ISO 13485:2016

All-in-One Package

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.

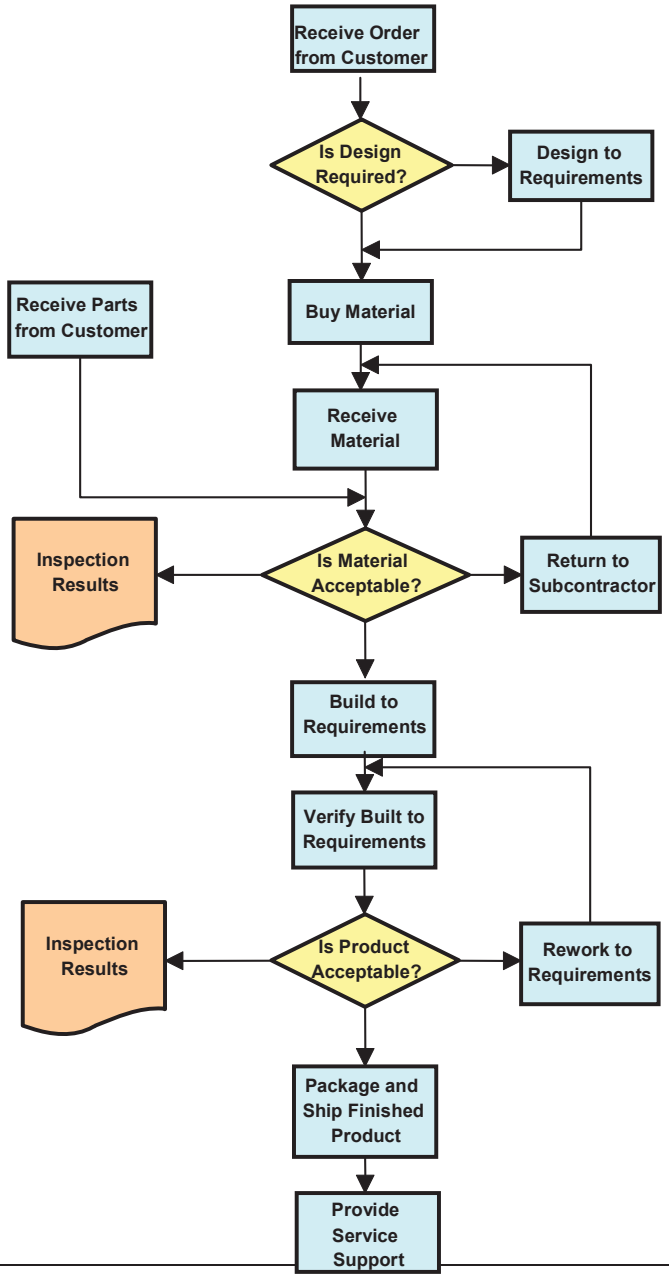
Sterile barrier system – Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

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.



ISO 13485:2016
Internal Auditor Training

Trainer's Guide

Overview

These course materials are meant to train people to conduct internal quality audits within your organization, which are necessary to meet the internal audit requirements of the ISO 13485:2016 standard.

The course is divided into two sections:

1. The first section will familiarize the students with the ISO 13485:2016 requirements for quality management system.
    - Allow 4 hours for this section.
2. The second section is devoted to the auditing process. The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting a mock audit of a fictitious company.
    - Allow 8 hours for this section.

We recommend that you print this guide as you'll need the PowerPoint speaker notes to lead the class. This guide contains everything the instructor needs to lead the class.

Notes:

- It is assumed that the instructor has certified Lead Auditor credentials or equivalent experience. This is not meant as a self study course.

- It is recommended that the first audit the student is involved with be under the leadership of a lead auditor who has audit experience.

Requirements of ISO 13485:2016

In the following slides, the ISO 13485 Standard is paraphrased for instructional purposes. Please refer to the standard for the actual text.

Each member country has representatives that make up a Technical Advisory Group (TAG).

These groups draft the standard, then members comment and vote on the standard.

The document then becomes and ISO standard.

These standards are not regulations.

They are a method of getting a standard set of criteria for quality management systems.

An outside agency, the registrar, will then audit to see if you have all the required elements in place.

If you do, you will get ISO 13485 registration. This registration tells others all over the world that you have this quality system in place.

As we go through the training, and cover the requirements you will see that these requirements are basically just good business practice.

Is it a Requirement?

The standard requires that: If the requirement is true, circle True and list the clause. If it is false, circle False and list the clause used.	True	False
1. For the ISO 13485:2016 Quality management system (QMS), the role(s) undertaken by the organization under the applicable regulatory requirements must be documented.	T *Clause:*	F *Clause:*
2. The Quality policy as defined by top management is required to be communicated, understood and applied within the company.	T *Clause:*	F *Clause:*
3. Top management must define, document and communicate the responsibility & authority for the management system.	T *Clause:*	F *Clause:*
4. Internal communication regarding quality matters must be established.	T *Clause:*	F *Clause:*
5. It is not necessary to identify and control documented information from external origin.	T *Clause:*	F *Clause:*
6. Management must review the QMS at least every quarter of the year.	T *Clause:*	F *Clause:*
7. The QMS must include documents and records determined to be necessary for an effective QMS.	T *Clause:*	F *Clause:*
8. Persons performing tasks that may affect the performance and effectiveness of the QMS must be competent.	T *Clause:*	F *Clause:*
9. Employee training must include the awareness of the relevance and importance of their activities and how they contribute to achieving quality objectives.	T *Clause:*	F *Clause:*
10. The scope of the QMS including justification for any exclusion is not required to be documented.	T *Clause:*	F *Clause:*
11. Medical device files for each device type or device family and containing relevant documents are not required to be established and maintained.	T *Clause:*	F *Clause:*
12. Purchasing information requires a written agreement for a supplier to notify the company prior to implementing changes to purchased product.	T *Clause:*	F *Clause:*
13. A risk based approach to the control of the QMS processes needs to be applied.	T *Clause:*	F *Clause:*
14. Monitoring and measurement resources to provide evidence of conformity to requirements need to be determined and provided.	T *Clause:*	F *Clause:*