# 1. Introduction

## 1.1 History

The founder of Giles Chemical, John L. Giles, came to Waynesville, North Carolina in 1948. His previous ventures were with Morton Salt and prior to World War II, he formed Michigan Chemical, producer of magnesium compounds and bromine.

The Defense Department took over Michigan Chemical and Mr. Giles became a dollar-a-year member of the War Production Board. He was assigned the task of finding magnesium deposits which brought him to Asheville, North Carolina. His search for olivine (20% magnesium) led him to Balsam, North Carolina where, after the war, he purchased an area that had an outcropping of olivine.

This mineral was processed for refractory use and sold to brick manufactures, as well as, for the atomic energy project in Oak Ridge, Tennessee.

Michigan Chemical operated a magnesium oxide (MgO) facility in Florida whose purity was 99% MgO, while olivine contained only 20% MgO. The source in Florida displaced the ore from Balsam, North Carolina.

While olivine was selling for $15 per ton, Epsom Salt brought $50 per ton. As a result, Mr. Giles worked out crystallizing techniques for the manufacture of Epsom Salt in Waynesville, where production began in 1950.

His first customers were the tanneries all along the Appalachian Mountains. Rayon manufacturers were next followed by wood pulp producers, resale druggists, animal glue manufacturers and dye divisions of the textile industry.

In 1965, the plant was bought by Howard Split whose 28 years in the industrial chemical distribution helped expand the business.

In 1995, the business was purchased by Richard N. Wrenn, Jr.

On February 27, 2007, Giles Chemical merged with Premier Magnesia, LLC. Premier Magnesia manufactures a wide variety of magnesium oxide and magnesium hydroxide products. Giles Chemical produces Magnesium Sulfate Heptahydrate also known as Epsom salt. Our Repackaging plant repackages Epsom salt into cartons and pouches.

Giles Chemical has been a leader in magnesia chemicals for over 30 years. Premier Magnesia is the primary manufacturer of magnesium oxide and magnesium hydroxide and offers more grades of magnesia chemicals that any other supplier.

The end uses have expanded to plastics, rubber, synthetic food sweeteners, animal feeds, agricultural and various other industrial usages as well as pharmaceutical industry products.

## 1.2 Giles Chemical Production Activities

Activities at Giles Chemical, a division of Premier Magnesia LLC, are the production of magnesium sulfate in both liquid and crystalline form and repackaging operations.

The company's facilities are located as follows:

**Giles Chemical**
**Manufacturing**
**102 Commerce Street**
**Waynesville, NC 28786**

**Giles Chemical**
**Repackaging**
**393 Smathers Street**
**Waynesville, NC 28786**

**Production Activity at the Manufacturing Facility:**

Magnesium Oxide, Sulfuric Acid, and Water are used in the manufacture of Magnesium Sulfate Heptahydrate. The principal ingredients are stored in tanks and silos and dispensed from there at prescribed rates to digesters where a chemical reaction occurs, and $MgSO_4$ brine is formed. The brine is filtered and directed to Vacuum Crystallizers where crystal growth is promoted. Next, crystals are separated from residual liquor, dried and packaged for shipment to customers. Liquid product is also produced in which the brine, at specified strength, is shipped direct to customers via liquid transportation. All raw materials arrive in bulk by either rail car or truck. Finished product is shipped out via truck and rail service.

**Production Activity at the Repackaging Facility:**

Bulk bags of Magnesium Sulfate are brought into the facility to be repackaged into much smaller retail presentations. We are able to provide a finished product ready to display on the store shelf in the following presentations: USP Pouch, USP Carton, and Scented Pouches.

**Production Activity at the Greendale Facility:**

Magnesium Oxide, Sulfuric Acid, and Water are used in the manufacture of Liquid Magnesium Sulfate. The principal ingredients are stored in tanks and silos and dispensed from there at prescribed rates to digesters where a chemical reaction occurs, and $MgSO_4$ brine is formed. The brine is filtered, diluted, and stored in tanks to await shipping to customers.

## 2.0 Scope

This Quality Manual and the Quality Management System at Giles Chemical, a division a Premier Magnesia, LLC (Giles) have been developed incorporating the recommended elements in International Conference on Harmonization (ICH) Q10 *Pharmaceutical Quality System*, Q7 *GMP Guide for APIs* and are in compliance with the requirements outlined in the FDA's current Good Manufacturing Practices (cGMP) 21 CFR 210/211.

This Quality Manual applies to the systems supporting the manufacture of Magnesium Sulfate Heptahydrate throughout the product lifecycle. The product lifecycle includes the following technical activities for new and existing products:

- Pharmaceutical Development
  - Process Development
  - Manufacturing of process development and scale-up
  - Analytical method development
- Technology Transfer
  - New product transfers during development through manufacturing
  - Transfer of processes to customers
- cGMP Manufacturing
  - Acquisition and control of materials
  - Provision of facilities, utilities, and equipment
  - Production (including packaging and labeling)
  - Quality control and assurance
  - Release
  - Stability
  - Storage
  - Distribution
- Product Discontinuation
  - Retention of Documentation
  - Sample Retention
  - Continued product assessment and reporting

## 3.0 Quality Objectives

**Achieve Product Realization** – To establish, implement and maintain a system that assures the delivery of products with the quality attributes appropriate to meet the needs of our customers (internal and external) and regulatory authorities.

*Measurable:* Customer Complaints
Customer and Regulatory Audit Results

**Establish and Maintain a State of Control** – To develop and implement monitoring and control systems for process performance and product quality, thereby providing assurance of continued suitability and process capability using quality risk management to aid in the identification of these systems.

*Measurable:* Trend Charting
Statistical Process Control (SPC)

**Total Quality Improvements –** Continuously improving all aspects of the total Quality System facilitated by applying the principals of quality risk management.

*Measurable:* Customer Returns
Internal Audits
Corrective Actions
Supplier Corrective Actions

**Employee Loyalty –** Building Long Term Relationships through the power of the "***Our House"*** philosophy and quarterly bonuses propelling improvements by the employee sharing in the gains of increased productivity.

*Measurable:* Turnover rates

**Manufacturing –** Implementing world class manufacturing and information systems.

*Measurable:* Yields and Utilization

## 4.0 Mission Statement

Giles' mission is to continually improve products and service, to meet the customers' needs and requirements, which will promote growth, improvement, and prosperity, as a business. Giles' will conduct all aspects of its business in an ethically moral and responsible manner.

To support the mission, Giles is committed to:

Servicing customers' needs with quality products which meet or exceed mutually agreed upon specifications and standards.

Continuously improving performance in delivering products to customers in a timely fashion.

Focusing on a total quality approach to processing as a means of preventing non-conformances and constantly improving systems to maintain the production of high quality products.

Protecting the safety and health of employees, the public and the environment by conducting operations in a safe responsible manner.

Building long-term partnerships with customers and suppliers and basing these relationships on mutual trust and respect.

Providing employees with the training and tools required to do their jobs efficiently and effectively, thus allowing them to contribute personally and individually to the achievement of quality.

Creating an atmosphere which encourages all employees to learn and grow professionally throughout their careers, and which allows them to participate in decision-making and problem-solving.

## 5.0 Quality Policy

To achieve excellence in all that we do, exceeding the expressed needs and expectations of our customers, focusing on never ending Quality Improvement, using World Class Manufacturing, Engineering, and Information Systems resulting in employee and customer trust within an environment that embodies the philosophy of ***"Do it right the first time, every time"***.

Giles' management is committed to the Quality Policy as the cornerstone of our quality management system. This policy is a living document that guides our strategic quality direction. Giles' Quality Policy is consistent with its organizational goals, the expectations and needs of its customers, complies with applicable regulatory requirements and facilitates continual improvement.

Giles ensures that this policy is understood, implemented and maintained at all levels throughout the company.

This policy is approved and will be reviewed periodically for continuing effectiveness by:

President, Jim Hill
Director of Operations, Matt Haynes
Director of Quality & Safety, Deborah Durbin
Manufacturing Manager, Jason Bumgarner
Repackaging Manager, Monte Plott

## 6.0 Management Responsibility

Senior management within Giles has the ultimate responsibility to ensure that an effective quality system is in place to achieve our quality objectives and that roles, responsibilities and authorities are defined, communicated and implemented throughout the company.

Giles' management demonstrates its commitment by:

- Participating in the design, implementation, monitoring and maintenance of the quality system.
- Providing strong and visible support for the quality system and ensuring its implementation throughout the organization.
- Ensuring that a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management.
- Defining individual and collective roles, responsibilities, authorities and inter-relationships of all organizational units related to the quality system and ensuring that these interactions are communicated and understood at all levels of the organization.
- Ensuring that an independent quality unit exists with the authority to fulfill the requirements for quality systems as defined within applicable regulations.
- Conducting management reviews of the quality system utilizing performance indicators that measure progress against quality objectives.

*Supporting Documentation:*

| | |
|---|---|
| *Management Review* | *Q12-PR-100-007* |
| *Internal Quality Audits* | *Q12-PR-100-008* |

## 7.0 Quality Management System

Giles' has established and implemented a Quality Management System in accordance with the applicable requirements and is dedicated to continual improvement. The Quality Management System includes the following elements:

**People:**

Giles has in place an adequate organizational structure and sufficient personnel to assure that product is manufactured in accordance with cGMP regulations. All employees have job descriptions and are suitably qualified and trained to carry out their allocated duties.

At Giles, the Quality System is managed by the Quality Assurance unit. The Quality Assurance unit is separate from and independent of Production (Manufacturing/Repackaging). Whenever there is a conflict or difference of opinion between quality and production, the quality decision shall not be able to be overruled by management or production.

The responsibilities of the Quality Unit are as follows:

- **To establish the quality system**
  - Establish the quality management system to describe how Giles complies to cGMPs and operates to maintain a state of control.
  - Keep current with good industry practices and apply to the mission of the operation.

- **To audit compliance to the quality system**
  - Audit for compliance to policies and procedures: on paper vs. practice.
  - Report on the performance of the quality system, including trends, that help in the decision making for targeted actions

- **To establish procedures and specifications**
  - Ensure that procedures and specifications are appropriate and followed.
  - Ensure that if third-party service providers are used, the procedures and specifications are also appropriate and followed, i.e. contract laboratories.

- **To establish manufacturing controls**
  - Ensure that appropriate manufacturing in-process controls are implemented.
  - Ensure in-process controls are performed during manufacturing operations and results are satisfactory.

- **To perform laboratory tests or examinations**
  - Perform laboratory testing of components, containers, in-process materials, packaging materials and final product using validated methods against scientifically-derived, fit-for-purpose specifications.
  - Approve or reject final products manufactured and packaged.

- **To review and approve or reject all things cGMP**
  - Review and approve/reject any document that gives work instructions and set requirements such as procedures, protocols, test methods, and specifications—including changes to these documents.
  - Review and approve/reject reprocessing and rework procedures.
  - Review and approve/reject production batch records and make the final decision to release a product lot into commerce.

- **To ensure investigation of nonconformance**
  - Ensure an investigation is conducted and the root cause is eliminated for production and control record errors, discrepancies, and failure to meet specification, including quality attributes.
  - Review complaints to determine if it relates to a failure to meet specification, if so investigate and report to FDA if it is serious and unexpected.

- **To keep management informed**
  - Report on product, process and system risks—and keep management informed.

- Report on outcome of regulatory inspections and ensure responses are complete and managed to verifiable closure—and keep management informed.

- **To describe responsibilities in writing**
  - Have a complete and compliant procedure that describes responsibilities
  - Follow the procedure

- **To remain independent**
  - Ensure there is no conflict of interest between regulatory responsibilities and actual daily activities.
  - Be independent reviewer and approver with respect to manufacturing and process/ product development units.

*Supporting Documentation:*

*Organizational Chart*
*Job Descriptions*

**Premises:**

All premises and equipment used for the manufacture, repackaging and testing of Magnesium Sulfate are constructed, validated, cleaned and maintained in order to ensure that products are adequately protected, minimizing the possibility of contamination.

**Equipment:**

All equipment used for manufacturing, repackaging and testing of product is validated, maintained and calibrated to ensure both reliability and reproducibility of operations.

**Processes:**
All manufacturing and repackaging processes follow specifications agreed upon between the Customer and Giles. All manufacturing and repackaging follow and are recorded on approved Daily Production Records such that full traceability of all operations and conditions are maintained. Daily Production Records are reviewed and approved by both Production and QA prior to issue and after completion of manufacturing and repackaging operations.

**Products:**

The only product that Giles manufactures is bulk Epsom salt. Giles has no repackaged product of its own. Therefore, there is no conflict between Giles' own products and those of its customers.

**Procedures:**

All cGMP production and testing activities are described in Quality approved procedures and analytical methods. Key quality system procedures include: Training, Validation, Change Control, Deviations, Complaints, Recalls, Vendor Assurance, Quality Agreements, Specifications, Analytical Method Qualification, Out of Specification, and Product Release.

**Product Release:**

All products, bulk or repackaged, are released by appropriately experienced and qualified members of the Quality unit.

## 8.0 Quality System Processes

### *8.1 Documentation System*

Good, detailed, precise, correctly completed and well controlled documentation is key to the successful and compliant manufacture of pharmaceutical products. Giles utilizes a comprehensive system of documentation for all cGMP manufacturing, repackaging and testing activities. All documentation is available for review by employees, customers and regulatory authorities.

*Supporting Documentation:*

| | |
|---|---|
| *Document Control Procedure* | *Q12-PR-100-002* |
| *Document Numbering Procedure* | *Q12-PR-100-003* |
| *Document Approval Form* | *Q12-PR-100-F002* |
| *Document Retention* | *Q12-PR-100-005* |

### *8.1a Procedures, Policies and Forms:*

All cGMP activities are detailed in Procedures, Policies and Forms which have been reviewed and approved by relevant, qualified personnel as being fit for purpose and in compliance with regulatory requirements.

Procedures, Policies and Forms are available for use in the work area. These documents are available as "read only" in electronic format on the *Document System* via company intranet. Procedures, Policies and Forms also form the basis for training. To ensure that all documents may be understood and followed, translation to Spanish is available.

*Supporting Documentation:*

| | |
|---|---|
| *Master Controlled Document List* | *Q12-PR-100-F003* |
| *IT and Electronic Records* | *Q12-PR-100-020* |
| *SOP Template with Instructions* | *Q12-PR-100-004* |

### *8.2 Training*

A system has been established which ensures employees are trained in quality awareness, occupational safety and health and specific job related functions. All employees engaged in cGMP activities undergo initial training in the principals and practices of cGMP prior to assignment in a cGMP area. Employees also undergo annual refresher training in cGMP.

Our training program is set up in multiple phases beginning with New Hire Training. The next phase is a job specific program for new employees engaged in cGMP activities. Employees are fully trained in the procedures or methods relevant to their activities in accordance with each area's training procedures. Employees will participate in an on-going training program throughout their employment. Where necessary, employees are certified to perform certain manufacturing or quality procedures and are recertified annually. All training will include measures of competency from tests to performance evaluations.

*Supporting Documentation:*

| | |
|---|---|
| *Employee Training* | *Q13-PR-100-006* |
| *Document Training Roster* | *Q12-PR-100-F006* |
| *Good Manufacturing Practices* | *Q12-PL-100-003* |
| *Good Manufacturing Practices in Spanish* | *Q12-Pl-100-004* |
| *Training Log – New Hire* | *Q13-FM-100-005* |
| *Training Log – Lab* | *L13-FM-100-011a* |
| *Training Log – Chemist* | *L13-FM-100-012a* |
| *Training Log – Assistant Operator* | *P13-FM-100-001a* |
| *Training Log – Repackaging Lead Operator* | *R13-FM-100-054a* |

### *8.3 Validation*

As a manufacturer of an active pharmaceutical ingredient (API), manufacturing processes and analytical methods are validated. Validation documents ensure, with a high degree of assurance, that the process is controlled and consistently produces a product that meets pre-determined specifications and quality characteristics.

A Master Validation Plan has been approved for all equipment used for cGMP manufacture and analysis, together with the facilities and utilities associated with these activities. The purpose of this program is to ensure that all equipment, analytical methods, and processes are fully validated, calibrated, and maintained in order to ensure their conformance to design, reliability and fitness for purpose. Validation documentation includes (as appropriate): validation master plans, protocols, design qualifications, installation qualifications, operational qualifications performance qualifications, and validation reports.

*Supporting Documentation:*

| | |
|---|---|
| *Validation* | *Q12-PR-100-018* |
| *Manufacturing Master Validation Plan* | *E13-VAL-PVP-001* |
| *Repackaging Master Validation Plan* | *E13-VAL-RVP-002* |
| *USP ICP Method Validation Protocol* | *L13-PR-100-050* |

### *8.4 Non-conforming and Out of Specification*

Giles has established and maintains documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use. This control provides for identification, documentation, evaluation, segregation and disposition of non-conforming and OOS product, and notification to the entities concerned. Giles does not produce a grade identified as Damaged Product.

The Quality Unit has the ultimate responsibility to review and authorize the disposition of non-conforming and OOS product. Records of these variances, including investigations, inspections, and testing performed shall be maintained.

Possible dispositions are:

a) reprocessed to meet specified requirements
b) accepted without reprocessing by concession
c) regarded for alternative applications
d) shipped to a willing customer by agreement
e) scrapped

*Supporting Documentation:*

| | |
|---|---|
| *Non-conforming Material* | *Q12-PR-100-017* |
| *Non-conforming Material Report* | *Q12-PR-100-F017* |
| *Returned Product* | *Q13-PR-100-011* |
| *Rework/Reprocess* | *Q12-PR-100-021* |
| *Out of Specifications (OOS)* | *Q13-PR-100-025* |

### *8.5 Change Control System*

All changes potentially impacting quality relating to Giles' cGMP facilities, systems, processes, methods, procedures or equipment are carefully controlled by the use of a formal Change Control System. This ensures that all potential benefits and risks are assessed in a controlled manner prior to a change being implemented. It also defines and tracks the actions required for successful implementation and closure of the change and where appropriate an assessment of the outcome. When it has been determined that re-validation/validation is required, it will be considered a part of the Change Control System. Pre- and post-change activities are approved by Quality.

The Change Control System ensures continual improvement is undertaken in a timely and effective manner. It provides a high degree of assurance that there are not any unintended consequences of the change. The Change Control System is applied throughout the product lifecycle.

*Supporting Documentation:*

| | |
|---|---|
| *Change Control System* | *Q13-PR-100-027* |
| *Change Control Logbook* | *Q13-PR-100-F027a* |
| *Change Control Request* | *Q13-PR-100-F027b* |

### *8.6 Deviations*

A Deviation is a non-permanent departure from approved quality procedures, policies, processes or where there have been unusual or unexplained events which have the potential to impact product quality, system integrity or personal safety. Deviations are documented and managed effectively. For compliance to cGMP and for the sake of continuous improvement, deviations are recorded in the form of a Deviation Report. When applicable, QA will oversee that deviations are fully investigated in a timely manner in order to determine root causes and the associated actions to prevent recurrence.

*Supporting Documentation:*

| | |
|---|---|
| *Deviation Reporting* | *Q13-PR-100-024* |
| *Deviation Report* | *Q13-PR-100-F024* |

### *8.7 Process Performance and Product Quality Monitoring*

Using quality risk management, Giles has identified and planned the production processes which directly affect quality and ensures that these processes are carried out under controlled conditions. Product characteristics are monitored and measured to verify that the product requirements have been met. Where appropriate, procedures are established to identify the required statistical techniques to evaluate data within our operations. This is carried out at appropriate stages of the product realization process.

Appropriate data is collected and analyzed to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.

*Supporting Documentation:*

| | |
|---|---|
| *Management Review* | *Q12-PR-100-007* |
| *Internal Quality Audits* | *Q12-PR-100-008* |
| *Daily Quality Audit* | *P12-PR-100-077* |

| | |
|---|---|
| *Continuous Process Control* | *Q13-PL-100-001* |
| *Calculating Daily MgO Yield* | *P12-PR-100-056* |

### *8.8 Vendor Qualification and Raw Material Release*

The quality of all raw materials and contracted services is appropriately assured depending on the use and criticality of the material or service being employed. Quality Assurance is responsible for performing an initial evaluation of a potential critical vendor, evaluating the vendor's quality system, assigning vendor status ('approved" or "not approved"), reporting vendor quality performance on a continuous basis and establishing and maintaining individual critical vendor archival files. This ensures the performance capabilities of vendors and maintains the internal controls for appropriate vendor selection and on-going vendor re-assessment.

All raw materials are inspected and released by the Quality unit in accordance with the relevant material specification before used in production. Testing of quality critical materials (raw, packaging) may be reduced depending on the performance of the vendor over a period of time and the criticality of the material.

*Supporting Documentation:*

| | |
|---|---|
| *Critical Vendor Qualification Program* | *Q12-PR-100-023* |
| *New Vendor Approval Request* | *Q12-PR-100-F023a* |
| *New Vendor Qualification Letter* | *Q12-PR-100-F023b* |
| *Vendor Self-Assessment Survey* | *Q12-PR-100-F023c* |
| *Vendor Approval Letter* | *Q12-PR-100-F023d* |
| *Vendor Re-assessment* | *Q12-PR-100-F023e* |
| *Vendor Site Quality Audit* | *Q12-PR-100-F023f* |
| *Approved Vendor List* | *Q12-PR-100-F023g* |
| *In-coming Raw Materials – Super Sacks and Liners* | *P13-PR-100-075* |
| *In-coming Raw Materials – MgO and H2SO4* | *P13-PR-100-076* |
| *In-coming Raw Material – Pouch – Carton* | *R12-PR-100-013* |
| *In-coming Raw Material - Fragrance Barrel* | *R12-PR-100-014* |
| *Incoming Raw Material – MgSO4* | *R13-PR-100-032* |

### *8.9 Stability Testing*

Product will not be released for consumer use without adequate determination of the product's stability. Stability studies include an evaluation of the product's physical and chemical properties to determine temperature sensitivity and susceptibility to degradation over time. The results of on-going stability testing are used to confirm appropriate storage conditions and expiry dates.

*Supporting Documentation:*

| | |
|---|---|
| *USP Stability Testing* | *L12-PR-100-010* |
| *USP Stability Testing Summary Worksheet* | *L12-PR-100-F010* |
| *USP Sampling Procedure for Testing and Sample Retention* | *L12-PR-100-009* |

### *8.10 Product Release*

The Manufacturing Facility is a continuous flow process where a sampling plan has been designed to assure quality through statistical process control. Critical processing variables and their effect on performance and quality have been identified with the goal of improving product quality by designing it into the process. Released product is defined by the date/time it was produced. This allows for characterization of the quality attributes of the raw materials and traceability in the event of a recall. At the Repackaging Facility, final product is tested, retained and released based upon a lot code that represents the expiry date. Traceability of bulk material is maintained throughout the Repackaging Facility.

The Quality unit is responsible for the appropriate laboratory determination of satisfactory conformance to final specifications and approves/releases or rejects product accordingly.

*Supporting Documentation:*

| | |
|---|---|
| *Batch/Lot Numbering and Sampling* | *Q13-PR-100-010* |
| *Liquid Load Release* | *L12-PR-100-024* |
| *Release of Arch Loads* | *L12-PR-100-038* |
| *Release to Repack* | *Q12-FM-100-003* |
| *Non-conforming Material* | *Q12-PR-100-017* |
| *Non-conforming Material Report* | *Q12-PR-100-F017* |

### *8.11 Corrective Action and Preventive Action (CAPA) System*

All complaints are dealt with promptly by appropriately experienced members of the Quality unit. A system exists for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections/findings and trends from process performance and product quality monitoring. Our CAPA methodology results in product and process improvements and enhanced product and process understanding. A documented procedure is established to define requirements for:

- Reviewing non-conformities (including customer complaints)
- Determining the causes of non-conformities
- Evaluating the need for action to ensure that non-conformities do not recur
- Determining and implementing action needed

- Recording of the results of any investigation and action taken
- Reviewing corrective action taken and its effectiveness

The process for handling and reporting adverse events is described within the Complaint Handling System.

*Supporting Documentation:*

| | |
|---|---|
| *Corrective and Preventive Action System* | *Q13-PR-100-014* |
| *Corrective/Preventive Action Request* | *Q13-PR-100-014a* |
| *Corrective/Preventive Report* | *Q13-PR-100-F014b* |
| *Complaint Handling System* | *Q13-PR-100-019* |
| *Complaint In-take Information and Initiation* | *Q13-PR-100-019* |

### *8.12 Recalls*

It is the responsibility of the Quality unit to approve and coordinate any final decisions and communications involving a product recall or withdrawal. Procedures have been established to define the recall/withdrawal of a product and the conduct of a mock recall exercise annually.

*Supporting Documentation:*

| | |
|---|---|
| *Recall / Withdrawal Procedure* | *Q12-PR-100-013* |
| *Notification of Recall* | *Q12-PR-100-F013a* |
| *Notification of Withdrawal* | *Q12-PR-100-F013b* |
| *Recall / Withdrawal Action Log* | *Q12-PR-100-F013c* |
| *Recall Team* | *Q12-PR-100-F013d* |
| *Recall / Withdrawal Report* | *Q12-PR-100-F013e* |
| *Quarantine and Auditing of Product* | *Q11-PR-100-012* |

## 9.0 Appendix

### I. Distribution

An updated Master Copy of the Quality Manual is maintained on the Giles Intranet Document System and a hard copy is kept in the Quality Laboratory. All employees are required to read the Quality Manual as part of their new hire training. It will be documented that the employee has read and understood its contents. Thereafter, the Quality Manual is available to all employees for reference either on the Giles intranet or in the Quality Laboratory. Revisions will be communicated to employees during monthly employee meetings.

### II. Document Approval

| DOCUMENT APPROVAL | | | | |
|---|---|---|---|---|
| **GILES QUALITY MANUAL** | | | | 2012 |
| **Approval Required** | **Date** | **Approved** | **Rejected** | **Signature** |
| President – ***Jim Hill*** | 11/16/12 | ✓ | | Jim Hill |
| Director of Operations – ***Matt Haynes*** | 11/16/12 | ✓ | | Matt Haynes |
| Director of Quality – ***Deborah Durbin*** | 11/15/12 | ✓ | | Deborah Durbin |
| Manufacturing Manager – ***Jason Bumgarner*** | 11/21/12 | ✓ | | Jason Bumgarner |
| Repacking Manager – ***Monte Plott*** | 11/21/12 | ✓ | | Monte Plott |

- The above approval signatures (on hard copy in cGMP Library) indicate review, approval and issue of every page within the attached document or manual. This manual must be re-approved either after 10 revisions have been made or after it has undergone its three year document review.

## III. Revisions List

| REVISIONS LIST | | | | |
|---|---|---|---|---|
| GILES QUALITY MANUAL | | | | 2012 |
| **DATE** | **SECTION / PAGE** | **PARAGRAPH** | **COMMENTS** | **APPROVAL** |
| 02/13/13 | N/A | N/A | Original Quality Manual completely revised to reflect ICH recommendations | DD |
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| **AFTER TEN (10) REVISIONS, THIS MANUAL MUST BE RE-ISSUED** | | | | |