Procedure: Control of Documents

|  |  |  |  |
| --- | --- | --- | --- |
| Document information, authorship and approvals | | | |
| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

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This procedure is based on ISO 13485 clause 4.2.3 Control of Documents. It provides general rules for controlling different types of documents on different media (paper and electronic). Larger companies using electronic systems may need to revise this procedure and add more specific instruction.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for control of documents throughout their life cycle. It includes preparation, review, authorisation, issue, distribution and revision of all controlled documents at [Company].

# Scope

The scope of this procedure includes the following types of documents:

Edit the list as appropriate but ensure it matches the one in Section 4.2 of the Quality Manual.

* quality manual
* procedures
* work instructions
* forms
* device, labelling and packaging specifications
* manufacturing, installation and servicing specifications
* quality assurance procedures and specifications
* standards and codes

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| All personnel | Prepare, revise or review a controlled document. |
| Quality Manager | Responsible for the authorisation, issue, identification, legibility, distribution, revision and withdrawal of controlled documents. |

# Procedure

## Device Master Record

ISO13484 has similar DMR and QSR requirements to CFR 820.181 and 820.186. The difference is in the organisation rather than in what is actually required.

The DMR (Device Master Record) holds the documents (or references them) that define the device, its manufacture and QA specifications. Procedure QP402: Device Master Record defines how DMRs are set up and maintained. DMR documents must comply with the rules that apply to other controlled documents (as described in this procedure).

## Quality System Record

A QSR (Quality System Record) contains the documents that define the QMS (Quality Management System). It includes the quality manual and procedures (and work instructions if required) that are not specific to a particular device or process.

QSR documents are established and controlled following the same rules that apply to controlled documents, e.g. as defined in this Control of Documents procedure.

## Identification

There are general requirements with which all controlled documents must comply. Some types of documents (e.g. engineering drawings) may have more specific identification and these are better described in a specific procedures or instructions.

As a minimum, controlled documents are identified by:

* a unique title
* a unique number
* revision number
* an effective date
* an approving/issuing authority

The specific format and method for applying the identification depend on the type of document and whether the document is in paper or electronic form.

An effective date may be used to identify the revision status of a controlled document. However, to facilitate management, an alphanumeric identification of the revision may be required for some types of documents, for example, the quality manual, procedures, work instructions, engineering drawings and specifications.

Edit this clause to define the company’s procedure for revision identification.

## New documents and revisions

All staff are encouraged to suggest changes to existing documents or identify the need for new ones. Staff should evaluate the documents they use and request revisions to correct any errors and inconsistencies identified.

The initiator of a change must submit a draft of the proposed document/revision to their supervisor or manager. The responsible manager may revise or reject the proposed change or draft. Requests for changes to QA documents must be submitted to the QA Manager.

Modify this clause to reflect the company’s process for changing existing or issuing new documents. A form may be used to track these changes.

## Initial issue

Documents must be reviewed for adequacy, correctness and conformity to quality policies before release. A document is considered to be formally issued when it is authorised and approved for release by the issuing authority.

Approved documents are identified with the name of the person who is approving/releasing it, the title, document number, revision number and the effective date. Hand-written signatures are not required although they may be used for particular types of documents (usually for those for external distribution).

## Revisions

Changes to documents are reviewed and approved by the same function or department that approved the initial document, unless specifically designated otherwise. Reviewers must have access to the same information as the originators of the document.

Issuing of revisions follows the same procedure that applies to the issuing of initial documents.

Revised documents are formally issued when the approving/releasing authority and the new effective date are identified in the document (as well as the new alphanumeric revision level, if appropriate).

This defines how draft documents are distinguished from approved and released documents. Edit to reflect how this is done by the company.

Documents may be changed by handwritten correction in RED, without the document being formally re-issued. Changes must be signed and dated by the authorising manager. If multiple controlled copies of a document are distributed, all copies must be changed.

Where hand-written corrections are allowed, modify this section to describe how corrections are controlled. If hand-written corrections are not allowed, modify this clause appropriately.

Printouts of electronically distributed documents (e.g. documents available on the network and printed out for information) may not be changed by hand.

## Circulation of new and revised documents

Distribution and recall of controlled documents may be subject to existing procedures using transmittal forms, etc. These are not a requirement of ISO 13485 but they should be described here if they are used.

Documents must be available where they are required to carry out an activity. They may be issued to a location or to person.

Documents directly related to the manufacture of specific devices are distributed to document stations in relevant areas. Special instructions may be enclosed with specific custom orders.

Describe practices in the company and coordinate with Section 7.5 of the Quality Manual and QP708.

ISO 13485 requires that changes to documents are communicated to users and that superseded documents are removed in a controlled way. How the company achieves this should be described here.

Superseded documents must be retained for at least the lifetime of the device but not less than the retention time of any resulting record. This must be defined by the company (refer section 3.10 below).

Revised documents are distributed to the same persons/locations where originally issued. They are distributed with a cover sheet that includes a brief description of the change, identifies any additional training required and provides instructions on replacing the superseded version.

Superseded copies of documents should only be kept by the persons responsible for Control of Documents. Superseded documents must be retained for a period of at least the life of the device and no less than 2 years after product release.

Electronic documents are posted on the network and are available for viewing and printing at appropriate workstations. When a document is revised, the old version is withdrawn from the network and substituted with the approved, revised document.

## Document master list

A document master list is not mandated in the standard but the company must be able to identify the latest revision of a given document and its distribution. A list or spreadsheet is the easiest way to achieve this.

It may be necessary to have a separate system for complex sets of drawings (e.g. engineering drawings).

Each department is responsible for issuing controlled documents and maintaining a list of its own documents.

Lists are maintained in form FM401-1: Control of Documents Master List. The list identifies each issued document by its code/number, title, approval/issuing authority, effective date, revision level and distribution.

## Customer engineering documents and changes

This section applies to subcontractors. If technical documents are not received from customers or other external sources, this section can be deleted.

If customer documents are received, a system for logging, reviewing and maintaining these documents must be in effect. Ensure that it includes the review and approval activities described in 3.7.

Engineering documents (standards, specifications, drawings, samples, etc.) and changes received from customers are logged. Once logged, documents are forwarded to Engineering, Production and/or Quality Assurance, as applicable, for review and approval. The scope of the review includes checking for:

* correctness and revision level
* identification of changes (for revisions)
* approval by the customer's issuing authority
* if ambiguities or errors are detected, the customer is contacted
* approval of external documents is indicated by a note stating the document is approved for production and by a signature of the authorised person

Only documents approved internally by an authorised representative from Engineering, Production or Quality Assurance, as applicable, may be used in production or inspection activities.

## Uncontrolled copies

Documents issued for information only are stamped UNCONTROLLED on the title page. These are not followed up with revisions.

Uncontrolled copies of documents may not be given to those who manage, perform, or verify work that is directly affected by the document.

## Retention of superseded documents

To ensure an accurate method of manufacture is available for the life of a product, at least one copy of superseded controlled documents must be retained.

Obsolete documents are retained for at least the lifetime of the device but not less than the retention period of resulting records (refer to Procedure QP403: Control of Records). The retention period must not be less than two years from the devices’ release date or as specified by relevant regulatory requirements.

A two year retention period is a requirement of 21 CFR Part 820.180. This is not specified in ISO 13485.

Retained copies of obsolete documents are stamped OBSOLETE and kept separate from active documents in a secure environment. Obsolete electronic documents are removed from the network and stored in secure directories, disks or other means and are only accessible to authorised personnel.

## Control of electronic documents

This section must define who directs/authorises the IT department to post approved controlled documents and revisions on the network, how this is done and how the authorisation is recorded. Security and backup of the electronic system must be addressed either here or in IT specific procedures.

Control of Documents requirements stipulated in this procedure apply equally to electronic documents.

Printed copies of electronic documents are not controlled and must be destroyed after use. When a paper copy of an electronic document is to be retained, it must be stamped UNCONTROLLED.

There should be a maximum time limit imposed on the retention of uncontrolled documents in the workplace, e.g. for the duration of the task.

Electronic documents must be regularly backed up.

You should refer here to some work instructions or other documentation defining the backup schedule and providing instructions for backing up the system.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
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|  |  |
|  |  |
|  |  |
|  |  |

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
|  |  |  |  |
|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP402 | Device Master Record |
| QP403 | Control of Records |
| FM401-1 | Control of Documents Master List |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END