13485 Academy
ISO 13485 Online Consultation Center

Clause-by-Clause Explanation of ISO 13485:2016

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Executive summary

Striving towards quality and compliance with all applicable regulations is the mission of every modern medical device company. ISO 13485 provides a framework for how to achieve this, and the first step in the implementation is to understand what the standard really requires. This whitepaper is designed to help top management and employees in organizations that have decided to establish and maintain an ISO 13485:2016-based Quality Management System by clearing up any misconceptions regarding the standard's requirements.

In this document, you will find each clause of ISO 13485 explained in plain English in order to facilitate understanding of the standard, in the same order and number of the clauses of the standard. In addition, you'll see links to additional learning materials.

0 Introduction

0.1 General

ISO 13485 specifies requirements for a Quality Management System (QMS) to be applied by organizations involved in the medical device industry. The standard can be applied by organizations performing design and development, production, storage and distribution, installation, servicing, and disposal of the medical device, and by suppliers or other external parties providing products to such organizations.

The medical device industry is highly regulated. As such, the standard sets requirements for an organization to identify all regulatory requirements that are applicable to its business activities, determine its role in these activities according to the regulatory requirements, and ensure that its QMS conforms to these regulatory requirements.

Implementation of the QMS is a strategic decision of the organization, which can be influenced by various factors such as organizational environment, varying needs, particular objectives, the products the organization provides, etc.

0.2 Clarification of concepts

The standard uses particular phrases to formulate the requirements, and this clause explains these phrases and concepts. The terms and phrases used are the following:

- **"As appropriate"** – The requirement doesn't have to be applied by the organization if the organization can justify the exclusion. The requirement will be appropriate if it is necessary to meet the requirements of the product and any legal requirements, to conduct corrective actions, and/or to manage risks.
- **"Risk"** – This term is used specifically for a risk to the safety or performance of the medical device or for meeting applicable regulatory requirements.
- **"Product"** – This term also includes "service," and it applies to intended outputs resulting from the product realization process.
- **"Regulatory requirements"** – This term is applied only to requirements for the QMS and the safety or performance of the medical device.

In addition, the standard uses the following words to indicate what is a requirement, versus a recommendation or an allowance: "shall" refers to a requirement; "should" refers to a recommendation; "may" refers to an activity that is permitted; "can" refers to an activity that is possible or that the organization is capable of conducting.

Information marked as "Note" does not include any additional requirements to the clause to which it belongs; rather, it provides guidance in understanding or clarifying the requirement.

0.3 Process approach

The process approach is key for an effective Quality Management System. This basically means that every operation of the company must be observed as a process, meaning that all of the inputs, necessary resources, documents, activities, and outputs must be identified from each operation. Once you set up your system based on the processes, you will be able to monitor and measure your processes, their effectiveness, and their efficiency, and then improve them, which is the reason why it is emphasized at the beginning of the implementation, before going into any other details regarding the standard requirements.

In simple terms, the process approach represents the concept of observing all operations in the company as processes. This includes breaking down the company into its processes and determining their sequence, interaction, inputs and outputs; identifying the processes in the company and which processes can start before other processes are finished; and determining what resources and information are needed to start the process and what results we can expect from the process.

The best way to start implementing the process approach is to create a process map, which should include all processes in your company and their interconnections. For example, the delivery process cannot be started before the production and sales processes, and the production cannot be started

before the purchasing of raw materials. Once you create this global process map and identify all the processes and their interrelations, you can start defining your processes in terms of the necessary inputs, what controls need to be applied, and the outputs of the process. But, this will be done throughout the implementation – it doesn't have to be done all at once.

0.4 Relationship with ISO 9001

Although ISO 13485 is a standalone standard, it is based on ISO 9001:2008, which has been replaced by ISO 9001:2015. Consequently, ISO 13485 does not feature the High-Level Structure we see in the other management system standards that made the transition in the last five years. The reason for this divergence is the set of new requirements brought by the new version of ISO 9001 that are not applicable for regulatory requirements, and therefore are not included in ISO 13485.

ISO 13485 has an additional set of requirements specific to the medical device industry, and it discards some of the requirements of the new ISO 9001. Therefore, compliance with ISO 13485 does not imply compliance with ISO 9001, and any organization that aims to be compliant with both standards has to implement all applicable requirements of both ISO 9001 and ISO 13485.

For more information, see: ISO 9001 vs. ISO 13485.

0.5 Compatibility with other management systems

ISO 13485 does not include any requirements specific to other management systems, such as environmental, occupational health and safety, information security, etc. However, it enables an organization to align or integrate its Quality Management System with the requirements of other management systems.

1 Scope

This standard specifies the requirements for a QMS for organizations that need to demonstrate their ability to provide medical devices and related services in compliance with customer and regulatory requirements. These organizations could be involved in one or more lifecycle stages of the medical device industry, or they could be a supplier or external party that provides products or services to organizations manufacturing medical devices.

Some requirements of the standard could be inapplicable to an organization and can be excluded from the scope of the QMS. Such requirements belong to clauses 6, 7, and 8 and for each exclusion, the organization needs to provide documented justification.

2 Normative references

The documents referenced in the standard are indispensable for its application. For dated references, only the cited edition applies. When the reference is not dated, the latest version applies.

3 Terms and definitions

All terms and definitions related to ISO 13485:2016 can be found in ISO 9000:2015. Unfortunately, ISO 9001:2015 does not provide any definitions for the terms used, and it is very important to understand the terms before the company starts implementing the requirements of the standard. Here are some of the most important terms and definitions.

Top management – the individual or group of individuals who coordinate and control an organization at the highest level. In cases when the scope of the management system covers just part of an organization, then top management refers to the individuals who direct and control that part of the organization.

Organization – a person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives.

Context of the organization – a combination of internal and external factors that can have an effect on the purpose, objectives, performance, and sustainability of the organization. Internal factors include values, culture, knowledge, and performance of the organization. External factors include the legal, technological, competitive, market, cultural, social and economic environment.

Interested party (stakeholder) – a person or organization that is involved or perceives itself to be affected by activities and actions taken by the organization. Interested parties can be customers, suppliers, contractors, local community, government, etc.

Process – a sequence of activities that use inputs to deliver an intended result. For example, the production process has several steps that must be conducted in the appropriate sequence; inputs in this process are raw materials, product specifications, and work instructions, while the outputs are the product, quality check report, etc.

Procedure – a defined way to execute an activity or a process. Procedures can be documented or not.

Quality – Quality is the difference between customer expectations and the customer's perception of the product or service that was received – the higher the difference, the better perceived quality.

Nonconformity – the failure to meet a requirement.

Risk – the "effect of uncertainty on objectives"; an effect is a positive or negative deviation from what is expected. For example, the company plans to deliver its products to the customers, but there is a risk of product nonconformity due to a poorly controlled production process.

Effectiveness – the level of success in achieving or producing the desired result. For example, the production process is effective if it is able to produce the products.

4 Quality Management System

4.1 General requirements

According to the requirements of ISO 13485, an organization must:

Establish. Establishing a QMS entails the planning phase, which includes:

- Defining the purpose of the organization. The organization should identify its users and other interested parties, as well as their requirements, needs, and expectations, in order to determine its intended output elements.
- Defining the policy and objectives of the organization. The organization's policy should be based on an analysis of the requirements, needs, and expectations. The policy should provide the framework for establishing the organization's objectives.

Document. The organization must determine process documentation, i.e., determine which processes need to be documented. The main purpose of documentation is to enable consistent and stable process execution.

Determining which processes should be documented should be based on:

- The size of the organization and type of its activities,
- The complexity of its processes and their interactions,
- Employees' competence.

Process documentation can be done using several different methods, including graphical, written instructions, control charts, flowcharts, etc.

Apply and maintain the Quality Management System. Once you have documented your QMS, you must behave in the way you defined within your QMS documentation.

Continually improve QMS effectiveness. Continual improvement is an ongoing activity to increase the organization's ability to fulfill the planned requirements set by the QMS.

Further, this clause requires the organization to:

Determine the processes necessary for the Quality Management System and apply them throughout the organization. These processes include management, resources, realization and measurement, analyzing, and improvement. The organization must manage these processes and appoint a process owner for each process. Top-level management must determine individual roles and responsibilities to ensure the application, maintenance, and improvement of each process and its interaction with other processes.

Determine the order and interaction between processes. While determining order and interactions between processes, the following should be considered:

- User for each process,
- Inputs and outputs of each process,
- Which processes are related,
- Logical sequence and order of related processes,
- Effectiveness and efficiency of each process.

Determine criteria and methods needed to ensure process execution and effectiveness of process management (see chapters 7 and 8).

Ensure availability of resources and information needed for support of processes and their monitoring (see chapter 6).

Monitor, measure, and, when appropriate, analyze the processes (see chapter 8).

Apply actions needed for accomplishing planned results and continual process improvement.

4.2 Documentation requirements

4.2.1 General

The QMS must be documented and the volume of documentation suited to the organization's needs, size, type of activities, processes, and employees' competence.

QMS documentation contains:

- Documents explicitly required by ISO 13485 (for more information, see: List of mandatory documents required by ISO 13485:2016).
- Documents and records defined by the organization as necessary – procedures describing processes, instructions for some activities, flowcharts, Quality Plans, records of monitoring and measurement, etc.

4.2.2 Quality Manual

The standard requires the organization to establish and maintain a Quality Manual. This is a high-level document, and it contains:

- Purpose and scope – define the organization and its organizational structure, responsibilities and authorities, location, and its business.
- Details about exclusions and their justification (exclusions can be made only in clauses 6, 7, and 8).
- Procedures or reference to them – the Quality Manual can contain all procedures or refer to procedures.
- Description of interactions between processes – this is usually given through a process model or process map, which can be part of the Quality Manual or given as a separate document.

For more information, see: How to manage the Quality Manual according to ISO 13485:2016 requirements.

4.2.3 Medical device file

In order to demonstrate compliance with the standard and legal requirements, each medical device or family of medical devices needs to have a medical device file. The content of the file must include, at a minimum, a general description of the file; specifications for the product; procedures for manufacturing, storage, packaging, handling, and distribution; procedures for monitoring and measuring; requirements for installation; and procedures for servicing.

For more information, see: How to meet ISO 13485:2016 requirements for medical device files.

4.2.4 Control of documents

The standard requires you to establish a documented procedure that defines control of documents. The documents will be reviewed periodically and updated with new information regarding processes. All changes must be identified, and if they change the essence of the document, then a new version of the document is issued. You must ensure that the old document is removed from the place of use and replaced with the new version.

For more information, see: Common mistakes with ISO 13485:2016 documentation control and how to avoid them.

4.2.5 Control of records

Record control should be determined with an appropriate procedure for document and record control that prescribes the method of identifying, preserving, and protecting records. Usually, the records are kept on a custom form you define based on standard requirements and your needs. Once filled in and signed, these forms become important documents that serve as evidence of performing certain activities, and they demonstrate conformity with standard requirements and the effectiveness of your QMS.

For more information, see: How to structure Quality Management System documentation according to ISO 13485.

5 Management responsibility

5.1 Management commitment

QMS implementation is your strategic decision that demonstrates your commitment to development and application of the QMS and continual improvement of its effectiveness. This commitment must be demonstrated through informing the organization about the importance of fulfilling customer requirements, compliance with legal and other requirements, establishing a Quality Policy and objectives, conducting management reviews, and providing needed resources.

5.2 Customer focus

In the QMS process model, the users make requirements for a product on one side and demonstrate their reaction by expressing their satisfaction with the product on the other side. Those requirements must be identified and fulfilled in a way that increases customer satisfaction.

5.3 Quality Policy

The Quality Policy is a high-level document containing statements about the general direction of the organization and its commitment to quality and customer satisfaction. It provides a framework for quality objectives and must be communicated to employees in a way they understand.

5.4 Planning

5.4.1 Quality objectives

The standard requires top-level management to establish quality objectives for appropriate functions and departments in the organization (HR, production, purchase, etc.).

Quality objectives must be measurable, quantitative, and timed. They must be in line with the Quality Policy so that it can be determined whether objectives are met and, if not, what should be done.

For more information, see: Setting good quality objectives for ISO 13485.

5.4.2 Quality Management System planning

The top-level management must plan the Quality Management System in order to:

- Fulfill the requirements of clause 4.1 of the standard. Most of these activities are performed during implementation of the QMS; new needs for planning can emerge from changes to a process or product/service, identifying possibilities for improvement, audits, etc.
- Accomplish quality objectives. To accomplish quality objectives, the organization must plan resources, deadlines, responsibilities, and appropriate evidence. Since the objectives are changeable, this planning is a continuous process.

Also, the top-level management is required to maintain the integrity of the QMS when changes are planned and implemented in the Quality Management System.

5.5 Responsibility, authority, and communication

Responsibilities and authorities must be precisely defined and communicated to all hierarchical levels of the organization. In specific situations (seasonal fluctuation of labor force, emergency situations, etc.), it is necessary to precisely document and communicate the authorities and, especially, the responsibilities of temporarily employed workers.

The top-level management must appoint one of its members to be the management representative who will, besides his regular duties, perform activities related to the QMS. The management representative can’t be someone outside the organization, and if the organization has multiple locations, it can appoint management representatives for each location who are subordinate to one head management representative.

Top-level management must establish communication processes in the organization. Basic directions of organizational communication are:

- Communication downwards (from manager to employee) – used for giving orders, coordination, and evaluation of employees; can be performed by any means of interpersonal communication.
- Communication upwards (from employee to manager) – allows managers to find out what employees think about their workplace, colleagues, organization, and ideas for business improvement. Some examples of this communications are reports, suggestion boxes, etc.

For more information, see: How to fulfill management responsibilities in ISO 13485:2016.

5.6 Management review

At least once a year, the top-level management must review the QMS in order to determine its:

- Appropriateness – does it serve its purpose and satisfy the needs of the organization?
- Adequacy – does the QMS conform to the standard's requirements?
- Applicability – are activities performed according to procedures?
- Effectiveness – does it accomplish the planned results?

This review must evaluate possibilities for improvement and needs for changing the QMS, Quality Policy, and objectives, and the results of the management review must be documented.

The difference between the management review and an audit is that results from an audit represent input elements for the management review, just like data analysis (clause 8.4 of ISO 13485).

For more information, see: How to perform management review according to ISO 13485.

6 Resource management

6.1 Provision of resources

The organization must provide resources (people, finances, infrastructure, etc.) in order to apply and maintain the QMS, continually improve its effectiveness, and increase the level of customer satisfaction through fulfillment of their requirements. Resources need to be reviewed periodically (especially if you increase business volume) to determine whether the available resources are enough or if you need to provide more.

6.2 Human resources

It is necessary to have a list of all jobs and their descriptions with necessary competence and defined responsibilities for the entire organization.

In order to reach the necessary competence, the standard allows you to, besides training, take other actions. Such actions can be, for example, to hire already trained and competent employees or to outsource some activities and processes.

Also, you must evaluate the effectiveness of undertaken actions. Criteria for effectiveness can be the number of employees who successfully completed training, whether the training is performed according to plan, etc.

Each training must be backed with appropriate records (Record of attendance, certificates, etc.) and entered into the employee's personnel file.

6.3 Infrastructure

The infrastructure includes buildings, workspace, equipment, process equipment (hardware and software), and support services. Many requirements for infrastructure could be included in legislation.

For more information, see: Managing medical device infrastructure requirements according to ISO 13485:2016.

6.4 Work environment and contamination control

6.4.1 Work environment

Working conditions (humidity, noise, light, temperature, vibration, etc.) are also, in most cases, defined by legislation. The organization must document requirements for infrastructure necessary to manufacture product compliant with the requirements.

Requirements for working conditions and procedures for monitoring and controlling of the work conditions need to be documented only if they can have adverse effects on the quality of the product or its conformity to legal or other requirements. This includes requirements for health, cleanliness, and clothing of the personnel when contact between the personnel and the product can have negative effect on the safety or performance of the product.

6.4.2 Contamination control

In order to prevent contamination of the work environment, product, or personnel, the organization needs to document a procedure for control of contaminated or potentially contaminated products.

In case of sterile medical devices, the organization must document a procedure for control of contamination with microorganisms.

For more information, see: Managing cleanliness of a product and contamination control according to ISO 13485:2016.

7 Product realization

7.1 Planning of product realization

All activities regarding product realization must be planned, as well as the method of realization, for example, defining quality objectives, product requirements, customer requirements, and product acceptance criteria. Outputs of product realization planning can be Quality Plans, project plans, etc.

The organization needs to establish and document one or more processes for risk management in product realization, and results of the risk management activities need to be documented.

7.2 Customer-related processes

7.2.1 Determination of requirements related to product

You must understand your customer requirements and know how to fulfill them. That is why the organization must determine:

- Requirements specified by users, including requirements for delivery and after-delivery activities. The customer usually defines its requirements in the order, contract, or agreement. Delivery activities include defining means of transport and deadlines, and post-delivery activities are related to installation, maintenance, or some other contractual obligation.
- Requirements that the customer hasn't stated, but that are necessary for the specific or intended use. Those are requirements that the organization recognized and implemented into the product (for example, instruction manuals, safety requirements, etc.).
- Legal and regulatory requirements regarding the product. Many products must fulfill certain legal requirements, such as maximum concentration of substances or functional and safety characteristics. Fulfillment of such requirements is mandatory, and it is usually proven by reports from (accredited) laboratories.
- All additional requirements that the organization finds necessary. Besides the above mentioned, the organization can define some additional product requirements.

7.2.2 Review of requirements related to product

After receiving the order, the organization must, prior to delivery, review the requirements related to the product and keep records about the review. If the customer changes its requirements, these changes also must be reviewed and recorded. Records of the product requirements review must be kept.

7.2.3 Communication

Good communication with customers can provide valuable information about the product and customer satisfaction. The organization must appoint a person for contact with customers, especially for orders, their changes, and complaints. This information is usually documented in a sales procedure.

For more information, see: How to comply with the latest changes in ISO 13485 clause 7.2.3 Communication.

7.3 Design and development

7.3.1 General

This clause refers to design and development management, from initial idea to final acceptance of product. ISO 9000 explains that the terms “design” and “development” are often used as synonyms, and sometimes define different phases of overall design and development. This means that design can’t be used apart from development, and that they represent one single process.

If the organization is performing the design and development process, it must have a documented procedure for design and development.

For more information, see: How to manage design and development of medical devices according to ISO 13485:2016.

7.3.2 Design and development planning

Design and development can be performed by one employee who will be responsible for design and development execution. If design and development are performed by a team, the responsibilities must be clearly defined; if other parties are involved in this process, then effective communication must be established.

During design and development planning, all its phases must be defined, along with appropriate activities of reviewing, verification, and validation for each phase.

7.3.3 Design and development inputs

Considering that ISO 13485 refers to design and development of product (not design and development of processes), design and development inputs relate to product requirements that include:

- Functional requirements and product performance requirements,

- Legal and regulatory requirements for the product,
- Information from previous similar projects,
- other requirements relevant to design and development, usually customer requirements, market information, package, etc.

Design and development inputs must be documented.

7.3.4 Design and development outputs

Design and development outputs must be in a form suitable for verification related to input elements and must be approved before acceptance. They can be in the form of a drawing, engineering documentation, plans, etc.

7.3.5 Design and development review

The purpose of this activity is to determine whether the design and development process goes in the intended direction. The review can be done in appropriate phases or at the end of the project.

The review identifies problems during design and development and suggests actions to resolve them; it can include other interested parties. The design and development review must be documented.

7.3.6 Design and development verification

Verification determines whether the design and development results fulfill the input requirements. It can be done in phases or at the end of the project. The method of verification is defined and documented in the design and development plan.

If the results of design and development don't suit the input requirements, appropriate decisions must be made and recorded and this record will be an input for the next review.

7.3.7 Design and development validation

Validation determines whether the product can fulfill requirements for intended use; it is performed before delivery or use of product and must be documented.

If the results of design and development validation don't suit the needs, appropriate decisions must be made and recorded and this record will be an input for the next review.

Validation is typically a simple process, but in some cases, it can be very complex and include computer simulation, animations, modeling, etc.

7.3.8 Design and development transfer

The procedure for transfer of design and development outputs to manufacturing must be documented. The purpose of this procedure is to ensure that the outputs are verified and suitable for manufacturing. The records of the transfer must be kept.

7.3.9 Control of design and development changes

Changes in design and development can happen in every phase; they must be reviewed, verified, validated, and approved before application. Records about changes must be kept.

7.3.10 Design and development files

Considering the importance and complexity of the design and development process, it is reasonable that the standard requires the organization to maintain a design and development file for each medical device type or medical device family. The purpose of this file is to demonstrate conformity to the requirements for design and development, and it must include reference to all relevant documents and records produced during the design and development process.

7.4 Purchasing

7.4.1 Purchasing process

Purchasing includes products and services you acquire from suppliers and outsourced processes. You need to establish and document criteria for supplier selection, which includes how crucial the purchased product or service is to the quality of your product. Results of the supplier evaluation must be kept.

For more information, see: How can ISO 13485 clause 7.4, Purchasing, enhance procurement?

7.4.2 Purchasing information

The standard requires purchasing to include, where applicable:

- Requirements for approval of products, processes, and equipment,
- Requirements for employee competence,
- Requirements for the Quality Management System.

These requirements are usually directed at suppliers that need to deliver key products/services to you, and verification of compliance with requirements is conducted on the premises of the suppliers.

7.4.3 Verification of purchased product

The organization must ensure that the purchased product suits its requirements; in some cases, the organization can conduct the monitoring and measurements at the premises of the suppliers. Such verification must be part of the contract with the supplier.

7.5 Production and service provision

7.5.1 Control of production and service provision

The conditions in which the production and service provision are executed are crucial for successful delivery of the product/service. These conditions include:

1. Availability of information regarding product characteristics. Information describing product characteristics can be contained in the project plan, product specification, etc.
2. Availability of working instructions, where needed. It is necessary to provide clear working instructions at the place of application (execution of activities); if the instructions are not enough, then training must be performed.
3. Availability and usage of monitoring and measurement equipment. Depending on the process and/or product, the organization must have appropriate monitoring and measuring equipment that must be calibrated periodically.

For more information, see: Production and service provision process in ISO 13485.

7.5.2 Cleanliness of the product

In cases when the product is cleaned by the organization before the sterilization, or when it cannot be cleaned before the sterilization or its use, the organization needs to document requirements for cleanliness of the product.

For more information, see: Managing cleanliness of a product and contamination control according to ISO 13485:2016.

7.5.3 Installation activities

Requirements for installation activities and acceptance criteria for verification of the installation also must be documented. In cases when the installation activities are performed by an external party that is not a supplier of the organization, documented requirements for medical device installation must be provided by the organization.

7.5.4 Servicing activities

In cases when servicing of a medical device is an explicit requirement, the organization must document the procedures and records; as well as materials and measurements for performing and verifying servicing activities.

The records of servicing activities are used by the organization to determine whether the information should be handled as a complaint, and for the improvement of process inputs.

7.5.5 Particular requirements for sterile medical devices

For medical devices that require sterilization, the organization needs to keep records of the sterilization process parameters for each sterilization batch. These records must be traceable to each manufacturing batch of medical devices.

7.5.6 Validation of process for production and service provision

Validation is performed before or during process execution when process outputs can't be verified with later monitoring and measurement, and when product defects are identifiable only after using the

product or service provision. It also demonstrates the capability of the process to deliver the intended results.

During identification and planning of such processes, the organization must determine appropriate preferences, including:

- Defined criteria for process review and approval. Criteria for process review and approval are defined requirements that need to be met so the process can deliver the desired results. Validation can be conducted by computer simulations and testing.
- Using special methods and procedures. In quality Plans, you can refer to all specific working methods and procedures, manuals, and instructions that are necessary to apply for undisturbed processes execution.
- Requirements for records. Records about verification activities must be kept. In most cases, they rely on criteria for reviewing and process approval.
- Revalidation. Validation will be repeated if there is a change in the product and/or process, and if previous validation didn't confirm the capability of the process to fulfill the requirements for the product. In that case, additional criteria must be established for reviewing and approving processes, equipment, and competence of the staff. That can lead to establishing new methods and procedures; validation records must be kept.

For more information, see: Using ISO 13485 to manage process validation in the medical device manufacturing industry.

7.5.7 Particular requirements for validation of process for sterilization and sterile barrier systems

The procedure for validation of the sterilization process and sterile barrier systems must be documented. The sterilization process must be validated before the implementation, and results of the validation and necessary subsequent actions must also be documented.

For more information, see: How to manage the medical device sterilization process according to ISO 13485:2016.

7.5.8 Identification

Identification of the products through the product realization process is one of the crucial means to ensure that nonconforming product does not reach the end user. The standard requires the organization to document the procedure for product identification and identify the product status with respect to monitoring and measurement requirements throughout the manufacturing process.

The identification must be maintained throughout the entire lifecycle of the product, from production and storage to installation and servicing, in order to ensure its compliance with requirements for the product. This helps organizations to ensure that the product has passed required inspections and tests before reaching the end user.

7.5.9 Traceability

Traceability is the possibility to follow the history, application, or location of what is considered (ISO 9000). When it is about a product, traceability may refer to the origin of the product, material and parts, history of processing (in which process phase is the product, material, or part), distribution, and product location after delivery.

Where traceability is needed, the organization must establish a unique identification system for the product and maintain records of traceability.

An established traceability system can ease product withdrawal from the market.

7.5.10 Customer property

Materials, equipment, personal data, or intellectual property given by the customer for product realization can all represent customer property. If this property is lost, damaged, or unfit for use, the customer must be notified, and communication must be recorded.

7.5.11 Preservation of product

The product and its components must be kept throughout the whole process of realization and delivery to the planned destination, for example, temperature, sterile conditions, etc. The organization must establish a documented procedure to ensure the product maintains its conformity to requirements during processing, warehousing, handling, and distribution. These rules must apply to all parts of a medical device.

The purpose of this requirement is to protect the medical device from any unintended changes to the product, contamination, or damage. According to the properties of the medical device and identified risks, the organization must define the storage conditions and, if special conditions are required, provide records of maintaining such conditions, for example warehousing temperature.

7.6 Control of monitoring and measuring equipment

The first step in complying with this requirement is to identify monitoring and measuring activities necessary to maintain compliance of the medical device with its requirements, and then to identify monitoring and measurement equipment necessary to perform the monitoring and measurement activities.

In order to accomplish this, the organization has to document a procedure for maintenance of the equipment. As necessary, the organization needs to ensure that the monitoring equipment is calibrated and fit for its purpose, and the records of these activities need to be maintained.

8 Measurement, analysis, and improvement

8.1 General

This requirement should not be equated with the requirement for managing equipment for monitoring and measuring from clause 7.6 of the standard. This is about a wider aspect of monitoring and measuring. Information derived from monitoring, measurement, and analysis represents an input in the process of improvement and management review.

The purpose is to demonstrate conformity of the medical device to the QMS and to maintain its effectiveness.

8.2 Monitoring and measurement

8.2.1 Feedback

One of the measures of QMS effectiveness is information on whether the organization met the requirements of its customers. Considering the importance of this process and the valuable input it provides for future improvement of the QMS, the organization needs to document a procedure for the feedback process, which will include the methodology for obtaining and using this information.

8.2.2 Complaint handling

As for any other Quality Management System standard, the customer is the main focus of the organization's activities. Any complaint filed by a customer must be dealt with in a timely manner and in accordance with applicable regulatory requirements.

The standard requires an organization to document a procedure that will define the process of complaint handling, from receiving and recording the information to handling the complaint-related product and determining the need to initiate corrective action.

For more information, see: How to comply with ISO 13485:2016 requirements for handling complaints.

8.2.3 Reporting to regulatory authorities

In cases when there is a legal requirement to notify appropriate authorities regarding complaints or issuance of advisory notices, the organization needs to document a procedure and keep records of reporting to regulatory authorities.

8.2.4 Internal audit

An internal audit is performed to determine whether the QMS conforms to its documentation, the standard, and applicable legal requirements. In addition, the audit should determine whether the QMS is effectively implemented and maintained.

The organization needs to document a procedure for internal audit to define responsibilities and activities necessary to perform the internal audit, from planning to reporting the results.

For more information, see: Five main steps in the ISO 13485:2016 internal audit.

8.2.5 Monitoring and measurement of processes

Do our processes deliver what we expect from them? The best way to determine this is by performing appropriate monitoring and measuring activities of the process parameters. In cases when the monitoring and measuring results are not satisfactory, the organization needs to take corrections and corrective actions in order to improve its process performance.

8.2.6 Monitoring and measurement of product

Clearly defined characteristics of a product to monitor and measure may be included in project documentation, product specification, product description, user requirements, etc. Monitoring and measurement of a product sometimes can be conducted during monitoring and measurement of a process. In each case, measuring of the product (dimensions, microbiological and chemical analyses, safety requirements, etc.) must be supported by calibrated measuring equipment and proper devices for monitoring. Monitoring can be done visually in cases like comparison of color, etc.

When deviation from defined product characteristics is identified, the delivery will be approved by a relevant authority, and eventually by the customer, or you will follow the requirements of clause 8.3 Control of nonconforming product.

8.3 Control of nonconforming product

8.3.1 General

Products that do not conform to the requirements must be identified and controlled to prevent their unintended use or delivery to customers or end users. In order to achieve this, the organization must document a procedure that will define the controls and roles and responsibilities in the process of control of nonconforming products, from identification to disposition of the nonconforming product.

Every nonconformity needs to be analyzed and evaluated to determine the need for investigation and notification of any external party responsible for nonconformity.

8.3.2 Actions in response to nonconforming product detected before delivery

Nonconformities are always inconvenient for the organization, but if you need to choose when to spot it, the best moment is before it reaches the customer or end user. In case when the nonconformity is identified before delivery, the organization can take one of the following actions:

- Eliminate the identified nonconformity,
- Preclude the original intended use or application,
- Authorize its use, release, or acceptance under concession.

The last option, acceptance under concession, is only possible if justification for the nonconformity is provided, approval is obtained, and applicable regulatory requirements are met.

8.3.3 Actions in response to nonconforming product detected after delivery

In cases when the nonconforming product is delivered to the customer or end user, the organization needs to take actions to minimize the adverse effects of the nonconformity. The documented procedure for issuing advisory notices must be in place and capable of being put into effect at any time.

For more information, see: ISO 13485:2016 nonconforming product – How to approach the post-delivery actions.

8.3.4 Rework

Any rework to be performed on a medical device must be in accordance with documented procedures that takes into account the potential adverse effects of the rework on the device. After the rework is performed, the medical device must be verified to demonstrate its compliance with applicable acceptance criteria and regulatory requirements.

8.4 Analysis of data

The organization must collect and analyze appropriate data to determine whether its QMS is suitable, adequate, and effective. The data to be analyzed is that gathered from monitoring and measuring and other relevant sources, such as customer feedback, suppliers, audits, etc. The process of data analysis must be documented in a procedure and the results of the analysis must be recorded.

8.5 Improvement

8.5.1 General

Appropriate actions must be taken in order to ensure continual improvement of your QMS. Those actions are taken based on the Quality Policy and objectives, audit results, data analyses, corrective and preventive actions, and management review.

8.5.2 Corrective action

Corrective actions are one of the most powerful tools at your disposal when it comes to improving your QMS and removing nonconformities. Their main purpose is not to remove the consequences, but rather to eliminate the causes of nonconformities and prevent them from happening again.

The standard requires an organization to have a robust process for conducting corrective actions, which includes reviewing the nonconformity, determining the cause, evaluating the need for corrective action, performing and verifying corrective action, and, finally, evaluating the effectiveness of the corrective action.

To ensure that the corrective action process is performed in the way you have defined it, it is necessary to have a documented procedure and records of the investigation and performance of the corrective action.

For more information, see: ISO 13485 continual improvement: Seven-step process for corrective and preventive actions.

8.5.3 Preventive action

The organization should not wait for nonconformities to occur in order to remove their causes. If potential nonconformities are identified, the organization has to take preventive action to prevent them from happening. To define preventive actions, data sources that indicate potential nonconformities must be identified. Data sources could be connected to data analyses, identified trends, statistical results, etc.

The Procedure for preventive actions must be documented, along with appropriate records.

Conclusion

ISO 13485 provides organizations with guidance as to the quality of their products and services, with the ultimate goal of achieving customer satisfaction. Delivering on all of the clauses of the standard and truly understanding them can benefit your organization and drive your company along the road of continual improvement. Certification and compliance can bring reputational, motivational, and financial benefits to your organization through improved efficiency, quality of products and services, and avoiding nonconformities and customer complaints, along with improvements in your supply chain. All of these elements are closely related to your organization's ability to deliver satisfaction to your customers and fulfill the expectations and wishes of your stakeholders. Having all of this in mind, can your organization afford *not* to have ISO 13485?

Why not download our free Checklist of Mandatory Documentation Required by ISO 13485:2016 to find out what documents and records are required and start implementing the standard in your company?

Useful resources

- Here you can download a free preview of the ISO 13485 Documentation Toolkit. This will allow you to see samples of policies and procedures used in the implementation of ISO 13485:2016.
- This free webinar How to use a Documentation Toolkit for the implementation of ISO 13485 will guide you through the implementation process.

References

- 9001Academy
- 13485Academy
- ISO 13485:2016, International Organization for Standardization: http://www.iso.org

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