



A TRADITION OF QUALITY AND INNOVATION



Supplier Requirements Manual

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1.0 Introduction

Suppliers are as critical to OsteoMed 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 dedicated 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.

1.1 Vision Statement

The premier, global small bone implant company

1.2 Mission Statement

Improve patient outcomes through the design, manufacture and service of high quality, innovative and cost effective surgical products.

1.3 Core Values

- Integrity
- Accountability, Initiative & Empowerment
- Culture of Continuous Improvement
- Teamwork Based on Trust, Respect & Communication
- Uncompromised Quality, Innovation & Service
- Fiscal Responsibility
- Recognition of Employee Excellence

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 and specifications, there are also additional requirements which must be met. This manual assists in clarifying those implied requirements which are often left to interpretation by the supplier 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 of our business practices. Purchasing decisions will be made on the basis of quality, delivery, price, responsiveness 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 of interest. Any known conflict of interest should be reported to the President of OsteoMed immediately.

Gifts received from suppliers or provided to 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 \$30 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 Supply Chain Management Team

OsteoMed's diversified Supply Chain Management Team (SCMT) provides a balanced and comprehensive review of suppliers. The Team consists of members from Purchasing, Quality, Production Control, Manufacturing, Manufacturing Engineering and Engineering. As a group, the team concentrates on improving supplier selection and performance by evaluating quality, delivery, cost, responsiveness and service. The Supply Chain 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 performance metrics, administers the Supplier of the Year program and maintains OsteoMed's Supplier Requirements Manual. The Supply Chain Management Team is committed to improving supplier performance.

5.0 Request for Quote

A quote request may be emailed or faxed. Each request will be accompanied by the appropriate drawings and specifications. The request will also include a quantity and any specific requirements. Quotes should be responded to within three (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 goods/services. Only the buyer/planner 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 (5) 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 acknowledgement is not received within ten (10) business days. Service providers must contact OsteoMed's Purchasing Department immediately upon receipt of a Purchase Order if the expected delivery date cannot coincide with previously agreed upon lead-times.

6.1 Purchase Order Content

- ▶ Purchase Order Number
- ▶ Purchase Order Date
- ▶ Part Number
- ▶ Quantity
- ▶ Due Date (OsteoMed Dock Date)
- ▶ Unit Price
- ▶ Current Revision / 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.

6.2 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:

- ▶ Demand planning
- ▶ 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

6.3 Use of OsteoMed'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. Gauges must be calibrated and traceable to a national standard. 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).

6.4 References and Specifications

OsteoMed will only provide electronic files 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).

7.0 Delivery Requirements

Delivery dates are based on OsteoMed's requirements set by the ERP (Enterprise Resource Planning) system using Marketing Department forecasts. Deliveries are set according to lead-time, 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.

7.1 Supplier Performance Measurement

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.

Monitoring of suppliers is primarily based on performance metrics which include: quality acceptance, on-time deliveries, and timely responses to Non-Conformance Reports (NCR), if applicable. Suppliers are also rated annually on Request for Quote (RFQ) response time, NCR response time (if applicable), audit finding response time (if applicable), communications, engineering/manufacturability support and technical feedback.

Suppliers are provided with Supplier Performance Reports each quarter. The reports 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. Supplier quarterly performance is based on the following three parameters:

Quality Acceptance Rate: The goal for all suppliers is specified on the Supplier Performance Report and determined by lots accepted divided by lots received.

On-Time Delivery: The goal for Delivery is also specified on the Supplier Performance Report and is determined by lots received on time divided by lots received. If only a partial delivery is received on time and/or the lot is received and rejected, and not returned by the original due date, it is considered late.

Timely Closure of NCRs: The goal for NCR's is to have a response back from the supplier within 30 days. The NCR response will be reviewed by Quality personnel and either accepted and closed out or rejected and sent back to the supplier for further action.

7.2 Purchase Order Due Date

The OsteoMed Purchase Order Due Date is the date the product must be received at OsteoMed. 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 order has not been received. OsteoMed will not pay for priority shipping due to a supplier's delivery issues. The supplier is responsible for paying priority shipping on all late deliveries, unless otherwise specified. Failure to contact OsteoMed's Purchasing Department concerning an order that will be late will negatively impact the supplier's performance rating.

7.3 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.

7.4 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
- ▶ Inspection data

7.5 Packaging

The supplier is required to package and identify parts in a manner that prevents loss, 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, weight, 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/revisions must appear on all packing slips and invoices. Packing slips must be included with shipments.

7.6 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 focus on product quality. We rely on our suppliers to provide OsteoMed with high quality products, on-time delivery and reasonable costs. 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 the product, process, and/or service supplied will meet OsteoMed specifications. OsteoMed's Supplier Quality uses standardized 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 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 ten (10) working days.

8.1 Non-Conforming Report

All product/services 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 the requirements. The supplier may be required to sort, rework and/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) to address a negative trend.

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 implementation of corrective action could take time, as well as evaluation of the 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.

8.2 Return To Vendor

Products received that are found to be non-conforming will be processed as an NCR and sent to the CAPA board for disposition. This board includes a representative from Quality, Operations, Regulatory and Engineering. Once dispositioned as an RTV, the product will be forwarded to the Purchasing Department for return to your facility. Purchasing will verify the contents and quantity prior to requesting an RMA Number. We ask you to supply us with an RMA within 24 hours. We will request your preferred method of transportation for the return shipment. The paperwork that accompanies the returned product will be a Cover Letter from the Quality Information Specialist, Return To Vendor Form and the NCR Form. The RTV Form will instruct you to issue a Credit to OsteoMed for returned product. If the product is reworked or remade a new Invoice must be created for the new shipment.

8.3 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 may request a deviation or waiver by completing OsteoMed's deviation/waiver request form QAP-027-F1 and returning it 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. Failure to submit a deviation request form prior to delivery will result in an NCR that will affect the supplier's performance report.

8.4 Change Control

OsteoMed believes documentation change control is essential for 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 reviewed for consideration.

8.5 Inspection

Where required by the Purchase Order, copies of all final inspection data must be provided with each lot shipped. OsteoMed recommends the use of 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.

8.6 Traceability

Traceability is specified by the purchase order where required. When specified, components received at OsteoMed must contain a unique identification number that is clearly identified on each label and container. Some products 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. Requirements for traceability, including serialization, will be communicated through the Purchase Order. In some instances, lot identifications

that are required to be marked on products must be manufactured from the same predominate material and/or using the same predominate process.

8.7 Record Retention

Due to regulations, 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 seven (7) years. Contact OsteoMed for proper disposition (e.g., destruction, shipment to OsteoMed) when quality records have reached the seven (7) year minimum.

8.8 Management of Subcontractors

OsteoMed requires that suppliers manage their own suppliers and/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.

8.9 Invoicing Requirements

All purchases of product and services will be done via OsteoMed Purchase Order. 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.** OsteoMed's 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.

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

8.10 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 an item is 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.

8.11 Precedence

Should a conflict arise between the OsteoMed Supplier Requirements Manual, Terms and Conditions, Purchase Order, drawings, specifications, and/or other

applicable documents, the supplier must inform Purchasing of the discrepancy for clarification and/or resolution.

8.12 Quality Audits

As noted in Section 8.0, 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 must 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 Supply Chain Management Team will decide if a follow-up audit is required. Generally, audited suppliers should expect to be re-audited every two years.

8.13 Visits to OsteoMed

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

9.0 Attachments

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 MTL-003-F2 Supplier CAPA Investigation

Form QAP-037-F1 Deviation Request Form