

Company Form

Title: Corrective/Preventive Action Report Number: Q13-PR-100-F014b

Owner: Deborah Durbin Revision: 0
Effective Date: 05/15/16 Page: 1 of 5



CORRECTIVE/PREVENTIVE ACTION (CAPA) REPORT

CAPA Report Number:						
Date:	Due Date:	Assigned To:				
Corrective Action-CA (t	o existing problem)	☐ Preventive Action-PA (to potential problem)				
Γype of Investigation: □	Quality 🗌 Produ	uction				
1. <u>Identification</u> (To be com Information/Initiation Form		ubmit a CAPA Request or Complaint In-take A initiation)				
Source of Information: (C	ustomer Complaint,	OOS, Audit, etc.)				
Description of Problem:						
Evidence: (information that	the problem exists or s	source report #)				
2. Evaluation (To be comple	eted by Quality)					
Potential Impact of Proble	em: (costs, function,	product quality, safety, customer satisfaction)				
Risk Assessment: (Low, M	edium, High, SAE)					
Remedial Action Required	l: (If adequate, expla	ain and skip to #7 to close CAPA)				



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3. <u>Investigation Plan</u> (To be completed by area Manager)

Objective: (Statement of desired outcome of CA or PA)
Strategy: (Outline instructions to determine root causes)
Demonsibility and Desayuese Aggignments
Responsibility and Resources Assignment:
4. Root Cause Analysis (To be completed by area Manager)
List of Possible Causes:
Test Results and Data needed to determine Root Cause: (Place copies in folder with report)
Root Cause Analysis: (Use data collected for analysis. Distinguish between immediate cause and root cause)



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5. <u>Corrective/Preventive Action Plan</u> (To be completed by area Manager. Include changes to be made, person assigned responsibility for task and dates to be completed.)

Corrective/Preventive Actions to be Completed: (Tasks required to correct problem)	Initials	Date			
Document or Specification Changes: (Describe changes to processes, procedures, system					
modifications)					
Change Control Request Document Approval Form	7				
Employee Training: (Specify type of training and who needs training if changes of	are made)				



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6. <u>CAPA Implementation</u> (*To be completed by area Manager. A copy of this page may be circulated upon Quality's closure of investigation as verification of CAPA implementation.*)

Implementation Summary: (List and summarize all the activities that have been completed in Action
Plan that were taken to correct the problem to assure it will not recur.)
Documentation: (List all documents that have been modified; place copies in CAPA folder)
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Circulated:
CAPA Title:
CALA TIUC.
CAPA #:



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7. Follow Up and Closure (To be completed by Quality)

Evaluation of actions taken: (Have identified tasks been completed?)					
☐ Yes	□ No	Initials:			
Verification of Results: (Verify that appropriate information recorded provides proof that all actions have been completed successfully.)					
☐ Yes	□ No	Initials:			
Additional Comments:					

Approval Signatures/Dates: (all applicable parties)								
	Name	Title	Signature	Date				
Area Manager								
Quality	Deborah Durbin	Dir. Of Quality						
Operations	Matt Haynes	Dir. Of Operations						