THE ISO 13485:2003 STANDARD

THE DOCUMENTATION SYSTEM

THE REQUIREMENTS OF THE STANDARD

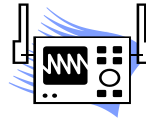
THE AUDIT PROCESS

ADDITIONAL MATERIALS AND TRAINING

QUICK REFERENCE GUIDES

THE ISO 13485:2003 STANDARD

WHAT EXACTLY IS ISO 13485?



ISO 13485 is an international standard containing requirements for establishing and maintaining a **quality management system** (QMS) for an organization that provides medical devices and related services. A quality management system is set up by an organization to:

- establish a quality policy and quality objectives, and
- establish the means to achieve those objectives.

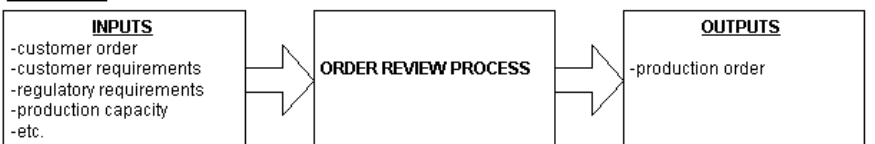
This standard specifies requirements for a QMS that can be used for the design and development, production, installation, and servicing of medical devices. It can be applied to almost any type or size of organization that provides medical devices and/or related services.

Rather than specify requirements for your medical device – *what* you produce – ISO 13485 focuses further "upstream" on the processes – or *how* you produce. ISO 13485 requires documented systems for controlling the processes you use to design, develop, produce, install, and service your medical devices. This standard is based on the idea that there

PROCESS

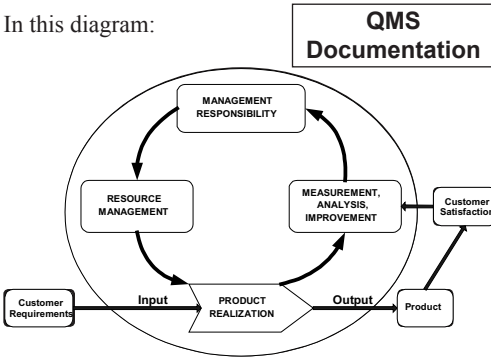
"A system of activities which uses resources to transform inputs into outputs.

Example:



You can see how these main sections relate to each other in the following diagram.

In this diagram:



- Management defines requirements and objectives for both the organization and the quality management system and identifies the resources needed to achieve them.
- Once we understand what the customer wants, we produce it.
- We measure customer satisfaction and other factors affecting the performance of the system.
- Finally, Management reviews the results of the measurements and takes action to improve.
- The QMS documentation provides the foundation on which the other elements of the system operate.

THE DOCUMENTATION SYSTEM

WHAT ARE THE DIFFERENT TYPES OF DOCUMENTATION?

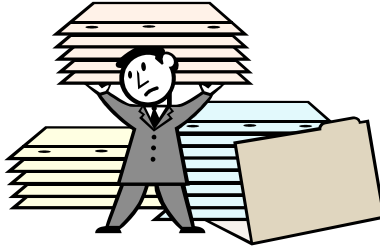
It is likely that one of the major changes your organization will go through is to expand or improve its documentation system. ISO 13485 requires that companies have a quality manual, quality procedures (and work instructions), and quality records. Each type of document serves a different purpose.

1. Quality Manual

The quality manual describes your organization's structure, the scope and processes of the quality management system, its approach to meeting customer's needs, its documentation structure, and the policy and responsibilities for meeting the requirements of the various ISO 13485 clauses. The quality manual is typically 30 to 50 pages long. It is usually written with the direct involvement of top management and input from all levels of the organization.

4. Quality Records and Forms

Records provide evidence that the required product or service quality was achieved, or that the organization's quality management system was implemented correctly. Forms provide a systematic way to collect information that can serve as records. Examples of quality records include inspection reports, shipping documents, purchase orders, and employee training records.



Clause 6.4 Work Environment

Essence of the clause: Your organization must identify and manage the human and physical factors of the work environment needed to provide a quality product or service.

Who's most involved: Management (of almost every department)

Management must provide the work environment necessary to produce a quality product or service. Issues that must be addressed and controlled if they could adversely affect the quality of the product include:

- Requirements for health, cleanliness, and clothing of personnel;
- Environmental conditions such a temperature, humidity, light, noise, space, language, etc.;
- Contaminated or potentially contaminated products; and,
- Qualification and/or supervision of temporary personnel working in special environmental conditions.

- Planning and conducting design reviews and final product testing or clinical evaluations;
- Reviewing and communicating design changes; and.
- Maintaining records showing the results of these activities.

Clause 7.4 Purchasing

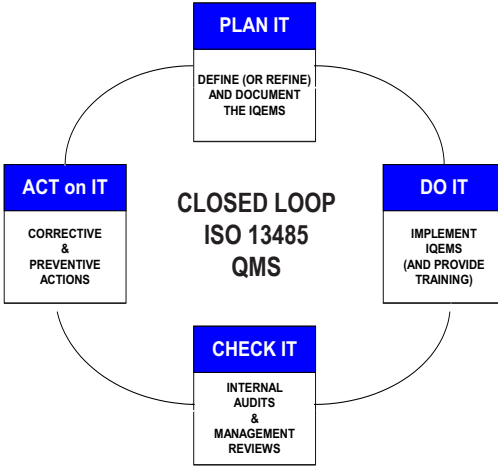
Essence of the clause: You must have a documented system for selecting suppliers– you can't simply buy based on cost. Your organization must also be sure that purchase orders are complete and accurate before they're sent to suppliers.

Who's most involved: Purchasing Department

Your organization must control the processes for making sure that the products and services purchased from suppliers meet all requirements

system per audit. Typically, every three years, the registrar will perform a full audit of the system in order to determine whether the registration should be renewed. These audits are very much like the original registration audit and have similar outcomes to those listed in the "What if we don't pass the registration audit?" section.

You'll find that auditing continues to be an important way of life for the organization, essentially "closing the loop" of the quality management system and providing a means for continual improvement.



QUICK REFERENCE GUIDE

ISO 13485:2003 Clauses 4 through 8

CLAUSE 4 - Quality Management System	
4.1	General Requirements
4.2	Documentation Requirements

CLAUSE 5 - Management Responsibility	
5.1	Management Commitment
5.2	Customer Focus
5.3	Quality Policy
5.4	Planning
5.5	Responsibility, Authority, and Communication
5.6	Management Review

CLAUSE 6 - Resource Management	
6.1	Provision of Resources
6.2	Human Resources
6.3	Infrastructure
6.4	Work Environment

CLAUSE 7 - Product Realization	
7.1	Planning of Product Realization
7.2	Customer-Related Processes
7.3	Design and Development
7.4	Purchasing
7.5	Production and Service Provision
7.6	Control of Monitoring and Measuring Devices

CLAUSE 8 - Measurement, Analysis & Improvement	
8.1	General
8.2	Monitoring and Measurement
8.3	Control of Nonconforming Product
8.4	Analysis of Data
8.5	Improvement

NOTES: