



Supplier Quality Manual





Supplier Quality Manual

Index

FOREWORD.....3

1. PURPOSE.....4

1.1 Scope.....4

1.2 General.....4

1.3 Quality System Requirements4

2. QUALITY SYSTEM4

2.1 First Article Inspections4

2.2 Critical to Quality (CTQ's).....4

2.3 Capability Studies5

2.4 Lot Traceability.....5

2.5 Receiving Inspection5

2.6 Control of Nonconforming Material5

2.7 Corrective Actions5

2.8 Process / Material Changes5

3. PURCHASING.....6

3.1 Communication6

3.2 Proprietary Information6

3.3 Purchase Orders.....6

3.4 Supplier Performance.....6



Supplier Quality Manual

Foreword

Advanced Engineering, Inc. is a contract manufacturer of plastic injection molding, assembly, packaging and kitting of medical components. We are ISO 13485 certified and FDA registered.

Advanced Engineering is committed to customer satisfaction for all of our customers. Advanced Engineering cannot achieve that goal without the support of our suppliers. Communication is the first step in a customer/supplier relationship. We want to build a successful relationship with all of our suppliers.

Advanced Engineering's Quality Policy

Advanced Engineering is committed to meeting ISO, regulatory, and customer requirements by using a risk-based approach to our quality system.



Supplier Quality Manual

1. Purpose

This Supplier Quality Manual details the quality requirements that Advanced Engineering expects its suppliers to meet. This manual is intended to strengthen the customer / supplier relationship by documenting quality and delivery requirements.

1.1 Scope

This manual applies to all production suppliers. This manual does not alter or reduce any contractual requirements covered by purchasing (purchase orders or contracts) or engineering documents (prints or specifications).

1.2 General

Advanced Engineering uses materials purchased from suppliers to manufacture, assemble, and package products for our customers. The quality of the items that are purchased is critical to the quality of our end product.

Advanced Engineering expects suppliers to deliver defect free products on time. If a supplier has the misfortune to ship defective product, they are expected to work with Advanced Engineering on replacing material in a timely manner. They must understand root cause and put corrective actions in place in order to prevent a re-occurrence.

1.3 Quality System Requirements

Advanced Engineering prefers that the suppliers be ISO certified. If not certified, suppliers will be required to complete a supplier selection / evaluation / re-evaluation.

All suppliers, certified or non-certified, are expected to meet quality and delivery expectations.

2. Quality System

2.1 First Article Inspections

Advanced Engineering may be required to submit first article inspections to its customers. Advanced Engineering may require its suppliers to submit first article inspections also. If a first article inspection is required, the quality department will detail the specific requirements and communicate to the supplier's quality department.

2.2 Critical to Quality (CTQ's)

Critical to Quality dimensions are significant for fit, form, function, and performance. CTQ's may be identified on the prints. If they are not, Advanced Engineering will communicate to the supplier any CTQ's. All CTQ's must be controlled by the supplier.



Supplier Quality Manual

2.3 Capability Studies

Capability studies may be required on CTQ's. CTQ's must meet a minimum of 1.33 Ppk unless Advanced Engineering agrees under special circumstances.

2.4 Lot Traceability

Suppliers must maintain lot traceability throughout the production process. Traceability must go from final product back to raw materials.

2.5 Receiving Inspection

Advanced Engineering requires a certificate of conformance on production material. Contact Advanced Engineering's quality department if there is a question on the C of C requirements.

Suppliers that provide sterile products may be required to provide sterile certification.

Packing slips with reference to the purchase order must accompany each shipment.

2.6 Control of Nonconforming Products

Suppliers are expected to deliver 100% defect free product. Advanced Engineering reserves the right to perform random audits on material received from suppliers. If an audit is performed and passes, defects may still be found and rejected from production.

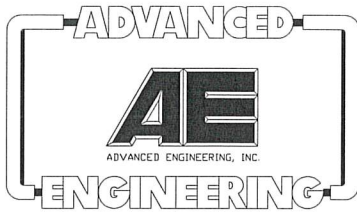
A product nonconformity report may be issued on defective product. Suppliers will be notified of the discrepancy. It is critical that the supplier respond in a timely manner with a return material authorization number and method to ship. Advanced Engineering prefers to receive replacement product over a credit. If production will be shut down due to the discrepancy, Advanced Engineering may be required to sort. The supplier may be asked to help cover the sorting costs until replacement product is received.

2.7 Corrective Action

If Advanced Engineering receives defective product, the supplier may be required to provide corrective action. Responsiveness is critical to Advanced Engineering. Suppliers are not required to use a specific form, but containment, root cause, corrective and preventive actions must be addressed.

2.8 Process / Material Changes

Advanced Engineering must be notified of all process and material changes. Advanced Engineering and possibly its customers will review and determine if there are any requirements for the change.



Supplier Quality Manual

3. Purchasing

3.1 Communication

Advanced Engineering encourages early and active involvement. If suppliers have suggestions for process improvements, cost reductions, or questions, please contact Advanced Engineering. Advanced Engineering is committed to building positive relationships with suppliers.

3.2 Proprietary Information

Suppliers will have access to proprietary information; such as prints. Suppliers may be required to sign non-disclosure agreements.

3.3 Purchase Orders

Suppliers are requested to confirm receipt of purchase orders. If there is a concern with delivery quantities or dates, it is the responsibility of the supplier to contact Advanced Engineering prior to accepting the purchase order or upon knowledge of a concern when the PO has been accepted.

Once the purchase order has been accepted, suppliers are expected to meet the due date of the purchase order. Advanced Engineering will accept early shipments, but late shipments are not acceptable. Advanced Engineering understands that there may be some instances outside of a supplier's control that they will not be able to meet the due date. In such instances, Advanced Engineering needs to be contacted.

3.4 Supplier Performance

Supplier performance is critical to Advanced Engineering's manufacturing capabilities. Quality and delivery are areas that Advanced Engineering will monitor and evaluate suppliers on a quarterly basis. High and Medium Risk Suppliers that directly impact production parts will receive a performance report **twice a year**.

Suppliers that are customer directed are required to meet the requirements of this Supplier Quality Manual. If there are consistent issues with a customer directed supplier, Advanced Engineering may request the customer's help with the supplier.