Procedure: Order Processing and Review Procedure

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This procedure covers two product types:

Section 5 – standard or catalogue products

Section 6 – custom products.

Most companies sell either custom products or catalogue products, usually not both. If the company sells only one type, delete the inappropriate section.

Ensure that names and titles used in this procedure reflect the practices the company.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for processing and reviewing customer orders.

# Scope

The scope of this procedure includes taking and processing customer orders and contracts and making amendments to existing orders at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Purchasing Manager |  |
| Shipping Officer |  |
| Accounts staff |  |
| Production Manager |  |
| Quality Manager |  |

Amend roles and responsibilities according to your company processes and structure.

# Definition of terms

If either Sections 5 or 6 are deleted, this Section may be deleted.

|  |  |
| --- | --- |
| Term/Abbreviations | Definitions |
| Standard or catalogue products | Products manufactured to [Company] standard specifications and sold from stock without modification or customisation. |
| Customised products | Products designed and manufactured to unique requirements. |
|  |  |
|  |  |

Add other definition of terms as required. Abbreviations may also be included.

# Processing orders for standard catalogue items

This procedure describes in-house order taking and processing. Orders are received by phone, fax, email or post, entered into the system, packaged and shipped.

Requirements of ISO 9001 are covered in the following sections of this document:

* confirmation of verbal orders (see “verbally” in 5.1)
* an order review process (4.2)
* confirmation of availability (4.3)
* verification of availability (4.4)
* processing of order changes and amendments (4.5)
* a record of the order review process (see “a record is kept”)

## Receiving orders

Orders received by email, facsimile or post are forwarded to the sales department for entry into the electronic orders system. Telephone orders are recorded either directly into the orders system or onto Form FM702-1: Order Form.

If appropriate, describe in this section, how the company handles its orders.

Enquiries or requests for customised products are forwarded to the Sales Manager. Processing of orders for custom products is described in Section 6 of this procedure.

This assumes that both catalogue and custom products are sold and that there is a separate order processing system for each. Delete above statement and Section 6 if not appropriate.

All orders, however received, are processed into the orders system as soon as is practical. Company policy is to enter them the day they are received or within 24 hours of receipt.

A template for the Order Form is not provided as company and product requirements differ significantly.

Information received verbally from phone orders is repeated back to the customer to confirm requirements, prices, shipping and billing address, etc.

## Determining product and order requirements

The only requirement for orders of off-the-shelf items is to determine quantities, prices and delivery and billing addresses. Product characteristics are predetermined and are not subject to variation by the customer.

When recording orders, sales personnel confirm the following requirements:

* the unique identification of the product being ordered
* the quantity required
* delivery date
* any requirements for product conformity records (inspection and test reports, SPC charts, certificates of analysis, etc.)

This is only likely to apply to subcontractors supplying materials or components. Delete the preceding dot-point if it does not apply.

* any special product marking or labelling
* any special packaging or shipping requirements
* shipping and billing addresses and any delivery instructions

The completed order is reviewed to identify any additional requirements, whether stated or not, that would apply and which are not listed above.

## Order review

After product and order requirements are determined, they are reviewed to verify that:

* catalogue numbers are valid and match the product description
* product descriptions are complete and the type or style of product(s) required is unambiguous
* any additional requirements for special marking, labelling, packaging or shipping are identified and can be met
* shipping and billing addresses are complete and valid
* terms of payment and credit status are acceptable

In the event of insufficient information, discrepancies or ambiguities, the customer is contacted for clarification. All corrections and additions made on the order are initialled by the person making the changes.

If the resulting corrections or order are difficult to understand (i.e. illegible, information obscure, small writing, etc.), the whole order must be transcribed onto a new order form that is stapled to and kept with the original order.

## Verification of availability

Before accepting an order, checks are made to ensure products are in stock and can be delivered as per the customer’s requirements. If there is insufficient stock, the production scheduler must be contacted to determine when further products will be available for shipping.

If the agreed delivery date cannot be met, the customer is contacted and a new date proposed and agreed on.

If no delivery date is indicated, it is assumed that the requested delivery date is the standard delivery time.

Define the company’s standard deliver time (e.g. five working days) in this procedure.

## Order changes and amendments

Order changes and amendments received from customers are sent to the order entry desk.

Amend process names as applicable for your company.

When a change is received:

* the original order is retrieved
* the change is reviewed for completeness and clarity and the customer is contacted if more information is needed
* the current status of the original order is determined
* the feasibility of the requested change and the impact on cost and delivery is assessed
* if acceptable, the change is entered into the orders system
* the changes are communicated to all effected personnel/departments

A record is kept of the results of the order review.

ISO 13485 Clause 7.2.2 requires that “Records of the results of the review and actions arising from the review shall be maintained.” This may simply be a “Reviewed by” signature or initial on the changed order (either on the paper copy or the electronic copy).

This may not be practical for high volume Internet or phone orders in which case it may be an initial review of product or catalogue information.

# Processing orders for custom products

This section describes basic, in-house order taking and processing. It may be necessary to expand or modify this to reflect the company’s actual procedures or to encompass more complex requirements.

Specific requirements of the standard include controls to demonstrate that:

* product and order requirements are determined
* requirements are understood and reviewed for completeness and consistency
* manufacturing is feasible
* there is sufficient capacity to meet the customer’s requirements

Departments affected by the order (e.g. Sales, Engineering, Production and QA) must participate in the review process and the review must be recorded.

## Receiving inquiries and requests for quotation

Modify this section to describe how enquiries are received and processed. If a procedure for preparing quotations already exists, reference or consider merging it with this procedure.

Enquiries by phone post, email or facsimile are delivered to the order entry desk.

Enquiries regarding customised products are forwarded to the Sales Manager. Orders for standard catalogue products are processes as per Section 5 of this procedure.

In some instances, discussions regarding customised products are held with the company’s production engineering staff. Modify this section to reflect [Company] practices.

If [Company] does not sell both catalogue and customised products, delete those sections of this procedure that are not relevant.

The Sales Manager assigns new customers to an appropriate person to liaise with the customer and prepare a quote. Phone enquiries for customised products will also be directed to the Sales Manager or an appropriate salesperson or engineer.

## Determining product and order requirements

ISO 13485 Clause 7.2.1 (c) specifies that organisations must ensure compliance with statutory and regulatory requirements. Whilst there is no requirement for a formal process, companies must be able to demonstrate that compliance has been achieved. Modify this section appropriately.

This procedure also needs to show how the company reviews and demonstrates that its products are fit for purpose - refer ISO 13485 clause 7.2.1 (b).

More detail will be required in this section for more complex devices.

During preparation of quotations, the following requirements must be considered:

* design of the device
* the company’s capability to manufacture it
* quantities and delivery date
* post-delivery support
* product conformity records (inspection and test reports, SPC charts, certificates of analysis, etc.)
* product marking or labelling
* any special packaging or shipping requirements
* shipping and billing addresses and billing instructions

Review the complete order and note any additional requirements, whether stated, not stated or implied, that would apply and are not listed above.

This may include requirements not stated by the customer but that are necessary for its intended use or delivery or are a statutory or regulatory requirement.

Production, engineering and QA should be consulted, as appropriate, to ensure that all requirements are met (whether they are customer, functional or regulatory requirements).

## Review of product and order requirements

Completed orders are reviewed to verify that:

* customer requirements are fully defined
* functional requirements are met
* statutory and regulatory requirements are met
* customer requirements do not conflict with other requirements

This review is carried out by the salesperson or engineer preparing the quotation and, when product design is required, by a design engineer.

If the review determines that additional information is needed or if a discrepancy or ambiguity is noted, the customer is contacted for clarification.

## Capacity and manufacturing feasibility

The final quotation must be reviewed by the production scheduler to confirm there is sufficient manufacturing capacity to meet the specified delivery date.

Engineering, production and QA must be consulted to ensure that any re-design of the device is fully considered by all relevant parties to confirm that it is feasible to be manufactured in the required time-frame and cost.

This review must consider whether existing technical and production capability and experience are sufficient to fully satisfy all requirements. The review should also include an estimate of capital equipment and tooling costs.

If the review determines that not all customer requirements can be met, the customer is contacted and modifications of the requirements are proposed.

## Order changes and amendments

There can often be a conflict between requirements and time frames and all changes should be reviewed by appropriate persons to thoroughly consider all implications before approval. This section may require expansion or modification to meet the company’s requirements.

Order changes and amendments received from customers are directed to the salesperson or engineer who processed the initial order. When a change request is received:

* the original order is retrieved
* the change is reviewed for completeness and clarity
* the status of the original order is determined (i.e. at what stage of production is it at?)
* the feasibility of the requested change and the impact on cost and delivery is determined and a change order is prepared
* as appropriate, the change order is forwarded to Production, Production Engineering and/or Quality Assurance for confirmation of manufacturing feasibility and conformance with regulatory requirements
* if all factors are acceptable, the agreed change offer is forwarded to the customer for approval
* once accepted by the customer, the change(s) is implemented and appropriate instructions issued to the departments concerned depending on the processing status of the original order (e.g. Accounts, Production Scheduling, Design Engineering, Process Engineering, Production, Purchasing, Shipping and QA)

If the change is urgent, the Sales Manager may authorise the immediate implementation of the change order before formal acceptance of commercial conditions by the customer.

## Order review record

The evidence and record of the order review process consists of a copy of the quotation or offer signed by the reviewing person and initialled by the production scheduler. When the proposed contract or change is reviewed for manufacturing feasibility, the quotation is also initialled by the managers conducting the review.

The above is an example of a record of the review process. Other forms of record are acceptable but they must at least contain the date and the names of persons who conducted the review.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| FM702-1 | Order Form |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END