[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR DOCUMENT AND RECORD CONTROL

Commented [AES2]: If you want to find out more about document control, see this article:

Some tips to make Document Control more useful for your QMS https://advisera.com/9001academy/blog/2014/05/20/tips-make-document-control-useful-qms/

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [AES3]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

Distribution list

Commented [AES4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy no.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to ensure control over creation, approval, distribution, usage, updates, retention, and disposition of documents and records (also called: documented information) used in the Quality Management System (QMS).

This Procedure is applied to all documents and records related to the QMS and medical device files, regardless of whether the documents and records were created inside [organization name] or whether they are of external origin. This Procedure encompasses all documents and records, stored in any possible medium – paper, audio, video, etc.

This Procedure doesn't apply to documents and records regarding [describe the parts of the organization that this Procedure doesn't apply to].

Users of this document are all employees of [organization name] inside the scope of the QMS.

Commented [AES5]: Include the name of your organization.

Commented [AES6]: E.g. finance, accounting, general and legal affairs.

Commented [AES7]: Include the name of your organization.

2. Reference documents

- ISO 13485:2016 standard, clauses 4.2.3, 4.2.4, and 4.2.5
- MDR 2017/745 article 10(9), Annex II, and Annex IX – Chapter I
- Quality Manual
- [other documents and regulations specifying document control]

Commented [AES8]: Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link https://advisera.com/13485academy/mdr/

Commented [AES9]: You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "03_Quality_Manual".

3. Control of documents

Internal documents are all documents created inside the organization, e.g. policies, working instructions, records etc., and are listed on the List of Types of Records.

3.1. Creation and identification of documents

All documents are identified by name, code, date of version, version number and copy number.

Identification of documents is performed as follows:

- Procedures are coded in the following way: [describe the organization's standard practice].
- [illegible]

[illegible]

Commented [AES10]: For example:

Procedures are coded with four alphanumerical characters: PRXX

The coding is as follows:
- PR – Letter marking of type of document – e.g. PR stands for procedure

[illegible]

Commented [AES11]: For example:

Records are coded with five alphanumerical characters: PRXX.Y

The coding is as follows:
- PR – Letter marking of document – procedure

[illegible]

3.2. Document approval

All documents, regardless of whether they are new documents or new versions of existing documents, record templates and working instructions must be reviewed and approved by [job title]

Commented [AES12]: In case there are several document levels, for example policies - procedures - instructions, which must be approved by different management levels, such requirements should all be specified.

[illegible]

for suitability and adequacy. [illegible]

3.3. Publishing, distributing and accessing documents

After approving a draft or a new version of a document, [job title] must publish the document on the intranet, in the folder [folder name] with reading rights only. When a new document or new document version is published, [job title] must inform all employees listed as users of the document by e-mail.

[illegible]

3.4. Withdrawal of outdated documents

The new version of a document is immediately distributed to the place of use upon creation and approval (as explained in the previous clause). [Job title] must delete the older version of the document from the valid documents folder and move it to [folder name].

[illegible]

3.5. Document updates and changes

The person listed as document owner has the responsibility for updating and changing the document. Updates and review are performed in line with the frequency defined in the List of Internal Documents.

[illegible]

Each document should preferably have a "Change history" table used to record every change made to the document.

3.6. Documents of external origin

Each external document that is necessary for the planning and operation of the QMS must be recorded in the Incoming mail register. The Incoming mail register must contain the following information: [illegible]

Commented [AES13]: If your organization does not have a [illegible]

Commented [AES14]: If you are using paper documents you can write: [illegible]

Commented [AES15]: You can find a template for this [illegible]

Commented [AES16]: If you are using a paper document, you can write: [illegible]

Commented [AES17]: E.g. Quality Manager, Office Manager

Commented [AES18]: Delete if you use electronic documents.

Commented [AES19]: Adapt the document name to the [illegible]

Commented [AES20]: Add additional information if required [illegible]

The person who receives mail and courier parcels must forward them to [job title], who must make a record in the Incoming mail register; [illegible]

Commented [AES21]: E.g. Quality Manager, Office Manager

3.7. Records control

Commented [AES22]: If you want to find out more about record control, see this article:

[illegible]

3.7.1. Record managing and labeling

Each internal document in the QMS must define how records resulting from the use of such a document should be managed; i.e., it must specify the following: (1) record name, (2) storage location, (3) person responsible for storage, (4) controls for record protection, and (5) retention time.

[illegible]

Records that arise from legal or regulatory requirements or from IT systems are accepted in defined form and they are not subjected to marking described in this Procedure.

[illegible]

3.7.2. Managing of changes

[Job title] must ensure that all changes in records are clear and traceable.

Commented [AES23]: E.g. Management Representative

[illegible]

Commented [AES24]: E.g. Management Representative or R&D Manager

Commented [AES25]: Adapt to the applicable corresponding regulations / standards in the organization.

[illegible]

3.7.3. Medical device file

For each medical device type or medical device family, [job title] must ensure the existence of documents containing proof of conformity to ISO 13485, [illegible]

Commented [AES26]: E.g., R&D Manager

Commented [AES27]: Delete this if your medical device is not

Commented [AES28]: Delete this if your organization does not

[Job title] must ensure that the device file for each medical product contains:

Commented [AES29]: E.g., R&D Manager

- general description of the medical device, intended use/purpose, and labeling, including any instructions for use;
- specifications for product;
- specifications or procedures for manufacturing, packaging, storage, handling, and distribution;
- [illegible]

All documents regarding the medical device file will be kept for at least 10 years after the last device has been placed on the market.

Commented [AES30]: Delete this if your organization does not

Commented [AES31]: Delete this if your medical device is not

3.7.4. Record protection, availability and retrieval

If health records are kept as part of the medical device production or service provision, [job title] must ensure the protection of health records' confidentiality in accordance with applicable regulations.

Commented [AES32]: E.g., Management Representative or R&D Manager

Commented [AES33]: Regulations / standards in the organization.

Access and retrieval rights for records are determined by the owner of individual records. [Job title] is responsible for destroying all records of which the retention time has expired.

Commented [AES34]: More details should be provided if

If the records are stored on computer they must be backed up at least [describe the usual practice in the organization].

Commented [AES35]: E.g., once a day.

Commented [AES36]: E.g., Management Representative

3.7.5. Record archiving and destroying

Records with expired retention times are destroyed in a way that prevents their further use

4. Managing records kept on the basis of this document

Record name	Code	Storage			
List of Internal Documents	PR00.1				
List of External Documents	PR00.2				

Commented [AES37]: Alter these records to match what you

Commented [AES39]: Adapt the information in this column to

Commented [AES38]: Adapt the information in this column to

Commented [AES40]: If the record is in electronic form, write

		[illegible]		[illegible]	
List of Type of Records	PR00.3	[illegible]	[illegible]	[illegible]	[illegible]
Registry of Records for Retention/Central Archive	PR00.4	[illegible]	[illegible]	[illegible]	[illegible]
Incoming mail register (electronic form – Excel spreadsheet)		[illegible]	[illegible]	[illegible]	[illegible]

Only [job title] can grant other employees access to the records.

Commented [AES41]: E.g., Quality Manager, Office Manager

5. Appendices

- Appendix 1 – List of Internal Documents
- Appendix 2 – List of External Documents
- [illegible]
- [illegible]