



QUESTIONNAIRE ASSESSMENT OF EXTERNAL PROVIDERS OR SUB-CONTRACTORS

Supplier: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Address: \_\_\_\_\_

Fax Number: \_\_\_\_\_

\_\_\_\_\_

Email: \_\_\_\_\_

Contact Information:

Quality: \_\_\_\_\_

Phone #/ Email: \_\_\_\_\_

Engineering: \_\_\_\_\_

Phone #/ Email: \_\_\_\_\_

Sales: \_\_\_\_\_

Phone #/ Email: \_\_\_\_\_

Management Rep: \_\_\_\_\_

Supplier's Primary Business/Products: \_\_\_ Broker \_\_\_ Distributor \_\_\_ Franchised \_\_\_ Manufacturer \_\_\_ Other \_\_\_\_\_

Years in business? \_\_\_\_\_

Average Lead Time: \_\_\_\_\_

Personnel:

Total Number of Employees: \_\_\_\_\_ Quality: \_\_\_\_\_ Manufacturing \_\_\_\_\_ Engineering \_\_\_\_\_ Support \_\_\_\_\_

Facilities/Capabilities:

Facility Size: Total \_\_\_\_\_ SQ. FT. Manufacturing \_\_\_\_\_ % Administrative \_\_\_\_\_ % Current Capacity Utilized \_\_\_\_\_ %

Processes Subcontracted: \_\_\_\_\_

Franchised Manufacturers: \_\_\_\_\_

Core Manufacturing Technologies: \_\_\_\_\_

Quality:

Do you have a documented quality system in compliance with a nationally recognized standard: Yes \_\_\_ No \_\_\_

If yes, which standard(s): \_\_\_\_\_ Valid through date: \_\_\_\_\_

\_\_\_\_\_ Valid through date: \_\_\_\_\_

I have received a copy of QSP 8.4\_1 EXTERNAL PROVIDERS QUALITY SYSTEM REQUIREMENTS

Survey Completed by: \_\_\_\_\_ Title \_\_\_\_\_ Date: \_\_\_\_\_

Table with 4 columns: OTHER, YES, NO, N/A. Rows include counterfeit materials program, IT security process, and ITAR compliant processes.

STOP If you are ISO registered, you may stop here. STOP

PLEASE PROVIDE US WITH A COPY OF YOUR CURRENT ISO CERTIFICATE.

If you are NOT ISO registered, please answer the questions on the following pages.



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| <b>A. QUALITY MANAGEMENT SYSTEM</b>   | YES | NO | N/A |
|---|-----|----|-----|
| Does your company have a Quality Manual? <span style="float:right">Revision: _____</span>   |     |    |     |
| Is there a Management Representative responsible for the implementation and maintenance of the Quality System?  |     |    |     |
| Does your company have documented procedures & work instructions?   |     |    |     |
| Are instructions readily available at necessary locations?  |     |    |     |
| Are obsolete documents removed from use and isolated?   |     |    |     |
| Are there written procedures for the identification and control of external documents?  |     |    |     |
| Do records show conformity to the process requirements and are they stored in such a way to prevent damage, loss, or deterioration?   |     |    |     |
| Are documents controlled to prevent unauthorized use?   |     |    |     |
| What is your record retention period? _____   |     |    |     |
| <b>B. MANAGEMENT RESPONSIBILITY</b>   | YES | NO | N/A |
| Do the people associated with your processes understand the importance of meeting customer requirements?  |     |    |     |
| Does your company have a Quality Policy and is it understood by the people associated with the processes?   |     |    |     |
| Does Quality report at a level equal to Production, Engineering, and Purchasing?  |     |    |     |
| Do procedures exist for development, defining, and documenting how quality requirements will be met through the quality plan?   |     |    |     |
| Are company responsibilities clearly defined and in place to ensure product conformance, identifying quality problems, corrective action, and documented solutions?   |     |    |     |
| Do people associated with the process know how the process interacts with other processes?  |     |    |     |
| Does top management review the effectiveness of the quality system at regular intervals?  |     |    |     |
| <b>C. RESOURCE MANAGEMENT</b>   | YES | NO | N/A |
| Do the people associated with the process have the education, training, skills, and/or experience designated for the process?   |     |    |     |
| Has your company determined training needs for a given process?   |     |    |     |
| Does your company have training records?  |     |    |     |
| Are the buildings, workspace, and associated utilities adequate to achieve conformity to product requirements?  |     |    |     |
| Is the process equipment adequate to achieve conformity to product requirements?  |     |    |     |
| Is maintenance performed on a regular basis for process equipment?  |     |    |     |
| Is housekeeping maintained in line with commodities being produced?   |     |    |     |
| Is the work environment appropriate for product production?   |     |    |     |
| <b>D. PRODUCT REALIZATION</b>   | YES | NO | N/A |
| Do you formally review customer requirements, statutory, and regulatory requirements as well as requirements that are not stated but are necessary for the product realization?   |     |    |     |
| Is there a documented procedure for examining and reviewing contract requirements to ensure they are adequately defined?  |     |    |     |
| Has your organization determined and implemented effective arrangements for communicating with customers regarding product information, enquiries, contracts, amendments, customer feedback, and complaints?  |     |    |     |
| <b>Design</b>   | YES | NO | N/A |
| Are there written procedures to plan and control the design and development of a product?   |     |    |     |
| Are there documented procedures detailing the requirements for product outputs to include, but not limited to, meeting input requirements, providing information for purchasing and production, product reference criteria, and safe/proper use criteria? |     |    |     |
| Do you have a documented procedure for deviation requests to your customers?  |     |    |     |
| When product brand or type is not specified in the purchase order or requirements do you notify your customers for approval of selected product?  |     |    |     |
| Is there a documented procedure detailing verification be performed to ensure that the development outputs have met the development input requirements?   |     |    |     |
| Do you have a procedure for maintaining serialization requests on your products?  |     |    |     |



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| <b>Purchasing</b>  | YES | NO | N/A |
|--|-----|----|-----|
| Do purchasing documents clearly state quality requirements?  |     |    |     |
| Are procedures in place to evaluate suppliers and select them based upon their ability to supply product in accordance with requirements?                |     |    |     |
| Do you have an approved suppliers list?  |     |    |     |
| Do you have a method for tracking supplier performance?  |     |    |     |
| Do you report these results back to the supplier for feedback?   |     |    |     |
| <b>Manufacturing</b>   | YES | NO | N/A |
| Are there documented procedures and/or instructions defining the manner of production?   |     |    |     |
| Is production equipment suitable and capable to perform specified functions in an acceptable manner?   |     |    |     |
| Are qualified equipment and personnel certified/approved for the process?  |     |    |     |
| Are there procedures to identify the inspection and test status of the product throughout the production process?  |     |    |     |
| Are there procedures for verification, storage, and maintenance of customer supplied product?  |     |    |     |
| Are there procedures for handling, storage, packaging, and delivery of the product?  |     |    |     |
| Are methods prescribed which prevent damage or deterioration of product?   |     |    |     |
| Are materials stored according to a FIFO system?   |     |    |     |
| Is there an established program for the identification and control of calibration of all test and inspection equipment?                                  |     |    |     |
| Is calibrated equipment traceable to the NIST?   |     |    |     |
| Is calibration performed by an outside certified lab?  |     |    |     |
| Is past production re-verified when inspection or test equipment is found to be out of calibration?  |     |    |     |
| Are there procedures to safeguard measuring and test equipment from adjustments which would invalidate the calibration setting?                          |     |    |     |
| <b>E. MEASUREMENT, ANALYSIS, AND IMPROVEMENT</b>   | YES | NO | N/A |
| Are there documented procedures for monitoring information relating to customer satisfaction?  |     |    |     |
| Is there a documented procedure for internal quality audits?   |     |    |     |
| Are the results of the audits required to be documented and brought to the attention of personnel responsible for the area being audited?                |     |    |     |
| Are internal audits carried out by personnel independent of the department/area being audited?   |     |    |     |
| Are there procedures for monitoring, measuring, and controlling quality characteristics and processes of the QMS during production?                      |     |    |     |
| Are there documented procedures for Receiving Inspection?  |     |    |     |
| Are there documented procedures and inspection points for In-process Inspection?   |     |    |     |
| Are there documented procedures for final inspection and do they ensure that all previous inspection has been carried out?                               |     |    |     |
| Do you have sampling plans for Receiving, In-process, and Final Inspection?<br>Describe:   |     |    |     |
| Are there records established that show evidence the product has been inspected and shows a pass/fail to acceptance criteria?                            |     |    |     |
| Are there procedures for controlling and reviewing nonconforming product to be re-inspected?   |     |    |     |
| Are there procedures that require repaired and reworked nonconforming product?   |     |    |     |
| Are there documented procedures dealing with continually improving the effectiveness of the QMS and subsequent product realization?                      |     |    |     |
| Is there a procedure for monitoring corrective actions to ensure they are effective?   |     |    |     |
| Are there documented procedures to initiate preventive action to eliminate the causes of potential nonconformities in order to prevent their occurrence? |     |    |     |



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\*\*\*\*\* JG PLASTICS ONLY \*\*\*\*\*

Provider Name: \_\_\_\_\_

Provider Number: \_\_\_\_\_

Certification received (check all that apply)

ISO 9000

AS 91000

ISO 13485

ISO 17025

Other \_\_\_\_\_

Risk Assessment:

Low

Medium

High

Justification: \_\_\_\_\_  
\_\_\_\_\_

Additional controls (if applicable): \_\_\_\_\_  
\_\_\_\_\_

Approved? \_\_\_YES \_\_\_NO

Subject to Rating? \_\_\_YES \_\_\_NO

Scope of Approval: \_\_\_\_\_

If no: \_\_\_\_\_

F8.4\_9 Required? \_\_\_\_\_YES \_\_\_\_\_NO F8.4\_9 sent: \_\_\_\_\_ F8.4\_9 Rec'vd: \_\_\_\_\_

Comments:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Quality rating (for re-assessment only): \_\_\_\_\_

Vendor Exp date: \_\_\_\_\_

Approved Name: \_\_\_\_\_

Date: \_\_\_\_\_