ISO 13485:2016 FDA Compliant

All-in-One Package

Documents are in Microsoft Word for ease of editing

Insert Your Company Name/Logo Here

ISO 13485:2016

and

FDA.QSR (21 CFR 820)

Quality Systems Manual

Document No. QMD-002

Street Address

City,

State / Province

Zip / Postal code

Blue text throughout the manual highlight areas for customization

INSERT YOUR COMPANY LOGO HERE

Instructions:

This manual is used as a template in developing your ISO 13485:2016 Quality Management System. This Quality Manual is designed for ISO 13485 and can accommodate the FDA Quality System Regulation (21 CFR 820).

The basic additions for the Quality System Regulation are highlighted in yellow and the applicable part of the regulation is indicated.

For example, in section 3.0 of the manual, the QSR 820.3 bb notation refers to part 820.3 Definitions; and in section 4.2 of the manual, the reference to QSR 820.30.j indicates a requirement in part 820.30 Design controls.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QMD-002 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

1.0 Purpose

1.1 This procedure describes the process used for communicating with customers and reviewing information from the customer, including customer feedback.

2.0 Responsibilities

2.1 Customer Service or Sales and Marketing Representatives are responsible for taking orders from clients, determining customer requirements, and reviewing the orders for acceptance.

2.2 Project Managers are responsible for communicating with the client, keeping them informed as the project progresses and getting timely feedback from the client.

2.3 Employees that receive feedback from customers are responsible for communicating the feedback to the Customer Service department or the Project Manager.

3.0 Definitions

3.1 None

4.0 Equipment/Software

4.1 No additional equipment or software required.

5.0 Instructions

5.1 Request for product or service:

5.1.1 Orders are accepted electronically or by phone, fax or mail.

5.1.2 When a customer service or sales and marketing representative receives a request for product or services from a client or a potential client, the representative identifies the requirement and documents the customer requirements.

5.1.3 Identify how you determine all customer requirements for each type of order.

For example, for orders received electronically, by fax or by mail, the order is reviewed using a checklist (Create a checklist for your organization, and enter your form number here) to make sure all required information has been provided.

For orders received by phone, the representative will use the checklist to collect all required information from the customer and document the information in the order database. Requirements are confirmed with the customer before acceptance.

Contracts may be negotiated between the customer and sales or management. These contracts are reviewed and approved by management. Information from the contract is entered into the order database under the customer number so the customer may place multiple orders under the contract. When customer service receives an order that is part of a negotiated contract, the information in the order is reviewed against the information in the order database.

Required information includes: (list your required information here. Include information important to your product such as:

- Catalogue number or other ID
- Quantity
- Delivery date
- Special requirements
- Regulations that apply
- User training needs
- Delivery, installation and service
- Requirements unstated by the customer
- Statutory and regulatory requirements
- Post-delivery requirements provisions for (warranty, maintenance, recycling or final disposition),
- Additional requirements that Your Organization identifies

5.1.4 Customer service reviews the above requirements to make sure:

The client requirements are adequately defined and documented,

Your Company has the capability and capacity to meet the client requirements,

Any requirements that are different than previously expressed are resolved.

If Your Company is unable to meet the requirements, customer service will contact the client to resolve the differences between what you can provide and customer requirements, or tell the customer you cannot provide the product or service.

During the early review stages and while assessing the customer requirements, you can document their needs on a Client assessment memo, F-720-001.

5.1.5 If Your Company is able to meet the requirements, accept the order, contract or project.

INSERT YOUR COMPANY LOGO/NAME HERE

F-424-004-A
Document Revision Checklist

Document Name: _____

Document Number: _____

Changes	Revision approved by supervisor and plant quality control	
	Accept previous changes	
	Update header to current date	
	Date all attachments (new or changes only)	
	Update page numbering	
	Make new changes using revision tool	
	Run spell check	
	Reprint original (white paper), including all attachments	
	Password protect document	
Master List	Update document information in the master list including date, records, attachments, related documents and references.	
	If form, attachment or reference changes, search master lists for other affected documents and issue a document change request form. New references require number identification.	
	If there are related documents, check to see if review or changes are indicated.	
Training	a) Determine level of training required with supervisor (NN, RQ, EM)	
	b) Update training summary date of revision and level of training required for the revision	
	c) Check training summary for list of individuals trained on the document	
	d) For required training, send change memo to supervisor listing individuals to be trained	
	e) For employee training, send memo to manager or supervisor in charge of employee training	
Approval	Give new, original, and attachments to supervisor and quality control to sign	
Distribution	a) Check distribution summary for listing of controlled copies	
	b) Copy onto controlled paper.	
	c) Remove obsolete master copy and stamp it “Obsolete”. Attach change request and file in the “Obsolete” binders.	
	d) File new original in master binder	
	e) Distribute controlled copies as indicated by controlled copy list.	
	f) Remove & discard obsolete controlled copies.	

NN=None Needed RQ=Required EM=Employee Meeting
O=Original, no revision yet

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.

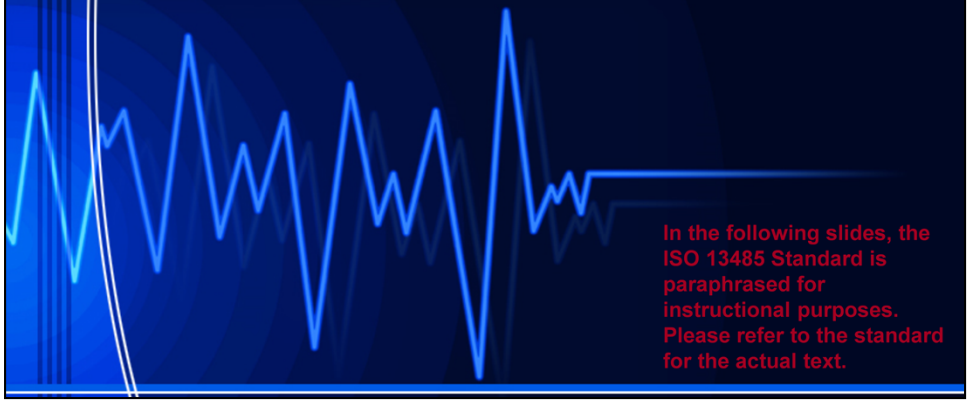
We recommend that you print this guide as you'll need the PowerPoint speaker notes to lead the class. This guide contains everything the instructor needs to lead the class.

Notes:

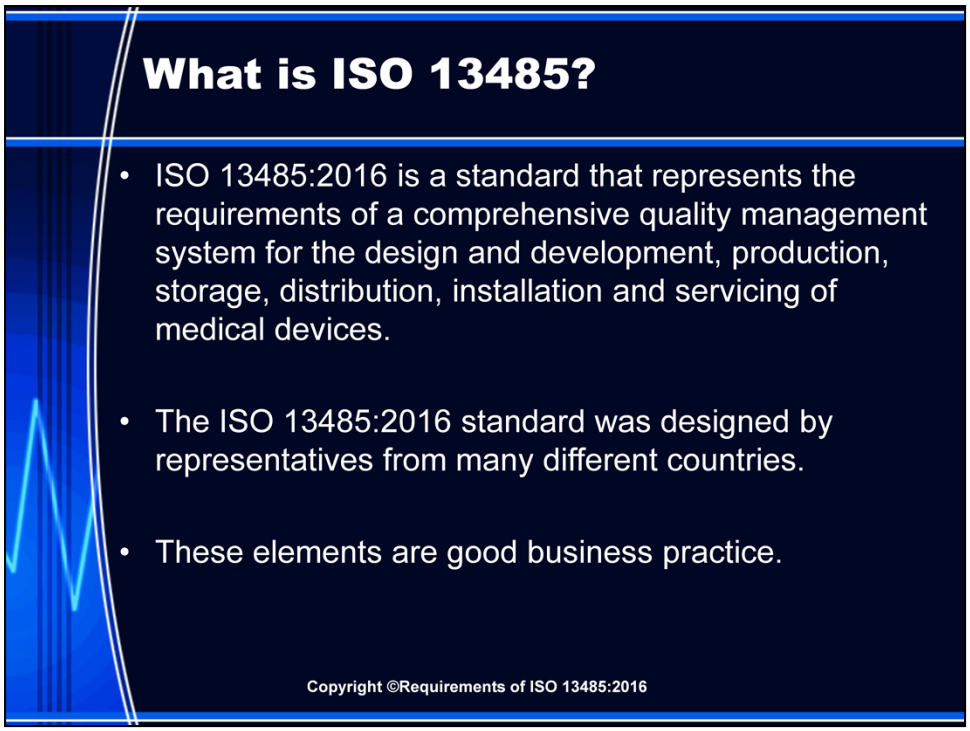
- It is assumed that the instructor has certified Lead Auditor credentials or equivalent experience. This is not meant as a self study course.

- 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.

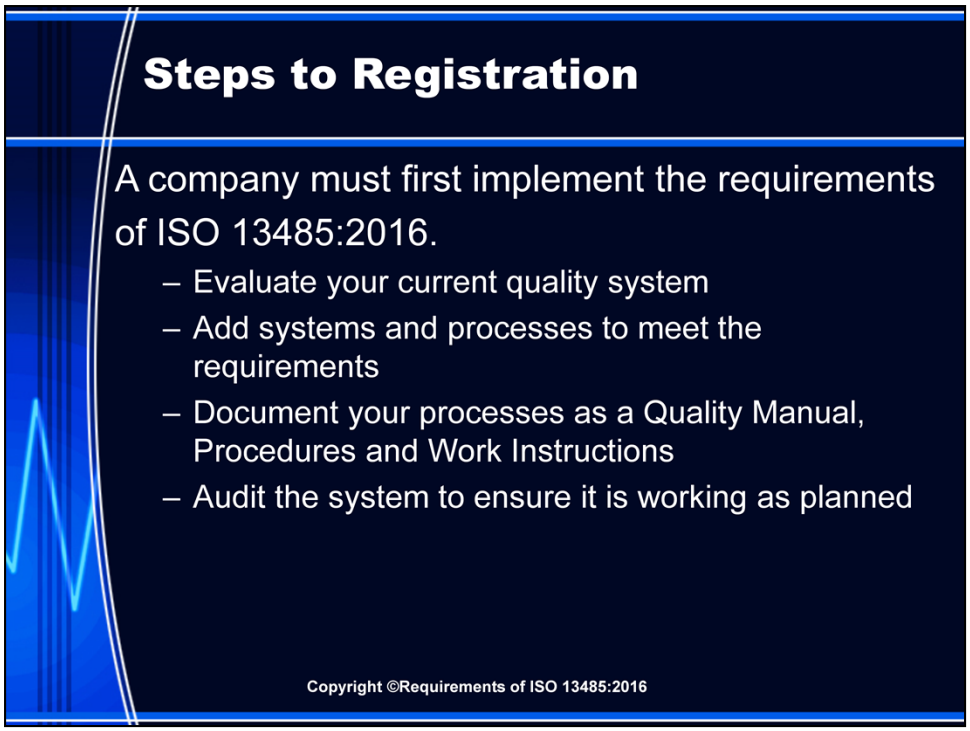
These standards are not regulations.

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.



Evaluate your current quality system:

Many of the requirements of the standard are already addressed by practices already in place.

These practices may or may not be documented.

Other requirements of the standard may not be addressed at all.

These need to be implemented and documented.

The standard is designed to bring control and consistency to the companies processes.

Documenting the processes is part of this control.

It helps ensure that people are doing the same thing, to get consistent results.

The document Pyramid:

Quality Manual: A top level document that describes briefly what you have in place to meet the standard.

Procedures: Describe what is done, for example the overall procedure for purchasing or training. What is included in the process?

Work Instructions: Detailed documents that describe how to perform a process, for example how to fill out a purchase, etc.

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:*