[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

QUALITY MANUAL

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1. About organization

1.1. Organizational structure

Commented [AES4]: Adapt to organization needs.

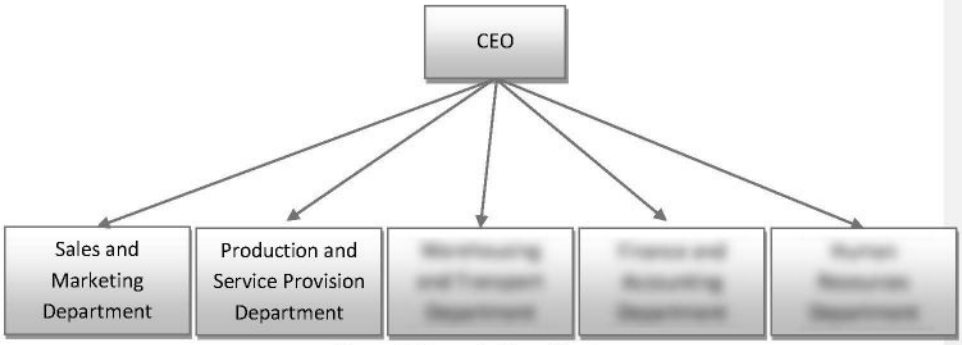

Figure 1: Organizational chart

2. Purpose, scope and users

The Quality Manual documents the quality management system of [organization name] and demonstrates the capability of [organization name] to continuously provide products and services that address customer requirements.

Commented [AES5]: If the Quality Management System is

Commented [AES6]: Include the name of your organization.

The scope of this Quality Management System (QMS) is: [define scope]

Commented [AES7]: Write the scope of your Quality

Commented [AES8]: Include the name of your organization.

Commented [AES9]: Delete this if it is not applicable to your organization.

2.1. Exclusions and not applicable requirements

[Organization name] excludes the following clauses of ISO 13485:2016:

Commented [AES10]: Include the name of your organization.

Commented [AES11]: Exclusions can be made only from

- [clause] – [justification]

Commented [AES12]: Write the clause of the standard that you can exclude from your QMS.

Commented [AES13]: Include justification for why you have

3. Terms and definitions

For the purpose of this Quality Manual, [organization name] references the terms and definitions listed in the ISO 13485:2016

Commented [AES14]: Include the name of your organization.

The latest revision of these documents applies.

4. Quality Management System

4.1. General requirements

In order to function effectively, [organization name] adopted a process approach by:

Commented [AES15]: Include the name of your organization.

- Determining processes, their order and interaction shown in process map (see below)
- Determining criteria and methods needed to ensure execution and effective management of processes according to Matrix of Key Performance Indicators
- Ensuring availability of resources and information necessary for support of execution and monitoring of processes, described in chapter 6 of this Quality Manual
- [illegible]
- [illegible]

[Organization name] may choose to outsource a process and must manage outsourced processes when:

Commented [AES16]: Include the name of your organization.

- It's not competent to execute all processes needed for achieving quality requirements
- [illegible]

Commented [AES17]: E.g., for commercial reasons.

Control of outsourcing processes is executed according to Procedure for Purchasing and Evaluation of Suppliers.

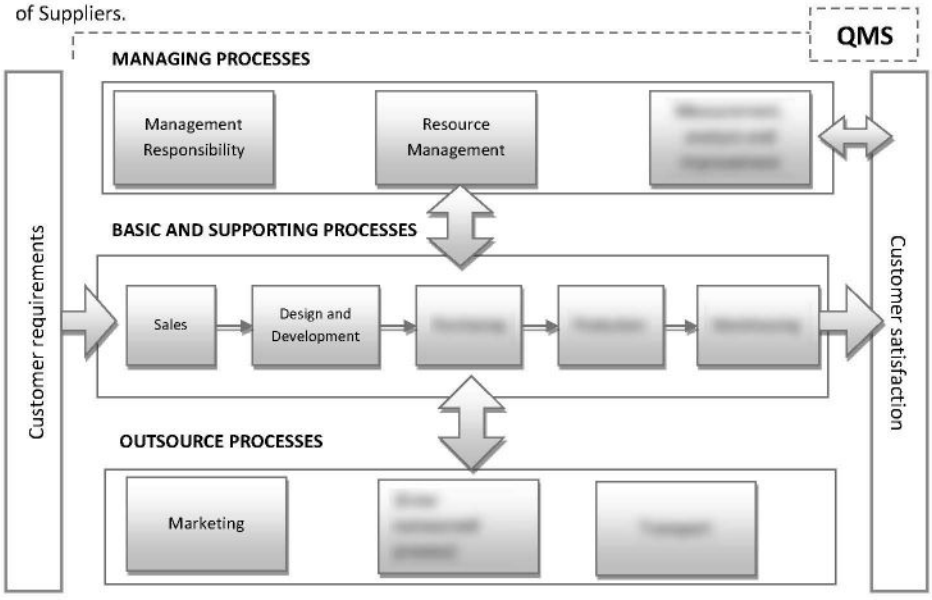

Figure 2: Process Map

4.2. Document requirements

4.2.1. General

[Organization name] documented the Quality Management System by:

- Quality Policy
- Quality Manual
- [illegible]
- [illegible]

Commented [AES18]: You can find a template for this [illegible]

4.2.2. Quality manual

A global description of the structure and way of functioning of the quality management system in [organization name] are given in the Quality Manual; detailed descriptions are given in referring procedures.

[illegible] Quality Manual, which is approved by [illegible]. The Quality Manual is periodically reviewed by [illegible] at least once a year.

Commented [AES19]: E.g., CEO

Commented [AES20]: E.g., CEO

The Quality Manual is delivered on request to customers, certification bodies or third parties with approval of [job title] as an UNCONTROLLED COPY.

Commented [AES21]: E.g., CEO

[illegible]

4.2.3. Medical device file

[Job title] must ensure that a medical device file exists for each medical device type or medical device family. [illegible]

Commented [AES22]: Adapt to organization practice.

E.g., CEO

4.2.4. Control of documents

[Organization name] controls documents required by the ISO 13485:2016 standard, documents which the organization determined as necessary and external documents according to [illegible]

Commented [AES23]: You can find a template for this [illegible]

4.2.5. Control of records

[Organization name] controls the records to provide evidence of conformance with requirements and about the functioning quality management system according to [illegible]

5. Management responsibility

5.1. Management commitment

Top-level management demonstrates its commitment to the development and application of the quality management system and continual improvement of its effectiveness by:

- Informing employees of [organization name] about the importance of meeting customer requests and legal and regulatory requirements through internal meetings, direct communication, and communicating the Quality Policy
- [illegible]
- [illegible]

5.2. Customer focus

Top-level management of [organization name] ensures that customer requests are determined and [illegible]

5.3. Quality policy

Top-level management of [organization name] defined [illegible]

5.4. Planning

5.4.1. Quality objectives

Heads of departments of [organization name] propose objectives for their departments to the CEO, who reviews and approves them. [illegible]

5.4.2. Quality management system planning

Regularly performed Management review is the basic means of planning the QMS. [illegible]

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

Top-level management defines responsibilities through QMS procedures and [titles of documents].

[illegible]

5.5.2. Management Representative

[Job title] appoints [name of employee] as Management Representative and assigns him responsibilities and authorities for:

Commented [AES24]: Name other documents that define [illegible]

Commented [AES25]: Delete this if it is not applicable to your organization.

Commented [AES26]: E.g., CEO

- Establishing, maintaining and improving of the QMS by monitoring the execution of corrective and preventive measures, and continual monitoring of system performance, nonconformities and possibilities for improvement
- [illegible]
- [illegible]

5.5.3. Internal communication

Internal communication is performed directly, by mail, [illegible]

Commented [AES27]: Adapt to organization practice.

5.6. Management review

Top-level management of [organization name] conducts regular reviews of the QMS, at least once a year, according to Procedure for Management Review.

[illegible]

Commented [AES28]: E.g., CEO, Management Representative

6. Resource management

6.1. Provision of resources

Top-level management of [organization name] is responsible for provision of planned resources in order to meet requests, needs and expectations of customers [illegible]

6.2. Human resources

During the planning and reviewing of resources, [job title] determines needs for staff and their competence, [illegible]

Commented [AES29]: E.g., CEO, Human Resources Manager

Commented [AES30]: You can find a template for this [illegible]

6.3. Infrastructure

[Organization name] provided and maintains necessary infrastructure for executing processes without nonconformities, including equipment, facilities and supporting services.

[illegible]

6.4. Work environment and contamination control

Commented [AES31]: If there are no specific requirements for [illegible]

[Job title] ensures that the working environment and contamination control meets the requirements [illegible]

Commented [AES32]: E.g., Production Manager, QA Manager

7. Product realization

7.1. Planning of product realization

[Job title] is responsible for planning and developing processes needed for product realization

7.2. Customer-related processes

[Job title] appoints persons responsible for determining and reviewing requests for product and

7.3. Design and development

[Job title] appoints persons responsible for planning, realization and management of product design and development

7.4. Purchasing

By documenting an adequate method for evaluation and selection of suppliers, [organization name]

7.5. Production and service provision

[Organization name] defined activities of planning and executing the product realization process under controlled conditions, in order to ensure full capability of the process and to prevent nonconformity occurrence. At the same time, all necessary resources for execution of these processes are provided according to Procedure for Production and Service Provision and Warehousing Procedure.

The preservation of the conformity of product to requirements during processing, storage, handling, and distribution of medical devices is described within Procedure for Production and Service Provision and Procedure for Sterile Medical Devices.

Activities in pre-requisite installation, calibration, and acceptance of medical devices are described within Procedure for Production and Service Provision.

Commented [AES33]: This can be excluded from QMS in cases

Commented [AES34]: Adapt to organization practice.

E.g., Production Manager

Commented [AES35]: You can find a template for this

Commented [AES36]: You can find a template for this

Commented [AES37]: This can be excluded from QMS in case

Commented [AES38]: Adapt to organization practice.

E.g., Sales Manager

Commented [AES39]: You can find a template for this

Commented [AES40]: You can find a template for this

Commented [AES41]: Delete if organization doesn't perform

Commented [AES42]: E.g., CEO, Management Representative

Commented [AES43]: You can find a template for this

Commented [AES44]: This can be excluded from QMS in cases

Commented [AES45]: You can find a template for this

Commented [AES46]: It is possible to exclude the following clauses from 7.5:

- 7.5.2 in situations where there is no specific product, when the medical device is a service
- 7.5.3 in cases when there are no installation activities
- 7.5.4 in cases when there are no service activities

Commented [AES47]: Include the name of your organization.

Commented [AES48]: You can find a template for this

Commented [AES49]: You can find a template for this

Commented [AES50]: You can find a template for this

7.6. Control of monitoring and measurement

[Organization name] identified processes where measurements are conducted to demonstrate quality of processes or products. [illegible]

Commented [AES51]: This can be excluded in cases when [illegible]

Commented [AES52]: You can find a template for this [illegible]

8. Measurement, analysis and improvement

8.1. General

[Organization name] has controls at all stages to demonstrate the conformity of both the product and the Quality Management System (QMS), and to continually improve the QMS.

[illegible]

Commented [AES53]: Adapt to organization.

[illegible]

Documented procedures are maintained to apply statistical techniques for the control, verification and continuous improvement of process activities. Production performance, in-process inspection, and test results are recorded in electronic databases and tracked.

[illegible]

8.2. Monitoring and measurement

Monitoring and measurements are conducted to determine customer satisfaction. [illegible]

8.2.1. Feedback

[Job title] gathers and monitors information relating to whether the organization has met customer requirements. [illegible]

Commented [AES54]: Adapt to organization practice.

E.g., Sales Manager

8.2.2. Complaint handling

Complaint handling in [organization name] is implemented according to [illegible]

8.2.3. Reporting to regulatory authorities

Reporting to regulatory authorities in [organization name] is implemented according to

Commented [AES55]: You can find a template for this

8.2.4. *Internal audit*

[Organization name] conducts internal audits in planned intervals to demonstrate conformance and effectiveness

Commented [AES56]: You can find a template for this

8.2.5. *Monitoring and measurement of processes*

Effectiveness of product realization processes is monitored and measured through parameters for

Commented [AES57]: You can find a template for this

8.2.6. *Monitoring and measurement of product*

Product characteristics are measured and monitored throughout the manufacturing process, to ensure the product meets established requirements.

Commented [AES58]: Adapt to organization practice.

8.3. Control of nonconforming product

Commented [AES59]: Requirement 8.3.4 can be "not

[Organization name] handles nonconforming product in a way that prevents its further use or delivery,

Commented [AES60]: You can find a template for this

8.4. Analysis of data

By systematic gathering, processing and analyzing of data, [organization name] evaluates the effectiveness of the organization

Commented [AES61]: You can find a template for this

8.5. Improvement

8.5.1. *General*

[Organization name] is committed to the continual improvement of the quality management system.

Commented [AES62]: Include the name of your organization.

8.5.2. *Corrective action*

[Organization name] has established a corrective action system to investigate and document the root cause and actions to correct internally and externally reported nonconformities.

Commented [AES63]: You can find a template for this

8.5.3. *Preventive action*

[Organization name] has established a preventive action system to report, investigate and prevent potential nonconformities. The preventive action system emulates the corrective action system.

Commented [AES64]: Include the name of your organization.

The preventive actions taken will be appropriate to the effects of the potential problems according to Procedure for Corrective and Preventive Action.

[job title]
[name]

_____
[signature]

Commented [AES65]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.