



# Quality Certification Alliance

Quality and Safety. Delivered.

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## **Measuring and Defining Quality Manufacturing Compliance**

“Compliance” is alternatively defined as the “act or process of complying to a desire, demand or proposal or to coercion,” “the act of conforming, acquiescing or yielding,” and “the act of cooperation or obedience.”

As “compliance” is used in relation to the standards advocated by QCA, it is complying to regulatory and legal standards, best practice standards and other applicable voluntary standards as appropriate. Companies’ practices that have been accredited under the auspices of QCA are deemed to MEET OR EXCEED requirements, whether those requirements are regulatory (legal) in nature or best practices.

### **Quality Systems Compliance**

QCA measures and evaluates the management practices – a company’s policies, procedures and protocols – that provide for the predictable output of quality product continuously manufactured and shipped under the company’s name.

The old adage “quality in, quality out” applies: “Quality” applies to the grade and characteristics of raw materials, as well as the workmanship. When substandard (noncompliant) materials are used, the expected performance of the product is jeopardized. Similarly, poor workmanship jeopardizes the utility of a product for its intended purpose.

All accredited companies must have:

- A documented protocol for assuring continuous adherence to quality and performance standards related to the company’s product line
- A documented format for communicating product requirements and performance standards
- A documented protocol for validating product prior to the commencement of manufacture, whether new product or new manufacturing facility
- A documented protocol for validating conformance of finished product with approved product
- A documented supplier selection program
- Quality compliance-related accountabilities assigned to a senior position

### **Quality Systems Best Practices**

Best practices are those activities implemented by individual companies that assist in achieving compliance over a set of processes. Not all accredited companies will adopt identical best practices. Companies frequently have different methodologies for

achieving the same outcome. Arguably, best practices are considered to be strategic decisions on the part of a company given their internal structure, size and product line.

Best practices advocated for the predictability they offer in manufacturing safer product include, but are not limited to:

- Development checklists include a review of performance requirements
- Pre-production approval processes that include testing of approval sample raw materials
- Supplier scorecards incorporating onsite evaluation
- In-line inspection of manufactured products
- In-house testing of a representative sample size of all lots or batches of finished product received
- Documented supplier corrective actions
- Quality compliance training provided to quality, design and development, manufacturing and import members of a company, as appropriate to their level of interaction with the product and the end user
- Appointment of a quality officer

### **Quality and Inspection**

Inspection may be performed at almost any point in the product realization process. Some manufacturers and importers require raw materials and finished componentry to be inspected prior to introducing it into the manufacturing process. Many manufacturers and importers require reporting on the manufactured product and nature of observed noncompliance (defects) on a defined period basis – daily, weekly or monthly.

Reporting may be provided by the importer's staff, a contracted third party inspection service or, if the factory is a trusted partner, by the factory using their own formats or those provided by the importer.

Frequently, inspection is performed as a post-manufacturing process. Many companies require the performance of pre-shipment inspections either at the factory or at the forwarding agent's facility. Some organizations choose only to inspect upon receipt of finished goods. QCA strongly advocates against such a blanket policy and practice.

Inspection can provide the assurance the product meets performance and visual requirements. Inspection incorporates a predefined approved standard and evaluation of the raw material, component or product for compliance with that standard. A common example of a performance standard in the promotional products industry might be the tape test which potentially reveals quality characteristics about the ink, the printing surface or the workmanship. Pull tests may indicate the quality of thread, adequacy of stitches or, again, workmanship. Inspection identifies nonconformities which, frequently, are only indicators of the nature of the issue. An inspector must look beyond the defect and into the process to determine the origin of the observation.

Evaluating conformance with design characteristics is the most common type of inspection. Inspection of this nature is a visual comparison ideally between specifications, an approved sample and a sample of the product from the bulk (mass) manufactured product.

### **Determining Inspection Standards**

The nature and use of the product are two of many factors used to determine the applicable inspection standard and the requisite frequency of inspection. End customer requirements may also be a consideration.

The recognized standard in quality is driven by sample size and visual observations of defects that may impact the outlook or intended performance of the product and are classified as minor (cosmetic), major (impacting utility for intended purpose) or critical (rendering the product hazardous or unusable for the intended purpose).

Potential defects are defined by the category of products. Category of products may also determine the acceptable defect rate.

In the promotional products industry, misspellings render product unusable and are, therefore, classified as critical defects.