1.0 Purpose

The purpose of this procedure is to define the Corrective and Preventive Action (CAPA) system and to outline the process for completing, documenting and implementing corrective or preventive actions in a formal and timely manner. Properly documented actions provide important historical data for continuous quality improvement and are essential for any product that must meet regulatory requirements demanded by FDA and other quality systems.

2.0 Scope

All processes, products and procedures of Giles' Quality System are areas where the CAPA process can be utilized. Input into the CAPA system can come from a variety of internal and external sources. Depending on the nature/scope of the CAPA, it may take many days or weeks to identify the root cause(s), implement a solution(s) and verify that the solution(s) were effective.

3.0 Responsibility

Quality Unit – is responsible for overall management of the activities described in this procedure.

Area Manager – of the department where the problem is identified is responsible for overseeing the investigation and preparation of an action plan as described in this procedure.

4.0 Safety Considerations

PPE required in designated areas shall be donned.

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

N/A

6.0 Procedure

CAPA is a fundamental management tool that is an essential element of Giles' Quality System. Regulatory risk-based CAPA requirements demand a well documented system that determines the root cause of non-conformances, system failures, or process problems, corrects the problems and prevents them from recurring. The documentation must indentify why something went (or may go) wrong and what has been done to make sure it does not happen again. A structured approach to the investigation process is used with the objective of determining the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk.

Corrective Actions: The process of reacting to an existing product problem, customer complaint or other non-conformity and fixing it.

Preventive Actions: A process for detecting potential problems or non-conformances and eliminating them.

The CAPA System consists of seven basic steps:

1. Identification – clearly define the problem
2. Evaluation – appraise the magnitude and impact
3. Investigation – make a plan to research the problem
4. Analysis – perform a thorough assessment
5. Action Plan – create a list of required tasks
6. Implementation – execute the action plan
7. Follow Up – verify and assess the effectiveness

6.1 Identification and CAPA Request

The initial step in the process is to clearly define the problem or potential problem. This should include the source of the information, a detailed explanation of the problem, and documentation of the available evidence that a problem exists.

- Source – document the specific source of the information. There are many possible sources including but not limited to:
  - Customer complaints
  - Product rejections
  - Non-conformances/OOS/Deviations
  - External and Internal audit observations

- Recalls
- Management Reviews
- Regulatory issues
- Trends from process performance
- Risk assessment

- Explanation of the Problem – write a complete description of the problem. The description should be concise but must contain sufficient information to assure that the problem can be easily understood from reading the explanation.

- Evidence – list the specific information available that demonstrates that the problem does exist and/or reference the source report number, if applicable (ie. Non-conformance #).

This information is to be recorded on the *Corrective/Preventive Action Request* form *(Q13-PR-100-F014a)* and submitted to the Quality Unit for evaluation and CAPA # assignment. A CAPA request may be made by any employee.

However, in case of a Customer Complaint, the completed *Complaint In-take Information/Initiation Form (Q13-PR-100-F019)* may be submitted in place of the *CAPA Request* form *(Q13-PR-100-F014a).*

6.2 Evaluation and Assignment

The Director of Quality (or Designee) will evaluate the information recorded on the submitted *Corrective/Preventive Action Request* form (or *Complaint In-take Information/Initiation Form)* to determine both the need for action and the level of action required. The potential impact of the problem and the actual risks to the company and/or customers must be considered.

- Potential Impact – determine and document specifically why the problem is a concern and what the impact to the company and/or customers may be. Concerns may include costs, function, product quality, safety, reliability and/or customer satisfaction.

- Risk Assessment – based on the result of the impact evaluation, assess the seriousness of the problem. The level of risk that is associated with the problem will affect the actions that are taken and the priority assigned to the situation.

- Remedial Action – the potential impact and risk assessment may indicate a need for some immediate action to remedy the situation until a permanent solution can be implemented. In some cases the remedial action may be adequate. If so, the CAPA can then be closed, after documenting the rationale for the decision and completing appropriate follow-up.

This information is to be recorded on the *Corrective/Preventive Action Report (CAPA) (Q13-PR-100-F014b)*. The Director of Quality (or Designee) will assign the CAPA within 24 hours of receipt to the appropriate department/personnel for investigation/completion. Usually, this responsibility will be assigned to the area Manager of the department where the problem was identified. It is recommended that the completed *CAPA Report* be returned to Quality within **30** days so that proper Follow Up can be conducted and any additional actions identified can be completed with the targeted closure date of **45** days.

Note: during this stage of the evaluation, consideration must be given to determine if the problem/non-conformance is an adverse event reportable to the FDA as described in *Complaint Handling System (Q13-PR-100-019)* or a recall/withdrawal event as described in *Recall/Withdrawal Procedure (Q12-PR-100-013).*

6.3 Investigation Plan

Using the *CAPA Report*, the individual assigned to lead the investigation shall outline a plan for conducting the investigation. This plan should include an objective for the actions that will be taken, the procedure to be followed and the personnel that will be responsible.

- Objective – the objective is a statement of the desired outcome(s) of the corrective or preventive action. State what the situation will be when the action is complete.

- Strategy – outline a specific set of instructions to determine the contributing and root cause of the problem. It must incorporate a comprehensive review of all circumstances related to the problem such as equipment, materials, personnel, procedures, training, etc.

- Assign Responsibility and Resources – assign someone the responsibility for each aspect of the investigation. Any additional resources (financial, equipment, etc.) should be indentified and documented.

6.4 Root Cause Analysis

Use the investigation plan to investigate the cause of the problem. The goal of this analysis is to determine the *root cause* of the problem described.

- Possible Causes / Data Collection – create a list of all possible causes of the problem. This will form the basis for collecting relevant information, test data, etc. By considering

all possible causes, appropriate information and data can be collected that will ultimately be used to determine the root cause of the problem.

- Results and Data – data may come from a variety of sources: testing results and/or review of records, processes and any other information that may lead to a determination of the fundamental cause of the problem. Organize the data collected into a useable form. This information is used to determine the root cause of the problem.

- Root Cause Analysis – use the data to complete a Root Cause Analysis by answering a series of 'why?' questions and digging deep into the situation until the fundamental reason for the problem is found. Distinguish the difference between an *immediate cause* versus the *root cause* of the problem.

Document the results of the Root Cause Analysis on the *CAPA Report* and place copies of all supporting documentation in the CAPA folder.

6.5 Corrective/Preventive Action Plan

Using the results from the root cause analysis, determine the best method(s) for correcting the situation (or preventing a future occurrence). Identify all of the tasks required to correct the problem and prevent a recurrence and incorporate into an Action Plan. The plan should include changes that must be made, person(s) assigned responsibility for tasks and dates tasks are to be completed by. Document the following in the appropriate sections of the *CAPA Report*.

- Corrective/Preventive Actions to be Completed – list all the activities and tasks that must be accomplished to either correct the existing problem or eliminate a potential problem. Identify all actions that will be required to address everything related to the situation.

- Document or Specification Changes – describe needed changes to documents, processes, procedures, or other system modifications. Enough detail must be included so it is clearly understood what must be done and what the outcome of the changes should be. Changes must be processed/approved by Quality through the *Change Control System (Q13-PR-100-015).*

- Employee Training – employee training is an essential part of any change that is made and should be part of the action plan. To assure that the actions taken will be effective, any modification made to documents, processes, etc. must be effectively communicated to all persons or departments that will be affected. Training must be documented and filed with the Quality Unit.

6.6 CAPA Implementation

The Corrective/Preventive Action Plan that has been developed is now implemented. Initiate, complete and document all of the required tasks listed and described in the Action Plan.

- Implementation Summary – list and summarize all the activities that have been completed as required in the Action Plan. This section should contain a complete record of the actions that were taken to correct the problem and assure that it will not recur. This includes changes, preventive measures, process controls, training, etc.

- Documentation - list all documents or other specifications that have been modified. Place the documentation with the final *CAPA Report.* This will facilitate verification of the changes for the follow up.

Submit the CAPA folder containing the *CAPA Report* and all supporting documentation to the Quality Unit for follow up.

6.7 Follow Up and Closure

The Director of Quality (or Designee) will be responsible for completing an evaluation of the actions that were taken. This evaluation must not only verify the successful completion of the identified tasks but also assess the appropriateness and effectiveness of the actions taken.

- Key Questions – consider the following questions when evaluating the actions taken:
    - Have all of the objectives of this CAPA been met? (Did the actions correct or prevent the problem and are there assurances that the same situation will not happen again?)
    - Have all recommended changes been completed and verified?
    - Has appropriate communications and training been implemented to assure that all relevant employees understand the situation and the changes that have been made?
    - Is there any chance that the actions take may have had any additional adverse effect on the product?

- Verification of Results – make sure that appropriate information that has been recorded provides proof that all actions have been completed successfully.

- Results / Effectiveness of the Actions – verify that actions taken were effective by documenting the following:

    - The root cause of the problem has been solved
    - Any resulting secondary situations have been corrected
    - Proper controls have been established to prevent a future occurrence
    - The actions taken had no other adverse effects
    - Adequate monitoring of the situation is in place

- Completion / Closure – when the Follow Up evaluation is complete, the formal indication that the CAPA has been completed is to obtain approval signatures from the appropriate and authorized personnel. At that point the CAPA will be considered closed.

Management of Timely Closure

- The targeted closure date for CAPAs shall be **45** days from the date of assignment. CAPAs involving equipment shall be issued a targeted closure date of **90** days from the date of assignment as this may involve installation, repair, or validation/re-validation. However, it is strongly encouraged that CAPAs are closed as promptly as possible.

- Due to the nature of the investigation of the root cause, or the implementation of the corrective/preventive action required, the closure date **may** be extended upon the discretion of the Director of Quality (or Designee). Requests for due date extensions shall be submitted in writing (email acceptable) providing justification for the extension and the proposed closure date. The Director of Quality shall review the request and disposition accordingly.

Tracking and monitoring Corrective / Preventive Action

Corrective / Preventive actions shall be tracked and monitored by the Quality Unit to determine the following:

- Trends in the cause of the incident/non-conformance
- Repetitive issues
- Average days required to complete the corrective preventive action

This information shall be analyzed by the Quality Unit and reviewed during Management Reviews as a measurement of the effectiveness of the Quality System.

Records Retention

CAPA folders containing *CAPA Reports* and supporting documentation will be retained in the cGMP Library for a period of at least 4 years.

7.0 Reference Documents

Corrective/Preventive Action Request form	*(Q13-PR-100-F014a)*
Corrective/Preventive Action Report (CAPA)	*(Q13-PR-100-F014b)*
Complaint Handling System	*(Q13-PR-100-019)*
Recall/Withdrawal Procedure	*(Q12-PR-100-013)*
Change Control	*(Q13-PR-100-015)*

8.0 Change Information

New Document