1.0 Purpose

1.1 The purpose of this procedure is to ensure all Giles Chemical Employees have a general knowledge of Current Good Manufacturing Practices (cGMP).

1.2 cGMP is the part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use. cGMP is aimed primarily at diminishing the risk inherent in any pharmaceutical production. Such risks are essentially of two types: cross-contamination (in particular, with unexpected contaminants) and mix-ups (for example, false labeling).

2.0 Scope

2.1 cGMP training will be conducted upon hire and annually thereafter. Effectiveness will be assessed with a cGMP test. Scoring will be as follows: 90-100 = A, 80-89 = B, 70-79 = C. Any score below a C will have to be retaken until a passing score is achieved. All documents will be maintained by the Quality Unit and filed in a secure location.

3.0 Responsibilities

3.1 Quality is responsible for this procedure.

3.2 All employees are responsible for having a general knowledge of cGMP's.

4.0 Safety Considerations

4.1 Steel toed shoes and safety glasses are required in the Manufacturing and Repackaging areas. 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 the community.

5.0 Materials/Equipment

5.1 N/A

6.0 Procedure

6.1 Record Keeping and Documentation

6.1.1 Use only black or blue ink when documenting data on Quality records.
6.1.2 Use military time when documenting time on Quality records.
6.1.3 When making real time corrections to a document (i.e. any document that may contain applicable dates, times, weight, volumes, and testing results) strike through the item to be corrected with one horizontal line and write in correct

information. Employee must then initial and date beside the item in place of their full name.

6.1.4 Original data should never be destroyed. Never copy, erase, write-over, use whiteout, correction tape or otherwise make the original data illegible.

6.1.5 Backdating a document is never allowed. The "month-date-year" format is used within Giles Chemical.

6.1.6 Information spaces should not be left blank. Put an "NA" or "N/A" in blank information spaces for "Not Applicable." Do not use ditto marks or an arrow to complete consecutive data fields.

6.1.7 Transcribing data onto another document with the intention of destroying the first document is not allowed. Do not use post-it notes or scratch paper that will later be transferred to a quality document.

6.1.8 Incidents of lost documentation must be reported immediately.

6.2 **Quality**

6.2.1 The Quality Director and Quality Unit approve or reject all product, packaging, and labeling of incoming, in-process, and final product.

6.2.2 The Quality Director and Quality Unit are responsible for maintaining adequate laboratory facilities: clean work environment, calibration of all laboratory equipment and documentation of all laboratory testing and outside contractors for lab calibrations.

6.3 **Personnel Qualifications**

6.3.1 All Giles Chemical employees will receive continuous job specific training.

6.3.2 Giles Chemical will provide all shifts with an adequate number of personnel to run the shift.

6.4 **Personnel Responsibilities**

6.4.1 Giles Manufacturing plant is a closed system; therefore employees are not required to wear any protective clothing other than their uniform or Personal Protective Equipment (PPE) when appropriate.

6.4.2 Giles Repackaging Facility is required to wear hairnets, smocks, gloves, and usual PPE when in production areas. **Employees should never touch product without wearing gloves.**

6.4.3 All Giles Chemical employees will follow good sanitation and health habits. Employees will wash hands after visiting the restroom before returning to work. Employees will wear clean clothing and maintain a clean personal appearance.

6.4.4 Food, drink, gum, cell phones and tobacco are prohibited in Production areas and Repackaging. Food, drink and gum are restricted to offices, break rooms and the

smoking area. Cell phones should be kept in lockers and used during break times. Tobacco products are restricted to the smoking area.

6.4.5 Employees must keep their work areas neat and clean.

6.5 **Maintenance**

6.5.1 Maintenance is responsible for ensuring that all equipment is suitable for intended use.

6.5.2 The Facilities and Maintenance Manager is responsible for the coordination of calibration of all production equipment.

6.5.3 The Facilities and Maintenance Manager is responsible for ensuring that all grease and lubricants that come in contact with finished product is food grade. Giles Manufacturing Plant uses food grade grease in areas that have the potential to come in contact with product. Giles Repackaging Facility uses food grade grease in all areas of production.

6.6 **Procedures**

6.6.1 It is the responsibility of the Maintenance Manager, Production Manager, Process Engineer, Director of Operations and Director of Quality to ensure that procedures are written so that employees can perform their job.

6.6.2 cGMP Coordinator or designee is responsible for ensuring that all procedures are placed on the electronic documentation system. A hard copy of the procedure is filed by the Quality Unit and kept in a secure location.

6.7 **Quality Hold**

6.7.1 Giles Chemical Manufacturing Plant employees and Management are responsible for holding any questionable material before release.

6.7.2 Material that is questionable must be tagged with a “Quality Hold” Placard with a statement identifying a reason the material is being held. The material is then placed in the Quality Hold area. This is a designated area in the warehouse of the Manufacturing Plant. Material can also be held in a bin, as long as the bin is clearly marked with “Quality Hold” Placard and roped off with “DO NOT SHIP” tape. Giles Repackaging Facility must rope off material with “DO NOT SHIP TAPE” and place a “Quality Hold” Placard stating a reason for the Hold on the material.

6.7.3 Quality Director or Quality Unit must be notified of the material on Hold. The Quality Unit and Production Manager will review the material and make a decision on whether material can be shipped to a customer or must be discarded.

6.8 **Cleaning of Facility**

6.8.1 Giles Chemical Manufacturing Plant and Repackaging Facility are responsible for maintaining a clean work environment for FDA regulations and the safety of employees.
6.8.2 Giles Chemical Production Manager is responsible for cleaning of all production equipment.
6.8.3 Giles Production Manager is responsible for providing cleaning logs to Quality Department for filing.
6.8.4 Maintenance is responsible for clean-up of their area after service of equipment.
6.8.5 Quality Director, Maintenance Manager, and Production Manager are responsible for providing employees procedures on how to clean their area and equipment.
6.8.6 Procedures will contain cleaning logs where employees must sign off specific items and areas in which cleaning has been performed.
6.8.7 Production Management, the Quality Unit and Operators are responsible for doing weekly Safety/Housekeeping audits and posting it on the bulletin board. Employees are responsible for signing off items that they have corrected and this list should be completed within one month from the assigned date.

6.9 **Pest Control**

6.9.1 Maintenance is responsible for the Pest Control program to prevent entrance of pests and animals from entering the facilities.
6.9.2 Giles Chemical is required by FDA regulations to maintain pest control in their facilities.
6.9.3 Giles Manufacturing Plant, Repackaging Facility and RCF Warehouse controls pest through a contract with Licensed Pest Management.
6.9.4 Licensed Pest Management Contractor performs monthly inspections and bi-monthly spider spray.

7.0 Reference Documents

7.1 cGMP Test

8.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
5	02/12/13	KC	In the scope, added training maintained by the Quality Unit. Changed Main Plant to Manufacturing. Added Maintenance responsibility for the Pest Control.