

The University of Iowa Dezii Translational Vision Research Group

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TITLE: Competency Based Training Program

SOP Number: D-GLO-TR-002

Revision Number: 0

Effective Date: 09 Aug 2015

- 1.1.2. The employee reads the relevant documents and must demonstrate knowledge of them by passing an ICON based quiz.
- 1.2. Demonstration of the technique by trainer.
 - 1.2.1. The technique being trained on is demonstrated by a trainer to the employee.
 - 1.2.2. The employee is now allowed to participate or conduct the technique with supervision (i.e., the employee is in training).
- 1.3. Demonstration of the technique by employee.
 - 1.3.1. When the trainer has determined that the employee is capable of performing the technique without supervision, the trainer will evaluate the accuracy of the technique and provide documentation, where possible, to confirm training.
 - 1.3.2. When the training has been approved by QA, the employee will be able to conduct the technique without further supervision (i.e., the employee is trained).

G. TRAINING ON CRITICAL SOPS

1. Each new employee will be trained on critical SOPs as designated by the department. The SOPs on this list may be read without the corresponding technical training being performed until a later date at which time the SOP will be reviewed.
2. Each department will provide a list to be maintained by the Quality Assurance (QA) group, identifying the critical SOPs for that department.
 - 2.1. This list will include the SOP code and title as well as which training report(s) to complete.
 - 2.2. The list may be modified by the department supervisor based on the position of the employee (e.g., a scientist maintaining equipment in the Functional Analysis group would need a modified QA critical checklist that includes equipment and procedures from QC).
3. A copy of this list will be created for each employee and placed in the training file when complete. When all the training report(s) have been completed on the list, the QA Officer will inform the department supervisor that the training on the critical SOPs has been approved.

H. TRAINING ON SOPs AND/OR OTHER DOCUMENTS

1. SOPs, cGMPs and other guidance documents (e.g. USP, ICH, FDA, etc.) should be grouped together by technique as they relate to piece(s) of equipment or process(es).
 - 1.1. SOP training should be conducted as detailed in SOP D-GLO-PRO-001.
 - 1.2. Some documents that have been previously trained may need to be reviewed as some techniques are demonstrated.

For example, a balance or group of balances being trained on may include the operational SOP(s), the verification SOP(s), USP <41> Weights and Balances, USP <1251> Weighing on an Analytical Balance, USP General Notices section 6.40.20 Dried to Constant Weight and 21 CFR 211 Subpart D on Equipment.

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2. Once the relevant documents have been identified by the trainer, the employee will read them.
 - 2.1. A Standard Operating Procedure Training Report (F-D-GLO-TR-001) will be filled out capturing SOP training. The applicable quiz should be attached.
 - 2.2. A Training Report for DTVR Personnel (F-D-GLO-TR-013) will be filled out capturing cGMP and other guidance document training. Any applicable quizzes or training sheets should be attached.
 - 2.3. If SOP training is conducted at the same time as the technical training, the applicable quizzes may be attached to the Technical Training report (F-D-GLO-TR-014). The SOP should be read and the quiz passed prior to the demonstration by the trainer.
3. For some processes there is no technique to demonstrate (e.g., SOP D-GLO-TR-001 Training Protocol) and the training is complete when the quiz on the SOP has been passed.
 - 3.1. The department supervisor will make the initial assessment on what training (e.g. SOP only or demonstration also) is required for a process.
 - 3.2. The QA group will make the final decision if additional training other than what was completed (e.g. a demonstration of technique) is needed.
 - 3.3. In some cases, completion of SOP training is sufficient for review purposes without further demonstration.
4. Quizzes for training sessions or competency based training that combine training on the SOP, cGMPs and/or other guidance documents may have questions from any of the materials covered (e.g., a training session on SOP D-GLO-PRO-001 Protocol for Standard Operating Procedures may contain questions from 21 CFR 210 and 211 if covered during the training session).
5. If the employee fails a quiz for a training session or initial cGMP training, the trainer will complete the Remedial Training Report (F-D-GLO-TR-010) and determine an appropriate course of action.

I. DEMONSTRATION OF A TECHNIQUE BY A TRAINER TO AN EMPLOYEE

1. The trainer will review each of the listed SOPs, cGMPs or other guidance documents with the employee in detail and, where appropriate, demonstrate the described techniques. More than one trainer may be involved.
2. A Technical Training Report (F-D-GLO-TR-014) will be filled out capturing the demonstration by the trainer in the appropriate section.
 - 2.1. On the Technical Training Report (F-D-GLO-TR-014), the 'Technique Being Trained:' will typically list a piece or group of equipment and an analytical method or process (e.g., performing a Western Blot).
 - 2.2. The document number, revision number and title will list all documents relative to the training (e.g., for analytical method training the document will be the method number, revision number and title).
 - 2.3. The trainer verification of SOP reading and quiz being passed must be completed before the demonstration by the trainer.

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3. The employee is now allowed to participate in or conduct the technique with supervision (i.e. in training).
 - 3.1. The supervisor or qualified trainer may offer guidance or suggestions for improvement to the technique until it is acceptable.
 - 3.2. In some cases, completion of SOP training and a demonstration is sufficient for review purposes without further training. In this case, the Technical Training report should explain the reason for training ending at this stage.

J. DEMONSTRATION OF A TECHNIQUE BY AN EMPLOYEE TO A TRAINER

1. When the trainer has determined that the employee has the necessary knowledge of the technique, the employee will demonstrate the technique without guidance from the trainer.
2. If the technique demonstrated by the employee is satisfactory, the Technical Training Report form (F-D-GLO-TR-014) will be filled out capturing the demonstration by the employee to the trainer (this trainer may be different than the one the employee witnessed from section I) in the appropriate section.
 - 2.1. The trainer at this stage must be qualified to assess the abilities of the employee (see section K).
 - 2.2. The demonstration by the employee may occur months after demonstration by the trainer.
3. Specifications and results or other criteria, as applicable, to evaluate the accuracy of the technique will be listed under Specifications on the Technical Training Report (F-D-GLO-TR-014).
 - 3.1. These specifications may be found in the SOP, analytical methods, batch records and the like.
 - 3.2. The trainer will determine the specifications prior to beginning the demonstration.
4. A reference to a log book, digital laboratory notebook (LabGuru) or batch record to the information of the employee meeting the criteria should be listed under Reference(s) on the form.
 - 4.1. The actual result achieved should also be reported in the Comments section.
 - 4.2. The Reference(s) section on the form may also say 'See attached' with appropriate print outs or copies of the employee meeting the criteria.
5. If the technique demonstrated by the employee is unsatisfactory, the trainer will offer guidance or suggestions for improvement to the technique until it is acceptable.
6. The GMP Trainer, QA Officer, or designate will sign the form verifying the results are within specification or that other criterion has been met and approve that training is successful. The QA Officer will notify the department supervisor that training has been approved (i.e., the employee is trained).

K. QUALIFIED TRAINERS

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1. The QA Officer and GMP Trainer are qualified to train employees at DTVR in cGMP compliance based on their industry experience and continuing training in those areas.
 2. A subject matter expert is qualified to train employees at DTVR on GMP, equipment and processes on the specific task.
 - 2.1. A subject matter expert is an individual who through training, study or experience has extensive knowledge about a particular task to be able to teach or train others.
 - 2.2. This includes, but is not limited to, an individual who installed, wrote or completed the qualification of equipment or software, completed the finalization, transfer or validation of an analytical method, researched or set the steps of a process to ensure compliance with regulatory guidelines, or received training from an outside source or vendor on equipment or a process.
 3. A supervisor is qualified to train employees within their department on GMP, processes and areas of expertise based on experience within their department.
 - 3.1. A supervisor is defined as an individual within a department whose authority is greater than the person being taught or trained within the same department.
 - 3.2. Department Directors will determine which employees are qualified to train a new hire or existing employees within their department on equipment and processes provided they meet the criteria as trained as described in section H, I and J, as applicable.
 - 3.3. Supervisors may sign as trainers to new or revised SOPs provided they are one of the three signors of the SOP or have read the SOP and passed the quiz prior to training remaining department staff.
 4. Any employee may provide cGMP training for employees at DTVR or within their department to meet specific needs. The QA group will review and approve the proposed training materials prior to presentation.
 5. If there is no one currently capable of training on equipment or processes at DTVR (i.e., all qualified individuals have left the WIVR), the QA group or the department will draft a protocol for the training or an employee may be sent for training from the vendor or another reputable outside source.

L. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original document