

All Approved/*Critical Suppliers (Suppliers) of products or services shall be required to meet the following requirements and shall understand Elite RFs' QMS requirements to AS9100 and ISO 13485 (current revision) concerning control of externally provided processes, products, and services.

Requirements

1. Implement a QMS that includes control over approved external Suppliers.
2. Supplier is required to maintain control of quality records for a minimum of 7 years unless stated otherwise on PO. **In the case of medical device records, they shall be maintained for the lifetime of the device, but not less than 2 years (lifetime is defined as active at Elite RF).**
3. Supplier shall provide/maintain measuring and test equipment required to assure conformance to Elite RF PO requirements along with a corrective action process to eliminate causes of nonconformities in order to prevent recurrence.
4. Supplier shall provide verification of the product or service including objective evidence of product quality and compliance with all requirements (CofC).
5. Supplier shall notify Elite RF in writing of any process/product changes that could impact product form, fit or function, and/or any significant organizational or facility changes and obtain Elite RF approval. Supplier shall not ship any product that does not meet all drawing and PO requirements without prior written Elite RF approval.
6. In the event that nonconforming product has been inadvertently shipped, Supplier shall notify Elite RF ASAP and obtain organization approval for nonconforming product disposition.
7. Elite RF has the right of entry to all Supplier facilities to determine and verify product quality and accessibility to all quality records.
8. Perishable material must be clearly identified with the date of manufacture and date of expiration, and have at least 50% of shelf life remaining at time of delivery.
9. Hazardous materials shall be clearly identified as such and the supplier shall provide safety data sheets with first delivery.
10. Supplier shall have a program in place to preclude, detect and remove any counterfeit product parts or materials.
11. Product and materials shall be packaged using the best commercial practices to prevent damage, deterioration and degradation.
12. Supplier shall have a process in place to assure FOD free products (foreign object debris) are delivered to Elite RF.
13. Performance Criteria: Critical Suppliers will be evaluated on Quality by the number of SCARs issued. The expectation is zero SCARs, and consistently underperforming Critical Suppliers may lost approval status. Non-critical Suppliers will be evaluated on an exception basis.
14. Have a process in place to assure employees are aware of their contribution to product and service conformity, product safety and the importance of ethical behavior.
15. Supplier shall flow down the requirements of this specification along with any other requirements specified on the Elite RF PO as required to assure compliance with this process.
16. Any other customer specific requirement will be communicated on the PO.

*Critical Suppliers: Providers of products and services that are intended for incorporation into Elite RF's products.