



SUPPLIER HANDBOOK



Your Vision.

Designed.

Delivered.

Meeting Customer Needs Through Supplier Partnerships



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NOTE: Acceptance of a Xeridiam Purchase Order (PO) constitutes acknowledgement that the Supplier has read, understands, and will comply with the expectations of this Manual.

INTRODUCTION

Xeridiam's Quality Policy

We are committed to being **RIGHT THE FIRST TIME** by maintaining effective compliance, implementing defect free processes, and providing error free services.

Background

Xeridiam Medical Devices is a premier designer and developer of complex, single use medical devices sold worldwide. By bridging the gap between our clients' original concepts and commercialization, we facilitate the rapid launch of new products that can become well-established market leaders.

To achieve Xeridiam's goal of rapid launch we need the full participation and cooperation of the organizations which supply us with materials, components, assemblies and services. Xeridiam 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 Xeridiam'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 Xeridiam, and it is expected that the Suppliers will manage its entire supply base with these principles. A copy of this handbook can be found on our website www.xeridiam.com. This handbook does not apply to MRO purchases.

CODE OF ETHICS

Xeridiam values its supply partners who share the Company's commitment to quality and low cost, and who operate under a philosophy that focuses on integrity and "doing the right thing". Fundamental principles within our code of ethics are:

- Suppliers must follow the law
- Suppliers must treat all people with dignity and respect
- Suppliers must do business fairly, honestly and avoid conflicts of interest
- Suppliers must protect the environment
- Suppliers must provide a safe working environment for their employees
- Suppliers must protect Xeridiam's proprietary information and intellectual property

SUPPLIER EXPECTATIONS

Quality Provisions

Xeridiam expects its supply base to have a robust quality management system in place that complies with ISO 13485, FDA Regulation 21-CFR-Part 210/211/820 quality principals and/or ISO 9001. Suppliers must allow access to Xeridiam notified body if necessary. All materials received will be inspected to Xeridiam's internal specifications. These specifications are referenced on Xeridiam's purchase order. No correction fluid (white-out) shall be used on shipped lot paperwork.

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 and delivered to Xeridiam.

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.

General Guidelines/requirements

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.

Purchase Orders

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

Acceptance of Purchase Orders

- It is the Suppliers responsibility to review the purchase order and confirm the following to the buyer in 24 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.

Late Shipment Notification

Suppliers shall communicate any possible late shipments to Xeridiam Buyer as soon as a problem is acknowledged.

Certificate of Compliance

Supplier will provide Xeridiam with a written Certificate of Compliance for each lot to include the following when specified on the applicable procurement document:

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

Certificate of Analysis

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

Materials measured in grams or ccs shall include no more than one lot per shipment.

Packing Slip will contain the following information:

- Xeridiam Part Number
- Xeridiam Part Description
- Xeridiam Revision
- Xeridiam Purchase Order Number
- Supplier Batch Number
- Quantity
- Testing Results (as required by purchasing specification)

Packaging/Container labeling will contain the following information:

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

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
 - Xeridiam 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

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 Xeridiam is/has:

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

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

- Provide RoHS-compliant and Pb-free process-compatible parts upon the request of Xeridiam (via purchasing specifications)
- Supply information concerning materials content and manufacturing parameters for RoHS compliant parts.

Materials with flammable, explosive, reactive, poisonous or radioactive hazards must have an MSDS forwarded to Xeridiam's Purchasing Manager who will forward to the HSE Coordinator.

Supplier Product Change Notification

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

On-Time Delivery

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

Terms and Conditions

Xeridiam 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.xeridiam.com. Purchase order confirmation constitutes acceptance of the applicable terms and conditions.

Payment Terms

Xeridiam's standard payment terms are Net 30.

Shipping Method

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

Becoming a Xeridiam Supplier

Xeridiam qualifies suppliers based on needs and capabilities. We require all new suppliers complete a W9 Form, Xeridiam Supplier Capabilities Survey (Form 05-0011-F09), and a Supplier Qualification Questionnaire (Form 05-0011-F02) (these may be found on our website www.xeridiam.com). Our process for qualifying a new supplier or a new product is as follows:

Approval by Sample

Suppliers desiring to have material evaluated and added to Xeridiam's AVL must first obtain authorization from Xeridiam's engineering or purchasing and complete a Supplier Qualification Questionnaire (Form 05-0011-F02) if they have not been surveyed before.

Material submitted for evaluation shall typically require a minimum of 25 pieces. The 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 part submission. Once the engineer approves the part, Xeridiam sends written notification to the supplier. If the part does not meet requirements, Xeridiam documents the discrepancy, and the supplier is expected to provide a new first article 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.

Incoming Inspection

Xeridiam performs inspection on material. The inspection process may include dimensional, physical appearance, functional and non-destructive testing.

Supplier Rejection Disposition Report (SRDR)

Defective material is identified and documented in a supplier rejection disposition report (SRDR). An SRDR 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 SRDR's will be forwarded to suppliers as deemed necessary by Xeridiam personnel. If material is dispositioned as "return to supplier" parts may be returned for credit as requested. As a supplier, you are encouraged to act promptly in resolving nonconforming material issues. Xeridiam expectation is within 24 hours of receipt of SRDR, the supplier will return the SRDR with the following minimum action completed:

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

Supplier Corrective Action Requests (SCAR)

When non-conforming material is dispositioned as suppliers fault, Xeridiam 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
- 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

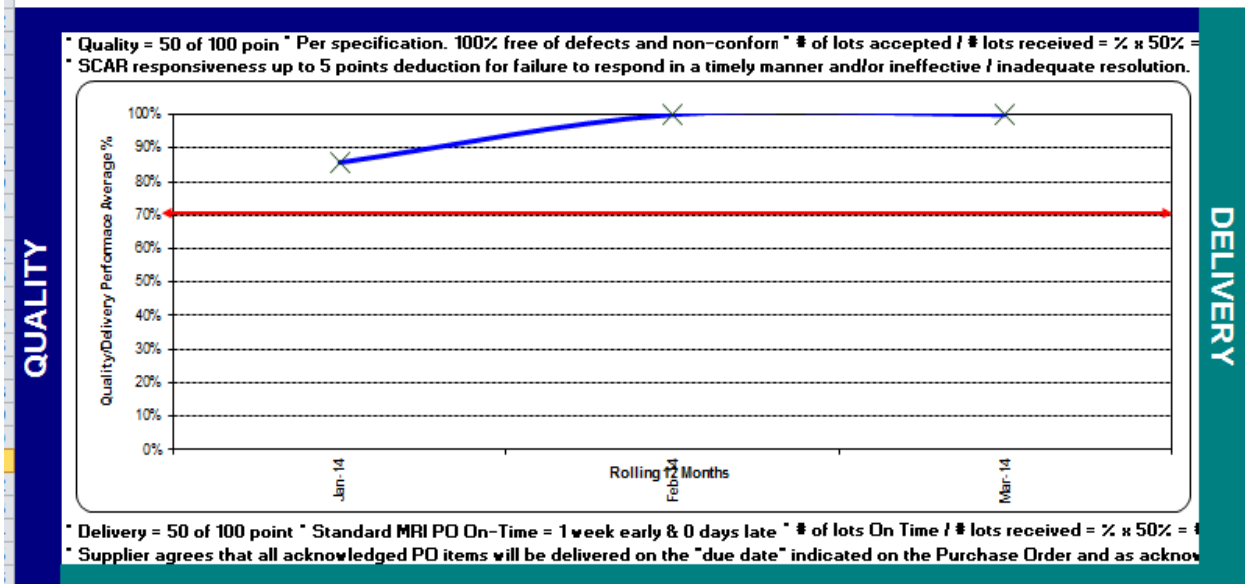
- Root cause analysis (5 Why's)
- Preventive – Corrective Action Plan and Effective Date
- Description of the Corrective Action permanent implementation and Effective Date
- Verification of Corrective Action effectiveness and Effective Date
- Name and Title of supplier representative responding to the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

Supplier Performance Metric

Supplier performance metrics are evaluated monthly for suppliers. Measurement is for on-time delivery, acceptable product and whether a supplier has had any SRDR's and/or SCARS. Supplier overall performance rating lower than 70% 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.

SUPPLIER PERFORMANCE METRIC												
YEAR	VENDOR ID	VENDOR NAME									RATING	
2014	ABC001	ABC SUPPLIER									HIGH	
MONTH	TOTAL DELIVERIES	QUALITY				DELIVERY				AVERAGE	SCAR# Or Justification if Needed (For Average Performance below 70%)	
		ACCEPTED	REJECTED	RATE %	POINTS	ON TIME	LATE	RATE %	POINTS			
Mar-14	10	10	0	100%	50	10	0	100%	50	100%		
Feb-14	2	2	0	100%	50	2	0	100%	50	100%		
Jan-14	7	7	0	100%	50	5	2	71%	36	86%		



Contact Information

Accounts Payable: 520-882-7794 Option #3
Purchasing: 520-882-7794 Option #6

1-520-882-7794

www.xeridien.com



xeridien®

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FDA-registered**