

TGA Sciences Quality Assurance Documentation System

TITLE Good Laboratory Practice (GLP) Training			DOC NUMBER GP-03-02
			VERSION NUMBER T-003
EFFECTIVE DATE March 9, 2009	SUPERSEDES March 13, 2006	LOT NUMBER n/a	PAGE NUMBER 1 of 3

1.0 PURPOSE AND INTRODUCTION

- 1.1 To outline the training, education and experience required of staff performing GLP Testing, including members of the Quality Assurance Unit.

2.0 REFERENCED DOCUMENTS

- 2.1 Employee Training, GP-03-01
2.2 Reagent Log, QC-01-02
2.3 Receipt, Handling and Storage of Client Samples, LW-11-01
2.4 Title 21 Code of Federal Regulations Part 58 Good Laboratory Practice for Non-clinical Laboratory Studies
2.5 Archiving Policy for Records and Samples, QA-01-01
2.6 GLP Tutorial – from Labcompliance.com

3.0 RESPONSIBILITIES AND PRECAUTIONS

- 3.1 It is the responsibility of Quality Assurance (QA) to administer this procedure. QA or designee is also responsible for maintenance of applicable training records.
- 3.2 All employees that intend to contribute to the conduct of a GLP Study protocol must receive formal training regarding the unique requirements of studies conducted in accordance with 21 CFR 58, and become certified as to the adequacy of their education, training and experience to perform their assigned functions.

4.0 DEFINITIONS

- 4.1 QAU – Quality Assurance Unit
4.2 SOP – standard operating procedure
4.3 IACUC – Institutional Animal Care and Use Committee
4.4 GLP – Good Laboratory Practices in accordance with 21 CFR 58

5.0 EQUIPMENT AND MATERIALS

- 5.1 Not applicable.

6.0 PROCEDURE

- 6.1 Training of GLP Testing Facility Personnel
- 6.1.1 Prior to contributing to a GLP Study, employees must review and become familiar with Title 21 CFR Part 58 and review the GLP Tutorial. In addition, other training materials relevant to GLP may be used as deemed appropriate by QA.

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- 6.1.2 Employees receive formal training from a member of QA regarding the requirements of 21 CFR 58 and the policies, practices and procedures which govern the conduct of GLP Study protocols at TGA Sciences, Inc.
- 6.1.3 Employees are taught that these regulations govern conduct of non-clinical laboratory studies that are intended to support applications to the Food and Drug Administration (FDA).
- 6.1.4 Employees review definitions in 21 CFR 58 Subpart A, 58.3, including the meanings of the terms “act, test article, control article, non-clinical laboratory study, application for research or marketing permit, sponsor, testing facility, person, test system, specimen, raw data, quality assurance unit, study director, batch, study initiation date and study completion date”.
- 6.1.5 Employees are reminded that they are to wear clothing appropriate for the duties they perform and must take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems and will report to their immediate supervisor any personal health or medical condition that may adversely effect the study, and will exclude themselves from the study until the condition is corrected.
- 6.1.6 Employees are taught that the study director has overall responsibility for the technical conduct of the study, represents the single point of study control, and as such, assures that the approved GLP study protocol is followed, that all experimental data are recorded, that any unforeseen circumstance that may affect the quality or integrity of the study is noted and corrective action is taken and documented, that all applicable regulations are followed, and that all data, documentation, protocols, specimens and reports are archived.
- 6.1.7 Employees are instructed that a separate and independent QAU monitors the facility and its equipment, personnel, methods, practices, records and controls so that they are in conformance with 21 CFR 58.
- 6.1.8 Employees are reminded that documented actions are required to correct any deviation from 21 CFR 58 reported by the QAU to the Study Director.
- 6.1.9 Employees are taught that all equipment used in the generation, measurement or assessment of data must be adequately tested, calibrated or standardized, and that all such calibrations, failures or malfunctions with equipment, and the remedial actions taken to correct equipment defects must be reported in writing to management and QA.
- 6.1.10 Employees are expected to have reviewed all relevant laboratory SOPs that describe standard methods for conducting the laboratory tests that have been assigned to them.
- 6.1.11 Employees are reminded that all reagents and solutions in the laboratory must be labeled to indicate identity, concentration, storage requirements and expiration date according to SOP QC-01-02.
- 6.1.12 Employees understand that any changes in or revisions of an approved protocol must be reviewed and approved by the Study Director and QA (and IACUC if applicable) and maintained with the protocol.

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- 6.1.13 Employees understand that a GLP study must be conducted in accordance with the study protocol, relevant laboratory SOPs, 21 CFR 58 and IACUC policies (if applicable) and will report any noncompliance to the study director or QA.
- 6.1.14 Employees are taught that all specimens received or collected during the study must be logged according to SOP LW-11-01.
- 6.1.15 Employees are reminded that all data generated during the conduct of the study must be recorded directly, promptly and legibly in blue or black ink, initialed by the person entering the data and dated on the date of entry.
- 6.1.16 Employees are instructed that any change in data entries must be made so as not to obscure the original entry, must be dated and signed at the time of the change by the originator of the entry (whenever possible) and should include the reason for the change.
- 6.1.17 Employees understand that all raw data, documentation, protocols, final reports and specimens generated as a result of a study must be retained and archived according to SOP QA-01-01.
- 6.1.18 Employees are expected to report all relevant education, training and experience that have prepared them to perform their assigned functions.
- 6.1.19 Employees provide TGA Sciences, Inc. with a copy of their curriculum vitae and sign a description of their job functions for their training files.