



GILES CHEMICAL ~ PREMIER MAGNESIA

Company Procedure

Title: **Employee Training**

Number: **Q13-PR-100-006**

Owner: **Rick Hall**

Revision: **02**

Effective Date: **8/01/2017**

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1.0 Purpose

This procedure describes the necessary steps for employee training to ensure all employees engaged in cGMP activities achieve competency in regulations, policies and procedures related to their duties in the production facilities.

2.0 Scope

This training procedure is used to ensure that training has taken place with each employee for procedures and methods that the employee performs. The procedure applies to new-hire training, job specific training and on-the-job training. The training is verified and documented.

3.0 Responsibility

Quality Unit is responsible for ensuring training is completed in a timely manner, maintaining training records and ensuring that trainers are knowledgeable and regularly perform the procedures in which they instruct others.

Area Managers, Supervisors or Training Coordinators are responsible for monitoring employee performance to identify the need for retraining or additional training on new or revised policies and procedures.

All employees are responsible for complying with training requirements.

4.0 Safety Considerations

Always wear facility required PPE including, but not limited to, safety glasses, steel toed shoes.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

- Appropriate training logs

6.0 Procedure

1. Upon employment, the employee will receive benefits orientation with the Human Resources Administrator.
2. After Human Resource's orientation is complete the employee will be sent to Quality Unit for New Hire Training. Training introduces the principles of current Good Manufacturing Practices and regulatory requirements for the manufacturing and repackaging of an Over the Counter Pharmaceutical along with policies and procedures outlining employee safety. Training also

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includes safety videos and quizzes on the material covered. The Training Log – New Hire (Q13-FM-100-005) is utilized for a sequence of topics. Upon completion of each topic of training the employee is to initial and date the form in the appropriate block. The quizzes administered are to measure competency per cGMP requirements. A score of 70% or above is acceptable. An employee score below 70% requires the employee to retake the quiz. If an employee's score is below 70% on the second quiz, the employee must review training module/DVD and retake quiz until score is 70% or above. Additional one on one training is available if needed.

3. After completion of New Hire training employee will be given the Training Log for their specific job responsibility with an assigned completion date. Upon completion of each topic of training, the employee is to initial and date the form. Training Logs are to be completed by the assigned date and turned back into the employee's Manager, Supervisor or Coordinator for sign off. After area Management signs off on the form, the form is to be turned into the Quality Unit. The Quality Unit will then file the form with the employee's training records.
4. Training records will be kept and maintained by the Quality Unit for the duration of the employee's employment with Giles Chemical. When employment is terminated the training records will be archived in the cGMP Library for three years.
5. Employees will be retrained whenever significant changes occur in policies, procedures, processes and methods or anytime a problem arises with the performance or competency of the employee to perform a specified job function. Employee will train or retrain on SOPs anytime procedures are created or revised.

7.0 Reference Documents

<i>Training Log – New Hire</i>	<i>Q13-FM-100-005</i>
<i>Training Log – Lab</i>	<i>L13-FM-100-011a</i>
<i>Training Log – Chemist</i>	<i>L13-FM-100-012a</i>
<i>Training Log – Assistant/Salt Operator</i>	<i>P13-FM-100-001</i>
<i>Training Log – Material Handler</i>	<i>P13-FM-100-002</i>
<i>Training Log – Warehouse Operator</i>	<i>P13-FM-100-003</i>
<i>Training Log – Lead Operator</i>	<i>P13-FM-100-004</i>
<i>Training Log – Repackaging Line Operator and Salt Hanger</i>	<i>R13-FM-100-053a</i>
<i>Training Log – Repackaging Lead Operator</i>	<i>R13-FM-100-054a</i>
<i>Training Log – Repackaging Utility Operator and Material Handler</i>	<i>R13-FM-100-055a</i>
<i>Training Log – Repackaging Shift Supervisor</i>	<i>R13-FM-100-056a</i>

8.0 Change Information

General edits for clarification

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