1.0 Purpose

The purpose of this policy is to outline the highlights of the Current Good Manufacturing Practices (cGMP) program employed by Giles Chemical. Understanding the content within this policy will ensure all Giles Chemical employees have a general knowledge of these mandatory guidelines. cGMP was designed to ensure that processes performed, equipment used, in-process testing and end process testing comply within the standards through proper traceable documentation. This document summarizes key aspects of cGMP in order to assist employees in understanding the meaning and importance of cGMP compliance.

2.0 Scope

This policy is established and is managed by the Quality Assurance Unit to ensure that our quality system containing interrelationships between policies, materials (including raw materials, packaging, equipment, facilities, in-process product, finished product, etc), processes, procedures, and employees are compliant with cGMP guidelines and regulations.

3.0 Responsibilities

Quality Assurance Unit: The Quality Unit is responsible for overseeing the conduct of the cGMP Training program as well as the overall adherence to all required regulations.

All employees: All employees are required to be knowledgeable about cGMP and to follow all applicable policies and procedures.

Management: Management is responsible for ensuring adequate resources are available to implement and maintain cGMP guidelines and regulations.

4.0 Safety Considerations

PPE requirements are to be observed in designated 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

N/A

6.0 Procedure

Giles' products include "over-the-counter" (OTC) products. The FDA specifically requires that all OTC products are required to be manufactured in accordance with cGMP. A manufacturer found to produce OTC products in a non-cGMP environment is subject to very serious and potentially costly actions of the FDA. These actions can include seizure of the product, injunction of the facility, and prosecution of employees.

Key cGMP Concepts

GMPs are changing concepts, so the term "current" is used to reflect that cGMP's are "state of the art" practices to ensure manufactured products are "safe and effective".

Following a Quality System approach, such as the one at our facilities, is a means to ensure compliance with cGMP.

Key cGMP concepts and practices include:

- quality must be built in, not tested into products
- a strong Quality Assurance Unit, independent from manufacturing, is required to ensure compliance
- there are designated areas for quarantine, release and reject material
- internal audits and supplier audits are conducted
- SOPs must be in place to describe how the organization will comply with cGMP.
- there are SOPs for receipt, storage, testing and approval of manufacturing components
- investigations may be performed on Out-of-Specification (OOS) results, non-conformances, deviations, change control, and the analytical laboratory
- investigations are performed on complaints and adverse reactions
- laboratory controls are in place, including the validation of analytical methods and qualification of laboratory equipment following Good Laboratory Practices (GLP)
- claims of expiration date labeling are supported by stability data
- facilities have adequate sewage, sanitation, and are clean and free of pest infestations
- product distribution records are maintained to aid in any necessary recall activities
- all employees engaged in cGMP activities shall wear protective apparel and practice sanitation and health habits
- training in cGMPs is performed, periodically reinforced and documented
- all personnel involved in supervising or consulting cGMP operations shall have the documented education, training, and experience to perform the functions
- change control and document control are critical to cGMP compliance
- product quality must be reviewed at least annually
- document retention requirements are adhered to and documents are readily available
- there are written procedures for the handling of returned product

- qualification of equipment and process validation are adequately planned, executed and documented
- all cGMP activities are clearly documented using Good Documentation Practices (GDP); the common phrase applicable is "if it wasn't documented, it wasn't done"

Areas of Emphasis

cGMP Training

1. FDA requires that all personnel be trained in cGMP practices. Failure to observe these guidelines can lead to legal action up to and including loss of certification(s) or jail.

2. 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 the cGMP Library.

Good Documentation Practices (GDP)

1. Use only black or blue ink when documenting data on Quality records. Erasable pens are not to be used when recording information on a Quality record.

2. Use military time when documenting time on Quality records.

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. Initials used must match the sample given on *Employee Signature Policy (Q12-PL-100-002).*

4. Raw data should never be destroyed. Raw data is created when someone records in writing something that they observed. Raw data should always be recorded by the same person that made the observation and should be recorded on a controlled Quality record. Never copy, erase, write-over, use whiteout or correction tape on or otherwise make the original data illegible.

5. Backdating or forward-dating a document is never allowed. The "month-date-year" format is used within Giles Chemical.

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 without proper approval.

7. Transcribing data onto another document with the intention of destroying the first document is not allowed.

8. Do not use post-it notes or scratch paper that will later be transferred to a quality document.

9. Incidents of lost documentation must be reported immediately.

10. Never sign your name for someone else's work or sign someone else's name to a Quality Record.

11. Remember: "If it isn't documented it didn't happen."

Sanitation

1. All employees and management are responsible for maintaining a clean work environment for FDA regulations and the safety of employees.

2. Procedures will contain cleaning logs where employees must sign off specific items and areas in which cleaning has been performed.

3. Safety and Housekeeping Audits are performed weekly. The results are posted on bulletin boards with corrective actions for employees to complete. The correction rates on these actions are used as part of a calculation for bonuses.

4. All employees will follow good sanitation and health habits per cGMP regulations.

5. All employees are expected to abide by the policies covered in their respective "Safety and Housekeeping Policy". Employees will be required to read and sign this policy upon hiring and periodically thereafter.

6. Employees must keep their work area neat and clean.

7. Eating, drinking, and the use of any tobacco products are restricted to designated areas.

8. A pest control program is in place as specified by cGMP and managed by maintenance.

9. Wood handled implements are not permitted to be in any open-system areas of production area during the manufacturing process.

Personal Hygiene

1. Because Giles manufactures what is considered to be an over-the-counter (OTC) pharmaceutical product, personal hygiene practices by its employees are essential to the production of a quality product free of any contaminants.

2. Employees must wash hands after any of these instances: eating, drinking, smoking, using the restroom, or anytime upon re-entering the work floor.

3. Employees shall wear clean clothing and maintain a clean personal appearance.

4. Employees with illness or any open lesions shall not come into contact with any product. Any cuts/abrasions must be covered by sufficient bandaging.

Quality

1. It is everyone's role at Giles to ensure that a quality product is produced on a consistent basis.

2. The Quality Unit has the final authority in the disposition of all materials including but not limited to raw, in-process, or finished good materials.

3. The Quality Unit's role in ensuring consistent product that meets certain specification comes in two parts:

   - Quality Assurance (QA) – QA is composed of non-production employees that audit all QC activities.

   - Quality Control (QC) - QC will typically be composed of production employees for the purpose of monitoring in-process product..

4. In the event of a product recall, Quality and Production personnel will work together to ensure that any product with possibility of contamination is returned and/or accounted for and in the investigation of circumstances that led to the recall.

Buildings and Facilities

In order to protect the integrity of our product and the safety of all employees, Giles must make all entrances to the building safe and secure. In order to do so, Giles has

implemented an onsite visitor policy and log. Any visitor inside a Giles building must be accompanied by a Giles employee. Also, all external pedestrian doors have been outfitted with a lock that has a security code.

Overhead Glass Policy

In order to prevent contamination, all overhead glass lights will be protected in order to prevent a glass bulb from falling or breaking. Fluorescent bulbs will have straps on them to prevent their falling from the light fixtures and high intensity bulbs will be constructed out of a non-breakable material. This policy applies to manufacturing and repackaging.

7.0 Reference Documents

Q12-PL-100-002 Employee Signature Policy
Q12-PL-100-003 Manufacturing Safety and Housekeeping Policy
R12-PL-100-001 Re-packaging Safety and Housekeeping Regulations
FAC-01 Pest Control for Main Plant
FAC-02 Pest Control for Repack Facility

8.0 Change Information

Updated policy to be more comprehensive and transferred to new *SOP Template Instructions (Q12-PR-100-004)* and Document Numbering *(Q12-PR-100-003)*.