**Scope:**
This document applies to all suppliers of parts, components, raw materials, or sub-assemblies purchased by Allen Medical Systems.

**Quality Elements:**

1. **Specifications**
   a. The Allen Medical Drawing Specifications govern the material(s) to be supplied. This drawing specification, defines the materials / components to be employed and physical characteristics of the materials / components to be supplied to Allen Medical. All questions of interpretation and or conformance to the drawing specification will be resolved prior to acceptance of a PO and the dispatch of product to Allen Medical.
   b. Specifications for new materials and revisions to the drawing specification will be promptly disseminated to the relevant supplier(s) upon approval within our system. The specification document and related purchase orders will clearly identify the revision level.
   c. The supplier will review and acknowledge receipt of the specification and or purchase order. This acknowledgment will be mutually understood as a complete and unqualified acceptance of the specification and an affirmation of their ability to supply materials that meet all drawing specification requirements.

2. **Notification of Change**
   a. The supplier will make no changes to the raw materials or part designs (as defined by the part drawing specifications), supplier manufacturing location change, significant change to their manufacturing process or changes to their critical sub-tier suppliers without a prior review and written approval from Allen Medical. In all instances, such changes will be proposed in writing to Allen Medical with adequate lead time to allow a sufficient review and approval by Allen Medical.
   b. A significant process change or change to a critical sub-tier supplier is one that could affect form, fit or function of the parts provided or affect other Allen Medical quality requirements.

3. **Auditing**
   a. Periodically, and to a mutually agreed upon schedule, the supplier will allow and facilitate an audit of their processes by Allen Medical.
   b. As warranted, Allen Medical may extend this auditing process to the supplier’s subcontractors. With concurrence, the supplier will facilitate this requirement.

4. **Corrective actions:**
   a. The supplier may be asked to open a CAPA if there are non-conformances in the materials being supplied to Allen Medical. The supplier will promptly address and conform to instructions from Allen Medical for corrective and preventative Action (CAPA). This will include the following:
      i. Containment Actions to prevent additional nonconformances from being received by Allen Medical.
      ii. Root Cause Analysis.
iii. Corrective Action Plan and submission of evidence of corrective action implementation.
iv. Submission of evidence to show effectiveness of the corrective actions.

5. **Compliance**
   a. Allen Medical is responsible for product recall/field action/withdrawals. Allen Medical will notify the Supplier, in writing of any product withdrawals that implicate the Supplier’s raw material or processes (e.g., manufacturing, packaging and/or distribution). If the supplier’s materials are implicated, Supplier, as requested by the Allen Medical, will conduct internal investigations. Supplier will report the findings of the investigation to Allen Medical within the stipulated timeframe.
   b. Supplier must notify Allen Medical, in writing, within 2 working days of any event that may impact the quality, purity, safety and effectiveness of the Product(s) in the field.

6. **Records**
   a. Supplier shall retain records pertaining to the production, inspection and testing of components and materials according to a documented record retention program. Records will be submitted to Allen Medical as requested (i.e. FAI Report).
   b. Records generated will follow good documentation practices (i.e. no write overs, no blanks, changes initialed and dated).

7. **Personnel**
   a. The Supplier will have sufficient personnel to produce and manage the components and materials being provided to Allen Medical. These personnel will be adequately trained.