Supplier Quality Guidebook

Commitment to Quality

Vision
Improving patients' lives one instrument at a time.

Mission
We provide innovative solutions that protect and save lives.

Values
Customer Focused, Excellence & Respect.

Table of Contents

List of Appendices

Supplier Quality Guidebook

HiARC believes in building lasting business partnerships with Suppliers and has provided this guideline to communicate the organization's thoughts on Supplier Quality. Acceptance of a Purchase Order (PO) signifies acknowledgment that the Supplier has read and understands the Supplier Quality expectations outlined herein.

1. Introduction

The purpose of this Supplier Quality Guide is to communicate the expectations including product quality expectations to current and potential suppliers.

These expectations are based on the philosophy of defect prevention and continuous improvement, by developing quality into products and services, rather than defect detection after they are produced.

The guidelines within this manual are provided as a supplement to, and do not replace or alter the terms or conditions within the Purchase Order, Quality Agreement, Engineering Drawings and/ or Specifications and/or any agreement between HiARC and the Supplier (existing Supplier Quality Agreements).

Additionally, this document identifies the importance of establishing defined and agreed upon requirements, expectations, current Good Manufacturing Practices, and continuous improvement.

Important! The use of "shall" is intended that the Supplier will comply with the stated expectation in the Guide Book. The use of "should" is intended that the Supplier may choose to comply with the statement as an industry practice, but it is not mandatory.

Important! Implementation of this Guide Book will be with a risk-based approach. Suppliers of critical components are of significant interest.

2. Applicability

This Guide applies to Suppliers, who provide:

- Components
- Materials
- Assemblies
- Printed Material
- Services which can impact product quality
- Finished goods, (i.e. Distributed product)
- Contracted Services (including Contract Design or Development)
- Custom Application or Embedded software

3. Key Businesses

HiARC provides highly complex medical instrumentation ideation, contract engineering, and contract manufacturing services for diagnostic market leaders and startup firms

across the industry. The organization specializes in molecular diagnostics and in-vitro diagnostic instruments.

4. Supplier Diversity

HiARC is committed to enriching its supply base by approving a wide-range of diverse suppliers; such as small businesses, women owned businesses, minority businesses, and veteran- owned small businesses. The organization focuses on partnering with Suppliers of high value to complete our vision of improving patients' lives, one instrument at a time.

5. Supplier Expectations

Suppliers shall demonstrate an appropriate level of management systems to assure reliable and repeatable conformance of their products, offerings, and services. Suppliers shall provide goods to specified requirements.

Suppliers are fully responsible and accountable for the quality of their products and their supply chain. Suppliers shall ensure products or services comply with all requirements agreed to with this organization.

Suppliers shall not deviate, modify, or otherwise change a required specification without the written authorization and approval by HiARC in advance of a proposed change. Examples include, but are not limited to, component changes, material or chemical composition changes, process or design changes, or temporary deviations. Suppliers that fail to comply with this directive may be subject to disqualification.

Business Ethics

- Suppliers shall comply with all applicable environmental laws and regulations.
- Suppliers shall not employ human trafficked, child, indentured, or any other forced labor.
- Suppliers shall operate in full compliance with the laws and regulations of their respective regions (local, state, federal, or other geographies).
- Company Employees shall not accept gifts from persons or agents associated with the organization's Supply Chain, regardless of value, to avoid the appearance or actual occurrence of a conflict of interest.
- Suppliers shall not discriminate against employees, contractors, or agents on the basis of their personal characteristics or beliefs (including race, color, gender, gender identity, ethnic or national origin, religion, age, maternity, paternity, sexual orientation, or marital status).
- Buyer/Planners purchase materials, parts, assemblies, printed materials, services and finished goods from suppliers that appear on the organization's Approved Supplier List (ASL).
- Supply Chain and Quality thoroughly evaluate and approve Supplier's using a risk-based approach when being added to the ASL.

6. Roles and Responsibilities

Supply Chain includes Supply Chain Management, Buyer/Planners, Sourcing, and Supplier Quality.

Buyer/Planners are the primary contact for all purchasing related activities. The Supplier must inform the respective buyer/planner of any delivery, quality, cost, or request for changes. Notification shall be timely, and failure may lead to Supplier disqualification.

Supply Chain Management is responsible for the relationship with the Supplier. Matters that require follow up, attention, clarification, or resolution shall be conducted through Supply Chain Management. The organization strives to build strategic partnerships with suppliers and views suppliers as an extension to the organization's operations.

Sourcing is responsible for linking Supplier capabilities with technology and specifications for company programs. Engineering or Manufacturing Engineering may assist this activity to provide component characterization, qualification, and ensuring product or services meet specification and reliability requirements.

Supplier Quality is responsible for maintaining this Supplier Quality Guide book, and for establishing, maintaining, and evaluating Suppliers for inclusion to the ASL. Supplier Quality is responsible for establishing a robust review and approval method as well as the correct metrics and oversight of established suppliers. Supplier Quality and Supply Chain perform audits and other assessments per Supplier Management procedures.

Suppliers shall identify a focal point of contact within their organization to communicate with this organization. Aspects include Customer Service, Delivery, Quality, and application of this Supplier Quality Guide.

Supply Chain/Sourcing, and Supply Quality evaluate and identify potential Suppliers prior to Supplier Approval. Supplier Evaluation is performed on a risk-based approach, and evaluates the potential Supplier's capability of meeting Quality, Delivery, Performance, and Continuous Improvement objectives. Additionally, the organization may consider a Supplier's cost, product expertise, financial standing, technology, logistics, supply chain integrity, and ability to manufacture using current Good Manufacturing Practices (cGMP) as additional factors prior to approval.

7. Supplier Requirements Overview

Suppliers shall meet all established requirements, reliability, and expectations. Audits, approvals, or any other verification activities performed by the organization on the Supplier's quality, process capability, or facility, does not release the Supplier of their responsibility to provide acceptable product, services, or offerings. In addition, this does not rule out the subsequent rejection of unacceptable product by the organization.

8. Environmental Compliance

The organization is an environmentally conscious organization and expects its supply base to comply with all applicable laws, regulations, and directives as required.

The list below is not all inclusive, however, consideration shall be made for:

- RoHS (Restriction of Hazardous Substances) EU 2015/863/EU and China RoHS 3 or the most recent Directives.
- REACH (Registration Evaluation Authorization and Restriction of Chemicals) Regulation 1907/2006/EC or the most recent Regulation which is revisited by the EC every 6 months.
- WEEE (Waste Electrical and Electronic Equipment) Directive 2012/19/EU or the most recent Directive.
- Conflict Minerals (SEC CMR) regarding any Tin (cassiterite), Tantalum (coltan), Tungsten (wolframite), and Gold (known as the 3 TG's).

9. Commercial Invoices and Wood Packaging

Commercial Invoices from outside the United States that are shipped to the organization in the United States, shall comply with the requirements of 19 CFR 141.86. Any false representation or statements in the documentation may result in delays or detention of goods by U.S. Customs. Federal penalties may be incurred.

Moreover, Wood Packaging Material is tightly regulated as it pertains to importation of goods into the United States. The Animal and Plant Health Inspection Service of the USDA, amended regulations for the unmanufactured wood items, and adopted an international standard, "Guidelines for Regulating Wood Packaging Material in International Trade". It was approved during an International Plan Protection Convention on March 15, 2002. Wood Packaging from outside the United States to the organization shall be clearly marked, certifying compliance by either heat treatment or fumigated processing according to the guideline noted above.

10. Non-Disclosure Agreements

This organization is a contract service provider to the Medical Instrumentation Industry, and at times may have competing customers and products in development or manufacturing; thus, confidentiality and non-disclosure agreements (NDA) are essential. The organization may require a signed non-disclosure agreement due to sensitive technology, or information disclosed during business. If required, Suppliers shall sign the organization's NDA established for this purpose.

11. Quality Management System

Suppliers should have a defined and documented Quality System. This should also include a stated Quality Policy and Quality Manual. Suppliers should identify and document their intent and direction with respect to Quality, and these documents serve as a general framework of their established Quality expectations.

Suppliers should establish quality objectives and key performance indicators, to ensure process control and effective business operations.

If a Supplier is ISO Registered (13485 or 9001) and the certification is suspended, expired, placed on probation, or receives any major nonconformances from a certification body, the Supplier shall notify this organization in a timely manner. In addition, if a Supplier is FDA Registered and receives a Form 483 or Warning Letter, the Supplier shall immediately notify this organization. This organization reserves the right to request copies of FDA communication and correspondence to resolve Quality issues of significance to the organization.

12. Management Responsibility

Suppliers' senior management is responsible for the suitability and effectiveness of its Management System, including Quality Management as established. Supplier senior management is also responsible to ensure adequate and suitable resources, organizational structure, and periodic review of key performance metrics.

If a supplier moves locations or has any major changes that could impact their operations, advance notice shall be provided to this organization. Updated registrations or certifications shall be provided promptly. Evidence of plant requalification after a significant event (such as a move, shut down, or act of nature) shall be provided to this organization in a timely manner.

13. Complaints and Product Investigations

Suppliers shall at the organization's request assist in Product Complaints as required to ensure product investigations are completed in a timely manner. When Supplier Corrective Action is required, the organization shall issue a Supplier Corrective Action Request (SCAR). Refer to section **"Material Corrective Action, SCAR"** for details.

14. Control of Documents and Records

Suppliers shall establish documented information essential to the control of their business practices and shall ensure that only approved and effective documented information, forms, and templates are used. Documented information shall be easily identifiable, located at appropriate work stations, and maintain legibility. As documents become obsolete, they shall be retained and segregated to avoid use by employees.

Suppliers shall identify how it identifies, stores, protects, and retains records. Records shall be readily available to this organization upon request.

Suppliers shall establish record retention practices to ensure Quality Records are kept for at least ten (10) years or until this organization requests said records to be transferred to the organization.

15. Resource Management and Training

Suppliers shall ensure appropriate resources are hired (contractor or full time) to meet specifications, quality, and reliability expectations. Resources must be qualified for the

work they perform through experience, education, certification, training, or a combination of the aforementioned.

When a Supplier offers third party training or takes other actions to improve the skills and knowledge of its workforce, Management should evaluate the effectiveness of the training.

The Supplier shall maintain appropriate training records of all resources, and resources shall understand their individual responsibilities to ensure quality product, service, and offerings.

16. Product Realization

Suppliers of custom parts shall work with this organization as part of the product/ component realization process. This activity may include:

- Flow Down of Requirements – Functional requirements that evolve from component, subassembly, and subsystem requirements.
- Planning – Technology planning with scientific application.
- Verification/Validation – Product and process capabilities shall be verified and/or validated to ensure product requirements can be met.

17. Change Management

Changes by HiARC:

At the direction of a customer requirement or engineering decision, the organization may revise product, part, or component specifications (especially during development programs) that may require additional qualification by the Supplier. The organization shall notify the Suppliers of all relevant specification revisions. Supplier shall implement all revisions by the required date set. The supplier shall ensure that they are capable of delivering product to the newly specified requirements.

Changes by Supplier:

The supplier shall notify HiARC in writing and the proposed change formally approved, **prior** to any changes being implemented by the Supplier.

18. Production

Suppliers should sufficiently control production conditions, to ensure reliable and repeatable process results that meet the required specification, and with a high degree of quality and reliability. Suppliers are responsible for ensuring production process control through appropriate measures, such as standard operating procedures, work instructions, reference material, test instructions, preventive maintenance instruction, visual inspection, control plans and statistically relevant sampling as required. This is not an all-inclusive list.

Suppliers should plan appropriate measurement methods to monitor process results, to confirm its product or material meet specified requirements. In addition, Suppliers

should establish methods and documented records for the calibration, control, and maintenance of measuring, inspection, test equipment, and facilities (i.e., water systems, air systems, humidity, temperature, etc.) to ensure product and processes maintain conformance to specified requirements.

19. Material Identification and Traceability

Suppliers should establish appropriate controls for all materials. In addition, Suppliers should establish procedures that identify product during various stages, such as production and distribution. At a minimum, product shall be segregated from work in process, non-conforming material, rejected product, product on-hold, and product that is conforming.

Suppliers shall make records available to this organization upon request without delay.

20. Material Handling, Storage, and Distribution

Suppliers should establish procedures for handling, storage, and distribution of material and or products. Attention should be provided to ensure the prevention of mix-ups, mislabeling, deterioration, damage, and contamination.

Suppliers shall comply with specified packaging requirements and meet all applicable regulations and standards.

In addition, Suppliers should establish adequate controls of incoming, in-process and final acceptance for material/product (lot, batch, or unit) to ensure acceptance criteria are met. Suppliers should have provisions to ensure the control of product until it is released.

Measurement, Analysis, and Improvement

21. Supplier Audits

The organization may choose to audit the Supplier's manufacturing process or Quality System per internal procedures and requirements. The organization employs a risk-based approach based on the criticality of the part Supplied and Supplier Risk assessment. It is the organization's expectation that during these audits the organization shall have reasonable access to production, personnel, and records. Audits shall be scheduled in advance with a mutually agreeable time frame and an audit schedule/agenda shall be provided. Supplier Audits may also be prior to the evaluation process to ensure the Supplier meets applicable criteria. Lastly, Supplier Audits may be 'for cause' based on a Supplier performance issue.

22. Internal Audits

The Supplier should have an independent audit program, and the program should ensure auditors cannot audit work that is their responsibility. In addition, Suppliers should perform internal audits per an established internal audit plan on a periodic basis.

The purpose of these audits is to ensure compliance to internal procedures established by the Supplier.

23. Control of Nonconforming Product

Suppliers shall have a documented process to control product that does not meet requirements. Nonconforming product shall be identified, sufficiently segregated to prevent use, and be evaluated. The evaluation and (investigation if required) shall be documented. The results of the evaluation of the nonconformity shall examine the impact to the product and determine what actions may be taken with the product. In addition, the Supplier shall have a procedure regarding the disposition of nonconforming product, and the decision shall be documented. The Supplier and HiARC shall jointly determine any "Use as Is" determinations. If the Supplier corrected the nonconforming product, defined acceptance criteria shall be used to confirm the product meets specified requirements. If a nonconformance is identified and is applicable to product already provided, HiARC Supply Chain and Supplier Quality must be notified as soon as possible.

Suppliers shall notify HiARC using Form 990-185 (current revision) Supplier Material Review Request (SMRR) see Addendum III. The SMRR Form shall be supported by applicable documentation demonstrating the acceptability of the change to their Buyer/Planner as required. A Supplier's Change Management activities shall be planned, documented, and approved to ensure they comply with specified requirements and specifications. HiARC is responsible to assess the impact of the proposed change to the stated requirements of the product. As applicable, approved Supplier Material Review Requests (SMRR,) Form 990-185, are to be provided with parts prior to the shipment of materials with known defects. If they ship prior to an executed SMRR being included they can be subject to material rejection.

24. Material Corrective Action, SCAR

When a product nonconformance is identified by the organization, a Supplier Corrective Action Report (SCAR) may be issued to the Supplier. If a SCAR is issued, root cause shall be determined along with corrective actions, to satisfactorily reduce or prevent recurrence of the nonconformance. A timely response (30 calendar days) on Supplier issued SCAR's is the expectation.

Suppliers should use appropriate techniques and analysis to identify defects or opportunities to prevent nonconformities. In addition, Suppliers should implement continuous improvement efforts. Please refer to the SCAR form, 00003626, and its appendix when a SCAR is issued for additional information as this document provides additional clarity on due dates and expectations for each section of the SCAR.

25. Corrective and Preventive Action (CAPA) System

Suppliers should establish appropriate documented procedures to implement Corrective Action and Preventive Action (CAPA). A Supplier's CAPA investigations shall be targeted to identify potential root cause(s), or causal factors leading to the actual or

potential nonconformities. CAPA activities taken to sufficiently reduce or eliminate the source of the nonconformance, shall be risk based and appropriate to the magnitude of the problem.

Suppliers shall provide action plans, action owners, and proposed due dates of committed actions within the agreed upon time frame, typically within thirty (30) calendar days of the Corrective Action notification. In addition, Suppliers shall meet commitment dates to provide transparency of issues and timely resolutions that could potentially impact organization's production or program schedules.

26. Supplier Monitoring

The following criteria may be used to rate a Supplier's performance, but it is not limited to:

- Quality of product provided (% defective, Supplier Generated Nonconformities)
- Delivery performance (% on time)*
- Total number of SCARs, supplier response time, and Supplier Generated NCRs
- Supplier responsiveness/communication

The performance will be communicated via the Supplier Quality Rating Scorecard, Form 10000683, for High Risk suppliers and based on data availability.

*HiARC plans production based on 100% on-time delivery. Suppliers not meeting this expectation should investigate each late delivery, to prevent future occurrences for continuous improvement. Repeatedly missed deliveries may result in removal from the ASL.

27. Shipments of Goods

Suppliers are to provide the following with each shipment of product:

- Packing Slip with the correct PO and quantity of parts within the shipment.
- RoHS 3 documentation via 990-200 form or an equivalent form that captures the same documentation with a supplier's quality representative live signature captured.
- Material and finish (anodize, electropolish, chem-film, clear coat, etc.) certifications that include the material type/callout as seen on the PO's print (to include finish classification(s) as applicable).
- FAIR (as applicable per PO requirements):
    - Change in part revision
    - Change in manufacturer's facility

28. First Article Inspections (FAI)

When Suppliers are to provide a FAI, it is to be detailed and capture that all print features are within specification and design requirements are fulfilled. An FAI report will be submitted to the organization for review and approval. If an FAI fails, then the organization will notify the supplier that it is rejected, and a repeating FAI will be required until a passing part is confirmed.

FAI packages should include (but are not limited to):

- Part Number, Part Revision, PO number, and a quality representative's legible signature.
- Specification requirements, dimensional measurement data, and pass/fail result.
- A bubble (balloon) drawing mapping out print characteristics to that identified on the print.
- Documented inspection tools or methodology for potential alignment (ex. CMM, caliper, height gage, etc.).
- Statistical process data, Gage R&R, etc.
- Material and Finish certifications.

Guidebook Notice

This document is for informational purposes only. Should additional information be required please contact your Buyer/Planner for assistance. All printed and downloaded copies are for reference only. Suppliers are responsible for acquiring and using the current version of the document. Please contact your Buyer/Planner to obtain the current version.

ADDENDUM I

Reference Documents	Description
ISO 9001:2015	Quality Management Systems – Requirements
ISO 13485:2016	Medical Devices Quality Management Systems Requirements
ISO 14001	Environmental Management Standard
ISO 14971	Medical Devices – Application of Risk Management
FDA 21 CFR 820	Quality System Regulation

ADDENDUM II

Glossary of Terms	Definition
Approved Supplier	Suppliers documented in the organization's Approved Supplier Database. Approved Suppliers have demonstrated their ability to meet specified requirements.
Batch	One or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specification.
Certificate of Conformance	A document provided by a supplier that asserts the product shipped complies with the purchase specifications. Typically, it makes no statement that tests were conducted. It does not provide test data.

Glossary of Terms	Definition
Certified Supplier	A Supplier that has met established Supplier criteria and has been granted a certified status.
Change	Any modification to design, intended use, structure, process or system within the scope of the established part specifications.
Component	Any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device. (21 CFR Part 820.3 (c)).
Correction	An immediate action taken to eliminate an existing nonconformance.
Corrective & Preventive Action	A robust system that identifies (proactively or reactively) undesirable situations and through root cause analysis prevent or eliminate the cause of an existing or potential nonconformity or defect to prevent recurrence (Corrective) or occurrence (Preventive).
Critical Component	During design a critical product feature may be classified as a critical component. Typically, critical components are associated with risk that should be mitigated to reduce or eliminate a hazard to a patient, user, or bystander.
Critical Process Parameter	Identified process parameter where variability has an impact on a critical quality attribute and shall be controlled and monitored to ensure acceptability and quality specifications.
Customer	HiARC or a HiARC Customer.
Design & Development	Activities in partnership with Suppliers according to applicable Quality System (i.e. 820.30 and/or 13485) requirements to design and develop a finished device/instrument.
Design History File (DHF)	A compilation of design records that describe the design history of a design & development effort and that detail the finished device/instrument.
Device History Record (DHR)	A compilation of records containing the complete production history of a finished device, as defined in the specific Manufacturing Program Quality Plan (From 21 CFR 820.3).
Essential Design Output	Design outputs required to achieve freedom from unacceptable risk. Examples include functions or features that are responsible for safety and effectiveness in the device/ instrument risk management file.

Glossary of Terms	Definition
Finished Device	Any device/instrument or accessory to any device that is suitable for use or capable of functioning whether or not it is packaged, labeled, or sterilized.
First Article	A 100% documented inspection of all obtainable dimensions per print, performed by Receiving Inspection or the Supplier.
ISO 13485	The International Standards Organization Quality Management System for Medical Devices – System Requirements for Regulatory purposes Standard.
ISO 9001	The International Standards Organization Quality Management System Requirements Standard.
HiARC Agreements	Purchase Orders including terms and conditions, Engineering Drawings, specifications, requirements, and contracts.
Nonconforming Product	Material or product that does not meet specified requirements. Examples include unapproved/counterfeit components or material, components, or material process with non-validated or unapproved parameters, and product built with an incorrect configuration. May also include incorrect labeling.
Preventive Action	An action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation.
Product	Components, manufacturing materials, in-process devices, finished devices supplied by the supplier.
Quality (Management) System	A documented set of procedures and systems that ensures regulatory requirements are suitably and effectively met as required to design, develop, manufacture, and store a finished device (see 21 CFR 820 and/or ISO 13485).
Quality Records	Written or electronic Quality Process outputs (tests, notes, records, etc.) that demonstrate objective evidence of the output.
Requirement	A need or expectation that is documented in writing. Requirements may be related to materials, a system, or a process.
Specification	The physical, chemical, biological, and performance parameters of a product written in sufficient detail (i.e. Engineering Drawing) that is used as the basis of a design.

Glossary of Terms	Definition
Supplier	A business or entity outside of the organization's Quality System that provides good and or services to organization for use in the design, development, or manufacturing of a finished device.
Supplier Excellence & Quality Manual	This document and all addendums.

HiARC
220 Daniel Webster Highway
Merrimack, NH 03054

Telephone
(866) 742-0442

Fax
(603) 594-7010

Toll Free
1 (866) 742-0442

hiarc.inc