

Company Form

Title: Vendor Assessment Survey Number: Q12-PR-100-F023c

Owner: Deborah Durbin Revision: 0
Effective Date: 08/27/12 Page: 1 of 5



In order to better understand your business, and as a step in establishing and maintaining a good business relationship with you, we request that you please provide us with the following information. Thank You.

GENERAL INFORMATION:

Company Name:	
Contact Name:	
Primary Address:	
City, State, Zip Code:	
Web Site:	
Division or Subsidiary of (if applicable):	
BUSINESS INFORMATION:	
When was your company established?	
Please describe your usual payment terms:	
Are you willing to provide us with a financial statement?	☐ Yes ☐ No
Are you willing to provide us with a change-notification agreement?	☐ Yes ☐ No
Is your company ISO/QA registered?	☐ Yes ☐ No
If yes, who is the regulating body?	
Please list three customer references:	
1. Company Name:	
Contact Name:	Telephone:
Address:	
2. Company Name:	
Contact Name:	Telephone:
Address:	



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3. Company Name:				
Contact Name:	tact Name:Telephone:			
Address:				
FACILITIES INFORMATION:				
Does your facility shut down for any extended periods (more than one week)?				
Do your plants operate in accordance with EPA and OSHA standards?				
Do you have a contingency plan in case of disaster?				
PRODUCT INFORMATION;				
Please list your top three product lines and their percentage of your business:		% of Busi	ness	
1				
2				
3				
QUALITY SYSTEM INFORMATION				
QUALITY SYSTEM	Yes	No	N/A	
Do you have a formal Quality Manual?				
Do you have a formal, company-wide quality procedure?				
Do you have procedures for performing, documenting and responding to intaudits?	ernal			
MANAGEMENT RESPONSIBILITY	Yes	No	N/A	
Does your Quality organization have a designated Senior Management Representati	tive?			
Do senior management representatives routinely review the quality system for effectiveness?				
PERSONNEL TRAINING	Yes	No	N/A	
Does your training system identify all relevant training needs of each employee performing all processes?				
Are training records maintained for individual employees?				



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DOCUMENT CONTROL	Yes	No	N/A
Do you have procedures for the control of production and system documents?			
Do you have procedures to ensure that only current documents are being utilized?			
PURCHASING CONTROLS	Yes	No	N/A
Do you have procedures for qualifying/approving suppliers that result in an approved supplier list?			
Are inspections performed on incoming materials?			
PRODUCTION AND PROCESS CONTROLS/STATISTICAL TECHNIQUES	Yes	No	N/A
Do you use statistical methods to control your processes?			
Is the sampling inspection defined by a procedure?			
Is your sampling inspection adjusted on the basis of inspection/test results?			
Do you have a procedure for the approval and release of new processes?			
Do you have a procedure for the approval and release of new equipment?			
Do you have procedures for the maintenance/replacement of production equipment?			
MANUFACTURING	Yes	No	N/A
Do you have manufacturing procedures?			
Do you maintain Device History Records?			
Do you maintain schedules for maintenance of manufacturing equipment?			
INSPECTION, MEASURING AND TEST EQUIPMENT (CALIBRATION)	Yes	No	N/A
Is the calibration of your inspection, measuring and test equipment defined by a procedure?			
Is all inspection, measuring and test equipment identified as to its calibration status?			
ACCEPTANCE ACTIVITIES	Yes	No	N/A
Are Acceptance Inspection activities performed on raw materials, intermediate products and finished goods, where applicable?			
NON-CONFORMING PRODUCT	Yes	No	N/A
Are there written procedures for controlling non-conforming materials in Receiving?			
Are there written procedures for controlling in-process non-conforming materials?			
Are there written procedures for controlling non-conforming materials in Final Inspection?			
Are procedures used for the repair, rework and disposition of non-conforming materials?			



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Do you have a CAPA system implemented for customer complaints? Do you have a CAPA system implemented for supplier defects? Do you have a CAPA system implemented for internal defects? Is your CAPA system defined by a procedure? Is your CAPA system defined by a procedure? Is CAPA effectiveness reviewed? Are CAPA reports maintained as part of quality records? HANDLING, STORAGE AND DELIVERY Is the identification and inspection status of each article maintained from the time of receipt of the material until delivery to the customer? Is there adequate control to prevent co-mingling of parts, lots and batches? Are limited shelf life materials controlled and identified? RECORDS Yes No N/A Do you maintain quality records on the quality and the manufacturing processes? Do you define which records are included and the time of retention? Are quality records current, complete and accurate? Does Management review quality records? Do quality/test records show failure and cause of failure? SERVICE ACTIVITIES Yes No N/A Do you provide detailed service reports explaining all work completed? Do you inspect completed work and validate the effectiveness?	CORRECTIVE AND PREVENTIVE ACTION	Yes	No	N/A
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JOINIMENTS (Please attach additional sneets if necessary)				
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Approved?	Yes	No	_ If no, state why and list any corrections necessary within this section. Indicate
timing of cor	rective act	ions if known.	
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