UDecide

MANAGEMENT OF QMS   
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SCOPE: This document contains the projects interpretation and management of the Quality Management System Standard (ISO 13485:2016)

REFERENCES:

REVISION HISTORY:

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| **Revision** | **Revised by** | **Revision date** | **Description of changes** |
| 1.0 | Sofie Bjørn & Emma Elbo | 12-03-2021 | First version of interpretation and management of the Quality Management System Standard (ISO 13485:2016) |
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APPROVAL:

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| *Author:* |  | | |
| *Reviewer:* |  | | |
| *Independent reviewer:* |  | | |

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| **Where in ISO 13485:2016** | **What the chapter/article is about** | **Our interpretation and management of the regulation** | **Reference to other standards/documents/annexes** |
| Chapter 0 (3)  Introduction | Process approach - Guidance document | Plan-Do-Check-Act: We shall have a process approach, which automatically incorporates the PDCA. It can be used on single processes or the QMS as a whole.  This PDCA method is automatically in the project work:  Plan: Documents and plan the product (OOAD)  Do: Make the system according to plan (OOP)  Check: Improve the things that can be improved (Discussion in our case). Then make a new plan for the new case.  In addition, PDCA is also used in smaller iterations. | “ISO13485 Practical guide” |
| Chapter 1: Scope | Scope of ISO 13485:2016 | It is our responsibility to comply with the standard. If we do not adhere to it, then we must argue why. |  |
| Chapter 3:  Definitions |  | 3.8: labelling:  Label, instructions for use and any other information that is related to identification, technical description, intended purpose and propoer use of the medical device - excluding shipping documents.  3.15 Product: result of a process. Software is one of four generic product categories. A car for instance has elements of more product categories.  Software consistes of information and is generalle intangible and van be in the form of approaches, transactions or procedures.  Others:  life-cycle, manufacturer, medical device, medical device family, risk, risk management | Most definitions are from ISO 9000:2015. |
| Chapter 4: | Quality Management System |  |  |
| Chapter 4(1.1) | General Requirements | We shall document the quality and maintain efficiency according to this standard.  “We shall establish, implement and maintain any requriments, procedure, activity, or argument required to be documented by this standard and regulation.”  We shall define our role (e.g. manufacturer, specification developer, supplier of raw materials,...)  We shall investigate external- and internal factors |  |
| Chapter 4(1.2) | Processes | Shall determine relevant processes for the QMS   * The v-model   Shall apply a risk-based approach   * The method is optional (so we can choose fx. SWOT)\*   The relevant processes and the risk-based approach shall be consistent.   * In our project, we use the v-model, which shall proceed with the risk analysis. | ISO 14971:2019 (RISK)  \* “ISO13485 Practical guide” |
| Chapter 4(1.3) | The method behind the processes | For each process, we shall  a.define criteria and methods for controlling whether or not the process is effective  b.have available resources to support the operation of the processes.  c.implement necessary actions to maintain effectiveness  d.Monitor/measure/analyse the process  e.document conformity to this standard.  \* This is done by asking questions like: “   * How will your organization know whether the process is effective? * What does it need to do to make sure that the process is operating effectively? * what controls are necessary to monitor the process? * How will your organization know that the controls on the process are effective? * What human and physical resources are needed for the operation and control of the process? * Who is responsible for the process and what competence requirements are there for the position(s)? * What information is needed to effectively implement and control the process? * Are the controls on the process covering all the requirements identified in the planning activities? * How will the outputs of monitoring of the process be analyzed? | \* “ISO13485 Practical guide” |
| Chapter 4(1.4) | Evaluation | If there are changes in the processes, then QMS must still ensure that we comply with the requirements of this standard.  This means that we have to evaluate how the change in process impacts the QMS.  \* There is a specific list of requirements for each element of change.  Et billede, der indeholder tekst  Automatisk genereret beskrivelse | \* “ISO13485 Practical guide” |
| Chapter 4(2.1)  Documentation Requirements | General | Requirements for documents and documents management:   * Quality policy and objectives   Documented: the size of our organization, type of activities undertaken, … .   * Quality manual   Work instructions must be simple and understandable.   * Procedures and records required by this standard.   Often define activities and describe:   * What is to be done, and by whom * When, where and how it is to be done * what materials, equipment, and documents are to be used, * how an activity is to be monitored and measured, and * what records are required. * Documents the planning, operation, and control of the processes   evaluation of the QMS criteria:   * Fitness for purpose, * ease of understanding and use, * resources required, * quality policy and objectives, and * interface used by your organization’s customers and suppliers. * Other documentations. |  |
| Chapter 4(2.2) | Quality manual | The quality manual shall include   1. scope of the QMS including reasons for non-application of requirements. 2. documented procedures for QMS or references to them 3. description of the interactions between the processes   This manual is dependent on the role of the organisation, because it is from this the potential reasons for excluding certain criteria stems. | Additional information relating to quality manuals is available in ISO/TR 10013. |
| Chapter 4(2.3) | Medical device file | For each medical device type (for us, just the “UDS”) we shall make a file either containing or referencing documents that demonstrate conformity to the requirements.  Content shall at least be:  a.general description, intended use/purpose.  b.specifications for product  c.Specifications or procedures for manufacturing, packaging, storage, handling and distribution  d.Procedures for measuring and monitoring  e.requirements for installation  f.Procedures for servicing. |  |
| Chapter 4(2.4) | Controlled documents | All documents required by this standard shall be controlled. | “Skabelon til kontrollerede dokumenter” |
| Chapter 4(2.5) | Controlled records | Records are a special type of document. Shall also be controlled. They contain data/observations etc. used as evidence of conformity to requirements. |  |
| Chapter 5  (p. 9 ) | Management Responsibility |  |  |
| Chapter 5(2) | Customer focus | Shall ensure that the user requirements and regulatory requirements are consistent. |  |
| Chapter 7 | Product realization |  |  |
| Chapter 7(2) | Customer-related processes | We have to use customer requirements. If necessary, we must set additional requirements that are related to the customer.  Furthermore, there must be documentation of compliance between user requirements and system requirements. |  |
| Chapter 7(3) | Design and development | We shall document and justify our development processes  The output from risk-management shall be included in the analysis and design, as well as our intended purpose.  We shall plan verification and validation in the development of the system | (OOAD) |
| Chapter 8 | Measurement, analysis, and improvement |  |  |
| Chapter 8(5.2) | Improvement | If an error occurs in the system, we are obliged to correct it and to prevent future errors |  |