Volume

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Supplier Requirements Manual

OsteoMed Supplier Requirements Manual

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Chapter

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1.0 Introduction

Suppliers are as critical to s as our employees and shareholders. Accordingly, we want to ensure that we properly communicate our expectations, beliefs and requirements. Our goal is to develop long-term relationships which are profitable for all, and allow for future growth and opportunities. Just as there are good and bad suppliers, there are good and bad customers. OsteoMed is committed to being a good customer to our dedicated suppliers.

The OsteoMed Supplier Requirements Manual provides an outline of the requirements and expectations for strategic suppliers. OsteoMed is committed to establishing long-term relationships with those suppliers who are committed to continuous improvements in the areas of quality, delivery, cost and service.

We would like to take this opportunity to share our Vision Statement, Mission Statement and Core Values with all suppliers. Our expectation is that all suppliers are able to support our vision, mission and values.

Vision Statement

The premier, global small bone implant company

Mission Statement

OsteoMed designs, manufactures and delivers high quality, innovative and cost effective surgical products and services to improve patient outcomes worldwide.

Core Values

- Integrity and Character
- Employees are Our Most Valued Resource
- Pursuit of Performance Excellence
- Uncompromised Quality, Innovation & Service
- Customer Driven, Patient Focused
- Teamwork (Respect, Trust & Communication)
- Leadership (Responsibility, Accountability, Initiative & Empowerment)

2.0 Purpose

The OsteoMed Supplier Requirements Manual provides suppliers the details of requirements for approved suppliers, and communicates OsteoMed's expectations. While many of the product/service requirements are specified in the purchase orders, and attached drawings or specifications, there are also additional requirements which must be met. This manual assists in clarifying those implied requirements which are often left to interpretation or overlooked. The manual also discusses how suppliers are rated on performance.

3.0 Gratuities and Gifts

OsteoMed strives for professionalism and pursues sound ethical standards in all our business practices. Purchasing decisions should be made solely on the basis of quality, delivery, price and service. No other consideration is necessary or appropriate in the procurement process. Our goal is to succeed on business fundamentals and avoid any situation that can lead to a real or perceived conflict's of interest. Any known conflicts of interest should be reported to the President of OsteoMed.

Gifts received from our suppliers or provided to our customers are inappropriate and have the potential to cast doubt over our ethical standards and ability to establish sound and unbiased business relationships. As a general guideline, any gift over $25 is considered imprudent. Small tokens such as calendars, pens and similar articles are acceptable. Meals that are arranged to discuss business matters are also acceptable.

4.0 Supplier Management Team

OsteoMed's diversified Supplier Management Team provides a balanced and comprehensive review of suppliers. The team consists of members from Purchasing, Quality, Production Control and Engineering. As a group, the team concentrates on improving supplier selection and performance by evaluating quality, delivery, cost and service. The Supplier Management Team establishes and maintains OsteoMed's Supply Chain Strategy, evaluates current and potential suppliers, resolves supply chain issues, addresses supplier concerns, administers the Supplier of the Year program and maintains OsteoMed's Supplier Requirements Manual.

5.0 Request for Quote

A quote request may be emailed or faxed. Each request will be accompanied by a print and reference documentation. The request will also include a quantity to quote and any specific instructions for packaging requirements. Quotes should be responded to in 3 working days.

6.0 Purchase Order Requirements

All parts/services acquired by OsteoMed will be processed on a Purchase Order. Suppliers who proceed without a Purchase Order risk non-payment for parts/services. *Only the Purchasing Department has the authority to issue or make changes to Purchase Orders*. No "verbal" purchase orders should be accepted! All changes must be documented and a revised Purchase Order issued. Any discrepancies on a Purchase Order should be addressed within five working days after receipt of order. A written acknowledgement is preferred by OsteoMed after the supplier completes their review of the purchase order contract. The content and terms of the Purchase Order are considered accepted if a written acknowledgment is not received within ten (10) days.

OsteoMed must be notified if a product will be manufactured in a location other than the location in which the product was initially produced or validated.

Purchase Order Content

- ► Purchase Order Number
- ► Purchase Order Date
- ► Part Number
- ► Quantity
- ► Due Date (OsteoMed Dock Date)
- ► Unit Price
- ► Current Revision / Blue Prints
- ► Specification and documentation requirements including Certificates of Conformance, Material/Process Certifications, etc.
- ► Authorized Signature/Buyer's name
- ► Shipping method

Purchase Orders will be conveyed to the supplier via fax, email, U.S. mail or FedEx/Ups for larger packages.

Use of OsteoMed L.P.'s Gauges and Equipment

Suppliers of manufactured products are expected to have both the equipment and the gauges necessary to manufacture products to OsteoMed's specifications. Due to the demand of products being shipped and internal manufacturing needs, OsteoMed will not loan gauges. Remember to include all gauges and equipment necessary to manufacture our product during the ***RFQ*** (Request for Quote).

References and Specifications

OsteoMed will only provide electronic or hard copy versions of drawings, operation process specifications and manufacturing routers. The supplier is expected to procure their own copy of any required industry specifications, standards, and references, called out by OsteoMed documentation (e.g., an ASTM standard).

Cost Considerations

For continued success in a global market, OsteoMed and OsteoMed's supplier partners must provide greater value for our customers. Greater value can be achieved through process improvements, economies of scale, design enhancements, increased productivity, better planning and improved quality. Internally, OsteoMed implements lean manufacturing processes to reduce set-up/cycle times, Work-In-Process (WIP) and inventories, to ultimately reduce costs. Working together, we can assist each other in meeting the challenges of the global market. OsteoMed strongly encourages suppliers to develop a plan to reduce total costs.

Some ideas for improving costs and/or improving quality include:

- ► Reduce set-up and cycle time
- ► Reduce WIP
- ► Design for manufacturability
- ► Standardization
- ► Utilize corrective/preventive action program
- ► Implement lean six-sigma
- ► Consolidate freight, minimize overnight deliveries

7.0 Delivery Requirements

One of OsteoMed, L.P.'s core values states "***Customer Driven, Patient Focused***." OsteoMed's business relies on on-time delivery. There is no such thing as backorders to OsteoMed; these are lost sales to both OsteoMed and our suppliers. If we cannot deliver on-time, our customers know someone who can. Our goal is to provide 100% on-time delivery to our customers and use this as a competitive advantage. The results are increased sales for all of us.

Delivery dates are based on the requirements set by the ERP (Enterprise Resource Planning) system using our Marketing Department's forecast. Deliveries are set according to leadtime, order minimums and inventory levels. Should a supplier's lead-time change, notify OsteoMed's purchasing department as soon as possible to minimize the impact.

While OsteoMed promotes on-time delivery, we do not promote stocking excess inventory to cover delivery requirements. Excess inventory is costly to all. Instead of stocking inventory, OsteoMed encourages the implementation of Just-In-Time and Lean Six-Sigma as a means of providing reduced lead-times.

Delivery Performance Measurement

OsteoMed tracks supplier delivery performance and makes purchasing decisions based partly on on-time deliveries. OsteoMed's on-time delivery window is 5 working days early and 0 days late. Late deliveries are rated more negatively than the early deliveries. Consideration must be given to transit times, customs inspection and/or holidays. Should a supplier have reason to believe a delivery will not be made on the scheduled due dates, OsteoMed shall be notified immediately.

Purchase Order Due Date

The OsteoMed Purchase Order Due Date is the date the product is required in our Receiving Department. Suppliers are expected to deliver according to their commitments. Should there be any potential problem with delivery, notify the Purchasing Department immediately. There should be no reason for OsteoMed to call on the due date asking why the product has not been received. OsteoMed will not pay for priority shipping due to a supplier's delivery issues.

Order Quantity Deviations

Any deviation from the Order Quantity must be cleared with the Purchasing Department prior to receipt. OsteoMed will work with suppliers to make economical business decisions benefiting both companies, wherever possible.

Documentation

Documentation requirements are stated on the Purchase Order. These may include, but not limited to, the following:

- ► Certificate of Conformance
- ► Material Certification
- ► Heat Treat Certification
- ► Special Processing Certification (e.g., anodizing, electropolishing, sterilization)
- ► Calibration certificates

Packaging

The supplier is required to package and identify parts in a manner that prevents damage, deterioration or mixed product during shipment. The Purchase Order may specify special packaging requirements if necessary. The type of packaging used should be appropriate to the product type, the shipping method selected and the distance shipped. The supplier is responsible for any damage or lost product during shipment caused by improper packaging. P.O. Numbers and Part Numbers must appear on all packing slips and invoices. Packing slips must be included with shipments.

Hazardous Material

Suppliers must follow all relevant Local, State and Federal Health, Safety and Environmental regulations and ensure all proper markings are on containers and the appropriate paperwork is supplied. Copies of relevant Material Safety Data Sheets (MSDS) must be included with all shipments per OSHA regulations. OsteoMed reserves the right to refuse any delivery that does not conform to these delivery requirements.

8.0 Quality System Requirements

As a supplier to the medical industry, OsteoMed maintains a determined focus on product quality. We rely on our suppliers to provide OsteoMed with high quality products, delivered on-time. We are certified to ISO 13485 and are compliant to the FDA's Quality System Regulation. We require that our suppliers have a clearly defined Quality System to assure that the product, process, or service supplied will meet OsteoMed specifications. OsteoMed's Supplier Quality uses standard procedures to determine the integrity and scope of the supplier's quality system. Copies of these procedures are available upon request.

The supplier will appoint a representative, who reports directly to upper management, who has the authority to establish or make changes to the supplier's quality policy and quality system. All personnel who affect product quality shall be trained to meet their responsibilities.

All our outside processing and manufactured component suppliers are encouraged to be certified by recognized third-party registrars to the current ISO 13485, ISO 9001, or equivalent. If a supplier loses their Quality System certification, OsteoMed expects the supplier to notify OsteoMed's Purchasing Department in writing within 10 working days.

Non-Conforming Report

All materials supplied to OsteoMed must conform to contractual requirements and are subject to inspection and approval after delivery. If a nonconformance is found with the product, OsteoMed reserves the right to withhold payment. We will also reject and/or return at the risk and expense of the supplier, all or any portion of shipments which fail to comply with our requirements/specifications. The supplier may be required to sort, rework or replace the components. Should historical data indicate a trend towards a particular failure mode, OsteoMed may also elect to issue a separate NCR (Non-conformance Report).

In the event of a nonconformance, OsteoMed will issue a NCR and communicate this to the supplier by sending a copy of the nonconforming report along with a cover letter explaining our requirements for the completion and documentation of the corrective action. FDA regulations QSR 21 CFR 820, sections 820.90 sub sect (a) and (b), along with ISO 13485:2003, section 8.3 states that all nonconforming products are subject to evaluation and disposition.

It is essential that corrective action be taken immediately by the supplier. The evaluation of the nonconformance shall include a determination of the need for an investigation. The evaluation and any investigation shall be documented. Once the supplier has identified the root cause of the nonconformance, a target completion date of the corrective action will be set by the supplier. Although completion of corrective action could take time to evaluate its effectiveness, a response to OsteoMed on the NCR is required within thirty (30) days. OsteoMed will provide a copy of the form to be used during the investigation. Although the use of this form is not mandatory, it is a helpful guide to define the areas being investigated.

Corrective action responses will be part of the on-site audit for verification of effectiveness of the supplier's corrective action system.

Deviation/Waiver Requests

Non-conformities, such as non-critical specifications, materials, and assemblies that may be deemed useable in the judgment of the supplier, shall be marked as non-conforming product. A supplier deviation/waiver request form must be sent to Purchasing and approved by OsteoMed's Engineering and Quality departments prior to shipping non-conforming product to OsteoMed. Deviation requests forms are available upon request. The approved deviation/waiver request shall be submitted with the other documentation called out in the Purchase Order with each shipment of non-conforming product. The supplier shall identify the quantity or period for which the deviation/waiver request shall apply.

Change Control

OsteoMed believes documentation change control is essential to continued quality and reliability. Accordingly, once a product is qualified for production and released, the supplier cannot change the part/product, process, or location of manufacture without written approval from OsteoMed. Should the supplier wish to make changes, or foresee the need for changes due to capacity, material supply or process improvement goals, OsteoMed's Purchasing Department must be contacted so that the potential impact can be explored and defined together.

Inspection

Regardless of sample plan used, **all dimensions that are called out on our print as major or critical, must be inspected 100%.** Where required by the Purchase Order, copies of all final inspection data must be provided with each lot shipped. OsteoMed recommends the use a sampling plan based on ANSI/ASQ Z1.4 or Z1.9, Table 1 –General Inspection Level II, where C=0, with an AQL of 1.0%, or tighter.

Traceability

Traceability is specified by the purchase order. Components received at OsteoMed must contain a unique identification number that is clearly identified on each label and every container. Some products of a special nature may require a serial number. These identification numbers must ensure traceability of the product from the receipt of raw material by the supplier through each processing stage, including final shipment to OsteoMed. All requirements of traceability, including serialization, will be communicated through the Purchase Order.

Record Retention

Due to regulations that affect OsteoMed product, production and quality records are required to be maintained for a fixed period of time to allow for any needed investigation. Accordingly, suppliers must also maintain accurate records that show that OsteoMed's conformance requirements have been met. The supplier shall have a documented procedure in place that defines responsibilities for record control and retention. OsteoMed requires suppliers to retain quality records a minimum of five (5) years. Contact OsteoMed for proper disposition (e.g., destruction, shipment to OsteoMed) when quality records have reached the 5 year minimum.

Management of Subcontractors

OsteoMed requires that suppliers manage their own suppliers or subcontractors to ensure that OsteoMed specifications are fully met. Your suppliers are expected to qualify their suppliers, including periodic audits as deemed necessary, in accordance with your Quality System Requirements.

Invoicing Requirements

All purchases of product and services will be done via OsteoMed Purchase Order. All products purchased by an OsteoMed Purchase Order **must** come through Receiving. **Deliveries made to locations other than Receiving cannot be properly tracked and will result in delayed payment**. Our Accounts Payable Department requires a receiving/packing slip with each shipment. Upon the receipt of an invoice, Accounts Payable will match the packing list with the invoice, and pay according to the pre-arranged terms.

Please include only **one** Purchase Order on each invoice as this will expedite payment for your services.

OsteoMed Consigned Material

On occasion, OsteoMed may purchase or supply tooling, molds, fixtures, or materials specific to a part or job. Where purchased through an OsteoMed Purchase Order, OsteoMed retains ownership of any special tooling, molds, or fixtures specific to the order or parts. The items cannot be used by the supplier for non-OsteoMed production, or for another customer, without written approval from OsteoMed.

The supplier is responsible for identifying, verifying, and safeguarding OsteoMed property provided for use in the manufacture of OsteoMed product(s). If any items are lost, damaged or otherwise found to be unsuitable for use, the supplier shall report the incident to OsteoMed immediately. The supplier is responsible for any damages, excluding normal wear, to OsteoMed-supplied materials. Tooling, molds, fixtures, or other OsteoMed supplied material shall be returned upon request.

Quality Audits

As noted in Section 8, the supplier is required to maintain a quality system. Even though the supplier has been granted approval by a recognized third-party to a national and/or international standard, OsteoMed retains the right to perform an on-site audit. For on-site audits, any and all observances made will be identified and the supplier will be asked to provide a corrective action response. Based on the severity of the observation(s) and the cause and corrective actions identified by the supplier, OsteoMed's Supplier Management Team will decide if a follow-up audit is required. Generally, audited suppliers should expect to be re-audited every two years.

Precedence

Should a conflict arise between the OsteoMed Supplier Requirements Manual and Purchase Order, drawings, specifications, or other applicable documents, the supplier must inform Purchasing of the discrepancy for clarification and/or resolution.

Calls/Visits to OsteoMed

All visits to OsteoMed shall be scheduled through the Purchasing Department.

Supplier Monitoring

Monitoring of suppliers is based on performance metrics that include: Quality, On-time Deliveries, Non-Conformance Report (NCR) responses, number of Deviation Request, results of on-site audits, as well as the quality of the supplier's responses to observations resulting from on-site audits. Summaries of supplier performance are reviewed by OsteoMed Senior Staff as part of OsteoMed's Management Review.

Suppliers are provided with supplier performance letters each quarter. The letters are meant to be informative and no response is required, however it is in the suppliers' best interest to read and use the information provided. If the information provided does not match the supplier's records, contact OsteoMed Supplier Quality for clarification and/or correction.

9.0 Attachments

Form PUR-001-F1OsteoMed Purchase Order example
Form PUR-001-F2 Certificate of Conformance (may be used if Supplier does not have a form)
Form QAP-004-F1 NCR Initial Report
Form QAP-004-F2 Nonconformance Investigation
Form QAP-035 F1 Deviation Request

Revision Level	Date	Description of Change
A	01/01/2005	Initial Release – ECN 6226
B	11/15/2007	Added Request for Quote, added conflict reporting to Gifts and Gratuities section. Added PO identification requirement to packaging - ECN 7221.