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# Introduction

## Purpose

Establish a procedure for control of documents and records.

## Scope

Identification and control of documents

## References

ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 13485:2016 – sections addressed in this document

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 4.1 | 4.2 | 5.1 | 5.2 | 5.3 | 5.4 | 5.5 | 5.6 | 6.1 | 6.2 | 6.3 | 6.4 | 7.1 | 7.2 | 7.3 | 7.4 | 7.5 | 7.6 | 8.1 | 8.2 | 8.3 | 8.4 | 8.5 |
|  | X |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

## Related Documents

N/A

## Glossary

QMS - quality management system

DCR – document change request

ECO – engineering change order

# Identification of Documents

Documents shall be identified uniquely by the unique document number and version number, which shall appear on each page of the document.

## Document identification

<unique document number> - <document name>

Example: SOP-701 - Control of Documents

## Unique document number

<Doc type>-<optional: product ID (three digits)><number (three digits)>

Examples: SOP-701 or TD-WOR-001

## Version number

<incremental number (three digits)>

Example: 001

## Document type

|  |  |  |  |
| --- | --- | --- | --- |
| <Doc type> | Name | Description | Typical File Type |
| **Quality Documents** | | | | |
| QMM | Quality Management Manual | General description of and quick guide of the Quality Management System (QMS) | .docx |
| SOP | Standard Operating Procedure | Quality process, defines:  - when, how, by whom  - process inputs and outputs | .docx |
| DOC | Document | Used to plan what needs to be done:  - charts, flowcharts, organization charts  - used all the time, but are not historical as RECs are  Living DOC: document where the content may change (often referred to as list, log, index or matrix) | .docx .xlsx for living DOCs |
| REC | Record form | Records validate that processes have taken place and provide evidence that something was done. When a record form is completed, it becomes a record and is subjected to control of records. | .docx for record forms  .pdf for records |
| **Technical Documents** | | | | |
| TD | Technical Document | Document designs and other results of technical activity | .docx |
| WI | Work Instruction | Guidance for activities such as manufacturing, assembly and testing to ensure consistent outcomes | .docx |

# Control of Documents

## Required Change Control

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | QMM/SOP/DOC | Living DOC | REC | WI/ TD |
| Change Layout | Requires DCR | Requires DCR | Requires DCR | Requires ECO |
| Change Content | Allowed - same file name | Allowed - new file name (see control of records) |

## Authors, Reviewers and Approvers

The following functions are eligible as authors, reviewers and approvers of documents.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Author | Reviewer | Approver\* |
| Quality documents | Anyone | QM ADMIN | QM  MD |
| Technical documents | Anyone | QM  ADMIN  HWENG  SWENG  CLIND | QM  MD |

\*When a document is changed, it shall be approved either by the original approving function or another function that has access to pertinent background information upon which to base its decisions.

General requirements:

* Reviewers shall confirm that the information is correct, factual and with an adequate level of detail. Reviewers shall be competent contributors different from the author such as a supervisor or an expert.
* Approvers check the reviewed documents for formal compliance with regulatory requirements.

## Control of Documents of External Origin

Management of external documents shall follow the rules that apply for other quality documents or technical documents, including records.

Examples:

* datasheets are typically technical documents  
  (they may need to be obsoleted in the future)
* notification letters or certificates from a supplier are typically records  
  (they will be stored forever)

## Document Change Request (DCR) - how to update a quality document

The following process is used to update quality documents:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| # | What | Who | Details | Record |
| 1 | **Trigger: Need for new document or document update** | Anyone | Initiate document change request (DCR) | N/A |
| **If QM is initiator, steps 2-9 can be skipped:** | | | | |
| 2 | **Request change** | Anyone | Create DCR record | REC-701 - DCR |
| 3 | **Approve request** | QM | Approve the DCR | REC-701 - DCR  Note: make sure to identify impact on other documents |
| 4 | **Specify author, reviewer, approver** | Assign names based on Sect. Authors, Reviewers and Approvers |
| 5 | **Create folder** | Create a folder with the request in the QMS directory |
| 6 | **Create document(s)** | Author | Place the new document(s) in the folder, create PDF(s) | N/A |
| 7 | **Review and approve** | Author, Reviewer, Approver | Sign in PDF(s) | N/A |
| 8 | **Verify review** | QM | Verify that new document(s) have been reviewed and approved. | REC-701 - DCR |
| 9 | **Identify training needs** | Define training needs (if initiator is QM, QM will train immediately) | REC-701 - DCR |
| **Continue:** | | | | |
| 10 | **Obsolete old document(s)** | QM | Obsolete old document(s): use *git rm* command | N/A |
| 11 | **Stage changes** | Approve new document(s): use *git add* command to stage changes to the git repository | N/A |
| 12 | **Release** | Commit changes to git: use *git commit* command with commit message | commit message including change description and rationale |
| 13 | **Train** | QM | Inform affected team members, ask to confirm comprehension of the changes and implications | DOC-103 - Employee Training Log |
| **If QM is initiator, step 14 can be skipped:** | | | | |
| 14 | **Close DCR** | QM | Close DCR | REC-701 - DCR |

## Engineering Change Order (ECO) - how to update a technical document

The following process is used to update technical documents:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| # | What | Who | Details | Record |
| 1 | **Trigger: Need for new document or document update** | Anyone | Initiate Engineering Change Order (ECO) | N/A |
| **If QM is initiator and product is not on the market, steps 2-9 can be skipped:** | | | | |
| 2 | **Request change** | Anyone | Create ECO record | REC-702 - ECO |
| 3 | **Approve request** | QM | Approve the ECO | REC-702 - ECO  Note: make sure to identify impact on other documents |
| 4 | **Specify author, reviewer, approver** | Assign names based on Sect. Authors, Reviewers and Approvers |
| 5 | **Create folder** | Create a folder with the request in the QMS directory |
| 6 | **Create document(s)** | Author | Place the new document(s) in the folder in the QMS directory, create PDF(s) | N/A |
| 7 | **Review and approve** | Author, Reviewer, Approver | Sign in PDF(s) | N/A |
| 8 | **Verify review** | QM | Verify that new document(s) have been reviewed and approved. | REC-702 - ECO |
| 9 | **Identify product implications** | Identify impact on risk management file, regulatory submissions and stock of existing product | REC-702 - ECO |
| **Continue:** | | | | |
| 10 | **Obsolete old document(s)** | QM | Obsolete old document(s): use *git rm* command | N/A |
| 11 | **Stage changes** | Approve new document(s): use *git add* command to stage changes to the git repository | N/A |
| 12 | **Release** | Commit changes to git: use *git commit* command with commit message | commit message including change description and rationale |
| **If QM is initiator and product is not on the market, step 14 can be skipped:** | | | | |
| 13 | **Perform implied actions** | QM | Perform actions as identified in step 9 | REC-702 - ECO |
| 14 | **Close DCR** | Close ECO | REC-702 - ECO |

# Control of Records

Records are a special type of document. They shall be maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. Records must not be changed and shall be stored in the QMS directory. Records shall be identified uniquely by their

file name:

<document identification REC> - <specification text>\_<filing date (YYYY-MMM-DD)>

where:

<specification text> is mandatory

if no record form exists, <document identification REC> shall be REC-NAN  
examples:

REC-501 - Installation Protocol - SystemGoeteburg\_2019-Feb-17  
REC-NAN - MaterialiseISOCertificate\_2018-Dec-31

The following process shall be used to store records:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| # | What | Who | Details | Document |
| 1 | **Trigger: record form was filled  or** record **created from scratch** | Anyone | When a record form (REC) is completed, it becomes a record. | N/A |
| 2 | **Place record in the QMS directory** | Anyone | location: subfolder level below the record form (REC), else arbitrary folder of the QMS directory | N/A |
| 3 | **Stage to register** | QM | use *git add* command to add the record to the git repository | N/A |
| 4 | **Register** | use *git commit* command to register the record | N/A: no commit message required |

# Storage and Retention of Documents

## Storage

Documents (including quality records) are stored in the QMS directory of the Evolunis Dropbox.  
Documents are controlled using a git repository, which is stored along with the QMS directory in the Evolunis Dropbox.

## Retention

|  |  |
| --- | --- |
|  | Retention period |
| Quality documents | 10 years after obsoletion |
| Technical documents | 10 years after last batch produced |
| External documents | 10 years  after obsoletion |