EFFECTIVE 09/09/2022

KMC Systems

Supplier Quality Guide Book

KMC SYSTEMS
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

SUPPLIER QUALITY GUIDE BOOK

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

1. Introduction

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

These expectations are based on KMC's 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 KMC's Purchase Orders, Quality Agreements, Engineering Drawings and/ or Specifications and/or any agreement between KMC Systems 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 KMC Systems 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

KMC Systems provides highly complex medical instrumentation ideation, contract engineering, and contract manufacturing services for diagnostic market leaders and startup firms across the industry. KMC specializes in molecular diagnostics and in-vitro diagnostic instruments.

4. Supplier Diversity

KMC Systems 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. KMC focuses on partnering with Suppliers of high value to complete our vision of improving patients' lives, one instrument at a time.

5. Supplier Expectations

KMC Systems 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 KMC 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 KMC Systems.

KMC Systems Suppliers shall not deviate, modify, or otherwise change a required specification without the written authorization and approval by KMC Systems 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 shall be subject to disqualification by KMC.

Business Ethics

- KMC Suppliers shall comply with all applicable environmental laws and regulations.
- KMC Suppliers shall not employ human trafficked, child, indentured, or any other forced labor.
- KMC Suppliers shall operate in full compliance with the laws and regulations of their respective regions (local, state, federal, or other geographies.)
- KMC Employees shall not accept gifts from persons or agents associated with the KMC Supply Chain, regardless of value, as to avoid the appearance or actual occurrence of a conflict of interest.
- KMC 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 preference, or marital status.)
- KMC Buyer/Planners purchase materials, parts, assemblies, printed materials, services and finished goods from suppliers that appear on KMC's Approved Supplier List (ASL).
- KMC Supply Chain and Quality thoroughly evaluate and approve Supplier's in a risk-based approach when being added to the ASL.

6. Roles and Responsibilities

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

KMC 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.

KMC 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. KMC strives to build strategic partnerships with suppliers and views suppliers as an extension to KMC operations.

KMC Sourcing is responsible for linking Supplier capabilities with technology and specifications for KMC programs. This activity may be assisted by KMC Engineering or Manufacturing Engineering 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 KMC Supplier Management procedures.

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

KMC 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 KMC Systems Quality, Delivery, Performance, and Continuous Improvement objectives. Additionally, KMC 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

KMC Systems Suppliers shall meet established KMC Systems requirements, reliability, and expectations. Audits, approvals, or any other verification activities performed by KMC of 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 KMC Systems.

8. Environmental Compliance

KMC Systems 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 3TG's)

9. Commercial Invoices and Wood Packaging

Commercial Invoices from outside the United States that are shipped to KMC Systems in the United States, shall comply with the requirements of 19 CFR141.86. Any false representation or statements in the documentation, may result in delays or detention of goods at the border. Federal penalties may be incurred.

Moreover, Wood Packaging Material is closely 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 KMC Systems shall be clearly marked, certifying compliance by either heat treatment or fumigated processing according the guideline noted above.

10. Non-Disclosure Agreements

KMC Systems 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. KMC may require a signed non-disclosure agreement due to sensitive technology, or information disclosed during business. If required, Suppliers shall sign the KMC Systems NDA established for this purpose.

11. Quality Management System

KMC Systems 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 KMC Systems 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 KMC Systems in a timely manner. In addition, if a KMC Systems Supplier is FDA Registered and receives a Form 483 or Warning Letter, the Supplier shall immediately notify KMC Systems. KMC reserves the right to request copies of FDA communication and correspondence to resolve Quality issues of significance to KMC.

12. Management Responsibility

KMC 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 KMC. Updated registrations or certifications shall be promptly provided. Evidence of plant requalification after a significant event (such as a move, shut down, or act of nature) shall be provided to KMC in a timely manner.

13. Complaints and Product Investigations

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

14. Control of Documents and Records

KMC Systems Suppliers shall establish documented information essential to the control of its 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 as to avoid use by employees.

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

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

15. Resource Management and Training

KMC's 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 KMC Systems Supplier offers third party training, or takes other actions to improve the skills and knowledge of its workforce, the training effectiveness should be evaluated by Management. 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

KMC Suppliers of custom parts shall work with KMC 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 KMC Systems:

At the direction of a customer requirement or engineering decision, KMC may revise product, part, or component specifications (especially during development programs) that may require additional qualification by the Supplier. Suppliers shall be notified by KMC Systems of all relevant Specification revisions. Supplier shall implement all revisions by the required date set by KMC. KMC shall ensure the supplier is capable of delivering product to the newly specified requirements.

Changes by Supplier:
KMC shall be notified in writing, and the proposed change formally approved, **prior** to any change implementations at the Supplier. Suppliers shall notify KMC Systems by KMC 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 KMC Buyer/Planner as required. A Supplier's Change Management activities shall be planned, documented, and approved to ensure they comply with KMC requirements and specifications. KMC is responsible to assess the impact of the proposed change to the stated requirements of the product.

18. Production

KMC Systems 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.

KMC 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

KMC Systems 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 KMC Systems upon request without delay.

20. Material Handling, Storage, and Distribution

KMC Systems 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.

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

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

Measurement, Analysis and Improvement

21. Supplier Audits

KMC Systems may choose to audit the Supplier's manufacturing process or Quality System per internal procedures and requirements. KMC employs a risk-based approach based on the criticality of the part Supplied and Supplier Risk assessment. It is KMC's expectation that during these audits KMC Systems shall have reasonable access to production, personnel, and records. Audits shall be scheduled in advance with a mutually agreeable time frame, and KMC shall provide an audit schedule/agenda. 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

KMC Systems 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 KMC Systems shall jointly determine any "Use as Is" determinations. If the nonconforming product is corrected by the Supplier, acceptance criteria shall be used to confirm the product meets KMC's requirements. If a nonconformance is identified and is applicable to product already provided to KMC, KMC Supply Chain, and Supplier Quality must be notified as soon as possible.

24. Material Corrective Action, SCAR

When a product nonconformance is identified by KMC Systems, 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) of Supplier SCAR's is the expectation of KMC Systems.

KMC Suppliers should use appropriate techniques and analysis to identify defects, or opportunities to prevent nonconformities. In addition, KMC Systems Suppliers should implement continuous improvement efforts.

25. Corrective and Preventive Action (CAPA) System

KMC Systems 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.

KMC Systems 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 potential impact KMC Systems' production or program schedules.

26. Supplier Monitoring

KMC Systems may use the following criteria 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 NCMRs
- Supplier responsiveness/communication
- Ability to meet commitments

The performance will be communicated via the Supplier Quality Rating Scorecard, Form 10000683.

*KMC Systems 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.

KMC VISION

Improving patients' lives one instrument at a time

This document is for informational purposes only. Should additional information be required please contact your KMC 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 KMC Buyer/Planner to obtain the current version.

ADDENDUM I

Reference Documents

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
EUCD 93/42	European Union Commission Directive – Medical Device
FDA 21 CFR 820	Quality System Regulation
Health Canada SOR/98-282	Canadian Medical Device Regulations (CMDR)
Health Canada GUI-0001	Canada Good Manufacturing Practices (GMP) Guidelines

ADDENDUM II

Glossary of Terms

Glossary of Terms	Definition
Approved Supplier	Suppliers documented in the KMC Approved Supplier Database. Approved Suppliers have demonstrated their ability to meet KMC 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.
Certified Supplier	A KMC Supplier that has met established KMC 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 KMC 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.

ADDENDUM II (cont.)

Glossary of Terms

Glossary of Terms	Definition
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	KMC Systems, or a KMC Customer.
Design & Development	KMC Systems 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.
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 KMC 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.
KMC Agreements	KMC Purchase Orders including terms and conditions, KMC Engineering Drawings, specifications, requirements, and contracts.

ADDENDUM II (cont.)

Glossary of Terms

Glossary of Terms	Definition
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	Goods supplied to KMC Systems by the supplier on or after the Effective Date of the signed Supplier Quality Manual.
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.
Supplier	A business or entity outside of KMC Quality System that provides good and or services to KMC for use in the design, development, or manufacturing of a finished device.
Supplier Excellence & Quality Manual	This KMC Systems document and all addendums.

EFFECTIVE 09/09/2022

KMCSystems

220 Daniel Webster Highway
Merrimack, NH 03054

Telephone
(866) 742-0442

Fax
(603) 594-7010

Toll Free
1 (866)742-0442

www.kmcsystems.com