

# INSERT YOUR COMPANY LOGO/NAME HERE

P-500-A

## Management Responsibility

### 1.0 Purpose

- 1.1 This procedure describes Management Responsibilities for the Quality Management System (QMS) at [Your Company](#).

Documents are all numbered to comply with document control requirements

### 2.0 Responsibilities

- 2.1 Top Management is responsible for establishing the Quality Policy and reviewing it for continuing suitability.
- 2.2 Top Management is responsible for Communicating the Quality Policy, the importance of meeting regulatory, statutory and customer requirements.
- 2.3 Top Management is responsible for identifying the Key Processes to be included in the QMS.
- 2.4 Top Management is responsible for identifying the data required for effective review of the QMS.
- 2.5 Top Management is responsible for identifying the management review team.
- 2.6 It is the responsibility of the management review team to schedule and conduct management review meetings in compliance with this procedure.
- 2.7 The Management Representative is responsible for collecting summary reports and data from the responsible functions and for ensuring adequate employee awareness of the regulatory and customer requirements.
- 2.8 The management review team members are responsible for bringing information and progress reports on action items assigned to them at previous management review meetings, information on planned changes that could affect the QMS, quality planning needs and activities and recommendations for improvements to the QMS.

### 3.0 Definitions

- 3.1 Top Management: [put your definition of top management here](#)
- 3.2 Management Review Team: [identify who will be on the management review team., by title of function, not individual names.](#)
- 3.3 Product realization processes: the processes that contribute or result in the product being produced or the product being provided.
- 3.4 Key Processes: product realization processes, customer related processes and quality management system processes that are included in the QMS.

### 4.0 Equipment/Software

- 4.1 Not Applicable

## INSERT YOUR COMPANY LOGO/NAME HERE

P-720-A

### Customer Related Processes

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#### 1.0 Purpose

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- 1.1 This procedure describes the process used for communicating with customers and reviewing information from the customer, including customer feedback.

#### 2.0 Responsibilities

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- 2.1 **Customer Service or Sales and Marketing Representatives** are responsible for taking orders from clients, determining customer requirements, and reviewing the orders for acceptance.
- 2.2 **Project Managers** are responsible for communicating with the client, keeping them informed as the project progresses and getting timely feedback from the client.
- 2.3 Employees that receive feedback from customers are responsible for communicating the feedback to **Customer Service department or the Project Manager**.

#### 3.0 Definitions

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- 3.1 None

#### 4.0 Equipment/Software

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- 4.1 No additional equipment or software required.

#### 5.0 Instructions

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- 5.1 Request for **product or service**:

Recommendations for customization are included in blue text

- 5.1.1 Orders are accepted **electronically or by phone, fax or mail**.
- 5.1.2 When a **customer service or sales and marketing** representative receives a request for **product or services** from a client or a potential client, **the representative** identifies the requirement and documents the customer requirements.
- 5.1.3 **Identify how you determine all customer requirements for each type of order.**

For example, for orders received electronically, by fax or by mail, the order is reviewed using a checklist (**Create a checklist for your organization, and enter your form number here**) to make sure all required information has been provided.

For orders received by phone the representative will use the checklist to collect all required information from the customer and document the information in the order database. Requirements are confirmed with the customer before acceptance.

Contracts may be negotiated between the customer and sales or

## Validation of Processes for Product Realization

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- 5.4 Documented procedures are established for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications are validated prior to initial use.
- 5.5 The validations are performed, and relevant documents are controlled with the procedure P-424 for document control.
- 5.6 The need for validation of processes for sterilization and sterile barrier systems is identified during the Planning of Product Realization Processes with procedure P-710 and Quality planning table F-710-001.
  - 5.6.1 The procedure P-730 for design and development is used to identify the transfer of sterile output requirements to manufacturing.
  - 5.6.2 If the planning identifies the need for validation, responsibility is assigned to a qualified employee, and performed according to the Process Validation work instruction.

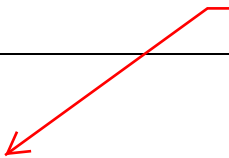
[An example of a typical process Validation Worksheet, F-756-001 can be used to monitor and record results.](#)
  - 5.6.3 The validation of sterilization and sterile barrier systems is performed prior to implementation and after product and process changes.
  - 5.6.4 Records showing results and conclusion of validation and needed actions from the validation are maintained with the procedure P-425 for control of records.

### 6.0 Forms and Records

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- 6.1 Records of validation
- 6.2 F-710-001 Quality planning table
- 6.3 [F-756-001 Typical Process Validation Worksheet](#)

Related forms, records, and documents are referenced to comply with document control requirements



### 7.0 Attachments

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- 7.1 None

### 8.0 Related Documents

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- 8.1 P-424 Document control
- 8.2 P-425 Control of Records
- 8.3 P-710 Planning of Product Realization Processes
- 8.4 P-730 Design and Development Planning

### 9.0 References

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- 9.1 None