

Documents are in Microsoft Word for ease of editing

Insert Your Company Name/Logo Here

ISO 13485:2016

Quality Systems Manual

Document No. QMD-001

Street Address

City,

State / Province

Zip / Postal code

Instructions:

Blue text throughout the manual highlight areas for customization



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Introduction

Provides general purpose and description of Quality Manual



Your Company developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Your Company meets the requirements of the international standard ISO 13485:2016. This system addresses the design, development, production, installation, and servicing of the company's products.

The manual is divided into eight sections that correlate to the Quality Management System sections of ISO 13485:2016. Each section begins with a policy statement expressing Your Company's obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

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Section 1: Scope

1.1 General

Describe the scope of your QMS:

The quality manual outlines the policies, procedures and requirements of the Quality Management System. The system is structured to comply with the conditions set forth in the International Standard ISO 13485:2016.

1.2 Application

Your Company has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- Identify permissible exclusions in clauses 6, 7 or 8.
- Document the justification for the exclusions that are made.
- If none, document that there are no exclusions.

Any text may be edited. Blue text provides examples of what you may want to use. Black text is text that describes the QMS developed by the 13485store.com.

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Section 3: Definitions

3.0 Quality Management System Terms and Definitions

a. The terms and definitions outlined in ISO 9000:2015 apply, such as [for example](#):

Customer supplied product - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.

Quality Records – Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable

- [Add, delete and revise definitions as appropriate to your quality system.](#)

You can search and replace "Your Company" with your own company name.

b. This section is for the definitions unique to [Your Company](#).

[Review Section 3 of ISO 13485:2016 and add, delete and revise definitions as appropriate to your quality system, such as for example:](#)

Medical device - Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medical device family – Group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function.

Sterile medical device – Medical device intended to meet the requirements for sterility.

Sterile barrier system – Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

Advisory notice - Notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action

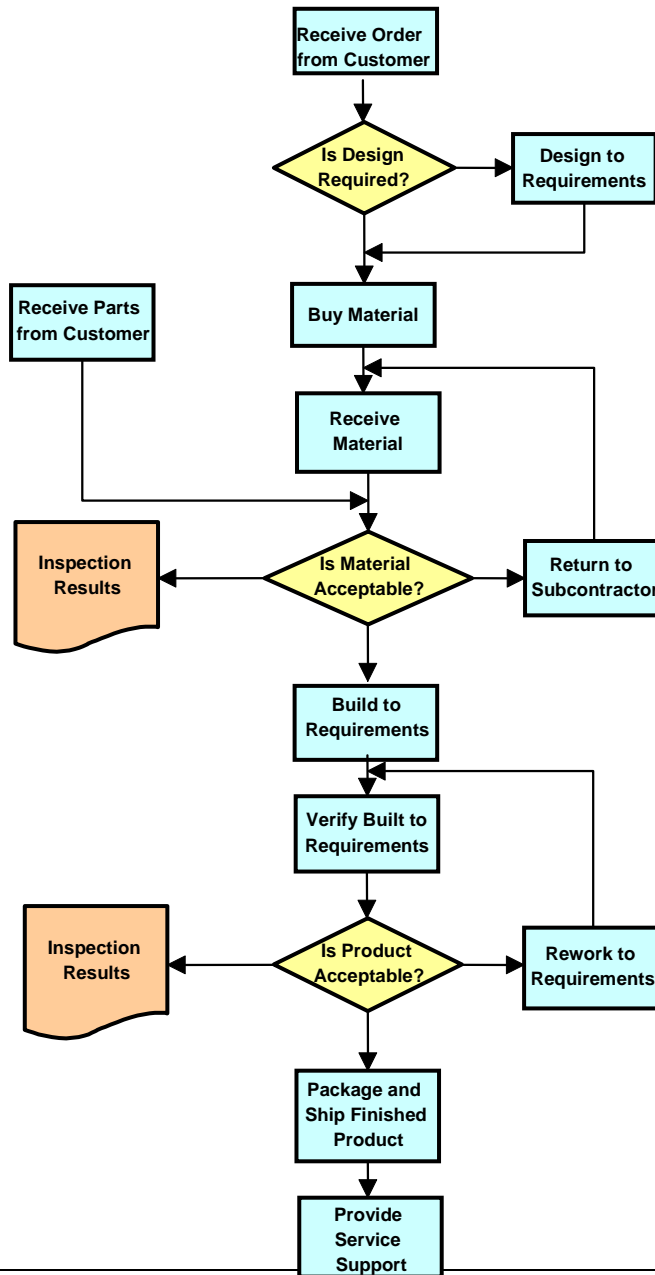
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Insert your process flow diagram A-710-001 here:

Example of a Manufacturing Process flow

Related documents are referenced.



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QMS Measuring, Monitoring and Analysis Table

Process Point	Planned Measurement	Frequency	Performed by	Analyzed by	Analysis Methodology	Documentation	Quality Objectives	Improvement Goals
Customer Request	On time delivery			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
	# of Customer Concessions			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Planning	Completeness of Planning Tables			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
R&D	# of New products or processes			Management Review			Future goal to be established	
Facility	# of maintenance issues			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Human Resources	Training effectiveness			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Equipment	Downtime			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
	Out of calibration equipment			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	

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Purchasing	Supplier quality reports			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Receipt and storage	Damage			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Processing	(List required summaries)			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Release of Product	Nonconforming product			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
	Customer concessions			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Customer feedback	# of Complaints			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
	Survey results			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	
Management	Corrective actions % effective			Management Review			Establish baseline, set goal next Mgmt Rev Meeting	

1.0 Purpose

- 1.1 This procedure describes the process for controlling the design and development of product or services.

2.0 Responsibilities

- 2.1 [The R&D Manager](#) is responsible for assigning a project manager and project numbers.
- 2.2 [The project manager](#) is responsible for initiating the design plan, getting appropriate approvals and holding design reviews.

3.0 Definitions

- 3.1 Design Verification: determination that the product meets requirements.
- 3.2 Design Validation: determination of the product's ability to meet user needs.
- 3.3 Design Changes: changes made to the inputs or plan during design and development activities.

4.0 Equipment/Software

- 4.1 No additional equipment or software required.

5.0 Instructions

- 5.1 Design and development projects are initiated for new product or process development. The need for a new product or process may arise based on customer requests, market conditions, new product or process ideas, new equipment or other situation.
- 5.2 [The R&D manager](#) designates a project manager for the project, assigns a project number, and logs the project in the log.
- 5.3 The project manager prepares a Project Plan form by documenting the following information on the Project Plan:
- 5.3.1 Competent design team and technical interface.
 - 5.3.2 Resources needed.
 - 5.3.3 Design and development stages and the review, verification, validation and design transfer activities that are appropriate at each design stage. The design plan is updated as the design and development progresses.
 - 5.3.4 Design transfer activities ensure that design and development outputs are verified as suitable for manufacturing before they become final production specifications.
 - 5.3.5 Methods for traceability of design and development outputs to inputs
- 5.4 The design team collects design inputs and documents the inputs on the design

- plan or on an attachment to the design plan.
- 5.4.1 Inputs include:
- a) Functional, performance and safety requirements.
 - b) Applicable regulatory and legal requirements
 - c) Information from previous designs
 - d) Outputs of risk management
 - e) Other applicable requirements
 - f) [Estimated costs](#)
 - g) [Safety requirements](#)
- 5.4.2 The team reviews the inputs to make sure they are complete. Incomplete, ambiguous or conflicting inputs are resolved by the team.
- 5.4.3 Inputs are reviewed for adequacy and approved by [Management](#).
- 5.4.4 The team assigns a timeline to the project, determines appropriate design reviews, validation and verification activities and documents them on the design plan.
- [\(You may want to have a design review at this point in the project. Have the R&D manager or similar function review the project and approve it to move into the development stage. Others identified as technical interfaces may also have approval responsibilities at this point. Have these functions sign off on the project plan as evidence of their approval.\)](#)
- 5.5 Design outputs are documented and filed in the design project file. Design outputs are documented and updated in a manner that enables them to be verified against the design inputs.
- 5.5.1 Outputs include:
- a) [Product specifications](#)
 - b) [Documented processes including manufacturing specifications, inspection and test methods and criteria](#)
 - c) [Product quality plans](#)
 - d) [Engineering prints, drawings and diagrams](#)
 - e) [Engineering or research logbooks](#)
 - f) [Prototypes](#)
 - g) [Product inspection and process monitoring information \(to be documented on the Product Inspection and Process Monitoring Table\)](#)
 - h) [Records of outputs are maintained.](#)
- 5.6 The design team verifies the design output against design input by the method identified in the design plan.
- 5.6.1 Verification plans include the verification methods and acceptance criteria

and may include:

- a) Laboratory experiments
- b) Line Trials
- c) Prototype evaluation
- d) Calculations
- e) Inspection and Test
- f) Statistical techniques with the sample size rationale.

- 5.6.2 For medical devices that interface or connect to other medical devices, verification includes the confirmation that outputs meet design inputs when interfaced or connected.
- 5.6.3 Verification is documented and filed in the design project file and include records of results and conclusions of verification.
- 5.7 The team holds a design review meeting to review verification results. If verification is acceptable, the project will proceed to design validation. If results are not acceptable, the team will determine if a design change is required, if the project will go back to the development stage, or if the project is to be terminated. Decisions are documented in minutes of design review.
 - 5.7.1 Design validation is performed on representative product according to the project plan to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. Representative products include initial production units, batches or equivalent.
 - 5.7.2 Clinical evaluations or evaluation of performance of the medical device are performed as required by regulations. Such device is not considered to be released for customer use.
 - 5.7.3 For medical devices that interface or connect to other medical devices, validation includes the confirmation that the requirements have been met when interfaced or connected.
 - 5.7.4 Validation is completed prior to the delivery for use of the product.
 - 5.7.5 Validation plans include the validation methods and acceptance criteria and may include:
 - a) Statistical techniques with sample size rationale.
 - b) Customer Trials
 - c) Production Trials
 - d) Beta Testing
 - e) Production scale-up
 - 5.7.6 Results of validation activities are documented and filed in the design project file. And include results and conclusions of validation.

- 5.7.7 The team holds a design review meeting to review validation results and determines if they are acceptable. If they are acceptable, the design output documents are approved and released. If results are not acceptable, the team will determine if a design change is required, if the project will go back to the development stage, or if the project is to be terminated. Decisions are documented in minutes of design review.
- 5.8 Design Reviews are conducted as scheduled in the project plan, and as the need arises. The project plan identifies required participants for design review, including representatives of functions concerned with the design and development stage being reviewed and other specialist personnel.
- (In addition to the design team, this may include sales and marketing, production, or even the customer. Different participants may be required for different stages of the design.)
- 5.8.1 Design review may be conducted [as a meeting, a conference call or by circulation of an e-mail](#). The project manager is responsible to make sure all the required functions (or their representatives) are involved in the design review and feedback is obtained from all participants.
- 5.8.2 Design review is documented in the form of meeting minutes, conference call minutes or hard copy of e-mails sent and received. Documentation includes decisions, authorizations and all action items assigned.
- 5.8.3 The project manager files design review documentation in the design project file.
- 5.9 If the team identifies the need for a design change, the project manager documents the proposed change and the reason for the change on a design change form.
- 5.9.1 Consideration is given to the significance of the change to intended use, function, performance, usability, safety, and applicable regulatory requirements.
- 5.9.2 Review of changes also considers the effect of the changes on constituent product in process or delivered, and inputs or outputs of risk management and other product realization processes.
- 5.9.2 The design change must be approved by the original approvers of the project plan.
- 5.9.3 Design changes will be verified and validated as necessary before approval.
- 5.9.4 When a design change is made the project must go through verification and validation before being released.
- 5.10 Design and development transfer or release of outputs for production are verified as suitable for manufacturing before becoming final specifications and that production capability can meet product requirements. [You may want to detail a work instruction, WI-730-xxx to outline your method\(s\) for design and development transfer.](#)
- 5.11 When the design project is complete and all output documents are approved and