1.0 Purpose

1.1 The purpose of this procedure is to ensure documents are clearly written in a detailed and precise format, well controlled and traceable throughout the lifecycle of the document. Documentation provides the route for auditors to assess the overall quality of Operations within a company and the final product.

2.0 Scope

2.1 This procedure defines the standardization of how documents are written, received, approved, distributed, archived and maintained at Giles Chemical.

3.0 Responsibility

3.1 All employees that submit documents are responsible for following this procedure.

3.2 The cGMP Coordinator or designee is responsible for ensuring that all activities involved in the preparation, approval and administration of documents are carried out in accordance with this procedure.

4.0 Safety Considerations

4.1 Special safety precautions are not applicable. 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

5.1 N/A

6.0 Definitions

Document Owner – Person who authored the document or subsequent revisions.

Effective Date – The date assigned to an approved document to be published and will be available to all applicable employees.

Forms – Forms include documents that are written at a level of detail to render them self-explanatory, or stand-alone. Other forms are linked to a policy or procedure and can include recorded information demonstrating compliance with the associated policy or procedure.

Policy – A document that describes in general terms, not with step-by-step instructions, how specific GMP aspects (such as security, documentation and responsibility) will be implemented.

Procedure – Step-by-step instructions for performing operational tasks or activities.

Revision Number – The number assigned to a new or existing document after all revisions have been approved. The last revision number assigned is defined as the current effective document.

7.0 Submission Approval of New Documents and Revisions

7.1 All Procedures must be written using the standardized template defined in, *SOP Template with Instructions* Q12-PR-100-004.

7.2 All documents, new or revised, must be submitted for final approval to the cGMP Coordinator or designee using *Document Approval Form* Q12-PR-100-F002. The document owner will obtain relevant approval signatures from the departments affected by the new document or revision.

7.3 Submitted new documents will be assigned a unique document number. The cGMP Coordinator or designee will generate this number from *Master Controlled Document List* Q12-PR-100-F003 in accordance with *Document Numbering Procedure* Q12-PR-100-003.

7.3.1 Revision numbers will be issued sequentially where the original document will be Revision 0 (zero).

7.4 The cGMP Coordinator or designee will review the document and *Document Approval Form* Q12-PR-100-F002 for clarity and completeness. Upon completion the document will be released for training purposes.

7.4.1 The document owner shall coordinate circulation of approved documents with a *Document Training Record* Q12-PR-100-F006 for signatures. If an additional training format is needed, a copy of those training records will be submitted to the Quality Unit for filing in Personnel Files. In most cases training will be completed within two weeks of the effective date.

7.5 Once training records have been returned to the Quality Unit, the cGMP Coordinator or designee will approve the document for issuance and publish to the Electronic Document System (EDS) with an effective date.

7.5.1 In some cases an Effective Date can be issued before training is complete if approved by the cGMP Coordinator or designee.

8.0 Disposition of Approved Documents

8.1 Approved documents will be uploaded to an EDS located on Giles' Intranet in PDF format for security. A hard copy of all documents and approval forms will be managed by the cGMP Coordinator or designee for the purpose of maintaining revision history and change information. All documents will be stored in a secure location.

8.1.1 Approved documents printed from the EDS will be timed stamped when printed. However, it will be the responsibility of the employee to use the most current revision.

9.0 Document Revision

9.1 All controlled documents shall be reviewed every 3 years to determine if they are applicable for current operation and revised immediately if they are not.

9.1.1 The document owner will be notified to conduct a thorough review of the identified documents.

9.1.2 Upon completion of the review, the document owner must submit a completed *Document Approval Form* Q12-PR-100-F002 with the document regardless if changes or revisions are needed.

10.0 Document Archival

10.1 Original documents and subsequent revisions leading up to the current revision uploaded to the EDS will be retained and filed in a secure location for the life of the document. Access to these documents will be read only.

10.2 Documents no longer in use, including the original and revisions, will be considered obsolete. These documents will be stored in a secure off-site location for a minimum of three years.

11.0 Reference Documents

11.1 *SOP Template with Instructions* Q12-PR-100-004
11.2 *Document Approval Form* Q12-PR-100-F002
11.3 *Master Controlled Document List* Q12-PR-100-F003
11.4 *Document Numbering Procedure* Q12-PR-100-003
11.5 *Document Training Record* Q12-PR-100-F006

12.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
3	12/20/2012	KC	Original procedure completely revised to reflect ICH recommendations.

Figure 1. Flowchart on Document Control for New Documents, Revisions and Archived Documents.