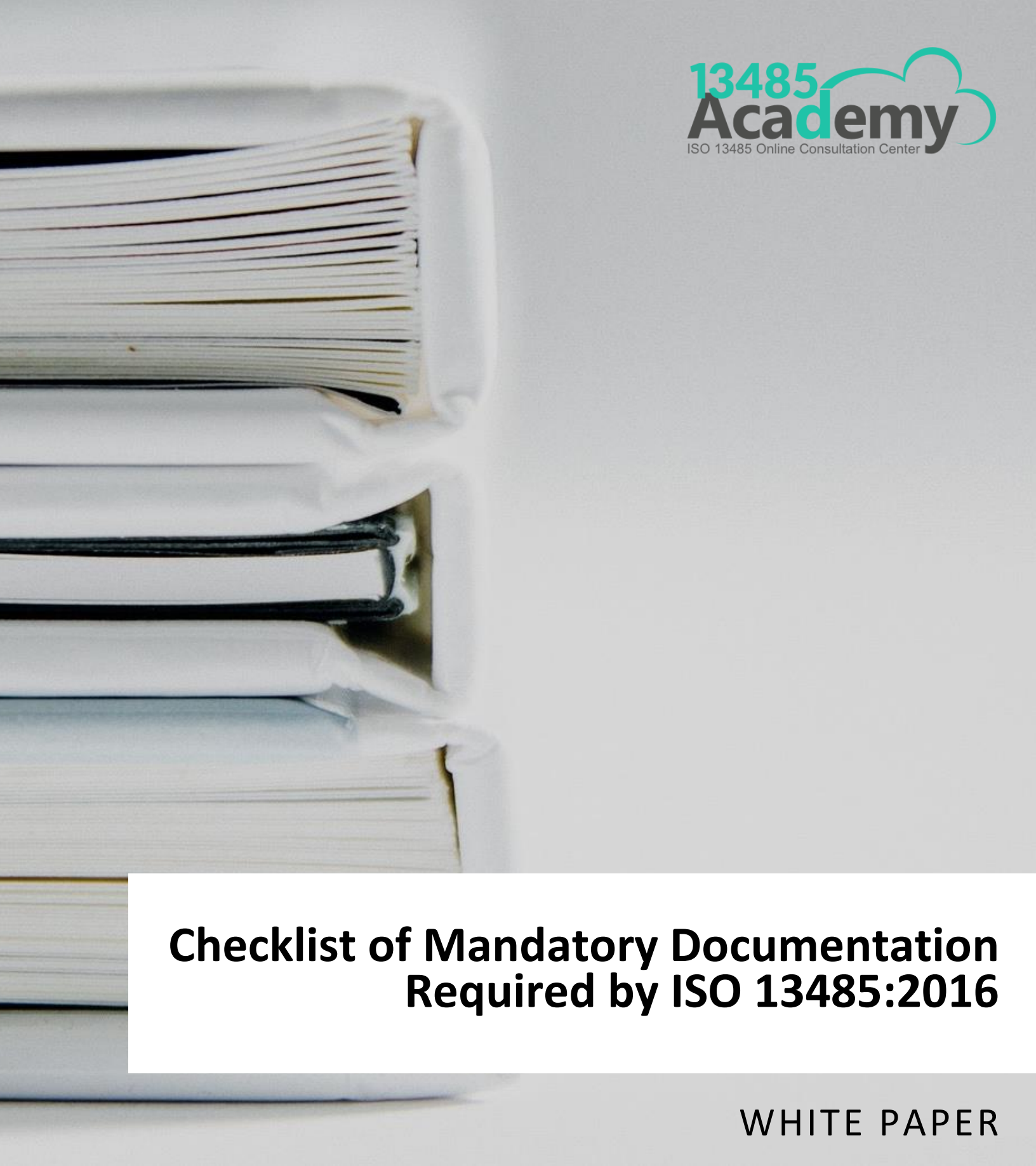

13485 Academy
ISO 13485 Online Consultation Center

Checklist of Mandatory Documentation Required by ISO 13485:2016

WHITE PAPER

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Executive summary

The latest version of ISO 13485 was published in 2016, which means medical device companies need to transition from the previous version of the standard and comply with the new requirements. One of the most important steps in the transition process, as well as in the initial implementation, is determining what documents and records are needed for an effective Quality Management System (QMS) based on ISO 13485. This white paper is designed to help top management and employees involved in ISO 13485 implementation or transition, and to clear up any misunderstandings regarding the documents required by the standard.

In this document, you will find an explanation of which documents are mandatory according to the ISO 13485:2016 standard, and which non-mandatory documents are commonly used in the QMS implementation, in the same order and numbered clauses as in ISO 13485.

Introduction

The documentation needed for implementation of ISO 13485 includes those documents explicitly required by the standard, plus those that the company determines to be necessary for effective maintenance of the QMS based on ISO 13485. Many companies go overboard with documentation in the belief that they need to document every single process that is in place in their organization, without realizing that this is not necessary to meet the requirements of the ISO 13485 standard. While trying to fulfill the standard's requirements, organizations tend to generate too many documents to be on the "safe side."

Although it is sometimes helpful, this can be counterproductive, because it makes the implemented processes and respective QMS hard to use and maintain, as well as making the QMS a bureaucratic burden. While taking such an approach, organizations are missing a chance to improve their processes for their own benefit, as well as that of their customers.

In this white paper, you will find, explained in plain English, what the minimum ISO 13485 requirements for the documentation are, as well as a list of documents that are commonly in place and can help you make your QMS more efficient.

Which documents and records are required?

Mandatory documents

Mandatory document	Clause of ISO 13485:2016
Document the role(s) undertaken by the organization	4.1.1
Written Quality Agreements with outsource partners	4.1.5
Procedure for the Validation of the Application of Computer Software	4.1.6, 7.5.6, 7.6
Quality Manual	4.2.1
Quality Policy	4.2.1
Quality Objectives	4.2.1
Procedure for Document Control	4.2.4
Procedure for Record Control	4.2.5
Responsibilities and Authorities	5.5.1
Procedure for Management Review	5.6.1
Procedure for Competence, Training and Awareness	6.2
Requirements for the infrastructure	6.3
Requirements for the maintenance activities	6.3
Requirements for the work environment	6.4.1
Requirements for health, cleanliness and clothing of personnel	6.4.1
Arrangements for the control of contaminated or potentially contaminated product	6.4.2
Requirements for control of sterile medical device contamination	6.4.2
Processes for risk management in product realization	7.1
Arrangements for communicating with customers	7.2.3
Procedure for Design and Development	7.3.1
Procedure for Purchasing and Evaluation of Suppliers	7.4.1

Mandatory document	Clause of ISO 13485:2016
Procedure and methods for the control of production	7.5.1
Requirements for cleanliness of product	7.5.2
Requirements for medical device installation and acceptance criteria for verification of installation	7.5.3
Procedure for Servicing Activities of Medical Device	7.5.4
Procedures for Validation of Processes	7.5.6
Procedure for the Validation of Processes for Sterilization	7.5.7
Procedure for Product Identification	7.5.8
Procedure for Traceability	7.5.9.1
Procedure for Preserving the Conformity of Product	7.5.11
Procedure for Monitoring and Measuring Equipment	7.6
Procedure for Customer Feedback Gathering	8.2.1
Procedure for Complaint Handling	8.2.2
Procedure for Internal Audit	8.2.4
Procedure for Control of Nonconforming Product	8.3.1
Procedure for Issuing Advisory Notices	8.3.3
Procedure for Rework	8.3.4
Procedure for Analysis of Data	8.4
Procedure for Corrective Actions	8.5.2
Procedure for Preventive Actions	8.5.3

Mandatory records

Mandatory records	Clause of ISO 13485:2016
Quality Agreement with Outsourced Processes	4.1.5
Records of Software Validation Activities	4.1.6, 7.6
Medical Device File	4.2.3
Records of Management Review	5.6.1
Records of Education, Training, Skills and Experience	6.2
Records of the Maintenance Activities	6.3
Records of Risk Management Activities	7.1
Outputs of Product Realization Planning	7.1
Records of the Results and Actions Arising from Review of Requirements Related to Product	7.2.2
Records of Product Requirements Changes	7.2.2
Design and Development Planning Documents	7.3.2
Design and Development Inputs	7.3.3
Design and Development Outputs	7.3.4
Records of Design and Development Review	7.3.5
Records of the Results and Conclusions of the Design and Development Verification	7.3.6
Design and Development Validation Plans	7.3.7
Records of the Results and Conclusion of Design and Development Validation	7.3.7
Results and Conclusions of the Design and Development Transfer	7.3.8
Records of Design and Development Changes	7.3.9
Design and Development File	7.3.10
Records of the Results of Evaluation, Selection, Monitoring and Re-evaluation of Supplier	7.4.1
Records of the Purchased Product Verification	7.4.3
Record for Each Medical Device or Batch of Medical Devices	7.5.1

Mandatory records	Clause of ISO 13485:2016
Records of Medical Device Installation and Verification of Installation	7.5.3
Records of Servicing Activities	7.5.4
Records of the Sterilization Process Parameters	7.5.5
Records of the Results and Conclusion of Validation	7.5.6
Records of the Results and, Conclusion of Sterile Medical Device Validation	7.5.7
Records of Traceability	7.5.9.2
Records of the Name and Address of the Shipping Package Consignee	7.5.9.2
Report to the Customer about Changes on his Property	7.5.10
Records of the Results of Calibration and Verification of Monitoring and Measuring Equipment	7.6
Customer Feedback Report	8.2.1
Complaint Handling Records	8.2.2
Records of Reporting to Regulatory Authorities	8.2.3
Internal Audit Plan	8.2.4
Internal Audit Report	8.2.4
Evidence of Conformity of Products with the Acceptance Criteria	8.2.6
Identity of the Person Authorizing Release of product	8.2.6
Identity of Personnel Performing any Inspection or Testing of Implantable Medical Devices	8.2.6
Record of Nonconformity	8.3.1
Records of the Product Acceptance by Concession and the Identity of the Person Authorizing the Concession	8.3.2
Records of Actions relating to the Issuance of Advisory Notices	8.3.3
Records of Rework	8.3.4
Records of the Results of Data Analyses	8.4
Records of Corrective actions	8.5.2
Records of Preventive actions	8.5.3

These are the documents and records that are required to be maintained for the ISO 13485 Quality Management System, but you should also maintain any other records that you have identified as being necessary to ensure that your management system can function, be maintained, and improve over time.

Commonly used non-mandatory documents

While ISO 13485 does not require that you document all of the procedures, there are a lot of processes that must be established in order to generate the required records that are outlined in the first section. Unlike ISO 9001, which leaves a lot of freedom in deciding whether to document a procedure or not, ISO 13485 doesn't leave much room for different interpretations—basically, all major procedures must be documented. In the table below, you can find examples of the documents that are not required by the standard, but that can be beneficial to the QMS:

Document title	Clause of ISO 13485:2016
Procedure for measuring customer satisfaction	5.2
Procedure for identification of regulatory and customer requirements	5.2
Procedure for internal communication	5.5.3
Procedure for planning product realization	7.1
Quality Plan	7.1
Sales procedure	7.2

One rule of thumb when deciding if you want to document a process is this: if there is a chance that the process won't be carried out as planned, then you should document it. In many cases, this is the best way to ensure that your Quality Management System is reliably implemented.

How to structure documents and records

ISO 13485 has a lot of requirements regarding documentation, so it is imperative to optimize the volume of your QMS documentation so that you develop enough to meet all of the requirements, while keeping it simple and light. Although there are requirements for more than 20 procedures, many of them can be merged together; this approach can provide you with a smaller number of documents, which is especially important for the small and midsize companies that want to implement the standard. The general advice is to identify common requirements, or requirements that relate to the same element of your QMS, and try to merge documented procedures.

The following recommendations take into consideration best practices in developing QMS documentation:

Written Quality Agreements with outsource partners. Between the manufacturer and the subcontractor, there must be an agreement with detailed roles and responsibilities; for example: whether or not the subcontractor needs to be certified, whether or not the manufacturer will conduct an audit of the subcontractor, how the subcontractor will report non-compliances during the process, how these non-compliances will be resolved, and how the manufacturer will report the subcontractor if it receives a complaint related to the outsourced process.

Procedure for the Validation of the Application of Computer Software. Once the software is installed, it must be checked periodically to make sure that it's configured correctly and working as it should. This could be when a new version of the software is obtained, or in any other case when considered necessary.

Quality Manual. This is a roof document for your QMS; it usually includes the QMS scope, role(s) undertaken by the organization, exclusions from the standard, references to relevant documents, and the business process model. For more information on how to write the Quality Manual, see: ISO 13485: How to write a short quality manual.

Quality Policy. A policy represents a declarative statement by an organization. A Quality Policy should state the commitment of the organization to quality and continual improvement and provide a framework for setting quality objectives. For more information on how to write the Quality Policy, see: How to Write a Good Quality Policy. The article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

Quality Objectives are derived from the goal stated in the Quality Policy, and they are the main method used by companies to focus this goal into plans for improvement. The objectives are intended to be S.M.A.R.T. (specific, measurable, achievable, realistic, and time-based) and should have relevance at all levels of the company, meaning that all employees should understand how their jobs support meeting the Quality Objectives. The article Setting good quality objectives for ISO 13485 gives more information on this process.

Procedure for Document and Record Control. This document defines how you approve, update, and re-approve your documents. When a document is changed, how do you identify changes and make sure that the people who need the current document have it and stop using older documents? How do you make sure the documents can be read, and how do you control documents that come from outside of your organization for use? Find out more about documentation with Some Tips to make Document Control more useful for your QMS; the article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

How do you maintain records that show your product is acceptable to use, and how do you identify, store, and protect the records so that they can be retrieved as necessary, for the correct amount of time, and destroyed when no longer needed but not before? In order to make the documentation more efficient, this procedure for managing records is commonly merged with the procedure for document control; here you can find a free preview of the Procedure for Document and Record Control.

Responsibilities and authorities. Each employee needs to know who is responsible for the various elements of the management system to ensure a successful implementation. This is usually accomplished through an organizational chart and job descriptions where roles, responsibilities, and authorities are clearly defined. This organizational chart can be part of the Quality Manual.

Procedure for Management Review. How do you conduct your review of the system to ensure that all areas of the system are functioning and that improvements are happening where planned and expected? How do you control the flow of information on management decisions out to the company? Learn more in this article about How to make Management Review more practical; the article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

Procedure for Competence, Training and Awareness. This procedure should describe how the process of identifying and achieving necessary competence is performed, as well as how the company raises its employees' awareness regarding the QMS. For more information about training and awareness, see: Improving quality through effective training and ISO 9001 awareness training material: How to create it, what it should contain; both articles explain ISO 9001 requirements, but they are also applicable to ISO 13485.

Requirements for infrastructure. The standard requires an organization to define and document requirements for infrastructure needed to achieve conformity to product requirements, prevent product mix-up, and ensure orderly handling of product.

Requirements for maintenance activities. In cases when the maintenance activities can affect the product quality, the organization needs to document those requirements.

Requirements for work environment. When conditions for the work environment can have an adverse effect on product quality, the organization needs to document the requirements for the work environment and the procedures to monitor and control the work environment**.**

Requirements for health, cleanliness, and clothing of personnel. When contact between personnel and the product or work environment could affect medical device safety or performance, the organization needs to document requirements for health, cleanliness, and clothing of personnel.

Arrangements for the control of contaminated or potentially contaminated product. In order to prevent contamination of the work environment, personnel, or product, the organization needs to plan and document arrangements for the control of contaminated or potentially contaminated product. For organizations that aim to decrease the number of documents in the QMS, the requirements for infrastructure, maintenance, and work environment can be merged into a single procedure. Here you can find a free preview of the Procedure for Infrastructure and Work Environment.

Requirements for control of sterile medical device contamination. For sterile medical devices, the organization must document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

Processes for risk management in product realization. Part of the planning of product realization is the assessment of risks that can result in noncompliance with the requirements for product or processes of the Quality Management System. The organization needs to document one or more processes for risk management for product realization.

Arrangements for communicating with customers. The organization must document arrangements for communicating with customers in relation to product information, inquiries, contracts, or order handling, including amendments, customer feedback (including complaints), and advisory notices. These requirements are often merged with the Sales Procedure.

Procedure for Design and Development. Requirements regarding the design and development process are among the most demanding in the standard. Every step of the design and development process needs to be documented in the form of a record, from design and development inputs, controls, and outputs, to changes in design and development. Considering all the requirements regarding the design and development process, it is best to document the Procedure for Design and Development and define all mandatory records that should accompany the procedure.

Procedure for Purchasing and Evaluation of Suppliers. The standard requires companies to establish control over its externally provided processes, products, and services. Documenting the criteria for evaluation, selection, monitoring, and reevaluation of the suppliers will enable the organization to ensure that purchased product conforms to specified purchasing information. For more information about the purchasing process, see Purchasing in QMS – The Process & the Information Needed to Make it Work; the article explains ISO 9001 requirements, but it is also applicable to ISO 13485. With outsourced companies, there needs to be a written Quality Agreement for Subcontractor.

Procedures and methods for the control of production. Control and monitoring procedures may include in-process and/or finished device acceptance activities as well as environmental and contamination control measures. Review the specific procedure(s) for the manufacturing process selected and the methods for controlling and monitoring the process. Verify that the process is controlled and monitored. The procedures are best documented in the Procedure for production and service provision.

Requirements for cleanliness of product. The organization needs to define requirements for cleanliness of product or contamination of product in cases when product is cleaned by the organization prior to sterilization or its use, the product cleanliness is significant in use, and process agents are to be removed from product during manufacture. This can be documented either separately, or within Procedures and Methods for the Control of Production, or in some other appropriate document.

Requirements for medical device installation and acceptance criteria for verification of installation. Requirements need to be documented, and the records of the installation and verification activities need to be maintained. This can be a standalone procedure, or it can be a part of the Procedures and Methods for the Control of Production.

Procedure for Servicing Activities. In cases when servicing activities are required, the organization needs to document the servicing procedure, as well as reference materials and measurements, if they are necessary for performing the servicing activity. Organizations with complex servicing activities will document the procedure as a separate document, but those with a more simple servicing process can include this procedure in the Procedures and Methods for the Control of Production.

Procedure for Validation Process. When the resulting output of the production and service provision process cannot be verified by subsequent monitoring and measuring, the organization needs to validate such processes and document the procedure for validation. It is also possible to merge this procedure with the Procedures and Methods for the Control of Production in cases of more simple validation activities.

Procedure for Validation of the Sterilization Process. Organizations that perform sterilization and have sterile barrier systems need to validate the process prior to implementation, and the procedure for sterilization needs to be documented.

Procedure for Product Identification. The product must be identified through processes of production, storage, installation, and servicing of product to ensure that only product that has passed the required inspections and tests is used or installed. The procedure for identification of the products must be documented and, again, in the case of less complex processes, the procedure can be merged with the Procedures and Methods for the Control of Production.

Procedure for Traceability. The organization needs to define the extent of traceability in accordance with applicable regulatory requirements and to document the procedure for traceability. Depending on the complexity of the traceability activities, the procedure can be merged with the Procedures and Methods for the Control of Production.

Procedure for Preservation of Product. The organization must protect product from alteration, contamination, or damage during processing, storage, handling, and distribution, and this can be achieved with a documented procedure for preservation of product. These requirements are usually documented in the Warehousing Procedure and in procedures defining each of the above-mentioned processes.

Procedure for Monitoring and Measuring Equipment. The purpose of the monitoring and measuring is to provide evidence of conformity of product to determined requirements. In order to ensure that

monitoring and measuring can be carried out and are carried out properly, the organization needs to document the Procedure for Equipment Maintenance and Measurement Equipment.

Procedure for Gathering Customer Feedback. ISO 13485 emphasizes customer feedback over customer satisfaction. As one of the measurements of the effectiveness of the QMS, the organization needs to gather and monitor information relating to whether the organization has met customer requirements and document the methods for obtaining and using this information. Since the sales process is most commonly in contact with the customers, this procedure is often merged with the Sales Procedure.

Procedure for Complaint Handling. Considering the possible impact that some medical devices can have on the quality of life of customers, there is a requirement to document how the complaint handling process will be carried out. Again, very often, the sales process is the first in line when it comes to contact with customers, so it can be useful to document the complaint handling process as a part of the Sales Procedure.

Procedure for Internal Audit. The internal audit is the process that determines whether the QMS is effective and performing as planned. The most important information regarding the internal audit, such as responsibility for planning, method of conducting and reporting, as well as the follow-up activities, need to be documented in the Procedure for Internal Audit.

Procedure for Control of Nonconforming Product. This procedure needs to provide answers to the following questions: What controls are in place, and who is responsible, to make sure that nonconforming product is not used? Are there terms that can be put in place to allow the use of nonconforming product, such as Rework, Repair, or Acceptance by Customer? How do you ensure that corrected product is re-verified, and what records are kept of the process? Find out more about ISO 13485:2016 nonconforming product – How to approach the post-delivery actions.

Procedure for Issuing Advisory Notices. In cases when the nonconforming product is discovered after delivery or use has started, the organization must not only take action to resolve the nonconformity, but also to issue advisory notices to customers. The procedure for issuing advisory notices must be aligned with relevant legislation and documented. Since this is a part of communication with customers, this procedure can be merged with the Procedure for Customer Communication, Feedback and Complaints.

Procedure for Rework. The rework needs to be done in a way that takes into account the potential adverse effects of the rework on the product. The procedure for rework needs to be documented and undergo the same review and approval as the Procedure for Production and Service Provision, so it is reasonable to merge these two procedures to decrease the amount of documentation in small and mid-size companies.

Procedure for Analysis of Data. The organization needs to determine, collect, and analyze appropriate data to demonstrate the suitability, adequacy, and effectiveness of the QMS and to document how this process is conducted. The Procedure for Data Analysis defines how the data are gathered and processed.

Procedure for Corrective Action. The procedure for reviewing nonconformity, determining the causes, and implementing and evaluating necessary actions needs to be documented. To learn more about the

corrective action process, see: ISO 13485 continual improvement: Seven-step process for corrective and preventive actions; the article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

Procedure for Preventive Action. How do you handle nonconformity before it occurs? Preventive actions are used to address such situations and, since the method of conducting the preventive actions is not so different from the corrective action, it is common to merge those two procedures into the Procedure for Corrective and Preventive Action.

At a minimum, these are the documented procedures that are necessary to meet the requirements, and they are all that is needed to document a simple QMS. However, there is often a need to provide written documents for more, and the trick is in knowing what else your company needs to document. If you are implementing a Quality Management System, you may struggle with the decision of what needs to be written down. This is common, but wisely answering the question "What should I document?" can avoid complexity in your Quality Management System, saving time and money.

Conclusion

ISO 13485 implementation can turn into a problematic project if you don't set it up correctly right from the beginning. Documentation that is required by the standard, extended by non-mandatory documents, forms a significant part of the QMS implementation. Knowing what the standard requires as mandatory documentation helps the organization to be well prepared for the certification audit. On the other side, the decisions on adding non-mandatory documents should represent a balance between competence of employees and administrative controls that can help the organization avoid nonconformities. Implementing both mandatory and non-mandatory documents in an optimal scope increases the efficiency of the QMS and creates benefits for both the organization itself and its customers.

Sample documentation templates

Here you can download a free preview of the ISO 13485 Documentation Toolkit – in this free preview, you will be able to see the Table of Contents of each of the mentioned policies and procedures, as well as a few sections from each document.

References

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