

The Promotions Dept. Quality Systems Compliance Requirements

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

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
- Pre-shipment inspection on manufacturing site to ensure performance and visual requirements are met
- 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