

**Company Form** 

Title: Vendor Self-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:	_ Telephone: _		
Primary Address:			
City, State, Zip Code:			
Web Site:			
Division or Subsidiary of (if applicable):			
When was your company established?			
Is your company ISO/QA registered?		☐ Yes ☐ No	
Are you willing to provide us with a change-notification agreement?		Yes No	
If yes, who is the regulating body?			
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 st	d OSHA standards?		
o you have a contingency plan in case of disaster?		☐ Yes ☐ No	
PRODUCT INFORMATION;			
Please list your top three product lines and their percentage of	f your business:		
Product Line		% of Business	
1.			
2.			



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#### **QUALITY SYSTEM INFORMATION**

OHAL PRV CVCTEM	Vac	No	NI/A
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 internal			
audits?			
MANAGEMENT RESPONSIBILITY	Yes	No	N/A
Does your Quality organization have a designated Senior Management Representative?			
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?			
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?			



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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
	103	110	14/11
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?			
CORRECTIVE AND PREVENTIVE ACTION	Yes	No	N/A
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 CAPA effectiveness reviewed?			
Are CAPA reports maintained as part of quality records?			
HANDLING, STORAGE AND DELIVERY	Yes	No	N/A
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?			



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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?			
Do you provide service quotes prior to initiating work?			

SURVEY INFORMATION COMPLETED BY:
Printed Name:
T'A
Title:
Signature:
Date:



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TO BE COMPLETED BY GILES CHEMICAL	
COMMENTS (Please attach additional sheets if necessary)	
Approved? Yes No If no, state why and list any corrections necessary within this section. Indicate timing of corrective actions if known.	
SURVEY INFORMATION REVIEWED BY:	
Title:	
Signature:	
Date:	