1.0 Purpose

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. As an FDA regulated facility that manufactures an over-the-counter (OTC) drug, regulatory and third party audits are routinely conducted to evaluate compliance with cGMPs. The purpose of this policy is to outline a few basic principles that must be met to assure that the products are of high quality and do not pose any risk to the consumer or public.

2.0 Scope

This policy applies to receipt of materials, production, packaging, repackaging, labeling, quality control, release, storage, distribution, testing, quality assurance and facilities whether manufacturing an API (Active Pharmaceutical Ingredient), OTC or food/feed additive.

3.0 Responsibilities

It is the responsibility of all involved personnel at any level to apply this policy and to act immediately if a risk of violating this policy is detected. The final authority concerning any cGMP issue is with the Director of Quality and/or Director of Operations.

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 Policy

Practices are recommended with the goals of safeguarding the health of humans, animals and environment as well as producing good quality products. Our Epsom salt could be deemed "adulterated" even though it has passed all of the specifications and USP testing if it is found to be manufactured in a facility or condition which violates or does not comply with current manufacturing guidelines. A manufacturer found to produce OTC products in a non-cGMP environment is subject to very serious and potentially costly actions by the FDA. These actions can include seizure of the product, injunction of the facility, and prosecution of employees. Therefore, cGMP compliance is mandatory.

Key cGMP Principles:

- Quality must be built in, not tested into products
- a strong Quality Assurance Unit, independent from manufacturing
- facility must maintain a clean and hygienic production area; all employees engaged in cGMP activities shall wear protective apparel and practice sanitation and health habits
- controlled environmental conditions in order to prevent cross contamination
- manufacturing processes are clearly defined and controlled, all critical processes are validated to ensure consistency and compliance with specifications
- any changes to the manufacturing process are evaluated using Change Control, changes that have an impact on the quality of the product are validated as necessary
- instructions and procedures are written in clear and unambiguous language, operators are trained to carry out and document procedures
- records are made, manually or by instruments, during production that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected
- records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form
- the distribution of the products minimizes any risk to their quality
- a system is available for recalling any batch of product from sale or supply; product distribution records are maintained to aid in any necessary recall activities, adverse reactions will be investigated
- complaints are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective products and to prevent recurrence (CAPA)
- investigations may be performed on Out-of-Specification (OOS) results, non-conformances, deviations, change control, and returned product
- there are designated areas for quarantine, release, and rejected material
- internal audits and supplier audits are conducted
- there are SOPs for receipt, storage, testing, and approval of manufacturing components
- 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
- 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
- product quality is continually reviewed in Management Review
- document control and document retention requirements are adhered to and documents are readily available
- qualification of equipment and process validation are adequately planned, executed and documented
- all cGMP activities are clearly documented using Good Documentation Practices (GDP)

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).

2. Training will be conducted upon hire and annually thereafter. Effectiveness will be assessed with a cGMP quiz. 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. Standard or military time may be used 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. Under certain circumstances, Julian dates are used i.e. expiry dating.

6. Information spaces should not be left blank. Mark all unused spaces with an "N/A" for "Not Applicable." Do not use ditto marks or arrows for repeated information on any controlled document. When there is a block of spaces that are not used, a single diagonal line may be used to mark as "Not Applicable". In this case, use "N/A" and date, initial, and give reason. Footnote designations may be used if more space is needed for an explanation.

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 per FDA regulations and for 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 findings 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 hire 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 the Quality Unit.

9. Wood handled implements are not permitted to be in any open-system areas of production.

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. The presence of such (even if acquired outside of work) must be reported immediately to the area Supervisor, Lead, Manager and/or Q&S Associate; failure to do so may result in disciplinary action.

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. There are two complimentary Quality functions that ensure product meets all specifications:

- 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 the possibility of contamination is returned and/or accounted for and will conduct an investigation of the 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 *On-site Visitor Procedure* (*S12-PR-100-005)* 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 all production areas

7.0 Reference Documents

Employee Signature Policy	*(Q12-PL-100-002)*
Manufacturing Safety and Housekeeping Policy	*(P12-PL-100-001)*
Re-packaging Safety and Housekeeping Regulations	*(R12-PL-100-001)*
Pest Control	*(Q12-PR-100-009)*
On-site Visitor Procedure	*(S12-PR-100-005)*

8.0 Change Information

Added reporting requirement for cuts/abrasions.