Your Company Name, Inc.
City Name, State - www.yourwebsite.com - youremail@yourwebsite.com

QM-05	Management Responsibility (full text)		
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5.1 MANAGEMENT COMMITMENT

This section acknowledges ISO 13485 Clause 5.1, by generally responding to the five requirements, a) through e), for demonstrating management commitment, and pointing to other sections in the manual and to various operational procedures where the corresponding activities are defined and explained in more detail.

5.1.2 Top management is committed to communicate the importance of meeting customer as well as statutory and regulatory requirements. Management Representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of Management Representative is defined in *QM-05 Section 5.5 Organization and Communication*.

5.1.3 Top management defines the purpose and objectives for the quality management system. They are documented and communicated in the form of quality policy and quality objectives. Processes for establishing the quality policy and quality objectives are defined in this manual in *QM-05 Section 5.3 Quality Policy* and *Section 5.4 Quality System Planning*, and are further detailed in operational procedure *QOP-56-01 Management Review*.

5.1.4 Top management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions to maintain the effectiveness of the system. The process for conducting management reviews is defined in operational procedure *QOP-56-01 Management Review*.

5.1.5 Top management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. *QM-06 Section 6.1 Provision of Resources* defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

5.2 CUSTOMER FOCUS

5.2.1 The principal objective of the quality management system is to focus our organization on the customer, and in particular, on determining and meeting customer requirements and applicable regulatory requirements.

5.2.2 Top management ensures that customer requirements are determined and are well understood. This is done through the process of order and contract review, as defined in this manual in *QM-07 Section 7.2.1 Determination of Requirements Related to the Product* and *QM-07 Section 7.2.2 Review of Requirements Related to the Product*, and in associated operational procedures.

5.2.3 Top management ensures that customer requirements are met by inspecting and testing products at various stages of production and upon completion, as defined in this manual in *QM-08 Section 8.2.4 Monitoring and Measurement of Product*, and in associated operational procedures.

5.3   QUALITY POLICY

The role of this section is to define requirements for the quality policy and the process for formulating and reviewing the policy. The quality policy itself is documented at the beginning of the manual in Section 1.

5.3.1   Quality policy is documented in this manual in **QM-01 Section 1.1 Quality Policy**.

5.3.2   Quality policy is established by the by the <President>. In formulating the quality policy, the <President> ensures that the policy is appropriate to the purpose of the company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system.

5.3.3   Quality policy provides a framework for establishing specific quality objectives. The use of quality policy in setting quality objectives is addressed in this manual in **QM-05 Section 5.4.1 Quality Objectives** and in operational procedure **QOP-56-01 Management Review**.

5.3.4   Quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees. The quality policy is also communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's internet site.

External communication of the quality policy is not required. Delete the last two sentences of this clause if not appropriate.

5.3.5   Quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure its continual relevance and suitability. The process for reviewing the quality policy is defined in operational procedure **QOP-56-01 Management Review**.

5.4   QUALITY SYSTEM PLANNING

In ISO 13485 quality planning is addressed in several clauses. This section responds to Clauses 5.4.1 and 5.4.2, and thus addresses only planning of the overall quality system and for achieving quality objectives. Requirements for planning of manufacturing processes and product verification and validation activities are included in Clause 7.1.

5.4.1   Quality objectives

This documentation includes a dedicated system for establishing, documenting and implementing quality objectives (defined in procedure QOP-56-01 Management Review).

5.4.1.1   Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to maintain the effectiveness of the quality system.

5.4.1.2   Quality objectives are established at the management reviews of the quality system. Management reviews also initiate and monitor projects for achieving quality objectives. These processes for establishing, implementing and monitoring quality objectives are defined in operational procedure **QOP-56-01 Management Review**.

5.4.2   Quality system planning

5.4.2.1   Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is to:

- Achieve the quality policy;
- Ensure and demonstrate our ability to provide medical devices and related services that consistently meet customer requirements and applicable regulatory requirements;
- Comply with requirements of ISO 13485 standards and applicable regulatory requirements for quality management systems.

5.4.2.2   The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all processes of the quality system (refer to **QM-04 Section 4.1 Quality System Processes**).

5.4.2.3   Changes to the quality system are planned within the framework of management reviews (refer to operational procedure **QOP-56-01 Management Review**). These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational changes; or to maintain the effectiveness and efficiency of the quality system.

5.4.2.4   Planning of product realization, verification, and validation processes is addressed in this manual in **QM-07 Section 7.1 Planning of Product Realization**.

5.4.2.5   Approval and implementation of changes are controlled. The change control processes are documented in procedures **QOP-42-02 Control of Document Changes**, **QOP-73-03 Control of Design Changes**, and **QOP-75-04 Control of Process Changes**.

5.5   ORGANIZATION AND COMMUNICATION

The purpose of this section is to define the organizational structure for the quality system, to appoint a management representative, and to outline the system for internal communication.

5.5.1   Responsibility and authority

In this documentation, specific responsibilities are assigned directly under the quality manual sections and in operational procedures where the pertinent activity is defined. For example, the Corrective and Preventive Action procedure defines who is authorized to request corrective actions, and who is responsible for implementing them. Responsibilities and authorities are also defined in job descriptions (refer to QM Section 6.2 and to operational procedure QOP-62-01).

In addition, some auditors like to see a big matrix or a list with a summary of all responsibilities and authorities in the quality system. If you think that such a general matrix would help you in managing your system and you would like to make this documentation more "auditor friendly", you can establish such matrix and include it in this quality manual immediately following the organizational chart.

5.5.1.1   Interrelation of all personnel who manage, perform and verify work affecting quality is identified in the **Organizational Chart** enclosed at the end of this Clause 5.5.1, and in operational procedures and other documents defining these activities. Top management

ensures that the personnel have sufficient independence and authority to perform these tasks, in particular, internal auditors and personnel responsible for monitoring experience from the post-production stage and reporting adverse events.
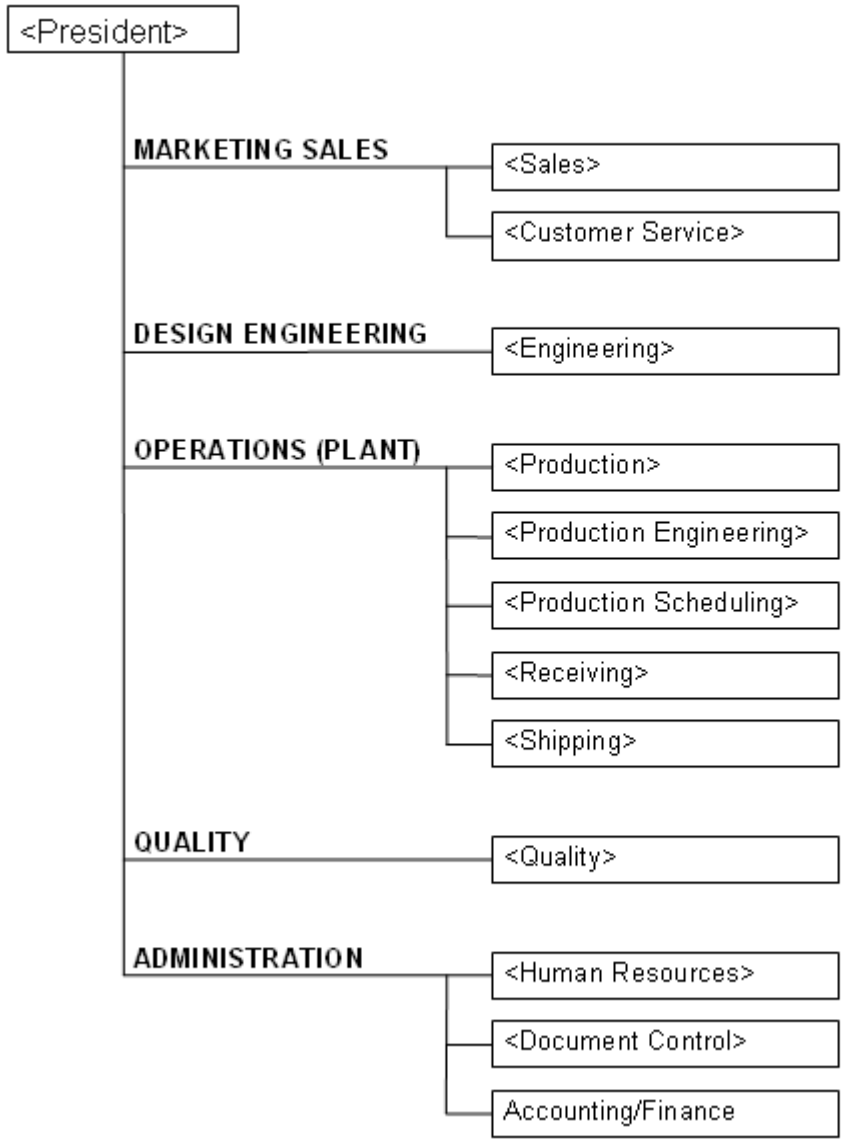
5.5.1.2   All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

5.5.1.3   Authorities and responsibilities for specific processes of the quality management system are defined:

- Throughout this quality manual and in every operational procedure where the specific quality system process or activity is documented;
- In Quality System Process sheets in **QM-04 Section 4.1** (as Process Owners); and
- In job descriptions.

    Job descriptions are not explicitly required under this section, but they are necessary to satisfy requirements of ISO 13485 Clause 6.2.2. Competence, Awareness and Training.

<COMPANY> ORGANIZATIONAL CHART

<President>

MARKETING SALES
- <Sales>
- <Customer Service>

DESIGN ENGINEERING
- <Engineering>

OPERATIONS (PLANT)
- <Production Engineering>
- <Production Scheduling>
- <Receiving>
- <Shipping>

QUALITY
- <Quality>

ADMINISTRATION
- <Human Resources>
- <Document Control>
- Accounting/Finance

This is a schematic organizational chart identifying all the functions that are referenced in this template quality manual and associated operational procedures (except for 'Accounting/Finance' which is not referenced anywhere but is depicted on the chart).

One of the first things you have to do when editing this documentation is to substitute this schematic functional chart with the actual organizational chart of your company, representing real departments, managers and supervisory personnel, and their interrelations.

After you establish your organizational chart, you will then associate all the functions from this schematic functional chart with the actual managers and supervisory personnel depicted on your own chart. For example, in a very small company, there may be an 'Office Manager' who is responsible for <Human Resources>, <Purchasing>, <Receiving>, and

<Document Control>.

The next step is to carefully review the manual and all operational procedures, and change the assignments of authorities and responsibilities to reflect the actual organization of you company. Continuing with the example, every time the quality manual or a procedure invokes <Human Resources>, <Purchasing>, <Receiving>, or <Document Control>, these bracketed expressions (in red font) must be substituted with 'Office Manager'.

This simple substitution will work in most cases, but sometimes you will need to do a little more involved editing, especially in a larger company with more specialized functions. For example, in this documentation there is only one <Quality> function responsible for both the quality system and the QC/Metrology. If in your company these are separate functions, you will need to edit the procedures carefully to reassign these responsibilities accordingly.

The importance of proper coordination of this documentation with the actual organizational structure of your company cannot be overemphasized. Any discrepancies will cast a doubt on the integrity and relevance of the whole documentation. If a company is not willing to make the effort to coordinate the documentation on this basic level, why should anyone trust that the documentation was adapted to the actual products, processes, and practices.

5.5.2 Management Representative

The manager responsible for regulatory affairs and/or for quality assurance is a natural choice for Management Representative. However, anyone form the management team may be appointed, irrespective of his or her other responsibilities. It is not required that the representative be actively involved in the day-to-day operation of the quality system.

5.5.2.1 <Company Name> appoints as the Management Representative the <Quality Assurance Manager>. Management Representative has the authority and responsibility to:

- Ensure that the quality management system is implemented and maintained;
- Promote awareness of regulatory and customer requirements throughout the organization;
- Report to the top management on the efficiency and performance of the quality system, and
- Coordinate communication with external parties on matters relating to the quality system and ISO 13485 registration.

5.5.3 Internal communication

This section responds to ISO 13485 Clause 5.5.3 requiring that "Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality system". The section outlines various methods for communicating this type of information, and references appropriate procedures, in particular those pertaining to document control, training, and management reviews.

Although an operational procedure for internal communication is not explicitly required in the standard, such procedure would be quite useful, and even expected, in a larger organization, especially with multiple divisions and/or locations.

As written, this section is rather generic and vague. Try to refer to more specific communication methods and events. For example, if there is a weekly production meeting, or a monthly newsletter, or a bulletin board, or an intranet site, etc.; this is the place to document it (or, better, in an operational procedure).

5.5.3.1   Internal communication regarding the quality system flows two ways:

The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

The organization communicates to the management information and data regarding quality performance and the effectiveness of the quality system

5.5.3.2   The information is communicated through:

- Paper or electronic documents, such as manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.;
- E-mails, memos, and meetings;
- Bulletin boards and the intranet site and newsletter;
- Training and awareness programs; and
- Employee suggestions, surveys and feedback.

> *Edit this list to delete the types of documents and communication modes that are not used in your company.*

Operational Procedures *QOP-42-01 Control of Documents* and *QOP-62-01 Competence, Awareness and Training* define processes for distributing documents and for providing training and awareness programs.

5.5.3.3   Management review meetings have a special role in ensuring proper communication between the top management and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate and communicate policies and directives to change and/or improve the quality system. This process is defined in Operational Procedure *QOP-56-01 Management Review*.

5.5.3.4   <Quality Manager> has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the top management.

5.6   MANAGEMENT REVIEW

> *This section of the manual is basically a brief summary of operational procedure QOP-56-01, Management Review. If you feel that it is still too detailed, you can cut it back further. All you really need is a clear reference to the procedure, as in Clause 5.6.1.1.*

5.6.1   General

5.6.1.1   Management reviews of the quality management system are conducted at least once a year. More frequent reviews are scheduled in periods when organizational, technological, product, or other changes require increased attention and input from the top management. The processes for initiating and conducting management reviews and for documenting their conclusions are defined in Operational Procedure *QOP-56-01 Management Review*.

5.6.1.2   The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

    If you only need to comply with ISO 13485 (not ISO 9001), you can delete the last bullet, as there are no requirements for continual improvement.

5.6.1.3   Management reviews are chaired by the \<President\> and are attended by \<Quality\>, \<Sales\>, \<Customer Service\>, \<Engineering\>, \<Production Engineering\>, \<Purchasing\>, \<Production\>, and \<Human Resources\>.

    Edit to name the specific managers who must attend the management reviews. Coordinate with procedure QOP-56-01.

5.6.2   Review input

5.6.2.1   Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Feedback;
- Complaint handling;
- Reporting to regulatory authorities;
- Audits;
- Monitoring and measurement of processes;
- Monitoring and measurement of product;
- Corrective action;
- Preventive action;
- Follow-up actions from previous management reviews;
- Changes that could affect the quality management system;
- Recommendations for improvement;
- Applicable new or revised regulatory requirements.

5.6.3   Review output

5.6.3.1   Management reviews are concluded with setting new quality objectives and other actions related to:

- improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
- improvement of product related to customer requirements;
- changes needed to respond to applicable new or revised regulatory requirements;
- resource needs.

5.6.3.2   Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for

implementation of these actions.