



Purchase Order Quality Assurance Requirements

The following Quality Assurance requirements are applicable for Approved Vendors as specified in the Approved Vendor List and/or on the Purchase Order.

Q1 -- Q3 CSI Inspection Requirements

Q1. At Vendor Facility

CSI reserves the right to inspect all items on this order at the vendor's facility.

Q2. Vendor Inspection Process Review

Vendor's inspection system and manufacturing process are subject to review/approval, verification and analysis by authorized CSI representatives.

Q3. CSI Source Inspection

All items covered by this purchase order are subject to source inspection and surveillance during fabrication by CSI quality representative. Notify the CSI QA department 48 hours in advance for source inspection. Evidence of source inspection shall accompany each shipment.

Q4. Changes

All changes in design, processes or fabrication must be authorized in writing by CSI prior to proceeding.

Q5. Report of discrepancy

All departures from drawings, specifications, or other purchase order requirements must be reported to CSI for approval prior to shipment.

Q6. Resubmitted Material

Vendor shall reference the applicable Non conformance Report Number on all shipping documents for resubmitted material.

Q7. Quality Systems

Vendor will provide and maintain a system that complies with any one of the following systems (depending on the product supplied):

- a. ISO 9000-900
- b. FDA CFR 21 Part 820 – Quality System Regulation (QSR)
- c. MIL-Q-9858A
- d. MIL-I-45208A
- e. ISO 13485:2003

Compliance with all sections of the applicable specification is required unless specifically excluded or stipulated in the purchase order.

Q8. Vendor's Controlled Products

The initial shipment of this purchase order must be accompanied by legible copies of applicable drawings, specifications and/or catalogs for CSI Receiving Inspection.

Q9. Statement of Compliance

Each shipment must be accompanied by a legible copy of a Certificate of Compliance listing the drawing, specification, process and applicable revision letter to which the material, parts or services comply and be signed off by vendor's QA representative.

Q10. Control of Nonconforming Supplies

The vendor shall provide and maintain an effective system for the control of nonconforming supplies, procedures for its identification, segregation and disposition.

Q11. Corrective Action

Vendor shall provide and maintain a system for Corrective Action, to perform investigations, detection of problem areas and take actions to prevent recurrence.

Q12. First Articles

First articles must be inspected and accepted by CSI quality representative prior to a production shipment, unless otherwise authorized by CSI. The first articles must be inspected for compliance to the requirements of applicable engineering drawings and specifications. First articles must be so marked and identified with part number.

Q13 -- Q15 Reports

Q13. Inspection/Test Results

Vendor shall furnish a copy of actual inspection/test results identifiable with inspection/test parameters defined as operational, mechanical, electrical, environmental, etc., of material submitted. Vendor to provide 1 complete inspection dimensioning tolerance report for each lot shipment and identify the part from the shipment used to generate the dimensioning report. All PCB assemblies received from suppliers require test data included with each unit unless the assemblies are to be tested at CSI.

Q14. SPC Chart

Vendor shall furnish a copy of the SPC chart identifiable to the material submitted to CSI.

Q15. Material Safety Data Sheet

Vendor shall furnish a Material Safety Data Sheet (MSDS) for products which are considered hazardous in compliance Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).

Q16 -- Q18 Traceability

Q16. Traceability Records

All items on this purchase order shall be traceable to the raw materials used. All traceability and inspection records must be identifiable with raw materials, parts, or assemblies to which they are applicable and shall be available upon request or audit by CSI representatives.

Q17. Lot Numbers

Each part, component, or assembly furnished shall be identified by lot or batch, traceable to the actual manufacturing process. The lot or batch number may be a date or vendor shop order code, but must provide the capability for a lot or batch purge in the event of determination of discrepant condition.

Q18. Serial Numbers

Each part, component, or assembly furnished under this purchase order shall be identified with a distinct serial number. Serial numbers shall not be duplicated for one part, component, or assembly number when manufactured in sequential lots.

Q19. Limited Shelf Life Items

Each individual tube, can, bottle, or roll must be marked with date of manufacture and shelf life. Materials must have at least 3/4 to maximum usable shelf life when received at CSI.

Q20. Special Processes

Special processes together with equipment and material, when directed by specifications or contract, require review and approval by CSI prior to beginning of production. When required by contract provisions, process procedures, any changes/modifications made to the special processes during performance of the purchase order, will require CSI approval prior to implementation.

Vendor shall perform systematic, periodic audits of personnel, equipment, methods, and material required in these special processes to assure positive control at all times. Evidence of these audits shall be maintained and made available to CSI upon request.

Q21. Batteries

Each individual battery must be marked with a date code, date of manufacture or expiration date. Lead-acid batteries must be no more than six months old (less than three months preferred) when received at CSI's main facility. Alkaline batteries must have at least two years left before they expire. All other types of batteries must be no older than six months when received at CSI.

Q22. Static Sensitive Components and Assemblies

All static sensitive components and assemblies shall be packaged in static shielding packages or containers and identified with ESD warning labels.

Q23. Device History Record

All finished products bearing the CSI logo must be supplied with copies of the device history record including all test and routing reports. The test and routing reports must contain the serial number of each unit and must consist of one set of reports per unit.

NOTE

Q1, Q2, Q4, Q5, Q6, Q7, Q10, Q11 and Q16 are mandatory for every vendor that supplies any items that are used to build CSI products.

Q3, Q8, Q9, Q12, Q13, Q14, Q15, Q17, Q18, Q19, Q20, Q21, Q22 and Q23 will be assigned to the individual products listed on the Qualified Supplier List.