

TGA Sciences Quality Assurance Documentation System

<small>TITLE</small> Employee Training			<small>DOC NUMBER</small> GP-03-01
			<small>VERSION NUMBER</small> T-005
<small>EFFECTIVE DATE</small> February 23, 2009	<small>SUPERSEDES</small> March 2, 2006	<small>LOT NUMBER</small> n/a	<small>PAGE NUMBER</small> 1 of 7

1.0 PURPOSE AND INTRODUCTION

- 1.1 To establish and provide a program that will adequately document the employee training program.

2.0 REFERENCED DOCUMENTS

- 2.1 Good Laboratory Practices (GLP) Training – SOP GP-03-02
 2.2 Good Documentation Practices – SOP GP-08-01

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.

4.0 DEFINITIONS

- 4.1 **Qualified Person** – an individual who is sufficiently trained and knowledgeable in a particular procedure or technique as determined by one or more of the following: experience, documented training, originator of a method (individuals who develop a method and originate the SOP are automatically deemed qualified in that particular method).

5.0 EQUIPMENT AND MATERIALS

- 5.1 Emergency Response Procedures – TGA Sciences, Inc. Training Document
 5.2 Chemical Hygiene Program/OSHA Standards – TGA Sciences, Inc. Training Document
 5.3 Bloodborne Pathogen Safety/Working with Human Blood – TGA Sciences, Inc. Training Document
 5.4 Building Security – TGA Sciences, Inc. Training Document
 5.5 Care and Use of Laboratory Rodents – TGA Sciences, Inc. Training Document
 5.6 Animal Allergies – TGA Sciences, Inc. Training Document
 5.7 Glassware Washing Hazards – TGA Sciences, Inc. Training Document
 5.8 Centrifugation 101 – TGA Sciences, Inc. Training Document
 5.9 Solutions to Dilutions – TGA Sciences, Inc. Training Document
 5.10 GLP Tutorial – TGA Sciences, Inc. Training Document
 5.11 Pre-Employment Health Evaluation

6.0 PROCEDURE

- 6.1 Orientation (New Employee)
- 6.1.1 Soon after starting, a new employee will attend a New Employee Orientation Session coordinated by QA. The orientation will give the employee an understanding of TGA Sciences policies and FDA requirements. Visual and audio aids may be utilized to cover various topics.

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6.1.2 Management or QA will review health and safety principles with all new employees so they are informed of potential hazards associated with their work, understand how these hazards are controlled, and have knowledge of safe work practices and the use of protective supplies and equipment. Minimally, all new employees will be trained on the following topics either internally or by an outside source:

Laboratory personnel: Building Security, Bloodborne Pathogen Safety, Emergency Response Procedures, Chemical Hygiene/OSHA Standards, Good Documentation Practices and Good Laboratory Practices (GLP)

Non-laboratory personnel: Building Security, Bloodborne Pathogen Safety, Emergency Response Procedures, Chemical Hygiene/OSHA Standards

6.1.3 Employees will complete the Pre-Employment Health Evaluation Form which will be kept confidential in the employees personnel file.

6.1.4 Employees are provided comprehensive health services by Mt. Auburn Hospital consisting of serological documentation of immunization with Hepatitis B (or immunization series if required), diphtheria/tetnus vaccines and documentation of PPD skin test of tuberculosis. Mt. Auburn Hospital makes the results of these health assessments and vaccinations available to TGA Sciences.

6.1.5 The Office Manager or management will introduce new employees to the TGA Sciences, Inc. Handbook which explains proper procedures for work schedules, calling in sick, requesting time off, general conduct, etc.

6.2 Departmental Required Training

6.2.1 TGA Sciences' employees directly impacted by approved Standard Operating Procedures (SOPs) require training. Training within a given department will be performed on the latest versions of each applicable SOP.

6.2.1.1 The training should consist of a detailed review of all SOPs relating to the assigned tasks by means of verbal presentation, demonstration, documentation review and, if applicable hands-on training.

6.2.1.2 Each new employee, jointly with QA or management is required to complete the New Employee Training Checklist (7.1) during the training period. The new employee training checklist is designed for the review and sign-off of SOP's relating to standard policies, practices and procedures as well as equipment use. QA or management will determine which SOP's are required based on the employee's specific function. The checklist should be completed within 4 weeks and will be submitted to QA for review and incorporated into the employee's training file.

6.2.1.3 Hands-on training is required for advanced procedures and will be executed by a qualified person (trainer) in the following manner: Trainee will first observe the trainer perform the procedure with verbal instruction. Second, the trainee will perform the procedure side-by-side with the trainer. Side-by-side training will be performed until the trainee has exhibited an understanding of the material. Lastly, the trainee will perform the procedure independently. Once the trainee has performed the procedure

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independently, the results generated from such training will be compared to the results generated from the trainer. An individual is deemed trained when there is no significant difference in results between trainer and trainee determined by % difference or other appropriate statistical mean. In cases where assay acceptability parameters exist, an individual may be deemed trained when an acceptable assay is generated.

- 6.2.1.3 Throughout the training period, employees should be closely supervised by a qualified person. They will be instructed in all relevant techniques associated with the procedure being performed and the required equipment. They should be made aware of the potential problems that may be caused by not following the procedure as written.
- 6.2.1.5 Upon completion of departmental required training, the employee will sign the appropriate training record (Section 7.2, Document Training Record). Check off type of training performed, (i.e., read-only or hands-on training). The training record is then reviewed by QA and incorporated into the employee's training file.

NOTE: The employee's signature certifies that he/she has been given instruction through verbal presentation or hands on training on the performance of the SOPs or has reviewed the listed SOP. The employee has an understanding of the revisions, material, and/or techniques required to perform the procedure. Any questions were addressed to the supervisor or designated trainer before signing.

- 6.2.1.6 Attach appropriate training documentation or training syllabus, if appropriate. This can include raw data results or excel spreadsheets which document hands-on training of a procedure.

6.3 New or Revised Approved SOPs

- 6.3.1 Following approval of new SOPs or new versions of existing SOPs, QA will coordinate and facilitate appropriate training using a Document Training Record (section 7.2). It is the responsibility of QA and the appropriate manager to ensure that appropriate training or retraining is provided to those employees who will use the new or revised SOPs. Upon completion of the appropriate training, the approved SOPs will be given an "Official Use" effective date.

6.4 Training on Special Topics

- 6.4.1 Training on special topics will be performed as necessary by QA, management or an outside source based on the employee's job description and indented function (i.e. Care and Use of Laboratory Rodents, Animal Allergies, Glassware Washing Hazards, Centrifuge Safety, etc). This training will be documented on the Special Topic Training Record (section 7.3). When possible and appropriate, a summary of the training material should be attached to the training record or if an employee attends a seminar or course outside the company, if applicable, a copy of the Certificate provided by the sponsor should be provided to QA for filing.

6.5 Retraining

- 6.5.1 Retraining will be coordinated with QA if determined appropriate by an employee's department manager or supervisor.

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6.5.2 All employees will be re-trained annually on cGMP or GLP guidelines using appropriate training material. Training material will be deemed appropriate by QA. This training will be documented on the Special Topic Training Record (section 7.3). When possible a summary of the training material should be attached to the training record.

6.6 Training Record Maintenance

6.6.1 Document Training records will be maintained by Quality Assurance.

6.6.2 A training summary sheet will be completed and maintained by QA or designee.

6.6.2.1 The training summary will be completed during initial employee training and updated by QA as needed.

6.6.2.2 The training summary will be updated each time a new version of a document is issued and training has occurred. Each time a training summary is updated, a new copy is printed and placed in the employee's training file.

6.6.2.3 In the event that the employee is the originator of the document and is therefore deemed a qualified person, the individual's training summary will state "originator" next to the date of origination.

6.6.2.4 Training records will include the employee's job description along with a curriculum vitae (CV) or resume. The CV must be updated bi-annually.

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7.2 DOCUMENT Training Record

DOCUMENT Number: _____ Version Number: _____

7.2.1 The following employee(s) have been trained on the above SOP by the following qualified person _____ . The employee's signature certifies that he/she has been given verbal presentation or hands on training on the performance or reviewed the new or revised SOP listed and has an understanding of the material and techniques required to perform the procedure. The employee addressed any questions to the area supervisor or the designated trainer and all issues were clearly understood.

Training Performed: (Please check appropriate training method)

Read Only:	Hands On Training:	
NAME (PLEASE PRINT)	(SIGNATURE)	(DATE)
_____	_____	_____
_____	_____	_____
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Comments: _____

Reviewed By/Date: _____

