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

Blue text throughout the manual highlight areas for customization

Instructions:

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.

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.

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.

b. This section is for the definitions unique to Your Company.

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

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.

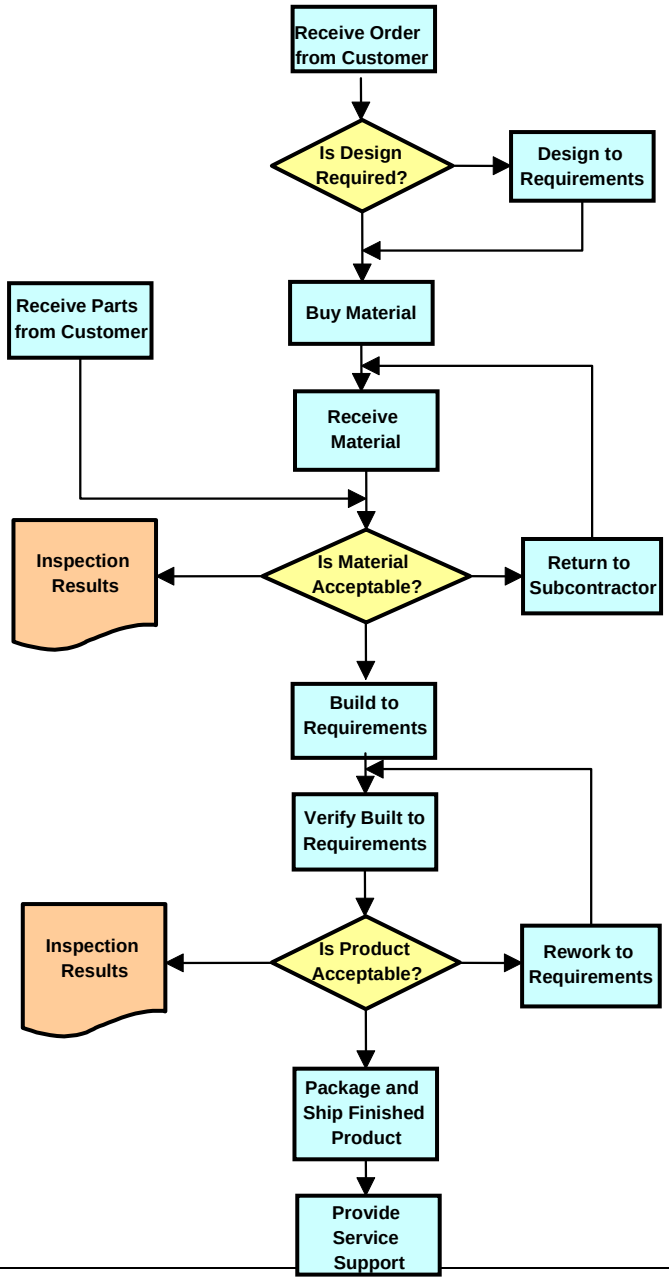
Sterile barrier system – Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

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

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

Example of a Manufacturing Process flow

Related documents are referenced.



INSERT YOUR COMPANY LOGO/NAME HERE

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	

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

ISO 13485:2003 to ISO 13485:2016 QMS Upgrade Instructions / Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from the ISO 13485:2003 version to the ISO 13485:2016 version for Quality management systems used by organizations involved in the medical devices industry.

The above Quality Management Systems are compatible with each other and have common requirements.

In both versions, the requirements are described in:

- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product Realization
- Clause 8 Measurement, analysis and improvement

You have the 2003 version in place and now have the objective of upgrading the system to the 2016 version. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward where documented information for the QMS sets the stage for an understanding of the requirements and of the international standard as a whole.

Essentially, the documentation package for the management system will contain:

- One Manual with updates to the documented information required for ISO 13485:2016.
- A group of procedure/system documents in your QMS with updates to reflect a document numbering system related to the new clause numbers and to incorporate the upgrades for ISO 13485:2016 requirements,
- A group of forms and attachments needed for the procedures and systems.

The documentation will need to be reviewed, upgraded and implemented. The first step is to assign a person responsible for the QMS, such as with a Management Representative to become familiar with the changes for 2016 version of the ISO 13485:2016 standard. Visit http://13485store.com/ for training materials, resources and information on quality management systems requirements.

The following table with detailed instructions focuses on the areas of the documentation required for the ISO 13485:2016 quality management system. As you undertake the task of upgrading your quality management system from the 2003 version to the 2016 version, note that in the left hand column of the instructions, the ISO 13485:2016 clauses shown in **bold numbers** have changes from 2003 to 2016. The intent of the main clauses is shown in blue font and the text in *italics* indicates where requirements were included in previous ISO 13485:2003.

Use a copy of the ISO 13485:2016 standard along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

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ISO 13485:2003 to ISO 13485:2016 QMS Upgrade Instructions / Checklist

ISO 13485: 2016 Clause	Changes to the existing ISO 13485:2003 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The international standard for Medical Devices - ISO 13485:2016 is updated and contains 8 sections or clause 1 through clause 8.	ISO 13485:2016	The requirements for the revised standard are described in Clause 4 through Clause 8. Your company needs to become familiar with the changes and subsequently upgrade the Quality Management System (QMS).		
All	----	ISO 13485:2016	A project manager or the appointed management representative (per clause 5.5.2) will be integral in setting the stage for an understanding of the requirements and the upgrade of the QMS.		
All	----	Manual	Make use of the information provided with this QMS Upgrade Instructions / Checklist to rework your existing QMS documentation and include the new and revised requirements of ISO 13485:2016.		
All	----	Manual	Begin by revising the cover page of the Manual to specify ISO 13485:2016		
1	*In ISO 13485:2003, justifiable exclusions were only permitted in clause 7.*	Manual	In the scope section of the manual, add a note to say that requirements in clauses 6, 7 or 8 that do not apply to your organization are excluded from the QMS. Document any justifications for the exclusion of requirements.		
2	*In ISO 13485:2003, the standard ISO 9000:2000 is a normative reference.*	Manual	In the normative references section of the manual, update the QMS – fundamentals and vocabulary standard to ISO 9000:2015.		
3	*In ISO 13485:2003, a total of (8) definitions are listed*	Manual	For the definition section of the manual, review the (20) definitions included in section 3 of the standard and identify and record the ones that apply to your organization.		
4	This first clause of the standard deals with the Quality Management System in general and requires that you identify your role as an organization and how management applies a risk based approach to achieve the efficient control of processes and an effective quality system. The scope of the QMS and the QMS processes along with their applicability and interactions need to be determined. In addition, documentation requirements need to be addressed via a Quality Manual, medical device files, and procedures for control of documents and control of records.				

The intent of the main clauses is shown in blue font

ISO 13485: 2016 Clause	Changes to the existing ISO 13485:2003 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
7.2.3	*In ISO 13485:2003, the arrangements for communicating are determined and implemented.*	Procedure	Ensure that arrangements for communication with customers are planned and documented.		
7.3	*In ISO13485:2003, the requirement for design and development was also in clause 7.3.*	Procedure	When your role as a company includes the design and development of medical devices, document the information (in a procedure P-730) to outline the process for the design and development.		
7.3.1	*In ISO 13485:2003, the requirements for design and development were outlined in par 7.3.1 through 7.3.7.*	Manual	If you are a designer or developer or inventor of medical devices, review section 7 of the manual and update it to agree with the structure for clauses 7.3.1 through 7.3.10. Add new sections for clause 7.3.8		
7.3.2	*In ISO 13485:2003, the requirement for design and development planning was in par 7.3.1 and (3) items listed for planning.*	Procedure	Specify (in a procedure P-730) that planning documents are maintained and updated as the design and development progresses. Review the (6) items required to be documented for design and development planning.		
7.3.3	*In ISO 13485:2003, the requirement for design and development inputs was in par 7.3.2.*	Procedure	Include the requirement that inputs need to be able to be verified or validated.		
7.3.4	*In ISO 13485:2003, the requirement for design and development outputs was in par 7.3.3.*	Procedure	Review the items required as design and development outputs.		
7.3.5	*In ISO 13485:2003, the requirement for design and development review was in par 7.3.4.*	Procedure	Review the items required for design and development review.		
7.3.6	*In ISO 13485:2003, the requirement for design and development verification was in par 7.3.5.*	Procedure	Review the items required for design and development verification. Include the new requirement that verification plans with methods, acceptance criteria and statistical techniques are documented. Include the new requirement that when medical devices are connected or are interfaced with other devices, verification includes confirmation that design outputs meet design inputs.		

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The ISO 13485:2003 to ISO 13485:2016 Gap Analysis Checklist

This list has been prepared for you by the 13485 Store. You will need to have a copy of the ISO 13485:2016 Standard to use along with this checklist. You will see questions on the checklist that refer to the standard where each requirement is expressed as a question. This checklist is based on the information provided in the 2016-03-01 release of the ISO 13485:2016 international standard.

You have the ISO 13485:2003 quality management system in place and to help you with the implementation of ISO 13485:2016, we have highlighted in yellow the requirements that are revisions / additions to the 2003 version.

After you have prepared your audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist and the section of the standard for the auditors working with that section.

As you work through the checklist take notes on what is in place, and what needs to be developed. Reference procedures or other documents that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, will they need to be revised for the new system or can they be used as is? Also note where processes are in place, but documentation is needed.

Focus on what is in place, and what needs to be developed. While you do want to know if procedures and processes are being complied with, compliance is not your main focus for this audit. Remember that the final outcome of this audit should be a list of things that your organization needs to do to comply with ISO 13485:2016.

Keep in mind that the standard requires six (6) mandatory procedures. In the checklist, we have highlighted in **Bold letters** where **a documented procedure is required,** such as with clauses 4.2.4, 4.2.5, 8.2.4, 8.3, 8.5.2, and 8.5.3. For other clauses of the standard, the phrase such as ‘documented procedures’ is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented. For your purposes, you may apply the most appropriate word.

Quality Manual, Procedures and Forms

For a complete set of ISO 13485:2016 documentation, visit the 13485 Store, We have designed and documented a Quality Management System for you to use as the foundation of your documentation system. This system addresses all of the requirements of the standard, from setting quality objectives and measurement criteria for your processes to internal audits and continual improvement. All the procedures interrelate to provide you with an efficient, effective quality management system.

Customize these documents instead of starting from scratch and benefit from the expertise of our ISO 13485 professionals. We guarantee our products and are confident that using our documentation will save you time and effort and result in a superior Quality Management System.

Our ISO 13485 professionals support our products and are available to answer your questions as you proceed with your project. Add our expertise to your implementation team and let us help you succeed.

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Yes / No Estimated % Complete	ITEMS NEEDED
4.1	**General Requirements**			
This clause asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in maintaining the effectiveness of the quality system. Specifically, this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and documented.				
4.1.1	Is there a Quality Management System in place that has been established and documented to meet the requirements of the ISO 13485:2016 Standard and the applicable regulatory requirements?			
	Are the role(s) undertaken by your company under the regulatory requirements (*as a manufacturer, a distributor, an authorized representative, or an importer*) documented?			
4.1.2	For the undertaken role(s), are the processes needed for the QMS applied throughout the company?			
	Is a risk based approach to the control of processes applied?			
	Are the sequence and interaction of the processes determined?			
4.1.3	Is the system maintained and is there evidence that its effectiveness is maintained?			

	• Look for methods and criteria needed to ensure that operation and control of the processes are effective.			
	• Look for the resources and information needed to support the operation and monitoring of the QMS processes.			
	• Ask Management how actions are implemented to achieve planned results and maintain effective processes.			
	• Ask how they measure, monitor and analyze the QMS processes.			
	• Look for records that demonstrate conformance to ISO 13485:2016 and comply to applicable regulatory requirements.			
4.1.4	Are changes to QMS processes evaluated for their impact on the QMS? How are changes to the processes evaluated for their impact on the medical devices produced under the QMS? Are changes to the QMS processes controlled in accordance with the ISO requirements and regulatory requirements?			