

Instructions for Completing the GA-ASI Supplier Corrective Action Preventive Action (CAPA)

- The Corrective Action Plan (along with Containment and Root Cause Analysis) must be provided to GA-ASI for review and approval prior to implementation of the plan.
- Extensions may be granted on an exception basis. Any request for extension must be made prior to the due date with a valid reason as to why an extension is needed and a revised response due date.
- Use the GA-ASI form to document the Corrective Action when possible. Using your own form is permissible; providing all required information is presented.
- Be sure each section of the CAPA form fulfills the following expectations; otherwise the CAPA will be returned to the supplier for further work.

Containment

Describe the actions taken to contain to prevent further discrepant material from being processed or shipped.

- Define how the issue escaped outgoing inspection and actions taken to correct the escape issue.
- Describe how you addressed any items currently in receiving, WIP, finished goods or delivered to GA-ASI that may be affected by the reported condition.
 - Include details as to quantities inspected, inspection results and how the items were dispositioned.
 - Be specific with part numbers, revision letters and serial numbers if applicable.
 - Be sure to account for other product (not mentioned in the Problem Description) which could also be affected by virtue of having undergone similar manufacturing or inspection processes.
- If the nonconformance relates to an element of the quality management system, describe what temporary measures have been put in place to immediately to correct the deficiency, pending permanent changes to the process and formal re-training of staff.

Root Cause

Explain the underlying cause and/or contributors, including how (problem solving method used) the root cause was determined.

Use systemic problem solving methodologies to identify the true root cause, for example:

- 5-Whys
 - Fishbone Diagrams
 - Experimentation
 - Brainstorming
 - Process Flowcharts
- "Operator error" will not be accepted as the root cause, unless a detailed explanation is provided as to how all other possible underlying causes were ruled out, such as:
 - Adequate operating procedures
 - Training
 - Management supervision
 - Working conditions/environment
 - Tooling or equipment

Corrective Action Plan

Describe the action/s necessary to prevent recurrence.

- o Descriptions of the actions to be taken; be specific and directly address the root cause and related contributors.
- o Corrective actions need to be comprehensive and preventive in nature, as to account for other product that may share similar manufacturing processes and product not yet manufactured.
- o Provide dates to be implemented (or implemented) for each action.
- o When new procedures are created (or existing procedures revised), affected personnel must be trained accordingly.
- o For each action taken, provide objective evidence of implementation. Examples of objective evidence include:
 - Excerpts of modified work instructions, procedures or quality manual
 - Sign-in sheets for training conducted
 - Quality Alerts or other internal supplier communiques
 - Photographs of improved parts, equipment or work areas
 - Test/inspection reports
 - Document change notices
 - Corrective action requests to sub tier suppliers
 - Screen shots from electronic ERP systems
 - Tool modification documentation
 - Others

Verification of Effectiveness

Explain the action to be taken (or taken) to verify that the corrective actions implemented did in fact prevent recurrence.

- o Examples of possible verification measures include:
 - Periodic monitoring of factory metrics
 - Internal audits
 - Out-of-cycle or heightened inspections
 - Follow-up training
- o Describe results of the verification effort, with dates completed.