



SUPPLIER QUALITY REQUIREMENT - MEDICAL

ABOUT FLEX

Flex is a leading sketch-to-scale™ solutions company that designs and builds intelligent products for a connected world. With more than 200,000 professionals across 30 countries and a promise to help make the world Live smarter™, the company provides innovative design, engineering, manufacturing, real-time supply chain insight and logistics services to companies of all sizes in various industries and end-markets. For more information, visit www.flex.com or follow us on Twitter @flexintl.

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1.0 BACKGROUND/INTRODUCTION

- 1.1 This document Supplier Quality Requirement – Medical (“document”) defines supplemental and more specific quality agreements to the Supplier Quality General Requirements, FMS-QMS-3-005-00 between all Flex legal entities (“Buyer”) and Flex suppliers (“Seller” or “Supplier”).
- 1.2 Changes to this “document” can only be made by approval from the Supplier Quality Systems team supporting Global Procurement and Supply Chain or the Medical Segment.

2.0 SCOPE AND PURPOSE

- 2.1 Buyer companies serve a variety of industries and business segments and as such, a Buyer has unique supplier quality requirements specific to these industries and business markets.
- 2.2 This “document” defines the special Medical industry requirements for Suppliers relating to the quality of all products or services, to be used in Medical applications, purchased by the Buyer from Suppliers during the term of any Agreement, including but not limited to purchases made pursuant to Purchase Orders (POs), General Business Agreements (GBAs), any other contract or any other document with a link to or referencing this “document.” Any deviations, exceptions or additional requirements shall be mutually agreed in writing between Buyer and Supplier. Specific quality criteria, targets and similar measures will be mutually agreed in product specific Component Quality Plans (CPQ), if not already defined in a product specification. When referenced by the applicable contract or agreement or in a purchase order issued by Flex, all of these requirements will comprise a complete quality agreement between Buyer and Supplier.
- 2.3 The terms of purchase transactions between Buyer and Supplier are governed by a General Business Agreement (GBA) or Terms and Conditions Checklist. If neither of those Agreements exists, the terms governing purchase transactions between Buyer and Supplier are the Buyers Standard Terms and Conditions which are transmitted with every purchase order.

3.0 DEFINITIONS AND ABBREVIATIONS

- 3.1 CPQ: Component Quality Plan
- 3.2 FDA: Food and Drug Administration (USA)
- 3.3 FMEA: Failure Mode and Effects Analysis
- 3.4 GPSC: Global Procurement and Supply Chain
- 3.5 ISO: International Organization for Standardization
- 3.6 IQ: Installation Qualification
- 3.7 MSA: Measurement Systems Analysis
- 3.8 OQ: Operation Qualification
- 3.9 PCBA: Printed Circuit Board Assemblies
- 3.10 PQ: Process Qualification
- 3.11 SPC: Statistical Process Control

4.0 REFERENCES

- 4.1 Supplier Quality General Requirements, FMS-QMS-3-005-00
- 4.2 ISO 13485, *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, current version
- 4.3 ISO 9001, *Quality Management Systems -- Requirements*, current version
- 4.4 FDA 21CFR Part 11, *Electronic Records; Electronic Signatures*

5.0 SUPPLIER REQUIREMENTS

5.1 Communication and Document Submission:

- 5.1.1 While Flex has multiple manufacturing locations worldwide, the official communication and document submission language between Flex and its suppliers is only English.

5.2 Supplier Quality System:

- 5.2.1 Supplier shall be certified according to ISO 13485, current version. ISO 9001, current version is seen as a first step in becoming ISO 13485 certified.
- 5.2.2 Supplier shall ensure that the latest valid versions of standards and regulatory frameworks are implemented (e.g., ISO, FDA, etc.) at all times.

5.3 The following requirements apply for all deliveries of medical products:

- 5.3.1 Supplier shall use the latest versions of Potential Failure Mode and Effects Analysis (FMEA) and Measurement System Analysis (MSA).
- 5.3.2 Supplier shall use Statistical Process Control (SPC) as the guideline for their system development.
- 5.3.3 Business Resumption Plan: Supplier shall guaranty product availability over the complete customer project life time. A business resumption plan including all environmental relevant risks must be submitted before the first delivery for mass production.
- 5.3.4 Acceptance Criteria: Supplier shall indicate in writing product conformance with Buyer's acceptance criteria. Acceptance status shall be maintained throughout manufacturing, packaging and labeling processes to ensure that all products passing the required acceptance criteria are shipped. Supplier shall validate product acceptance and provide such evidence with each product shipment to Buyer.
- 5.3.5 Process Validation:
 - Where process output cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to an established procedure. The validation activities and results, including the date and signature of the individuals approving the validation and where appropriate the major equipment validated, shall be documented.
 - Supplier shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Only qualified individuals shall perform validated processes.
 - For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individuals performing the processes or the major equipment used shall be documented.

- When changes or process deviations occur, the supplier shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.
- For a supplier providing medical-grade printed circuit board assemblies (PCBAs) to Flex potential groupings of common technology boards / PCBA Family Group are NOT ALLOWED. Process verification and validation in the assembly of medical-grade PCBAs shall be based on individual assembly process. At the other extreme, a very complex PCBA assembly will require all facets (IQ/OQ/PQ) of a process validation.

5.3.6 Calibration:

- Calibration shall be performed according to approved standard operating procedures with measurements traceable to defined national or international standards.
- The usage range of the equipment/instrument/system must be within the calibration range.
- All calibration instruments shall be registered in the calibration program prior to validation execution and routinely calibrated.

5.3.7 Electronic records and signatures: Where electronic systems are used for tracing of records and signatures, these systems must comply with FDA 21CFR Part 11.

6.0 RESPONSIBILITIES

- 6.1 Changes to this “document” can only be made by approval from either the Supplier Quality Systems team supporting Global Procurement and Supply Chain or the Medical Segment.
- 6.2 Site and Segment/Business Unit supplier quality and materials personnel are responsible for ensuring their suppliers are familiar with this “document”.
- 6.3 The Supplier Quality Systems team supporting Global Procurement and Supply Chain, the Medical Segment and the site's supplier quality and materials organization are responsible for ensuring this “document” is referenced in all supplier contract documents.
- 6.4 The Supplier Quality Systems team is responsible for ensuring the current version of this “document” is available at the Flex Supplier Quality Webpage.

7.0 DOCUMENT REVIEW AND APPROVAL REQUIREMENTS

- 7.1 This document shall be reviewed and approved as defined in Control of Documented Information, FMS-QMS-1-001-00.