[Organization logo]

[Organization name]

Commented [134851]: All fields in this document marked by square brackets [ ] must be filled in.

QUALITY MANUAL

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [134852]: Adapt to the existing practice in organization.

Distribution list

Commented [134853]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

Date	Version	Created by	Description of change
	0.1	13485Academy	Basic document outline

Table of contents

1. About organization 4
1.1. Organizational structure 4
2. Purpose, scope and users 4
2.1. Exclusions 4
3. Terms and Definitions 4
4. Quality Management System 4
4.1. General requirements 5
4.2. Document requirements 5
4.2.1. General 5
4.2.2. Quality manual 6
4.2.3. Medical device file 6
4.2.4. Control of documents 6
4.2.5. Control of records 6
5. Management responsibility 6
5.1. Management commitment 6
5.2. Customer focus 7
5.3. Quality policy 7
5.4. Planning 7
5.4.1. Quality objectives 7
5.4.2. Quality management system planning 7
5.5. Responsibility, authority and communication 7
5.5.1. Responsibility and authority 7

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5.5.2. Management representative 7
5.5.3. Internal communication 8
5.6. Management review 8
6. Resource management 8
6.1. Provision of resources 8
6.2. Human resources 8
6.3. Infrastructure 8
6.4. Work environment and contamination control 8
7. Product realization 8
7.1. Planning of product realization 8
7.2. Customer-related processes 9
7.3. Design and development 9
7.4. Purchasing 9
7.5. Production and service provision 9
7.6. Control of monitoring and measurement 9
8. Measurement, analysis and improvement 10
8.1. General 10
8.2. Monitoring and measurement 10
8.2.1. Feedback 10
8.2.2. Complaint handling 10
8.2.3. Reporting to regulatory authorities 10
8.2.4. Internal audit 10
8.2.5. Monitoring and measurement of processes 11
8.2.6. Monitoring and measurement of product 11
8.3. Control of nonconforming product 11
8.4. Analysis of data 11
8.5. Improvement 11
8.5.1. General 11
8.5.2. Corrective action 11
8.5.3. Preventive action 11

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1. About organization

1.1. Organizational structure

Commented [134854]: Adapt to organization needs.

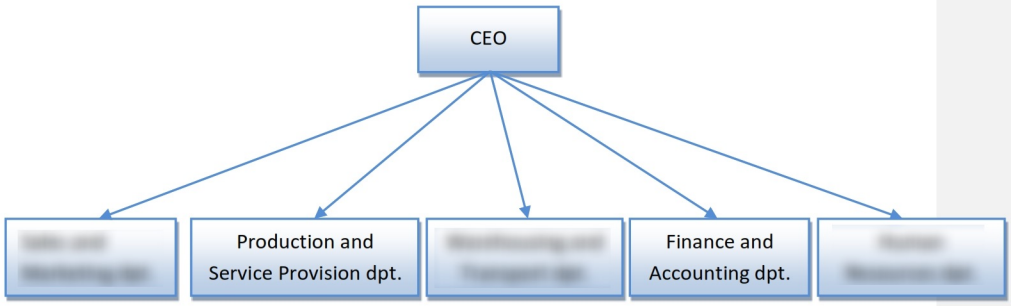

Figure 1: Organizational chart

2. Purpose, scope and users

The quality manual documents the quality management system of [organization name] and [illegible] that address customer requirements.

Commented [134855]: If Quality Management System is applied only to part of organization, name that part of organization.

2.1. Exclusions

Commented [134856]: Exclusions can be made only from clause 7 ISO9001:2008 standard. Name the clauses excluded from QMS and provide justifications for exclusions.

[Organization name] excludes the following clauses of ISO 13485:2016 and ISO 9001:2015:

Commented [134857]: Delete if your organization hasn't implemented ISO 9001:2015

-

[illegible]

3. Terms and Definitions

For the purpose of this Quality Manual, [organization name] references the terms and definitions [illegible]

The latest revision of these documents applies.

4. Quality Management System

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4.1. General requirements

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

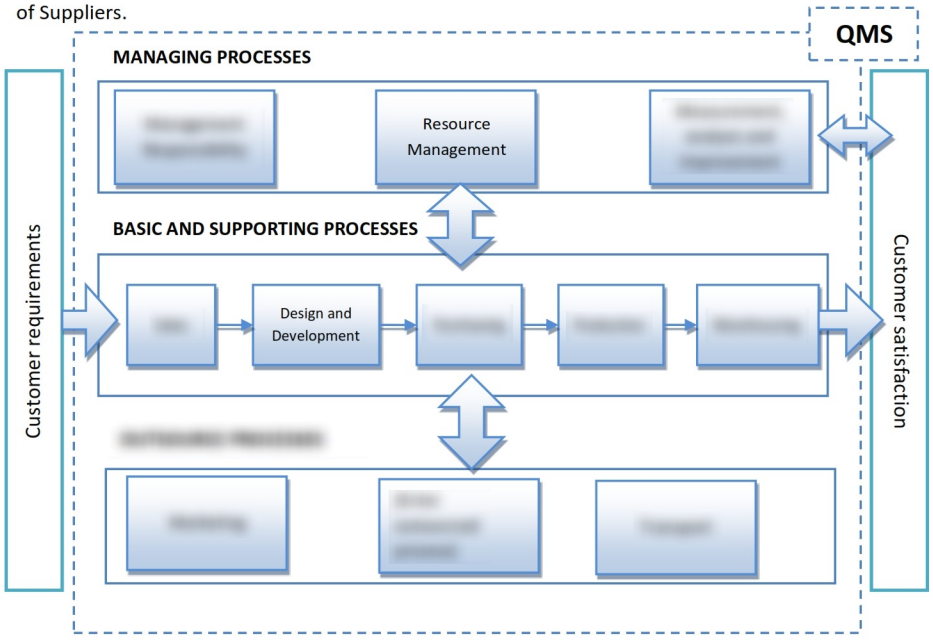
- Determining processes, their order and interaction shown in process map (see below)
- [illegible] processes according to Matrix of Key Performance Indicators
- [illegible] monitoring of processes, described in chapter 6 of this Quality Manual
- [illegible] described in chapter 8 of this Quality Manual
- [illegible] processes, as described in chapter 8 of this Quality Manual

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

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

Commented [134858]: E.g. for commercial reasons.

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



4.2. Document requirements

4.2.1. General

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[Organization name] documented the Quality Management System by:

- Quality Policy
- Quality Manual
- Procedures
- Records

4.2.2. Quality manual

[organization name] are given in the Quality Manual; detailed descriptions are given in referring procedures.

A Management Representative creates the Quality Manual, which is approved by [job title]. The Quality Manual is periodically reviewed by [job title] at least once a year.

Commented [134859]: E.g. CEO

Commented [1348510]: E.g. CEO

The Quality Manual is delivered on request to customers, certification bodies or third parties with

Commented [1348511]: E.g. CEO

4.2.3. Medical device file

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

Commented [1348512]: 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 to Procedure for Document and Record Control.

4.2.5. Control of records

[Organization name] controls records to provide evidence of conformance with requirements and according to Procedure for Document and Record Control.

5. Management responsibility

5.1. Management commitment

[Top-level management] demonstrates its commitment to the development and application of the

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- Informing employees of [organization name] about the importance of meeting customer [illegible] communication, and communicating the Quality Policy
- [illegible]
- Providing necessary resources, as described in chapter 6 of the Quality Manual

5.2. Customer focus

[Top-level management] of [organization name] ensures that customer requests are determined and met by complying with clause 7.2.1 and clause 8.2.1 of this Quality Manual.

5.3. Quality policy

[Top level management] of [organization name] defined the Quality Policy as a separate document.

5.4. Planning

5.4.1. Quality objectives

Heads of departments of [organization name] [illegible] who reviews and approves them. Quality objectives are defined during management review in a separate document. Objectives must be measurable and aligned with the Quality Policy.

5.4.2. Quality management system planning

Regularly performed management review is the basic means of planning the QMS. Special attention [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].

Commented [1348513]: Name other documents that define responsibilities and authorities within organization. E.g. Job classification, Job description, etc. Delete if such documents don't exist.

5.5.2. Management representative

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

- [illegible] nonconformities and possibilities for improvement
- Raising awareness of employees about the importance of meeting customer requests by [illegible] objectives of the organization
- [illegible]

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5.5.3. Internal communication

Internal communication is performed directly, by mail, intranet, email and phone.

Commented [1348514]: 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.

[Job title] reviews the organization's Quality Management System at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness.

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 and to ensure continuous improvement of QMS effectiveness.

6.2. Human resources

During the planning and reviewing of resources, [job title] determines needs for staff and their competence, education, skills and experience according to Procedure for Human Resources.

6.3. Infrastructure

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

By conducting documented activities, [organization name] provides constant availability and reliability of equipment according to Procedure for Infrastructure and Work Environment and Procedure for Equipment Maintenance and Measuring Equipment.

6.4. Work environment and contamination control

[Job title] ensures that the working environment and contamination control meets the requirements of process, product, and laws and regulations according to Procedure for Infrastructure and Work Environment.

7. Product realization

7.1. Planning of product realization

Commented [1348515]: This can be excluded from QMS in cases when organization executes routine activities that don't affect QMS, or in simple products and services, e.g. handcraft shop.

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[Job title] is responsible for planning and developing processes needed for product realization according to Procedure for Production and Service Provision and the Procedure for Risk Management.

Commented [1348516]: Adapt to organization practice. E.g. Production Manager

7.2. Customer-related processes

Commented [1348517]: This can be excluded from QMS in case of catalogue sales, TV shop, etc.

[Job title] appoints persons responsible for determining and reviewing requests for product and communication with customers according to Sales Procedure and Procedure for Customer Communication, Feedback and Complaints.

Commented [1348518]: Adapt to organization practice. E.g. Sales Manager

7.3. Design and development

Commented [1348519]: Delete if organization doesn't perform design and development process or if it's an outsourced process.

[Job title] appoints persons responsible for planning, realization and management of product design and development and project management according to Procedure for Design and Development.

7.4. Purchasing

Commented [1348520]: This can be excluded from QMS in cases when organization performs only small procurements that doesn't significantly affect its business, e.g. legal office, consulting agency, etc.

By documenting an adequate method for evaluation and selection of suppliers, [organization name] ensures that delivered product is compliant with specified purchasing requests according to Procedure for Purchasing and Evaluation of Suppliers.

7.5. Production and service provision

Commented [1348521]: The whole clause is rarely excluded. It's possible to exclude only subsections:

[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 process of identification and traceability allowing for complete and up-to-date histories of all batches of products from the starting materials to the complete final product in [Organization name] is carried out according to Procedure for Production and Service Provision.

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.

The activities for the documentation and validation of computer software used in the Quality Management System and production and service provision are described within Procedure for Software Validation.

7.6. Control of monitoring and measurement

Commented [1348522]: This can be excluded in cases when organization doesn't use equipment for monitoring and measurement in order to verify product compliance with customer request.

[Organization name] identified processes where measurements are conducted to demonstrate quality of processes or products. Based on needs for controlling and testing of product, [organization

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name] identified necessary measuring equipment according to Procedure for Equipment Maintenance and Measuring Equipment.

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.

[Organization name] identifies required statistical techniques and maintains procedures to implement statistical techniques to control and verify process capabilities and product characteristics.

Commented [1348523]: Adapt to organization.

[Organization name] is responsible to identify activities requiring control through statistical techniques.

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.

Individual employee performance is tracked and recorded as part of production performance.

8.2. Monitoring and measurement

Monitoring and measurements are conducted to determine customer satisfaction. This information is gathered from various sources and placed into reports for management to understand and take appropriate action when necessary.

8.2.1. Feedback

[Job title] gathers and monitors information relating to whether the organization has met customer requirements. All activities related to the sales process, feedback, the customer's requests to delivery of product and service are described in Procedure for Customer Communication, Feedback and Complaints.

Commented [1348524]: Adapt to organization practice. E.g. Sales Manager

8.2.2. Complaint handling

Complaint handling in [Organization name] is implemented according to Procedure for Customer Communication, Feedback and Complaints.

8.2.3. Reporting to regulatory authorities

Reporting to regulatory authorities in [Organization name] is implemented according to Procedure for Adverse Event Investigation and Reporting.

8.2.4. Internal audit

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[Organization name] conducts internal audits in planned intervals to demonstrate conformance and effectiveness of the Quality Management System according to Procedure for Internal Audit.

8.2.5. Monitoring and measurement of processes

Effectiveness of product realization processes is monitored and measured through parameters for every identified process defined in Matrix of Key Process Indicators.

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. Evidence of conformity with the acceptance criteria is maintained, and electronic records identify inspection and test activities according to Procedure for Production and Service Provision.

Commented [1348525]: Adapt to organization practice.

8.3. Control of nonconforming product

[Organization name] handles non-conforming product in a way that prevents its further use or delivery, according to Procedure for Control of Non-Conforming Product.

8.4. Analysis of data

By systematic gathering, processing and analyzing of data, [organization name] evaluates the effectiveness of the organization related to defined plans and objectives and identifies areas for improvement defined in Procedure for Data Analysis.

8.5. Improvement

8.5.1. General

[Organization name] is committed to the continual improvement of the quality management system. This is accomplished through the use of the quality policy, quality objectives, analysis of quality data, audit results, corrective and preventive actions, and management reviews.

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. Corrective actions are assigned to a responsible individual and tracked by number and completion date according to Procedure for Corrective and Preventive Actions.

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.

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

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