



**SUPPLIER QUALITY
ASSURANCE REQUIREMENTS
(SQAR)
REV 1B**

1 OVERVIEW

It is the established policy of Datalink Electronics Ltd to comply with the requirements of the Quality Management System standards BS EN ISO 13485, BS EN ISO 9001, and AS 9100. This is achieved through the effective implementation of company procedures, including the management and evaluation of suppliers whose products or services have a direct impact on product quality or performance.

2 PURPOSE

The purpose of this Supplier Quality Assurance Requirements (SQAR) document is to provide our suppliers with clear guidance on the requirements and expectations of Datalink and its customers. This document forms an integral part of the Datalink purchase order process.

This manual does not define product or service specifications. Datalink is not the legal manufacturer of any Aerospace or Medical device, as defined by ISO 13485 or AS9100. However, it remains Datalink's responsibility to ensure that suppliers comply with the specified material and component requirements.

3 DEFINITIONS

Manufacturer – a supplier of custom-engineered parts fabricated or machined (or the likes of) to a supplied drawing or specification that operates a quality management system.

Distributor – an authorised/franchised/OEM component supplier.

4 SCOPE

This SQAR applies to the purchase, receipt, storage, manufacture, testing, distribution, repair, product lifecycle and Integrated Management System (IMS) requirements of the supplied products, including final products, purchased products (components) and services. Nothing in this SQAR shall limit a Party's obligation to comply with all applicable laws and requirements.

Only products purchased by Datalink for use in Aerospace or Medical devices are subject to this agreement. All parts covered under this agreement will carry the prefix 'DATALINK' in accordance with Datalink's process specification PI13 (available on request).

Where requirements differ between **manufacturers** and **distributors**, such distinctions are clearly defined.

5 SUBCONTRACTING OF WORK

Suppliers shall not be permitted to subcontract any aspect of its obligations under this SQAR without the prior written approval from Datalink. The Supplier shall ensure that any subcontracting arrangement it enters will fully impose the requirements of this SQAR on the sub-contractor; however, the Supplier is solely responsible for ensuring its obligations under this SQAR are met and is not permitted to pass this responsibility to a Third-Party. The Supplier shall remain responsible for the acts and omissions of any permitted subcontractors as if those acts and omissions had been carried out by the Supplier itself.

6 APPROVAL STATUS

If Datalink deems that the provisions of this SQAR are not being met by the Supplier, both Parties will work together to rectify the situation within a reasonable timescale: SMART (Specific, Measurable, Achievable, Results-focused, and Time-bound) milestones for resolution should be established within 10 days of the communication of the concern. If the process is unsuccessful, Datalink reserves the right to perform an onsite audit within 10 days of it notifying the supplier.

7 REVISION

This SQAR will be reviewed and modified when necessary or at a minimum of every three years. If no changes have been made this review can be made by Datalink in isolation.

The Supplier is responsible for maintaining the current revision of this document when providing products and services to Datalink. Any questions pertaining to this document should be made in writing to your Datalink point of contact.

The latest version of the document will be sent to Suppliers and will be available for download at www.datalink-electronics.co.uk

8 THIRD-PARTY SUPPLIERS

Manufacturers. In selecting Third-Parties Suppliers, the Supplier shall apply the requirements of this SQAR. The Supplier shall have an appropriate SQAR with Third-Party Suppliers used for production, packaging, testing, processing, or release of the Supplied Products. Upon the request, the Supplier will provide a copy of the SQAR to Datalink.

When used on, applied to, or incorporated into the Supplied Product, the Supplier shall only purchase the goods or services from a Third-Party Supplier or a distributor that provides the exact same item/component. The performance evaluation and management of a Third-Party Supplier is the responsibility of the Supplier.

If required, the Supplier shall provide Datalink with performance reports on the Third-Party Suppliers, including the number of purchase order lines placed with the Third-Party Supplier, the percentage of shipments received late, and the percentage of shipments rejected at receiving acceptance.

Note: Where the Supplier deems a Third-Party Supplier as confidential, additional dialogue and agreement may be needed.

9 PRODUCT REQUIREMENT SPECIFICATIONS

The Supplier shall operate a procedure for preventing the use or supply of counterfeit parts.

Manufacturers. Datalink shall define the specifications of the product to be provided by the Supplier. Both Parties must agree that sufficient information has been provided in the appropriate form, including, but not limited to, drawings, reference to commercial specifications, identity of brand names, and standards, to allow the Supplier to deliver the product in full conformance to the agreed specifications. The specifications may be provided as paper documents, electronic documents, or other appropriate media.

The Supplier shall be able to provide test specimens for design approval, inspection/verification, investigation or auditing.

The Supplier shall retain specifications in accordance with agreed Document Control procedures for a defined retention period. All documentation shall be made available to Datalink upon request.

Where products are provided to specifications that are not controlled by Datalink, the supplier is responsible for providing them in line with the intention of the specification owner. If unsure it is incumbent on the supplier to seek the approval of Datalink.

Where the supplier maintains a relationship with Datalink's 'end customer' it is not acceptable for the supplier to solely communicate or seek agreement with the ultimate customer, all communication must go through Datalink.

The Supplier shall ensure that persons are aware of:

- Their contribution to product or service conformity
- Their contribution to product safety
- The importance of ethical behaviour

Distributors. All purchased parts have specifications that are not controlled by Datalink or supplier; however, it is incumbent on the supplier to advise the customer of all changes to the specification prior to supply.

Where product specifications are amended by the Original Equipment Manufacturer (OEM), the Supplier must inform Datalink at the earliest opportunity in accordance with IPC J-STD-046. Datalink reserves the right to terminate any contract for the affected products where this does not happen.

Any Deviation to form, fit, function, or process must be approved in writing by the customer prior to implementation.

9.1 Change Requests

Manufacturers. Where the Supplier identifies the need to update or change a document, specification or drawing under Datalink's control, the supplier shall make the request to Datalink including sufficient description of the change (to allow potential risk to the Supplied Products, IMS and the company to be identified), the reason for the change, and the anticipated lead time before the change is implemented. Datalink shall acknowledge receipt of each change request within 10 working days of receipt and provide a decision on the change request within 30 days. The agreement shall include an effective date for the implementation of the change with provision for full analysis of the impact of the change.

Where product specifications are controlled externally it is the supplier's responsibility to gain agreement with the customer prior to delivery of the amended product. The supplier must give as much notice as possible of any change, and where this does not happen, Datalink reserve the right to terminate any contract for the affected products. Process/Product change notifications should be processed (PCNs) in line with IPC J-STD-046.

9.2 Deviations

Manufacturers. Any Deviation to form, fit, function, or process must be approved in writing by Datalink prior to implementation. A concession number will be supplied by Datalink for referencing on all delivery paperwork.

Where the Supplier needs to deviate from its standard validated processes the Supplier shall document the deviation request, specifying the deviation, its justification, and its effective period. Where products are 'verified' for conformity only products that are considered changed at the point of release need to be notified as per 8.1 and 8.2 above.

10 MANUFACTURING, STORAGE, PRESERVATION & LABELING

10.1 Production Process

Manufacturers. Where production processes are not fully verified the Supplier shall validate the process with a high degree of assurance according to a mutually agreed protocol between the Customer and supplier. The production processes shall be performed according to written methods and the results recorded. Records of the date the process was performed, the name of the operator, the identity of major equipment used, calibration date of equipment, and the setting of each input process parameter shall be maintained.

For this agreement, the term 'verification' is considered as 'inspection' to an international standard (such as IPC) or using an agreed method.

The Supplier shall ensure statistical techniques for product acceptance and related instructions for acceptance are made available to Datalink upon request.

10.2 Preservation of product

Manufacturers. As appropriate, manufacturers should establish procedures to ensure that the Supplied Product is preserved and delivered in the state defined on the product requirement specifications.

Distributors. Procedures shall be established to ensure that the Supplied Product is preserved and delivered in the state defined by the OEM.

Processes may include, but are not limited to:

- Environmental control
- Training of personnel
- Health, cleanliness, personal practices, and clothing of personnel
- Equipment validation for design, construction, placement, installation, calibrations or maintenance
- Software validation
- Packaging and shipping validation

The Supplier shall keep records of these activities according to agreed Document Control procedures and for a defined retention period. These records shall be made available to Datalink upon request.

10.3 Labelling

Manufacturers shall control all labelling and identification during and after production to prevent mix-ups.

Distributors shall control all labelling and identification during the processing of orders, ensuring ability is maintained.

Date or lot code information for each item received by Datalink shall be presented on delivery paperwork supplied by the supplier (or OEM where traceability from component packaging is possible).

Suppliers shall keep records of labels or identifiers used and make them available to Datalink upon request.

11 TRACEABILITY

Manufacturers. The supplier shall provide products that are fully traceable including batch traceability to raw material source and datasheet, personnel involvement, reported non-conformances and quality control evidence such as test and inspection records unless formally agreed in writing by Datalink.

At the point of delivery, suppliers should at a minimum provide material traceability, test and inspection records, and batch/serial numbers prior to, or as part of the delivery paperwork. Electronic records are preferred.

Distributors. All parts supplied must be purchased through official franchise routes unless agreed in writing by Datalink.

12 NON-CONFORMANCE, CAPA, AND COMPLAINTS

12.1 Disposition of Non-conforming Material

Manufacturers shall have processes describing the segregation, investigation, and disposition of all non-conforming material. Where non-conforming units are detected using validation or sampling, the Supplier shall inform Datalink at the first opportunity regarding any other potentially affected units.

Where the Supplier requests authorisation for a repair or concession disposition, the process shall be documented by the Supplier, including:

- Disposition
- QC inspections or tests
- Results (including raw data)
- Proposed repair/rework (if applicable)

Records of all non-conformances shall be made by the Supplier and be available for review.

Distributors shall have processes describing the segregation, investigation, and disposition of all non-conforming material.

12.2 CAPA

12.2.1 Supplier Initiated CAPA

Manufacturers shall initiate corrective action according to a documented process for all systemic nonconforming issues regardless of disposition. Corrective Action shall include at minimum documentation of:

- Root cause(s) analysis
- CAPA activity evaluation (including risk analysis of implementing versus not implementing actions)
- Effectiveness review

Distributors shall initiate corrective action according to a documented process for all systemic nonconforming issues that could potentially impact the supply to the customer.

Records of these activities shall be retained according to an established document control process and made available to Datalink upon request.

12.2.1 Datalink-Initiated CAPA

Datalink may initiate a CAPA for the Supplier when a non-conformance is identified after receipt of the product. This process shall require the Supplier to initiate a CAPA within 10 working days of receiving the information from Datalink. Both CAPA processes shall be aligned and include, at minimum, the following steps:

- Root cause(s) analysis
- CAPA activity evaluation (including risk analysis of implementing versus not implementing actions)
- Effectiveness verification

The Supplier shall report the results of the CAPA to Datalink within 15 working days of initiation. When the CAPA cannot be effectively completed within this period, the Supplier shall provide a status report every 5 working days until the CAPA is complete (unless agreed otherwise in writing).

The Supplier shall keep records of these activities and make them available to Datalink upon request.

10.3 Complaints

Where the Supplier receives a complaint related to Supplied Products or any similar products including products produced in the same manufacturing environment or using the same monitoring or measuring equipment the supplier should consider whether any other Supplied Product may also be affected. The Supplier shall notify Datalink within 5 working days of the original complaint as far as reasonably possible, considering the limitations of the Supplier's confidentiality and contractual agreements.

The Supplier shall grant the right of access by Datalink, their customer and regulatory authorities to the applicable areas of facilities and to applicable documented information at any level of the supply chain.

13 REPORTING

If the **manufacturer** files a report to a Competent Authority for the Supplied Product, or any similar product, the Supplier shall promptly notify Datalink as far as reasonably possible, considering the limitations of the Supplier's confidentiality and contractual agreements.

Both Parties shall cooperate in the exchange of information required to effectively manage the reporting activities.

14 INCIDENTS, NOTIFICATIONS, CORRECTIONS AND RECALLS

If the **manufacturer** files a notification, correction or recall, including field safety corrective action, of the Supplied Product, or any similar product, the Supplier shall promptly notify Datalink as far as reasonably possible, considering the limitations of the Supplier's confidentiality and contractual agreements. Both Parties shall cooperate in the exchange of information required to effectively manage the process.

Distributors. If the OEM files a notification, correction or recall, including field safety corrective action, of the Supplied Product, the Supplier shall promptly notify the Customer as far as reasonably possible, considering the limitations of the Supplier's confidentiality and contractual agreements.

15 AUDITS

15.1 Datalink Audits

Where custom products are supplied or from wherever the supplier distributes from, the Supplier shall allow Datalink or its authorized representative to perform audits of the Supplier's facilities, systems, documentation, and other requirements related to this agreement at mutually agreed dates and times.

Both Parties shall agree upon methods to protect intellectual property and confidential information.

15.2 Audit Findings

When conducting audits at the Supplier's location, Datalink will issue an Audit Report within 30 working days of the audit date

The Supplier shall issue a plan to determine the correction, cause, and corrective action for each finding within 30 days of the Audit Report's issue date.

15.3 Auditing Third-Party Suppliers

Manufacturers shall allow Datalink, or its authorized representative, to perform audits of the Third-Party suppliers as deemed necessary by Datalink at mutually agreed dates and times.

The Parties and Third-Party Supplier will agree upon methods to protect confidentiality.