Inspector is to undergo a GLP Inspector training programme. The first part of the training programme includes at least one GLP course or workshop organised by OECD or national/international GLP Compliance Monitoring Authority. The aim is to equip the Trainee Inspector with a comprehensive knowledge of the requirements and implementation as described in the OECD GLP document series, inclusive of the principles, guidance, consensus, test guidelines and managerial skills in communication, planning, organising, conducting and reporting of the inspection/study audit. The training may include the leadership skills in chairing opening and closing meetings, heading the inspection/ audit, dealing with conflicts and decision-making.	14; 5.3.3	The Trainee Inspector is to undergo a GLP Inspector training programme. The first part of the training programme includes at least one GLP course or workshop organised by OECD or national/international GLP Compliance Monitoring Authority. The aim is to equip the Trainee Inspector with a comprehensive knowledge of the requirements and implementation as described in the OECD GLP document series, inclusive of the principles, guidance, consensus and test guidelines.

SUMMARY OF CHANGES (ISSUE 4, 14 APRIL 2016)

Name of Document: STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL			
Page No; Clause No; Line No.	**Amendment (Issue 4)**	**Page No; Clause No; Line No.**	**Previous Issue (Issue 3)**
14; 5.3.4	The aim of the second part of the GLP Inspector training programme is to equip the Trainee Inspector with appropriate skills and attribute for conduct of GLP inspection.	14; 5.3.4	The aim of the second part of the GLP Inspector training programme is to equip the Trainee Inspector with right skills and attitude for conduct of GLP inspection.
14; 5.3.3	Combined with 14; 5.3.3	14; 5.3.5	Deleted and combined with 14; 5.3.3
14; 5.3.5	Amended to Standards Malaysia….. Additional statement: The appointed GLP Inspector to be evaluated during the first inspection.	14; 5.3.6	The Director of Accreditation can appoint a person to the position of GLP Inspector or GLP Lead Inspector,
15; 5.3.6	…..appointment letter has been signed by the GLP CP Manager.	15; 5.3.7	….. appointment letter has been signed by the Director of Accreditation.
15; 5.3.8	The GLP Manager should regularly monitor the performance of the GLP Inspectors and GLP Lead Inspectors as and when necessary by using GLP-R008 Evaluation Report of Inspector.	15; 5.3.9	The GLP Manager should regularly monitor the performance of the GLP Inspectors and GLP Lead Inspectors. Their performance shall be reported to the Director of Accreditation at least once in a three years using GLP-R008 Evaluation Report of Inspector.
15; 6.1	If no GLP study has been conducted within two years since the last inspection, a suspension for minimum 12 months will be given. Test Facility should advise Standards Malaysia as soon as possible that GLP study is to be performed. Hence, Standards Malaysia will conduct Test Facility Inspection/Study Audit in order to reinstate the suspension status.	15; 6.1	If no GLP study has been conducted within two years since the last inspection, a suspension for minimum 12 months will be given. Test Facility should advise STANDARDS MALAYSIA as soon as possible that GLP study is to conduct and Test Facility Inspection/Study Audit will be conducted to uplift the suspension status.

SUMMARY OF CHANGES (ISSUE 4, 14 APRIL 2016)

Name of Document: STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL			
Page No; Clause No; Line No.	**Amendment (Issue 4)**	**Page No; Clause No; Line No.**	**Previous Issue (Issue 3)**
15; 6.1	Additional statement on Standards Malaysia may also remove test facilities from the GLP CP in the light of: i) Failure to comply with GLP CP requirements as stated in this manual; ii) Failure to provide cooperation or facilities for Standards Malaysia, its inspectors and/or its authorised representatives to discharge their official duties; iii) Fraudulent practices, which include but not limited to; deception of claims and alteration of GLP certificate; iv) An individual or sole proprietorship test facilities is declared bankrupt or enter into composition with his creditors; or v) Compliant test facilities, being a company, enters into liquidation, whether compulsory or voluntary (but not including liquidation for the purposes of reconstruction) or enters into receivership		
16; 6.1	Additional statement on Standards Malaysia may conduct internal audit and management review as and when necessary together with other scheme under Accreditation Division, with the view to ensure compliance of GLP CP with OECD requirements.		

SUMMARY OF CHANGES (ISSUE 4, 14 APRIL 2016)

Name of Document: STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL			
Page No; Clause No; Line No.	**Amendment (Issue 4)**	**Page No; Clause No; Line No.**	**Previous Issue (Issue 3)**
16; 6.3.1	Pre-inspection will be conducted within 60 days upon receiving completed application documents. This pre-Inspection is normally carried out within one day to familiarise and to verify that the test facility has the resources to undertake GLP studies in respect of management structure, physical layout of buildings and type of studies.	16; 6.3.1	Pre-Inspection will be conducted within 30 working days upon receiving a complete application. It is normally carried out within one day for the first time to familiarise and to verify that the test facility has the resources to undertake GLP studies in respect of management structure, physical layout of buildings and type of studies.
16; 6.3.1	• the master schedule; • the management structure of the test facility including CVs, job description of key personnel; and • at least one study plan/protocol for completed study	16; 6.3.1	• the range of studies likely to be encountered during the inspection; • the management structure of the test facility including study reports, protocols, CVs, job description of key personnel.
18; 6.3.1	Inspection is scheduled within 6 months from completion of Pre-Inspection's report. If the test facility is still not ready for the Inspection, Standards Malaysia will consider performing a new Pre-Inspection or removed from the programme.	18; 6.3.1	Inspection is programmed within 6 months from the date of Pre-Inspection. If the test facility is still not ready for the Inspection, STANDARDS MALAYSIA will consider performing a new Pre-Inspection.
19; 6.3.3	First and second surveillance inspection will be conducted annually for the first two years after the date of granting. The next surveillance inspection will be conducted every two years based on granting date.	19; 6.3.3	First and second surveillance inspection will be conducted annually for the first two years after the date of granting or last date of inspection and continue further surveillance inspection every two years.

SUMMARY OF CHANGES (ISSUE 4, 14 APRIL 2016)

Name of Document: STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL			
Page No; Clause No; Line No.	**Amendment (Issue 4)**	**Page No; Clause No; Line No.**	**Previous Issue (Issue 3)**
19; 6.3.4	Amended to extension of new area of expertise	20; 6.3.4	extension of new category of product (test item)
20; 6.4	The following fees are payable by the Test Facility Management and will be effective once Standards Malaysia Fee Regulation has been gazette.	21; 6.4	The following fees are payable by the Test Facility Management and will be effective once STANDARDS MALAYSIA GLP CP has been accepted as Full Member of OECD Mutual Acceptance of Data (MAD).
	Deleted	21; 6.4	Other fees (only if applicable) Administrative fee for amendment of certificate Application for Extension of new category of product (Test Item)
21; 7.2 (i)	The corrective action period shall not exceed 1 month from the last date of inspection, but another delay of 1 month can be permitted if test facility can justify the delay. In case if the test facility fails to take satisfactory actions within the specified time, Standards Malaysia may consider verification inspection or removal from the programme.	21; 7.2 (i)	The corrective action period shall not exceed 3 months from the last date of inspection, but another delay of 3 months can be permitted if test facility can justify the delay.
22; 7.2 (i) & (ii)	When minor deviation is observed during Inspection, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed 3 months from the date of last inspection. During the Surveillance Inspection, the test facility will be given 3 months to take action of	23; 7.2 (i) & (ii)	When minor deviation is observed during Inspection, appropriate corrective action shall be taken by the applicant. The corrective action period shall not exceed 6 months from the date of last inspection. During the Surveillance Inspection, the test facility will be given 6 months to take action of such deviations.

SUMMARY OF CHANGES (ISSUE 4, 14 APRIL 2016)

Name of Document: STANDARDS MALAYSIA GOOD LABORATORY PRACTICE COMPLIANCE PROGRAMME (GLP CP) MANUAL			
Page No; Clause No; Line No.	**Amendment (Issue 4)**	**Page No; Clause No; Line No.**	**Previous Issue (Issue 3)**
	such deviations.		
22; 7.3	The inspection report may be authorised by the Manager of GLP CP and/or it will be approved by Director of Accreditation. For test facility found to be in compliance, the Director General of Standards Malaysia will grant/continue GLP compliance…..	23; 7.3	The inspection report may be authorised by the Manager of GLP CP and it will be approved by Director of Accreditation. For test facility found to be in compliance, the Director General of STANDARDS MALAYSIA will grant a statement of GLP compliance…..