1 Introduction 2

1.1 Purpose 2

1.2 Scope 2

1.3 References 2

1.4 Related Documents 2

1.5 Glossary 2

2 Identification of Documents 3

2.1 Document identification 3

2.2 Unique document number 3

2.3 Version number 3

2.4 Document type 3

3 Control of Documents 4

3.1 Authors, Reviewers and Approvers 4

3.2 Control of Documents of External Origin 4

3.3 Document Change Request (DCR) - how to update a quality document 5

3.4 Engineering Change Order (ECO) - how to update a technical document 6

3.5 7

3.6 Control of Records 7

4 Storage and Retention of Documents 8

4.1 Storage 8

4.2 Retention 8

# Introduction

## Purpose

Establish a procedure for control of documents and records.

## Scope

Identification and control of documents

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| To be performed by | MD | X | QM | X | ADMIN | X |
| SWENG | X | HWENG | X | QEXP | X |
| TECH | X | WAREHM | X | CLIND | X |
| SALESM | X |  |  |  |  |

## 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/ organization ID (three digits)><number (three digits)>

Examples: SOP-701 or TD-WOR-001

## Version number

<incremental number or letter combination (three digits)>

Order: 001, 002 .. 999, 00A .. ZZZ

## Document type

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| <Doc type> | Name | Description | Typical File Type | Change Control |
|  | **Quality Documents** | | | | |
| Specifications: “Say what you do” | | | |  |
| QMM | Quality Management Manual | Root document of the Quality Management System (QMS) | .docx | DCR |
| SOP | Standard Operating Procedure | Quality process, defines:  - when, how, by whom  - process inputs and outputs | .docx | DCR |
| DOC | Document | Used to plan what needs to be done:  - charts, flowcharts, organization charts  - used all the time, but are not historical as Records are | .docx | DCR |
| WI | Work Instruction | Guidance for activities such as manufacturing, assembly and testing to ensure consistent outcomes | .docx | DCR |
| REC | Record form | Forms for records | .docx/.xlsx | DCR |
| Evidence: “Do what you say” | | | |  |
| REC | Record | Records provide evidence that something was done. When a record form (REC) is completed, it becomes a record and is subjected to control of records. | .pdf/.zip/.xlsx | Control of Records |
|  | **Technical Documents** | | | | |
| TD | Technical Document | Product-related documents as created according to SOP-201 - Design and Development | .docx/ .pdf/.zip/.xlsx | ECO |

# Control of Documents

## 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  
  (example: REC-NAN - SiemensISOCertificate\_31DEC2018)

## 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 | REC-104 - 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 the version number is numerical, 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 training needs, customers to be informed and impact on: risk management file, validation and verification, 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 the version number is numerical, steps 13-14 can be skipped:** | | | | |
| 13 | **Perform implied actions** | QM | Perform actions resulting from product implications, as identified in step 9 | REC-702 - ECO |
| 14 | **Close ECO** | Close ECO | REC-702 - ECO |

## 

## Control of Records

Records 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> - <specification text>\_<filing date (DDMMMYYYY)>

where:

<specification text> is mandatory.

For logs, <specification text> shall be ACTIVE, <filing date (DDMMMYYYY)> shall be LOG.

For records based on technical documents, <document identification> shall be the TD name.  
If no record form exists, <document identification> shall be REC-NAN.

Examples:

REC-501 - Installation Protocol - SystemGoeteburg\_17FEB2019  
REC-104 - Employee Training Log - ACTIVE\_LOG  
REC-NAN - MaterialiseISOCertificate\_31DEC2018

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 or a log is updated, 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/ to backup the log | 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 Company Server; copies are not controlled. Documents are controlled using a git repository, which is stored along with the QMS directory in the Company Server. Obsoleted documents are hidden files in the git repository and can have the same unique document number as existing documents.

## Retention

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