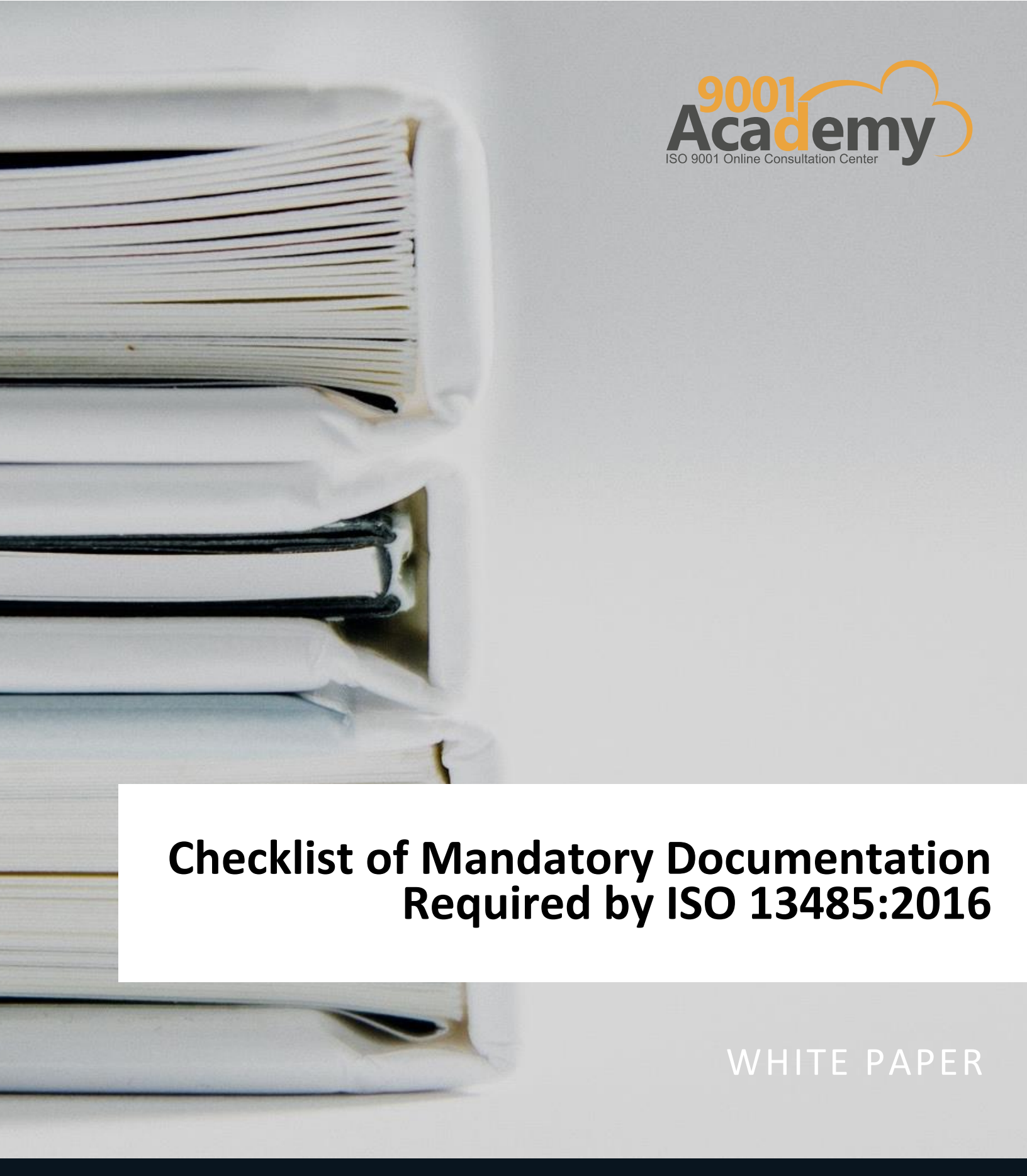

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Checklist of Mandatory Documentation Required by ISO 13485:2016

WHITE PAPER

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Executive summary

The latest version of ISO 13485 was published in 2016, and the transition from the previous version is ahead. 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 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 any documents explicitly required by the standard, plus any additional documents 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 standard 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 harder to use and maintain, as well as making the QMS a bureaucratic burden. With this approach, organizations miss opportunities to improve their processes for their own benefit, as well as that of their customers.

In this whitepaper, 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
Procedure to monitor and control 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

Mandatory document	Clause of ISO 13485:2016
Procedure for design and development	7.3.1
Procedure for purchasing	7.4.1
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 devices	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 record	Clause of ISO 13485:2016
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
Records of medical device installation and verification of installation	7.5.3

Mandatory record	Clause of ISO 13485:2016
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 necessary to ensure your management system can function, be maintained, and improve over time.

Commonly used non-mandatory documents

ISO 13485 does not require that you document all of the procedures, but there are a lot of mandatory 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, and 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 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 implemented reliably.

How to structure documents and records

ISO 13485 has a lot of requirements regarding documentation, so it is imperative that you optimize the volume of your QMS documentation by trying to develop documentation that meets all requirements, while remaining simple and light. Although there are requirements for more than 20 procedures, many of them can be merged together, and this approach can provide you with a smaller number of documents. This 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 the best practice in developing QMS documentation:

Document the role(s) undertaken by the organization. The organization needs to document its roles in the market under the applicable regulatory requirements. Those roles can be manufacturer, authorized representative, importer, or distributor. The roles of the company are rarely documented as a separate document; they are usually documented in the Quality Manual.

Written quality agreements with outsource partners. When the organization chooses to outsource any process that affects product conformity with requirements, it shall monitor and ensure control over such processes, because it retains responsibility for conformity of the product to customer and regulatory requirements. These arrangements can include the requirements for products, processes, and services, and are usually defined in the contract or the Procedure for Purchasing and Evaluation of Suppliers.

Procedure for the validation of the application of computer software. When the computer software is used in Quality Management System, the organization needs to validate it prior to initial use and after the changes to the software or its application. Requirements and description of the validation activities, together with the resulting records are defined in the Procedure for Documentation and Validation of Computer Software.

Quality manual. This is a roof document for your QMS, and 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: Writing a short Quality Manual. The article explains ISO 9001 requirements but it is also applicable to ISO 13485.

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 a 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. These are derived from the goal stated in the Quality Policy, and 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 How to Write good Quality Objectives gives more information on this process. The article explains ISO 9001 requirements but it is also applicable to ISO 13485.

Procedure for document 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 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.

Procedure for record control. How do you maintain your records that show your product is acceptable for use, including how 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 is commonly merged with the procedure for document control. Here you can find free preview of the Procedure for Document and Record Control.

Responsibilities and authorities. The standard requires responsibilities and authorities within the QMS to be defined, communicated and documented. This can be done in two ways, the organization can have a separate document that contains information about all roles and responsibilities or it can document the roles and responsibilities within the documents that describe processes and activities, e.g. procedures and work instructions.

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 identification and achieving necessary competence is performed, as well as how the company raises awareness of its employees regarding the QMS. For more information about the training and awareness, see: Improving quality through effective training and ISO 9001 awareness training material: How to create it, what it should contain. Both of the articles explain ISO 9001 requirements, but they are also applicable to ISO 13485.

Requirements for infrastructure. The standard requires the 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. This document defines what maintenance activities need to be performed and the interval of the activities. Instead of being a standalone document, it can be merged with the Procedure for Infrastructure and Work Environment.

Requirements for work environment and procedure for monitoring and controlling the 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. If 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 their QMS, 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.

Procedure for sterile medical devices. 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.

Procedure for risk management. Part of the planning of product realization is 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 and 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. The standard requires companies to establish control over their externally provided processes, products, and services. Documenting the criteria for evaluation, selection,

monitoring, and reevaluation of the suppliers will enable an 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.

Procedure for production. The standard requires production and service provision processes to be under control in terms of availability of necessary documented information about product or service characteristics, intended results, availability of needed resources, monitoring and measurement activities, etc. This rather complex process will hardly achieve the intended outcomes without clearly defined rules 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 with the Procedure for Production and Service Provision, or in some other appropriate document.

Procedure for medical device installation. Requirements for medical device installation and acceptance criteria for verification of installation need to be documented, and the records of the installation and verification activities need to be maintained. This can be a stand-alone procedure, or it can be a part of the Procedure for Production and Service Provision.

Procedure for servicing activities of medical devices. In cases when the 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 simpler servicing process can include this procedure in the Procedure for Production and Service Provision.

Procedure for validation of processes. 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. This procedure also offers the possibility to be merged with the Procedure for Production and Service Provision in cases of simpler 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 this procedure for sterilization needs to be documented. Depending on the complexity of processes, this procedure can be merged with the Procedure for Sterile Medical Devices.

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 product must be documented and, again, in cases of less complex processes, the procedure can be merged with the Procedure for Production and Service Provision.

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 Procedure for Production and Service Provision.

Procedure for preservation of product conformity. The organization must protect product from alteration, contamination, or damage during processing, storage, handling, and distribution, and this can be achieved through 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 is carried out properly, the organization needs to document a 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. Because 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 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 performing as planned, and if it is effective. The most important information regarding the internal audit, including responsibility for planning, method of conducting and reporting, and the follow-up activities, needs 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 non-conforming 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 the Customer? How do you ensure that corrected product is re-verified, and what records are kept of the process? Learn about the Five Steps for ISO 9001 Nonconforming Products here. The article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

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 issue advisory notices to customers. The procedure for issuing advisory notices must be aligned with

relevant legislation, and documented. Because this is a part of communications 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 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 data analysis process is conducted. The Procedure for Data Analysis defines how the data are gathered and processed.

Procedure for corrective action. The procedure for reviewing nonconformities, determining the causes, and implementing and evaluating necessary actions needs to be documented. To learn more about the corrective action process, see: Seven Steps for Corrective and Preventive Actions to support Continual Improvement. The article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

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

As a minimum, these are the documented procedures that are necessary to meet the requirements, and 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. The following are the most commonly used non-mandatory documents with the purpose of enhancing the QMS and decreasing the chance of nonconformity occurrence.

Procedure for measuring customer satisfaction. Although ISO 13485 does not require an organization to monitor customer satisfaction, it is very common for organizations to have such a process in addition to the customer feedback gathering requirements. A customer satisfaction survey allows an organization to find out more about the needs and expectations of its customers, and understand how they perceive the organization, and these can be valuable inputs for improvement of the QMS. For more information, see: Main elements of handling customer satisfaction in ISO 9001. The article explains ISO 9001 requirements, but it is also applicable to ISO 13485.

Procedure for identification of regulatory and customer requirements. The medical device industry is highly regulated, and failure to comply with the regulations can have a high price for the company. Documenting the manner in which the regulatory and customer requirements are identified and met, and

how the evaluation of the compliance is conducted, along with roles and responsibilities, can harness the greatest benefit for the company.

Procedure for internal communication. The internal communication process is vital to the effectiveness of the QMS. Especially in bigger companies, it can be beneficial to document the internal communication process to avoid miscommunication between employees. This procedure defines the "who, what, how, and to whom" of communication within the organization and ensures that the right information reaches its intended destination.

Procedure for planning product realization. In the case of a bigger company, it can be beneficial to document planning of the product realization. This procedure defines what information, documents, infrastructure, and work environment are needed prior to the beginning of the production process. Also, it defines resources, responsibilities, verification, validation, monitoring and measuring, and other activities needed to ensure that the production process will deliver the expected results.

Quality plan. Although not mandatory, this record can be useful for any size of company and complexity of processes as a simple way of documenting all information important for a process and easy monitoring and control of the process. Having information on activities, responsibilities, KPIs (Key Performance Indicators), and necessary documents and records in the process provides a clear overview on what is happening and whether it should be happening in this way. All of these benefits make the Quality Plan an irreplaceable record for an effective QMS.

Sales procedure. The ISO 13485 standard does not include a section on sales, but the requirements on customer-related processes are the main element in a documented sales process. How do you determine requirements related to the product regarding what the customer specifies (including delivery & post-delivery activities); what the customer does not specify, but is necessary; what the legal requirements are for the product; and any additional requirements the company knows are needed? How do you review these requirements to make sure the product requirements are all known, any contract questions are resolved, and the company can meet all requirements? Finally, how do you control communication with your customer?

Conclusion

ISO 13485 implementation can turn into a problematic project if you don't set it up correctly right from the beginning. The 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, decisions regarding the addition of non-mandatory documents should represent a balance between the 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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