
	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Procedure</b>		
	Title: <b>Corrective and Preventative Action – CAPA</b>	Number: <b>Q12-PR-100-014</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>02/06/12</b>	Page: <b>1 of 4</b>	

## 1.0 Purpose

- 1.1 The purpose of this procedure is to define the need for corrective/preventive action and outline the necessary activities and required documentation for implementing the corrective action.

## 2.0 Scope

- 2.1 This procedure applies to all activities initiated to correct outstanding non-conformances and to prevent potential non-conformances from occurring.

## 3.0 Responsibility

- 3.1 Quality Assurance is responsible for controlling the corrective and preventive action process.

## 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 Definitions

Immediate/Remedial Action: Immediate actions taken to disposition all affected product. Remedial actions include the disposition of product at the customer's location and the verification of inventory and work-in-process (WIP).

Short-Term Corrective Action: Interim actions taken to support current production. Actions to eliminate the root cause have not yet been identified or implemented. Short term actions might include additional inspection.

Long-Term Corrective Action: Permanent actions to correct the root cause of the non-conformance, or to detect the non-conformance should it recur. Long-term corrective actions might include changes to the quality plan, manufacturing equipment modifications/repairs, changing a specification, creating/modifying a procedure or work instruction, or implementing some device that will eliminate the potential of occurrence or provide automatic 100% inspection of all products for the observed non-conformance.

Preventive Action: Preventive actions are measures taken to prevent potential errors from occurring based upon reviews of relevant operational, process and quality information. Preventive action may also be in the form of recommendations made to the customer resulting from corrective actions that are

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beyond the immediate scope of the Giles/Premier corrective action system, such as modifying a carton machine.

## 6.0 Materials/Equipment

6.1 N/A

## 7.0 Procedure

### 7.1 Initiator: (Problem Information)

- Any Giles/Premier employee may initiate a CAPA request but is typically initiated by a CSR (See *Customer Complaint Procedure* Q12-PR-100-019) Production Manager, Production Engineer or Quality Assurance.

### 7.2 Director of Quality or Designee: (Assignment)

- Shall act as the “CAPA Coordinator”.
- Assigns an Action Team Leader to lead all Quality investigations and begins investigation documentation using the *Corrective and Preventive Action (CAPA)* Q12-PR-100-F014.
- Assists, as necessary, with Production and Mechanical investigations.



### 7.3 Action Team Leader and Team: (Interim Containment, Root Cause & Implementation)

- Conducts investigation in cooperation with the area involved.
- Performs remedial action, root cause analysis and suggests corrective action.
- Oversees implementation of corrective action.
- Recommends preventive action if applicable. May act as coordinator for implementation.
- Documents investigation using the Corrective and Preventive Action (CAPA) form issued for the investigation by the CAPA coordinator.

### 7.4 Director of Quality or Designee: (Solution Acceptance and Prevention)

- As the CAPA Coordinator, verifies effectiveness of CAPA
- Approves or Rejects CAPA

### 7.5 Director of Manufacturing: (Closure & Recognition)

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	Effective Date: <b>02/06/12</b>	Page: <b>3 of 4</b>	

- Performs final approval of CAPA

#### 7.6 Director of Quality or Designee: (Follow-up)

- Ensures electronic and/or hard copies of CAPAs are closed.
- Conducts any necessary follow-up activities such as with a customer.
- Maintain tracking of CAPA data.

#### 7.7 Management of Timely Closure

- The targeted date for the identification of Root Causes and the development of an Action Plan shall be **7** days from the date of assignment to the Action Team Leader with a closure date of **45** days. 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.
- 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 CAPA coordinator and/or Director of Manufacturing. Requests for due date extensions shall be submitted in writing (email acceptable) providing justification for the extension and the proposed closure date. The CAPA coordinator and/or Director of Manufacturing shall review the request and disposition accordingly.

#### 7.8 Serious Adverse Events

Any complaint that represents a serious and unexpected adverse drug experience is required to be immediately reported to the Food and Drug Administration.

#### 8.0 Reference Documents

8.1 *Customer Complaint Procedure* Q12-PR-100-019

8.2 *Corrective and Preventive Action (CAPA)* Q12-PR-100-F014

#### 9.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
0	02/06/12	DD	New Document



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Page: **4 of 4**

