

FLUKE®

Biomedical

Document Number: QSP-06-01

Rev.
3

Title: Fluke Biomedical Supplier Handbook


FLUKE®

Biomedical

Supplier Handbook



Fluke Biomedical.
Trusted for the measurements that matter.

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

Introduction to the Fluke Biomedical Supplier Handbook

Dear Fluke Supplier,

The Fluke Biomedical Supplier Handbook was written for you to better understand Fluke and Fluke's engagement with you, our valued supplier. I would especially encourage you to review our mission and quality policy along with the links to Fluke's Values, Fluke's Supplier Code of Conduct, and Fluke's expectations for Integrity and Compliance. This will go a long way in understanding Fluke, how we conduct business and how we expect our suppliers to do the same.

You will find two major sections in this handbook. The first focused on quality system expectations of suppliers and the second on purchasing processes and requirements. This is all what we consider "standard work". Please take the time to read and should you have any questions, please contact your Fluke Commodity manager for answers.


Thanks for your support of Fluke.

Sincerely,




Aleks Neubauer

Vice President, Global Procurement
Fluke Electronics Corporation

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

Contents

FLUKE BIOMEDICAL	4
1.0 QUALITY SYSTEM EXPECTATIONS FOR FBC SUPPLIERS	5
1.1 SUPPLIER RESPONSIBILITIES	5
1.2 Supplier Evaluation, Selection and Preference	6
1.2.1 APPROVED SUPPLIER LIST (ASL)	7
1.2.2 QUALITY MANUAL	7
1.2.3 ON-SITE QUALITY SYSTEM AUDIT	7
1.2.4 PREFERRED SUPPLIER PROGRAM	7
1.2.5 DISQUALIFICATION	8
1.2.6 QUALITY SYSTEMS ASSESSMENT	8
2.0 PURCHASING PROCESSES AND REQUIREMENTS	9
2.1 REQUEST FOR QUOTATION (RFQ) ACTIVITIES	9
2.2 PROPRIETARY INFORMATION	10
2.3 CONTRACT DECISION:	10
2.4 COMMUNICATION	11
2.5 COST REDUCTIONS/IMPROVEMENTS	11
2.6 SUPPLIER PERFORMANCE RATING	11

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

FLUKE BIOMEDICAL (FBC)

MISSION STATEMENT:

To continue as the market leader in providing equipment to clinical engineers, radiation physicists, and oncologists, while expanding our range of solutions to a broader range of health and safety professionals.

FBC'S QUALITY POLICY:

The personnel of Fluke Biomedical are committed to achieving quality through the following objectives:

- Focusing on the customer by applying innovation and flexibility to meet their needs
- Fostering a controlled atmosphere for continuous improvement and problem prevention
- Identifying the need for, and providing appropriate training to ensure the development and qualification of our personnel
- Communicating the mission and objectives to our personnel and customers
- Developing relationships with our customers that emphasize continuous improvement in product quality, service and support
- Promoting a supportive work environment that facilitates the delivery of a quality product on a consistent basis
- Working in a manner consistent with our documented quality-management system to ensure our products and services are safe and effective for their intended use

FBC's quality system complies with the requirements of the standard(s): ISO 9001, 21 CFR 820.20, 10 CFR 50 App. B part I, ISO 13485, ISO 17025, and CMDR.

CORE VALUES:


See <http://www.fortive.com/core-values>

SUPPLIER CODE OF CONDUCT:

See <http://www.fortive.com/suppliers>

INTEGRITY AND COMPLIANCE:

See <http://www.fortive.com/integrity-and-compliance>

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

FORTIVE BUSINESS SYSTEMS:

See <http://www.fortive.com/fortive-business-system>

The Fortive Business System (FBS) is who we are and how we do what we do. It is more than a management system or business model - it is part of the mentality of virtually every associate in the company. Through FBS, FBC achieves world-class excellence in customer satisfaction, beginning with the voice of the customer, continuously improving quality, delivery, cost and innovation.


FBS is at the core of our quality system. We focus on defect prevention contrary to defect detection. Suppliers must employ effective methodologies and error proofing of their manufacturing processes so that zero defects can be achieved. In order to achieve zero defects, it is imperative that the supplier has processes in place using six sigma and lean manufacturing methodologies.

1.0 QUALITY SYSTEM EXPECTATIONS FOR FBC SUPPLIERS

The ability of a supplier to develop and maintain an acceptable quality system is an essential factor in qualifying and continuing as a FBC supplier. This section defines the quality system expectations for suppliers (Sub-contractors, distributors, and OEMs) of production parts and assemblies to FBC.

1.1 SUPPLIER RESPONSIBILITIES


- Suppliers are responsible for maintaining a quality system that ensures each product complies with all the requirements included on the engineering drawing, prescribed on the purchase order, and outlined in this handbook.
- Suppliers are responsible for understanding all engineering drawing and specification requirements. If any questionable areas appear to exist, the supplier must contact FBC for clarification. Drawing clarifications are to be resolved prior to production part manufacture, and in no case shall the engineering drawings and specifications be superseded by any informal agreement.
- Suppliers who control the design of the product shall maintain sufficient technical documentation.
- Suppliers are responsible for the quality of their products and are not to rely on FBC to determine the quality level of their material or service. Use of sampling techniques is not intended to imply that defective material at any level is acceptable. Any defect found in a FBC factory requires prompt investigation of the product failure mode, understanding root cause and taking appropriate corrective action.

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

- Suppliers are responsible to notify FBC of any proposed changes in design, processing or manufacturing location prior to the change. Suppliers must obtain FBC’s written approval of any proposed changes.
- Suppliers are responsible for repairing or replacing non-conforming material with material satisfying specifications in time to meet FBC delivery requirements. In some cases, material urgently required to meet customer shipments may be reworked by FBC at the supplier's expense.
- FBC- owned tooling, instruments, fixtures, and any other piece of equipment shall be permanently identified as FBC property and be cared for per the terms and conditions outlined in the purchase order.
- Suppliers are responsible to provide quality performance records upon request.
- Suppliers are responsible for extending the requirements of the FBC engineering drawings, the FBC purchase order and this document to their suppliers.
- When conflicts exist between engineering drawings, purchase orders, and this handbook, engineering drawings shall supersede any other document and will be the primary source of quality requirements; purchase orders will be secondary, followed by this handbook.
- Suppliers are responsible for all the sub-contractor quality non-conformances and quality performance. When instances occur which warrant the review of a sub-supplier's process or control system, the supplier is expected to coordinate such review.
- Suppliers are responsible to comply with all specified regulatory and environmental compliance regulations that are detailed for FBC products and components. The supplier is also expected to be a collaborative partner in resolving compliance related questions with these regulations.
- Suppliers manufacturing medical devices are responsible to retain quality records at least equivalent to the lifetime of the device. Records are available for review by regulatory authorities, quality system auditors, and FBC personnel when specified as part of their contract.
- If the purchased product is flagged critical to safety in the Purchase Order (PO), then the supplier must meet FBC specification and/or PO instructions as indicated.

1.2 Supplier Evaluation, Selection and Preference

Suppliers who maintain a continuing business relationship with FBC must demonstrate that they have a quality system that meets or exceeds FBC requirements. Suppliers with ISO certification must provide copy of the ISO certificate. Current suppliers who do not meet these criteria are expected to be working toward a viable quality system complying with a standard, such as ISO 9001 or ISO 13485.

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

1.2.1 APPROVED SUPPLIER LIST (ASL)

Suppliers are selected after a thorough review and evaluation of their overall business health, technology, and their ability to manufacture products that meet FBC’s requirements. FBC reserves the right to audit the suppliers’ quality system. FBC may conduct audits at the supplier’s manufacturing facilities. Following an acceptable assessment of the supplier’s complete evaluation, the supplier is included on the **ASL**.

Ongoing supplier performance is measured by monitoring quality, delivery and cost performance as described in Section 2. Any supplier failing to meet the FBC performance requirements may be subject to removal from the ASL.

Supplier status is noted on the ASL as either:

- Preferred: Suppliers as defined in section 1.2.4
- Qualified: Suppliers who have been approved and are a candidate for preferred status
- Approved: Suppliers who have been assessed and meet the minimum requirements established by this document.
- Disqualified: Suppliers who have been assessed in the past but have been removed from the ASL or who have not met the minimum FBC’s requirements.

1.2.2 QUALITY MANUAL


Suppliers with ISO certification may submit a quality manual and complete a Supplier Assessment to initiate the FBC approval process. Suppliers without ISO certification must submit a Supplier Assessment only.

1.2.3 ON-SITE QUALITY SYSTEM AUDIT

After review of the quality manual and/or Supplier Assessment, an on-site quality system audit may be conducted. The audit conducted at the supplier's manufacturing location will determine conformance to the FBC quality requirements. **PREFERRED SUPPLIER PROGRAM**

Preferred suppliers are fundamental to FBC’s success. The objective of the preferred supplier program is to develop our supply base to consistently provide parts that meet the quality, delivery, cost, and service objectives to maintain FBC as a world-class manufacturer.

The preferred supply base is a managed group of suppliers who align with FBC’s strategic vision and performance expectations. FBC will focus growth and consolidation efforts with these suppliers. Select preferred suppliers will have the

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

opportunity to learn appropriate FBS tools and Kaizen to improve quality and processes. The preferred supplier program supports all commodities in FBC.

FBC awards preferred Supplier status to suppliers who work with FBC on the following objectives:

- It extends 5% per year over year (YOY) price reductions (contractual commitment across entire spend portfolio), proactive price benchmarking, and YOY productivity gains.
- It achieves less than 2,000 PPMs three months rolling.
- It achieves on-time delivery % of $\geq 98\%$ measured by dock date and no more than 3 days early and 0 days late.
- It can accept minimum 90-days payment term or accept P-card
- It participates in e-auctions with experience.
- It has a written business continuity plan.
- It has signed a Memorandum of Understanding (MOU) with FBC.
- It provides value engineering support through product lifecycle.
- It offers 24-hour turnaround on warranty/non-warranty repair support.
- It holding safety stock for unplanned upside in demand (lead-time = transit time = 5 days maximum).
- Recommends both product and process improvements to reduce total costs.

Preferred suppliers will have a preferential position relative to future sourcing opportunities.


1.2.4 DISQUALIFICATION

Any supplier failing to meet the quality or performance requirements is subject to removal from FBC's ASL.

1.2.5 QUALITY SYSTEMS ASSESSMENT

The supplier rating system or scorecard, which might include such performance factors as quality of received material, on-time delivery, etc.

The design and operation of the supplier's quality system must direct the quality approach toward prevention of defects through product qualification planning and process control techniques in place of defect detection through inspection, process controls or test methods. This type of system leads to increased productivity and

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

never ending improvement in quality, both of which mutually benefit FBC and the supplier.

FBC could perform an onsite-audit to verify the supplier's quality system and process validation.

If the supplier audit is unsatisfactory, they must submit a corrective action to improve performance.

The corrective action plan will be tracked by Quality Assurance (QA) and reassessed when corrective actions has been implemented.

2.0 PURCHASING PROCESSES AND REQUIREMENTS

This section defines the FBC procurement process including requests for quotation, initial supplier approval, contracts and purchase orders, shipping and transportation, communications, expectations concerning cost savings, proprietary information and supplier performance rating.

2.1 REQUEST FOR QUOTATION (RFQ) ACTIVITIES


The commodity manager, New Product Introduction (NPI) and Planner buyers will submit requests for quotation (RFQs) to potential suppliers.

The RFQ will include the following:

- Work Package
- Terms and Conditions
- Link to access the FBC Supplier Handbook.
- Fluke Appearance Standard
- Bid Due Date
- Method of shipment and F.O.B. point
- Terms of payment
- Engineering Drawing
- Request for Country of Origin
- All other pertinent information to ensure the accuracy of the suppliers' quotes

The Supplier quotation should be returned to the requestor and include the following:

- All requested quote information

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

- Supplier acceptance of FBC Terms and Conditions or provide a detailed list of exceptions to it.
- Suppliers shall use FBC endorsed carriers when transportation costs are incurred by FBC. A list of endorsed carriers is available from the buyer and is updated annually.
- RoHS certification
- FBC Supplier Handbook acknowledgement of receipt

2.2 PROPRIETARY INFORMATION

FBC will initiate a non-disclosure agreement (NDA) between FBC and the supplier early in the relationship.

FBC information such as drawings, materials used, technology, customers, and financial information is proprietary information. As such, the supplier will not divulge this information to other parties. In particular, drawings of parts designed by FBC are proprietary and as such, the supplier should not manufacture parts from these drawings for any party other than FBC.

2.3 CONTRACT DECISION:

The decision to require a contract is at the discretion of the Commodity Manager.


When making a contract decision the Commodity Manager:

- Selects a specific commodity
- Calculates annual spend by supplier
- Develops a list of the top 80% of spend suppliers
- Reviews the list of suppliers

Reviews the list of parts by supplier with Engineering and may discuss the following:

- Evaluate non-conformance data by part number. A score of > 80% is an unacceptable rating as defined by Supplier Scorecard
- Assess the current supplier risk assessment – if risk exceeds a score of 18 the supplier needs to be covered by a contract
- Review new designs in process

Once the data is reviewed, the Commodity Manager may send a contract to the supplier if one is not in place. The Commodity Manager will receive the signed contract from supplier after all discussions with the supplier are complete. The Commodity Manager loads the contract in the contract repository.

	Document Number: QSP-06-01	Rev. 3
	Title: Fluke Biomedical Supplier Handbook	

2.4 COMMUNICATION

The commodity manager, in conjunction with the FBC factory and supplier, will define the appropriate communication channel at the commencement of the agreement. The commodity manager is responsible for communications regarding:

- Price changes
- Multiple FBC factory quality / delivery issues
- Contractual changes
- Quality Issues

The commodity manager, will be responsible for providing the FBC Supplier Handbook to the supplier and organizing quality audits.

- All verbal instructions must be confirmed in writing. A Fax or email is considered an acceptable form of written communication.
- Changes to the purchase order will be communicated via a written change notice such as a purchase order change.
- Acceptance of the purchase order should be communicated to the appropriate buyer
- Supplier requests for temporary deviations or permanent changes may be documented and forwarded to FBC. Supplier could use its own deviation format and it should be used to request temporary deviations or permanent changes with materials, dimensions, cosmetic, processes, etc. FBC will review the request and respond to the supplier.
- Suppliers are required to communicate potential late deliveries and deviations to FBC as soon as the supplier is aware them. This communication can be verbal but must be confirmed in writing.

2.5 COST REDUCTIONS/IMPROVEMENTS

We expect Suppliers to proactively engage with Fluke to reduce costs on an ongoing/annual basis.

2.6 SUPPLIER PERFORMANCE RATING

FBC maintains a supplier rating system to measure supplier performance. This performance information will be one factor used by Purchasing to select suppliers and to determine the supplier's status in the preferred supplier program. The overall rating is based on the supplier's monthly performance, which is monitored by a supplier performance scorecard and reviewed in periodic business reviews. Though these rating systems vary by FBC factory location, suppliers can expect to dialog about overall performance. Below is an example of the FBC North America scorecard that is shared with suppliers routinely.

Include the below section



Document Number: QSP-06-01

Rev.
3

Title: Fluke Biomedical Supplier Handbook

PDM%	OTD%	MOQ Turn	WALT	Quality Rating	Delivery Rating	Cost Rating	MOQ Rating	LT Rating	Rating
99.96	96.81	36.14	6.79	0	0	1	.5	.5	Acceptable

The supplier scorecard rating is measured based on five criteria – quality, delivery, cost, weighted average lead time, and MOQ turns. If the supplier is not meeting acceptable score, a SCAR, Supplier action plan, or an on-site audit will be initiated. An attached data sheet provides to the supplier the supporting details.

Supplier Scorecard Rating Criteria

Final Rating	Description
Outstanding: Score of 3 or higher	These suppliers are considered growth partners for the future. New business should be directed towards these suppliers.
Acceptable: Score of 1 to 2.5	These suppliers are important to Fluke’s business and have the potential to become Outstanding Fluke partners.
Unacceptable : Score of less than 1	No new business should be awarded to these suppliers. Additionally, Fluke should pursue alternative sourcing.
Not Rated: No Score	Less than 3 months of data exists for the supplier.

Quality – Metric: PDM%			
PDM%	PPM	Sigma	Points
≥ 99.98	≤ 233	≥ 5	1
99.38-99.98	233-6210	4-5	0
< 99.38	> 6210	< 4	-1

Delivery – Metric: OTD%	
OTD%	Points
≥ 98	1
90-98	0
<90	-1

MOQ Turns – Metric : ΣEAU \$s/ ΣMOQ \$s	
MOQ Turns	Points
≥ 25	0.5
< 25	0

Cost – Metric: PPV%	
PPV%	Points
≥ 4	1
0 – 3.99	0
< 0	-1



Document Number: QSP-06-01

Rev.
3

Title: Fluke Biomedical Supplier Handbook

Weighted Average Lead Time – Metric : $\frac{\sum \text{EAU} * \text{Std Cost} * \text{Lead Time}}{\sum \text{EAU} * \text{Std Cost}}$	
WALT	Points
≤ 30 days	0.5
30-45 days	0
> 45 days	-0.5