

SOP Document and Record Control

ISO 13485:2016 Section	Document Section
4.2.4	(All)
4.2.5	(All)

Summary

This SOP describes how documents and records are handled. The goal is to understand how documents are typically structured and their current state as they move from draft to release. The most recent document must be available at a specified location while ensuring changes to documents are always traceable.

Process Owner	<i><enter role of process owner></i>
Key Performance Indicators	<i><enter KPIs to be tracked for the Management Review></i>

General Considerations

This whole template assumes that you're using Google Drive and Google Docs for your QMS. If you're using something else, then.. good luck. Just kidding. You need to customize it, of course. There's specialized QMS software out there which makes some of these tasks easier and lots of other tasks harder :) Make sure to describe somewhere (ideally in this first paragraph), in which tool your QMS documents will be managed and stored.

Documents are expected to change over time, whereas **records** are created once and not altered significantly afterwards.

All documents are written in English.

Document and Record Labeling

Documents are named according to this schema:

ASSOCIATED PROCESS-TYPE-NAME

Where "associated process" can be abbreviated in capital letters and "type" refers to an abbreviation of the document type (see below). "Name" refers to the actual file name.

Example: **SWD-SOP-Integrated Software Development**

For released documents, we add a "-a" suffix (as in: approved) to the document name.

Example: SWD-SOP-Integrated Software Development-a

For archived documents, we add a “-archived_ARCHIVE DATE” suffix to the document name.

Example: SWD-SOP-Integrated Software Development-archived_2021-03-01

Product records are labeled with a device number, device version and associated process.

Example: PR1-V1.2-SWD-SWDP-Software Development Plan

Document Type Abbreviations

There probably will be more types in the future when I add more templates. For now, this covers all types of the templates on open-regulatory.com.

Abbreviation	Description
AM	Attachment
LIS	List
SD	Supporting Documentation
SOP	Standard Operating Procedure (Process Description)
TPL	Template

Retention Periods

QMS documents and records shall be stored for at least 10 years after their archival date.

Technical Documentation shall be stored for at least 10 years after the lifecycle of the respective device has ended.

Checking Periods

We check our QMS documents regularly following a risk-based approach in order to ensure they remain up to date:

- *Category A*: following a new release or the release of a new version of a document, it is checked again 6 months later to see if any changes are necessary. If not, it's status can be changed to category B.
- *Category B*: once a document has passed a first checking cycle without any changes, it is sufficient to check it again only 1 year later. If found necessary during this time period, changes are applied and the status of the document is reset to category A. If no changes are required, it's status can be changed to category C.
- *Category C*: once a document has passed a second checking cycle without any changes, it is sufficient to check it again only 3 years later. If found

necessary during this time period, changes are applied and the status of the document is reset to category A. If no changes are required, its status can remain in category C.

- Our *core and safety processes* as defined in the quality management manual must be reviewed at minimum once per year (max. category B).
- In the case of *audit findings or related corrective action*, it is up to the discretion of the QMO to apply shorter review periods for a document (e.g. 6 months).

QMS Document List

We keep an overview list of all QMS documents, including document type, release date, next review date and respective process owners.

Process Steps

Handling of Documents

1. Creation of Documents

This assumes you have three folders in your GDrive: “drafts”, “under review” and “released”.

All documents are saved in the Quality Management System (QMS) which is a folder in Google Drive.

New documents can be created by anyone in the company in the “drafts” folder. Naming of documents follows the general considerations of this SOP (see above). Standard Operating Procedures (SOP) should specify a process owner responsible for typically updating, reviewing and releasing all associated documents.

Participants

Any employee

Input	Output
Content	New Document (draft)

2. Documents Ready for Review Once a document is ready for review, its author moves it to the “under review” folder. Importantly, the author selects appropriate reviewers and approvers and notes them at the bottom of the document.

Participants

Any employee

Input	Output
Document (draft)	Document (under review)

3. Review of Documents The respective reviewer(s) and approver(s) review the document. If changes are required, they create comments in the Google Doc and/or suggest changes. If the review is successful, they sign their initials at the bottom of the document.

Participants
Process owner and/or designated reviewer(s) and approver(s)

Input	Output
Document (under review)	Document (review successful)

4. Release of Documents The Process Owner moves the document to the “released” folder and assigns “-a” to the document name as outlined by the general considerations for document naming.

Access to the “released” folder is restricted to prevent unauthorized changes to released documentation.

The QMO (and, if applicable, the process owner) decide if employee training is required. In general, training for minor changes/corrections is not necessary.

Participants
QMO, Process Owner

Input	Output
Document (review successful)	Document (released)

5. Changes to Documents If changes need to be made to a document, any employee with knowledge about the document and those changes can perform them. For that, the currently-released document is copied to the “drafts” folder and edited by the employee. After finishing the edit, it moves to the **Document Ready for Review** stage (step 2), following the same steps as above.

Changes to documents should be reviewed and approved by the original author, process owner or by a designated role with sufficient background information to make a qualified decision.

A QMS document change can trigger a substantial change. Before release, it shall be checked whether it may impact the organization’s process landscape and hence, overall organizational conformity with regulatory requirements. The QMO is responsible to evaluate such potentially major changes as part of the Change Evaluation List (reference change management process).

Participants
QMO, any employee

Input	Output
Document (released)	Document Copy (draft)

6. Archiving of Documents Documents get archived if they become obsolete or a newer released version becomes available. For that, the Process Owner removes the “-a” suffix, moves the document to the “archive” folder and assigns a respective archiving date following the general considerations for document naming in this SOP. We observe retention periods as outlined in this SOP and delete documents as soon as the retention period expired.

Participants
Process Owner

Input	Output
Document (released)	Document (archived)

Handling of Records

1. Creation of Records We create records as required by our processes. If available, we use templates and checklists for the creation of records. Naming conventions as outlined for documents do not apply. Records should include an author’s name and the date of creation.

Participants
Any employee

Input	Output
Content, Template Document (if applicable)	New Record

2. Review and Release of Records Unless specified differently in a template or SOP, records do not typically require a review and release process.

Participants
Designated reviewer(s) and approver(s)

Input	Output
Record (under review)	Record (review successful)

3. Storage of Records Records are not necessarily stored in our QMS folder. They also may reside in other applications as specified per respective processes. This is where records are typically stored:

Add all your tools which stores data which is mentioned in your QMS.

- *GitHub (Issues, Pull Requests)*
- *ZenDesk (Customer Support Tickets)*

4. Changes to Records Records are not significantly altered after creation / release. Where significant changes are required, we rather create a new record and archive the old one. Non-substantial changes (e.g. spelling mistakes) are considered corrections only, assessed and added on a case-by-case basis.

Participants
Any employee

Input	Output
Record (released)	Record (updated)

5. Archiving of Records Records are archived if they become obsolete or a new released version becomes available. For that, the process owner moves the records to a respective archiving location. If possible, we follow the general considerations for document names and add the archiving date to the record name. We observe retention periods as outlined in this SOP and delete records as soon as the retention period expired.

Participants

Process Owner

Input	Output
Record (released)	Record (archived)

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