

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 1 of 8
	Doc Number: QSP 8.4	Rev: G	

1. PURPOSE

- 1.1 To document and implement an effective system to ensure supplier performance is consistent with the JG Plastics LLC, [JGP] quality requirements relative to supplied component, assembly or finished product function, in regard to safety, durability, specification compliance, traceability, workmanship, and aesthetic quality.
- 1.2 Improve overall supplier performance to reduce rework, scrap, discrepancy reports, and associated processing costs.
- 1.3 To provide a uniform and consistent method to identify and manage the risks associated with the external providers of processes, products, and services.

2. SCOPE

- 2.1 This procedure applies to all external providers of the following categories:
 - 2.1.1 Proprietary components, assemblies, and raw materials
 - 2.1.2 Distributors of catalog components and materials
 - 2.1.3 Original Equipment Manufacturers (OEM)
 - 2.1.4 Customer directed suppliers
 - 2.1.5 Consultants

3. RESPONSIBILITY

- 3.1 The Purchasing/Production Planner and or designee - responsible for initiating and reviewing all purchase orders for production related materials and supplies through approved external suppliers. Initiating vendor approval process and documentation. Purchasing/Production Planner and Quality are responsible for performing periodic evaluation of supplier.
- 3.2 Quality Assurance Manager and/or designee - responsible for the control and maintenance of the Approved Supplier List. Review, approve and document external providers assessment and status. Purchasing/Production Planner and Quality are responsible for performing periodic evaluation of supplier.
- 3.3 Controller – Reviews recommendation to change status of external suppliers to NOT ACTIVE/IN ACTIVE in IQMS.

4. DEFINITIONS

- 4.1 **ASL:** (Approved Supplier List); a list or database that is maintained to track qualification status and scope of approval of external suppliers from whom JG Plastics obtains goods and/or services. The ASL is used to identify the approval status of suppliers' abilities to supply components, assemblies or raw material for the used in manufactured products.
- 4.2 **APPROVED:** No restrictions on vendor
- 4.3 **DISTRIBUTOR:** A company that provides a distribution network or service of commonly used components, assemblies or materials to the manufacturing industry.

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 2 of 8
	Doc Number: QSP 8.4	Rev: G	

- 4.4 **EXTERNAL PROVIDER:** Person or company engaged by JG Plastics Group, LLC to supply or manufacture any of the work included in JG Plastics Group, LLC scope of work. External Providers include subcontractors and suppliers that have been designated by customers.
- 4.5 **INACTIVE:** External supplier is removed from ASL and must be re-qualified prior to additional purchases.
- 4.6 **NOT APPROVED:** Unable to transact or order from external supplier.
- 4.7 **QUALITY REQUIREMENTS:** Certifications with lot numbers are required on all parts, materials, colors, and inserts as well as statutory and regulatory requirements.

5. REFERENCE DOCUMENTS

- 5.1 Form F8.4_1 Questionnaire Assessment of External Provider or Sub-contractor
- 5.2 Form F8.4_3 Supplier Scope List
- 5.3 Form F8.4_4 Supplier Audit Schedule
- 5.4 Form F8.4_5 Quality Systems Audit
- 5.5 Form F8.4_6 Purchase Requisition
- 5.6 Form F8.4_7 Vendor Scorecard
- 5.7 Purchase Order (IQMS)
- 5.8 MI-0014 Receiving Procedure
- 5.9 QAOP-0039 External Providers Approval Process

6. PROCEDURE

- 6.1 Selection / Approval of (Potential) External Providers: (including sub-contractors and suppliers)
 - 6.1.1 Prospective External Providers shall be selected based on their capability and risk to satisfy the requirements of the appropriate specifications.
 - 6.1.2 Risk evaluation may include (but not limited to) items listed in section 6.1.9.
 - 6.1.3 Risk assessment results are noted on Assessment form F8.4_1
 - 6.1.4 Providers ranked as Critical suppliers are those which have a high-risk assessment to the operational activities of the business or represent potential high risk to the customer, such as medical device subcontractors or direct providers to medical customers.
 - 6.1.5 Providers that supply products / Sub-contractors to the medical industry must be approved by Quality Manager who will determine the criteria for approval based upon various regulatory requirements in addition to their criticality to the business and customers.
 - 6.1.6 Only approved External Providers shall be utilized for the procurement of any product, including services and outsourcing processes that may affect the final product quality. In cases of urgent need, a product may be purchased from unapproved External Providers provided the supplier evaluation process is initiated concurrently.
 - 6.1.7 Accounting or designee shall add the suppliers to the Approved Supplier List and undertake the approval process; status will be added to the ASL as "NOT

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 3 of 8
	Doc Number: QSP 8.4	Rev: G	

APPROVED” in the AP module/Rating tab until approval is reviewed, no scope of approval is required until reviewed.

- 6.1.8 Purchasing/ Planning or designee shall forward a copy of Form F8.4_1 Questionnaire Assessment of External Providers or Sub-Contractors and QSP 8.4_1 to potential suppliers.
- 6.1.9 The capability of External Providers shall be established based on a combination of the following:
 - 6.1.9.1 Survey at external providers facility
 - 6.1.9.2 Certification of External Suppliers quality system by a recognized certification authority.
 - 6.1.9.3 Provide a self-assessment using the Form F8.4_1 Questionnaire Assessment of External Providers or Sub-Contractors or a supplier provided survey which also satisfies the requirements of Form F8.4_1.
 - 6.1.9.4 Provide samples upon request, certificate of compliance for test or inspection results, along with test and inspection documents.
 - 6.1.9.5 Provide a copy of the supplier’s Quality Manual (upon request)
 - 6.1.9.6 Information that assures the qualifications of personnel.
- 6.1.10 Customer directed Suppliers: The customer provides written instruction to use specific suppliers. JGP will request the external provider to complete F8.4_1, and approvals shall indicate the provider has been “approved” by the customer.

NOTE: *Suppliers that are specified by the customer may be added to ASL as “APPROVED” prior to receipt of Questionnaire (Form F8.4_1) and are approved based on customer requirements.*
- 6.1.11 Distributors and external providers that provide catalog items are required to complete Form F8.4_1 but will not be surveyed as vigorously as suppliers that are direct manufacturers.
- 6.1.12 Where service is related to testing or calibration, where demonstrating conformance/compliance to germane industry test or service related standards (e.g. National Institute of Standards and Technology (N.I.S.T), American National Standards Institute (ANSI), applicable military and/or regulatory standards, ISO 17025, etc.) apply. Standard may be annotated in the certification field in the Ratings tab in the AP module/Rating tab.

NOTE: *Service providers (i.e. Federal Express etc..) are not required to provide a document or certificate.*
- 6.1.13 During the evaluation period, prospective suppliers can be granted a “NOT APPROVED” status for a reasonable period of time to collect supplier documentation and/or First Article results.
- 6.1.14 The approval or disapproval of a supplier shall be documented on the Questionnaire Form (F8.4_1), including the scope of approval and supporting documentation shall be included in the vendor file per QAOP-0039
- 6.1.15 Documentation package is submitted to QA for review.
- 6.1.16 QA establishes Scope of approval (Ref F8.4_3), expiration date, (not to exceed 3 years), typically aligns with ISO cert) and updates IQMS AP Module/Vendor Maintenance tabs per QAOP-0039

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 4 of 8
	Doc Number: QSP 8.4	Rev: G	

NOTE: *If an External Provider has more than one scope, it should be recorded in the Comments section of form F8.4_1 Questionnaire Assessment of External Providers or Sub-Contractors and in AP Module/Vendor Maintenance/User Fields/Scope.*

- 6.1.17 When supplier assessment documentation and/or first article assessments are deemed satisfactory, the supplier will be added to the Approved Supplier List as “Approved” under the AP Module/ Vendor Rating tab, in IQMS and the ISO certificate and expiration date (or review date) annotated. The “Scope of Approval” (Reference Form F8.4_3 Supplier Scope List) code will be added under the tab “**USER FIELDS**” in the “Supplier Scope” section”.
- 6.1.18 If the supplier documentation is not deemed satisfactory, an on-site assessment and or audit of the facility for acceptable quality levels will be considered in place of revision existing documentation. Every effort will be made to have the supplier conform to existing quality standards.
- 6.1.19 Suppliers who are not able to present a reasonable quality management system but offer purchased items suitable for a finished product may be qualified with a limited Scope of approval for only the designated purchased items, limited scopes shall be annotated in tab “**USER FIELDS**” in the “Supplier Scope” section.
- 6.1.20 Records are submitted to QA Department for retention and maintained in vendor file.
- 6.2 Scope of Approval
 - 6.2.1 Scope of approval is selected from External Provider Scope List (F8.4_3) and documented on form F8.4_1 per QAOP-0039. Scope # 15 (Employee) and 17 (customer) are not required to complete Survey form.
 - 6.2.2 Scope # 16 may or may not have third party certification, and can be added to the ASL without certification:
 - 6.2.3 Scope # 14 (non-MFG), Purchase of indirect items that are not part of Product Realization –Non-Product Supplier (ie: FDA, office supplies, utilities etc).
 - 6.2.4 All other codes listed on External Providers Scope List (F8.4_3) are selected based on products listed on the Self-Assessment Form (F8.4_1).
- 6.3 Supplier Status
 - 6.3.1 Suppliers are classified based on the products or services that they provide. There are three (3) supplier classes: Approved, Not Approved, In Active
 - 6.3.2 Criteria for each of these classifications are:
 - 6.3.2.1 **APPROVED:** No restrictions on external provider. External provider demonstrates a reasonable Quality Management System. This includes: General, Sole-Source, Customer Directed Suppliers
 - 6.3.2.1.1 Satisfies On-time Delivery performance criteria
 - 6.3.2.1.2 Satisfies Item Quality Performance criteria
 - 6.3.2.1.3 Ability to meet specific criteria mandated by purchase orders and/or customer requirements,
 - 6.3.2.1.4 Corrective actions answered in a timely manner.
 - 6.3.2.2 **NOT APPROVED:** Unable to transact or order from external supplier, may be used as temporary status while external provider is under evaluation.

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 5 of 8
	Doc Number: QSP 8.4	Rev: G	

6.3.2.3 NOT ACTIVE/INACTIVE:

6.3.2.3.1 When supplier has been disqualified or no longer a going concern, the vendor card shall be blocked from payment and all purchasing activities.

6.3.2.3.2 The external provider may be changed to INACTIVE in IQMS, under AP Module/Vendor Rating tab. These conditions will not permit any purchasing activity.

6.3.2.4 Conditions for NOT ACTIVE/IN ACTIVE:

6.3.2.4.1 Suppliers approval period has ended based on three-year approval period

6.3.2.4.2 Supplier Performance is not satisfactory.

6.3.2.4.3 Customer has directed JGP to disapproved supplier for specific items(s) previously directed by the Customer.

6.3.3 This condition is modified from the Vendor tab and reviewed with Controller. Refer to QAOP-0039 for processing details.

6.4 Supplier Evaluation / Re-evaluation

6.4.1 The status of the suppliers on the ASL is determined by historical performance. Status is further evaluated based on product and service quantitative and qualitative requirements and are documented in accordance with QAOP-0039 These include but are not limited to:

6.4.1.1 accept/reject history, (JGP score card / rating)

6.4.1.2 on-time deliveries,

6.4.1.3 ability to ensure, when required, provision of customer-approved special process

6.4.1.4 supplier certification

6.4.1.5 price,

6.4.1.6 terms and conditions

6.4.1.7 ability to meet requirements for approval of product, procedures, processes and equipment, (including validation / verification techniques as applicable)

6.4.1.8 requirements for qualification of personnel,

6.4.1.9 requirements for design, test, inspection, verification (including production process verification),

6.4.1.10 use of statistical techniques for product acceptance, and related instructions for acceptance by the organization,

6.4.1.11 critical items (including key characteristics),

6.4.1.12 requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing.

6.5 Control Over External Providers:

6.5.1 JG Plastics Group, LLC shall ensure that the product being procured satisfies the specified requirements of the External Providers through document reviews, incoming inspection and manufacturing processes.

6.5.2 The type and extent of the control over External Providers shall be specified in the Purchase Order or contract; taking into consideration past performance, the impact of

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 6 of 8
	Doc Number: QSP 8.4	Rev: G	

the product being procured on the final product if external provider is specified by customer.

- 6.5.3 Additional actions may include but not limited to:
 - 6.5.3.1 On-site supplier assessment and/or audit of the facility
 - 6.5.3.2 Increased Inspection size during receiving or in process inspections
 - 6.5.3.3 Increased sample size during initial and/or subsequent shipments for acceptable quality levels will be considered in place of revising existing documentation.

6.6 External Providers Rating:

6.6.1 External Providers performance shall be reviewed by Purchasing/Quality designee twice yearly (every 6 months). The report is generated electronically by IQMS, refer to QAOP-0039 for details

6.6.2 External Providers will be weighted on the following.

6.6.2.1 Quality Factor (50%)

Reject Percentage	Quality Rating
0-2.99%	100
3-4.99%	80
5-10.99%	50
11-75.00%	25
75.01-100%	0

6.6.2.2 Delivery Factor (50%)

Days Late	Delivery Rating
-29 - 6	100
7 - 10	50
11 - 75	30
75+	0

Example: Order is 2 days late with 7% rejects. The vendor rating would be calculated as 75.

Delivery Factor (50% of Total Rating)	Quality Factor (50% of Total Rating)	Vendor Rating Calculation
50	100	$(50 * 0.50) + (100 * 0.50) = 75$ <small>[Delivery Factor] [Quality factor] [Vendor Rating]</small>

6.6.3 External Providers that fail to meet expectations (vendor rating to be ≥ 90); will be notified by using Vendor Scorecard (Form F8.4_7) and / or issuing a CAPA. F8.4_7 will be saved in the IQMS Library under Vendor Rating.

Note: *If the supplier is customer directed: Communication may include a customer representative to manage/mitigate risks or issues directly related to their product or otherwise directed by contract/agreement.*

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 7 of 8
	Doc Number: QSP 8.4	Rev: G	

- 6.6.4 If an External Provider performance does not meet expectations, an onsite audit of their QMS may be initiated; the results will be recorded in the Quality System Audit Form.
- 6.6.5 Suppliers whose performance remains below an acceptable level may be disqualified from the ASL, unless authorized by customer (in cases of customer directed suppliers).

6.7 Outsourced Processes

- 6.7.1 Outsourcing is controlled through the purchasing process. Purchase Orders, contracts, or other purchase documents involving outsourcing clearly describe or reference the work to be done and any needed specifications.
- 6.7.2 Confirmation that the requirements have been met is verified by review of any required documentation and any required additional testing or inspection.
- 6.7.3 Where appropriate, Purchasing and Operations, (with Quality input), shall evaluate any possible risks involved with the procurement of materials. These risks can include (but are not limited to) factors such as:
 - 6.7.3.1 Supplier disqualification,
 - 6.7.3.2 Customer contract revision,
 - 6.7.3.3 Material shortage,
 - 6.7.3.4 Natural or man-made disaster,
 - 6.7.3.5 Supplier default (contractual obligations)
 - 6.7.3.6 End-of-life purchases

6.8 Verification of product

- 6.8.1 All purchased products and customer supplied property shall be received and inspected by Receiving designee to ensure that:
 - 6.8.1.1 The products received are undamaged,
 - 6.8.1.2 Verify received part number and quantity match the packing slip,
 - 6.8.1.3 Customer-supplied property complies with customer supplied documents,
 - 6.8.1.4 If a copy of the packing slip or details of products to be received is not available, it shall be obtained from the Production Planner and/or Customer Service.
 - 6.8.1.5 Certificate of Conformance/Compliance or Analysis information regarding lot number and quantity matches with the packing slip.
- 6.8.2 Once the order has been received, it is entered into the system and when applicable, a copy of certifications is forwarded to the Quality Department and processed per MI-0014.

7. RECORDS

- 7.1 Form F8.4_1 Questionnaire Assessment of External Provider or Sub-contractor
- 7.2 Form F8.4_3 Supplier Scope List
- 7.3 Form F8.4_4 Supplier Audit Schedule
- 7.4 Form F8.4_5 Quality Systems Audit

JG PLASTICS GROUP	EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES		Pg. 8 of 8
	Doc Number: QSP 8.4	Rev: G	

- 7.5 Form F8.4_6 Purchase Requisition
- 7.6 Form F8.4_7 Vendor Scorecard
- 7.7 Purchase Order (IQMS)

REVISION HISTORY				
LTR	DESCRIPTION	ORIGINATOR	RELEASED BY	RELEASE DATE
A	ECN 342	H. BRITAIN	C. URBAN	3/8/17
B	ECN 390	H, BRITAIN	C. URBAN	3/8/18
C	ECN 498	H, BRITAIN	C. URBAN	7/23/19
D	ECN 573	T. CONWAY	C. URBAN	3/5/20
E	ECN 667	T. CONWAY	L. FLORES	8/27/20
F	ECN 711	T. CONWAY	L. FLORES	10/14/20
G	ECN 1177	M. BRISTOW	L. FLORES	06/28/2023