1. **Purpose**

This document defines the policies and procedures for ensuring effective management and control of suppliers providing products and services. These policies and procedures include supplier planning and selection, supplier evaluation and acceptance, supplier controls, measurement and monitoring, and feedback and communication.

1. **Scope**

This document applies to suppliers that provide product and/or services that are associated with the Quality Management System. Suppliers that do not impact the quality of products or services provided to customers are exempt from this procedure.

1. **General** 
   1. **Definitions**

**Approved Supplier List (ASL) –** A list of suppliers that have been accepted through the qualification process to provide product and/or services.

**Critical Supplier –** A supplier of a product or service that the failure of which to meet specifications could cause unreasonable risk to the patient, clinician, or others, or could cause a significant degradation in performance. This may include suppliers of QMS or regulatory compliance and consulting services.

**OEM –** Original Equipment Manufacturer

**Supplier –** any organization that provides products or services to the company: manufacturers, distributors, contractors, or consultants.

**Supplier Corrective Action Request (SCAR) –** The documented request to a supplier for a formal response to an issue or issues regarding a given item or service. The supplier is required to investigate and correct the nonconforming issues providing the appropriate written response.

* 1. **Responsibilities**

**Operations** – Operations is responsible for maintaining the Approved Supplier List and all associated record requirements.

**Quality Management** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities and approving the Approved Supplier List.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirements** – All Quality, Engineering, and Purchasing personnel shall be trained on this document and the training documented.
  4. **Record Management** – Supplier Evaluation, Re-evaluation and Acceptance Activities records are managed and maintained by the Quality and Operations Departments, respectively.
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**ISO 13485** – Medical Device Quality Management Systems

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**MEDDEV 2.5/3 rev.2** – Subcontracting Quality Systems Related

**GHTF/SG3/N17:2008** – Control of Product and Services Obtained from Suppliers

**QP-0005** – Purchasing and Receiving Process

**QP-0015** – Quality Audit Process

**QF-0023-1** – Supplier Approval Form

**QF-0023-2** – Supplier Survey

**QF-0023-3** – Supplier Corrective Action Request (SCAR) Form

**QF-0023-4** – 1st Article Inspection Form

Approved Supplier List and Audit Schedule

1. **Supplier Management Procedure**

The company utilizes a tiered system for managing suppliers. The supplier level is dependent upon risk associated with the product or service provided and the potential for impacting the quality of the products and services provided to our customers. The supplier level is determined by the Quality Department and documented on QF-0023-1, Supplier Approval Form. Level 1 Suppliers are considered critical suppliers. The list below provides examples of suppliers for each category:

* **Level 1 Suppliers** – Suppliers of finished medical devices
* **Level 2 Suppliers** – Contract manufacturer of components and/or supplier of critical services including distribution and warehousing. Suppliers of components with a moderate to high associated risk.
* **Level 3 Suppliers** – Component suppliers, Calibration and Test Labs, Clinical Sites, Quality Management Services
* **Level 4 Suppliers** – Non-QMS Suppliers, Distributors and Manufacturers of Off-the-Shelf items with an acceptable quality history.
* **Non Production Resource (NPR)** – Business entity, government agency, or utility provider that provides a service or product that is not used in any products.

* 1. **Supplier Planning and Selection**

The need for a new supplier is generally identified through activities associated with Design and Development, Engineering Change Orders, and/or CAPA’s. The selection of a supplier to be approved is determined with input from Engineering, and Operations. Preference shall be given to expanding the qualification of an existing supplier with acceptable performance over approving a new supplier, where practical. When possible, multiple quotes shall be obtained for the desired product or service prior to selecting a supplier for evaluation. The table below identifies the minimum requirements for supplier selection based on the supplier level

| **Minimum Requirements for Initial Supplier Selection** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Level** | **Goods or Service** | **FDA Registration** | **ISO 13485/**  **17025 Cert** | **ISO 9001 Cert** | **Approved QS** | **Validated Processes** |
| I | Contract Mfg | Y | Y |  | Y | AR |
| II | Component Mfg | N | Y | Y | Y | AR |
| III | Component & Services | N | Y | Y | Y | AR |
| IV | Non-QMS | N |  |  |  |  |

\* As Required \* \_\_\_\_\_\_\_\_ - Minimum of one of the evaluation criteria indicated

* 1. **Supplier Evaluation and Approval**

Suppliers shall be evaluated to ensure the entity is capable of supplying products and/or services in accordance with company requirements and evidence of the evaluation shall be maintained within the supplier file.

If the supplier will perform processes that are required to be validated to ensure quality requirements of the final product have been met, the associated validation documents shall be obtained and reviewed for acceptability before the supplier will be approved.

Suppliers are evaluated to ensure the entity is capable of supplying products and/or services in accordance with company requirements and evidence of the evaluation is maintained within the supplier file. These records contain at minimum one of the following items demonstrating supplier evaluation where applicable. Additional Evaluation information may be included as desired.

Final supplier approval is documented on QF-0023-1, Supplier Approval Form

Evaluation Criteria may include the following criteria or other criteria as seen as sufficient to ensure final product quality requirements are met:

* Completed Supplier Survey (QF-0023-2), Supplier Audit Report (QP-0015) and/or QMS Certification
* Resumes, Curriculum Vitae, Licenses, or Certificates
* Contract Agreements
* Evidence of Supplier Controls
* Evidence of compliance to 21 CFR 820 quality system requirements for functions outsourced to the supplier
* Completed 1st Article Inspections (QF-0023-4)

Level 1 Suppliers of medical devices shall have a valid ISO 13485 certificate issued by a notified body with a scope of registration appropriate to the product being manufactured.

Level 1 Suppliers require an onsite audit to ensure compliance with applicable FDA regulations and Quality Management System requirements for the activities outsourced to the supplier.

Level 1 Suppliers shall be re-evaluated and/or audited every three (3) years to ensure continued compliance and performance. Tracking of these activities is maintained on the Supplier Audit Schedule.

* 1. **Supplier Controls**

Supplier Controls to be considered are listed below. Where sufficient objective evidence of supplier controls to ISO 13485, 21 CFR 820 or other Quality System Requirements cannot be verified, a supplier audit shall be conducted in accordance with QP-0015 – Quality Audits.

* **Process Input Controls** - raw material, machine programs/settings, revision control of process documentation, and (if applicable) temperature settings/speeds/feeds/etc.
* **Process Maintenance** - calibration of machines/process indicators, and maintenance of machine tools and periodic toll verification cycles
* **Traceability of Records** - raw material, finished lot, and inspection/acceptance data
* **Verification and Acceptance**:
  + Incoming, In-Process, and Final Inspection and Testing
  + Risk Assessment and Control Plan
  + 100% inspection for final acceptance or a sampling plan. If a sampling plan, is there rationale for the plan and was the plan approved?
  + Product yield information trending
* **Validation** - For any critical dimension that is not verified each time, what validation has been completed to support no verification of the specification? Validations are reviewed and approved for adequacy to ensure product quality requirements are met.

First Article Inspections (FAI’s) are utilized to verify the effective communication and implementation of product specifications and supplier controls. First article inspections are documented on QF-0023-4 and verify critical specifications of the product.

* 1. **Supplier Measurement and Monitoring**

Suppliers are monitored and measured to ensure acceptable performance and identify areas in need of improvement. Data is obtained from multiple sources including, but not limited to:

* NCR/SCAR’s
* On Time Delivery
* Customer Complaints
* Audit Reports

An evaluation of the supplier data is completed annually as part of the Management review process. Continual poor performance may initiate a supplier audit, SCAR’s, or debarment from the ASL.

* 1. **Feedback and Communication**

Performance feedback is provided to suppliers via corrective action requests, supplier audit reports, and general business correspondence. In the event that material is received out of specification, the supplier will be issued a Supplier Corrective Action Request (SCAR) (QF-0023-3).

* Containment Actions – Actions taken to quarantine and prevent the distribution of other impacted products.
* Root Cause Determination – An investigation to identify the root cause of the issue including potential impacts to other product and historical review.
* Corrective and Preventive Actions – The actions taken to correct the issues and prevent the issue from re-occurring.
* Effectiveness Check – Verification activities to ensure the corrective and preventive action were effective.

The supplier must make all reasonable efforts to complete corrective and preventive actions and provide documented evidence of completion. Root cause and corrective action shall be identified within 30 days and implemented within 90 days unless otherwise agreed to by Quality Assurance. Failure to supply products and/or services that meet company specifications or failure to respond to or complete SCAR’s will result in Debarred status on the ASL.

* 1. **Approved Supplier List**

Upon evaluation and acceptance, a supplier is added to the Approved Supplier List (ASL). The Approved Supplier List is approved by Quality.

* + 1. **Required Information**

The following information is recorded for all suppliers listed on the ASL:

| * Supplier Name |  |
| --- | --- |
| * Supplier Level |  |
| * Supplier Status |  |
| * Approved Location * Part # (If applicable) * Supplier Part Number (Is applicable) |  |
|  |  |

* + 1. **Supplier Status**

Each supplier on the ASL is assigned a status. This status can change as the results of Supplier Measurement and Monitoring, SCAR’s, and/or management review of ASL. Inactive suppliers shall be re-assessed against the supplier qualification requirements and assessment documented prior to being upgraded to an Approved status.

* **Approved**– a supplier that has met all requirements for approval and maintained an acceptable level of quality.
* **Debarred**– a supplier that is no longer usable or has failed to successfully establish and maintain an acceptable level of quality.
* **Inactive**– an approved supplier that has had a lapse in activity (receipt of product, or PO issuance) greater than 2-years.
* **Conditional**– a supplier that meets some, but not all the requirements for approval.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0023 |  |  | Initial implementation of the Supplier Management Process |