

SUPPLIER HANDBOOK



Meeting Our Customer's Needs Through Supplier Collaboration

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NOTE: This handbook applies to all Spectrum Plastics Group Companies (PPC Industries, Inc. D/B/A Spectrum Plastics Group “Spectrum” or “SPG”) including: Spectrum Plastics Group, Inc., Apollo Medical Extrusion Technologies Inc., Kelcourt Plastics, Inc., VitalMed Incorporated, Xeridiem Medical Devices, Inc., Fermatex Vascular Technologies, LLC, Laser Light Technologies, LLC, and PeelMaster Packaging Corporation. Acceptance of a Spectrum Purchase Order (PO) constitutes acknowledgement that the Supplier has read, understands, and will comply with the expectations of this Manual.

1. INTRODUCTION

1.1 Purpose

To provide an overview of the requirements and expectations for suppliers to Spectrum Plastics Group companies. SPG’s suppliers play an integral role in our ability to continuously provide products of the highest quality level and best service possible to our customers.

1.2 Background

SPG’s mission is to be the first-call solutions provider for development through scaled manufacturing of critical polymer-based components and devices for the medical and other demanding markets requiring quality, responsiveness, innovation, and technical expertise. By bridging the gap between our clients’ original concepts and commercialization, we facilitate the rapid launch, qualification and commercialization of new products that can become well-established market leaders.

To achieve Spectrum’s goal of rapid launch and continued timely supply of high-quality products to our customers, we need the full participation and cooperation of the organizations which supply us with materials, components, assemblies, and services. Spectrum looks to these selected suppliers for technology leadership in design, price and continuous improvement. Our supplier quality performance policy underscores this point.

The intent of this Supplier Manual is to eliminate surprises and special cause events that can impact upon Spectrum’s Customers. The requirements mentioned herein include all the Suppliers that are defined as companies providing the material, components, molds, tools, control and checking fixtures or services to Spectrum, and it is expected that each Supplier will manage its entire supply base with these principles. A copy of this handbook can be found on our website www.spectrumplastics.com. This handbook does not apply to MRO purchases.

1.3 Supplier Code of Conduct

Spectrum Plastics Group is committed to improving our employees lives at work and home by investing in programs that will help exceed expectations of our customers, and our customers’ customers, with innovative products that are more environmentally friendly.

Spectrum has operated with high ethical business standards and integrity in the communities where our employees work and live for more than 60 years. To preserve the trust placed in Spectrum, the Company counts on its network of Suppliers and business providers across the globe to commit to and uphold its high standards of integrity, values, and operating principles.

It is Spectrum’s expectation that Suppliers should be committed to upholding and supporting human rights of all workers; to treat them with dignity and respect; and to treat all workers equally. Our Suppliers should safeguard worker’s rights and we further expect that our Suppliers will provide employees with a safe and healthy work environment; and observe and comply with all applicable laws and regulations.

Spectrum is committed to ensuring our business is conducted in all respects according to rigorous ethical, professional, and legal standards. Our business partners must always adhere to the highest standard of ethical behavior. It is expected that our Suppliers will operate every facet of their business with the highest degree of integrity, prohibit bribery and corruption; provide accurate information on products and services; respect intellectual property and confidential information received; prohibit any impediment to fair, transparent and free competition; and prohibit the granting of any improper advantage in the marketplace.

Spectrum is committed to auditing Suppliers to ensure adherence to our guidelines as well as to an effective Management System.

*For a more detailed listing of Spectrum's Supplier Code of Conduct, please visit our website at: www.spectrumplastics.com.

2. SUPPLIER EXPECTATIONS

2.1 Spectrum's Quality Policy

Spectrum Plastics Group is Passionately committed to:

THE LIVES OUR PRODUCTS TOUCH,
Safety, Quality & Compliance, and Customers

ACHIEVING OUR CUSTOMERS' EXPECTATIONS
For quality, service, and total value

ADVANCING INNOVATION
With our ingenuity and expertise while fostering an engaging environment

THE CONTINUAL EVALUATION AND IMPROVEMENT
In the effectiveness of our Quality Management System (QMS), including product performance requirements.

Our commitments will be met through documented and reviewed quality objectives, a data driven accountable culture, and a focus on delivering results in a collaborative and trusted way.

2.2 Quality Provisions

Spectrum expects its supply base to have a robust quality management system in place that complies with ISO 13485, FDA Regulation 21-CFR-Part 820 quality principals, ISO 9001, or equivalent standard. Suppliers must allow audit access to Spectrum notified bodies if necessary. All materials received will be inspected to Spectrum's internal specifications. These specifications are referenced on Spectrum's purchase order. No correction fluid (white-out) shall be used on shipped lot paperwork or any production records.

2.3 On-Site Quality Audits

As part of the Supplier Approval process as well as ongoing monitoring of supplier performance an audit of the supplier's Quality Management System and production processes may be required. This is to verify compliance to applicable standards, regulations, agreements, requirements and specifications. It will also involve a review of processes and procedures in place to assure quality product is manufactured, requirements are met and delivered to Spectrum.

2.4 Audit Execution

During the audit, the process, procedure, personnel and documentation may be reviewed. This may involve the collection of objective evidence and interviews of personnel to support implementation and effectiveness of the supplier's Quality Management System. Areas that are found to be non-compliant against a standard, regulation, agreement, requirement, or specification, will be noted as findings and classified depending on their severity. These findings will be discussed at the close out meeting with the supplier's representatives.

3. GENERAL GUIDELINES/REQUIREMENTS

3.1 Quotes and Pricing

Suppliers must provide prices either by contract or quote before a purchase order (PO) can be issued.

- Discrepancies between quotes and actual prices must be resolved before the product ships and an invoice is issued.

3.2 Purchase Orders

- Purchase orders for materials used in the direct manufacture of Spectrum customer orders cannot be issued to suppliers not listed on Spectrum's Approved Vendor Listing (AVL) or Approved Supplier Listing (ASL) as determined by SPG location.
- Suppliers are not authorized to supply materials, products or services without an authorized purchase order.

3.3 Acceptance of Purchase Orders

It is the Suppliers responsibility to review the purchase order and confirm the following to the buyer in 24 (twenty-four) hours:

- The order has been received
- The scheduled date can be met (NOTE: the PO reflects the expected delivery date and not the ship date).
- The pricing is as agreed. Discrepancies in PO pricing must be communicated at the time of receipt of a PO; otherwise the supplier accepts the price listed on the PO.
- The product or service can be provided within the required specifications.
- The Supplier is responsible to meet all of the requirements agreed to and indicated in the provided documents.

3.4 Late Shipment Notification

Suppliers shall communicate any possible late shipments to Spectrum Buyer as soon as a delay is acknowledged.

3.4 Certificate of Conformity/Compliance

Supplier will provide Spectrum with a written Certificate of Conformity/Compliance (CoC) for each lot to include the following when specified on the applicable procurement document:

- Materials meet requirements of Spectrum purchase order
- Spectrum part number
- Revision of Spectrum specification
- Quantity
- Spectrum purchase order number
- Supplier's batch number must be clearly identified
- Authorized signature
- Reference any applicable standards

3.6 Certificate of Analysis

Supplier will provide Spectrum with a written Certificate of Analysis and test results (as required by purchasing specifications)

*A Certificate of Analysis refers to an authenticated document that is issued by Quality Assurance Department that ascertains that a product has met its predetermined product release specification(s) and quality.

3.7 Packing Slip will contain the following information:

- Spectrum Part Number
- Spectrum Part Description
- Spectrum Revision
- Spectrum Purchase Order Number
- Supplier Lot Number
- Quantity
- Lot Test Results (as required by purchasing specification)

3.8 Packaging/Container labeling will contain the following information:

- Spectrum Part Number
- Supplier Batch Number
- Product Description
- Quantity
- Spectrum Purchase Order Number

3.9 Invoicing:

- All invoices submitted for payment must clearly state INVOICE and include all of the following information or they may be returned, causing a delay in payment:
 - Supplier name and invoice number
 - Spectrum purchase order number
 - Terms of payment per purchase order
 - Description of parts/service ordered including part number (if applicable from PO)
 - Total number of units shipped, unit price and extended invoice amount
 - Supplier ship date and invoice date

4. Quality Environmental System

Core components of any quality management system must include the acknowledgment, monitoring and continuous improvement of key business processes.

To support our environmental policy Spectrum is/has:

- Developed RoHS and REACH-compliant products
- Evaluating all purchased products for REACH compliance
- Communicating applicable requirements as necessary to our supply base

In support of its (RoHS) Hazardous Substances Reduction initiative, Spectrum expects you, as a supplier to:

- Provide RoHS-compliant and Pb-free process-compatible parts upon the request of Spectrum (via purchasing specifications)
- Supply information concerning materials content and manufacturing parameters for RoHS compliant parts including as required:
 - Conflict Minerals, California Proposition 65, FDA Food Contact, Recycled Content
 - Biological Material, Latex, Phthalates, Endocrine Disruptors, Nanomaterials
 - EU Medical Device Regulation, EU Waste Framework Directive
- Materials with flammable, explosive, reactive, poisonous, or radioactive hazards must have an MSDS forwarded to Spectrum's Purchasing Manager who will forward to the HSE Coordinator.
- Other regulatory requirements as defined by our customers

5. Supplier Product Change Notification

Supplier will notify Spectrum of any product or process changes 90 (ninety) days prior to implementing them. Supplier will notify Spectrum of any lot specific deviations from specifications and gain Spectrum approval prior to shipping. For all items purchased by Spectrum within the current or previous 5 calendar years, a product change notification (PCN) from the manufacturer is required upon notification of any change affecting safety, quality, form, fit or function.

Distributors **must** forward PCN's from their suppliers for any parts meeting the above criteria ninety days prior to shipment and/or acceptance of purchase order.

6. On-Time Delivery

On time delivery is the percentage of line items received "On Time In Full" as compared to the supplier's measured delivery date on a purchase order. "On Time In Full" receipt is defined as delivery to Spectrum's dock from seven days early to one day late. "On Time In Full" delivery is measured by the receipt date compared to the purchase order "dock date".

7. Terms and Conditions

Spectrum has standard terms and conditions that apply to all purchase orders. If you do not have a copy of our latest terms and conditions applicable to your order, please contact your buyer for another copy or go to our website at www.spectrumplastics.com. Purchase order confirmation constitutes acceptance of the applicable terms and conditions.

8. Shipping Method

Spectrum's shipping method will be specified on the Purchase Order. All Spectrum's shipments are to be shipped collect using the shipping company indicated unless special instructions are provided. Suppliers are NOT to add insurance for any shipments to Spectrum unless otherwise indicated on the purchase order.

9. Becoming a Spectrum Supplier

Spectrum qualifies suppliers based on needs and capabilities. We require all new suppliers complete a W9 Form, Spectrum Supplier Capabilities Survey, and a Supplier Qualification Questionnaire (these may be found on our website www.spectrumplastics.com.) Our process for qualifying a new supplier or a new product is determined by the criticality of the material provided by the supplier. Table 1 below highlights the documentation requirements based on supplier rated criticality as determined by Spectrum.

Table 1. Required Quality Documentation by Supplier Criticality Ranking

Supplier Criticality Ranking	Supplier Quality Agreement (F11)	Supplier Qualification Questionnaire (F02)	W9	Capability Survey (F09)	3 rd Party Certification by an Applicable Accredited Agency	Initial Audit Requirements
Critical	X	X	X	X	X	Desk/On-Site
High	N/R	X	X	X	N/R	Desk/On-Site
Medium	N/R	X	X	X	N/R	N/R
Low	N/R	N/R	X	N/R	N/R	N/R
Development	N/R	N/R	X	N/R	N/R	N/R
Outsourced Process	X	X	X	X	N/R	Desk/On-Site
Service Provider	N/R	N/R	N/R	N/R	N/R	Request Qualifications
Customer Mandated	With Customer	N/R	N/R	N/R	N/R	N/R
Customer Supplied	With Customer	N/R	N/R	N/R	N/R	N/R

N/R – Not Required

9.1 Approval by Sample

Suppliers desiring to have material evaluated and added to Spectrum's AVL/ASL must first obtain authorization from Spectrum's engineering or purchasing and complete a Supplier Qualification Questionnaire (if they have not been surveyed before).

Material submitted for evaluation and required sample size must be specified by engineering. It may vary with the material type. The supplier may be required to provide additional information. Suppliers are responsible for documenting verifications results and providing this documentation with the material submission. Once the engineer approves the material, Spectrum sends written notification to the supplier. If the material does not meet requirements, Spectrum documents the discrepancy, and the supplier is expected to provide a new first article (or equivalent document) that conforms to the established requirements.

If the evaluation is disapproved, supplier agrees that the balance of unused evaluated components will be returned for a full refund and the balance of the purchase order will be cancelled.

If during subsequent processing, the approved components are found to cause product failures, purchases may then be suspended until the supplier can provide failure analysis and/or corrective action. Upon positive resolution of problems, purchases will resume. If positive resolution cannot be reached, all purchases of this product may be cancelled, and supplier's approval rating will be re-evaluated.

10. Incoming Inspection

Spectrum performs inspection on material. The inspection process may include any of the following: documentation review, dimensional, physical appearance, functional and non-destructive testing.

11. Supplier Material Rejection

Defective material is identified and documented in a supplier material rejection notice. A rejection notice can result from material which does not comply with the procurement specification, paperwork is not accurate, product is not labeled correctly and/or product failed in production. A copy of the rejection notice will be forwarded to suppliers as deemed necessary by Spectrum personnel. If material is dispositioned as "return to supplier" parts may be returned for credit as requested. As a supplier, you are required to act promptly in resolving nonconforming material issues. Spectrum expectation is within 24 hours of receipt of rejection notice, the supplier will return the notice with the following minimum action completed:

- Acknowledgment of the problem
- The immediate containment actions that have been implemented to protect Spectrum and its customers

12. Supplier Corrective Action Requests (SCAR)

When non-conforming material is dispositioned as suppliers' responsibility, Spectrum may decide to issue the supplier a SCAR. A SCAR may also be issued for chronic nonconformance on similar parts or operation issues. This will impact the supplier's score (see below for Supplier Performance Metric). It is imperative that supplier's identify cause and corrective action, complete the SCAR form, and implement procedures so further escapes do not occur. The supplier is responsible for filling out the following:

Supplier Review Part A: Reply requested within 2 business days of SCAR notification

- Problem description
- Immediate action taken
- Effective date of action taken
- Material Disposition or Performance Improvement Plan
- Name and Title of supplier representative responding to the SCAR
- Date of SCAR response

Supplier Review Part B: Reply requested within 4 weeks of SCAR notification

- Root cause analysis (5 Why's)
- Preventive – Corrective Action Plan and Effective Date
- Description of the Corrective Action permanent implementation and Effective Date
- Verification of Corrective Action effectiveness and Effective Date
- Name and Title of supplier representative responding to the SCAR
- Date of SCAR response

Costs and charges incurred associated with shipping, handling, processing, reworking, inspecting, engineering verification and replacing defective material including the costs of value-added operations prior to its discovery are the responsibility of the supplier.

13. Supplier Performance Metric

Supplier performance metrics are evaluated monthly or quarterly for suppliers. Measurement is for on-time delivery, acceptable product quality level and whether a supplier has had any non-conforming materials and/or SCARS. Supplier overall performance rating lower than acceptable will be reviewed by Quality and Purchasing to determine the need to release a SCAR based on supplier's performance. Upon release of a SCAR, Quality may audit supplier for continued approval and may disqualify the supplier if corrective action is not implemented or corrective actions are determined to not be effective.

ACCEPTANCE OF SUPPLIER HANDBOOK:

Company: _____

Address: _____

Printed Name: _____

Title: _____

Signature: _____

14. Contact Information

Accounts Payable: 952-927-2441
Purchasing: 404-564-8560; Option #1



2500 Northwinds Parkway, Suite 472
Alpharetta, Georgia 30009 USA
ISO 9001, ISO 13485, AS9100, and FSSC 22000
certified
FDA-registered