Procedure: Document Control

|  |  |  |  |
| --- | --- | --- | --- |
| 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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# Purpose

The purpose of this procedure is to describe the requirements for control of Good Manufacturing Practice (GMP) documents at .

It describes the system, provides instructions and identifies responsibilities for control of documents throughout their life cycle. It includes the preparation, review, authorisation, issue, identification, legibility, distribution, revision and withdrawal of all controlled documents.

# Scope

Edit this list to ensure it is appropriate for your company but ensure it matches the one in the Quality Manual.

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

* quality manual
* procedures
* master batch documents
* work instructions
* forms
* controlled notebooks
* specifications

Excluded from this procedure are:

* All human resource documentation or finance systems not covered by the Quality Management System (QMS).

Edit as appropriate.

# Responsibilities

The following roles and responsibilities are associated with this procedure.

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

# Procedure

## Identification

The numbering system can be changed to reflect company preference. Provide the numbering convention here.

Controlled documents (except for controlled notebooks) are identified as a minimum by:

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

The document numbering convention is as follows.

|  |  |
| --- | --- |
| Identifier | Document type |
| QM000 | Quality manual |
| QP000 | Procedures (SOPs) |
| FP000-X | Form |
| MFI000 | Manufacturing formulae (MF) instructions |
| PRI000 | PRocessing (PR) instructions |
| PAI000 | PAckaging (PA) instructions |
| TI000 | Testing (T) instructions |
| PROT000 | Protocols |
| AGR000 | Technical Agreements |

**Note**: For all document types, refer to FP401-1: Controlled Document Master List for the next available number where:

* 000 the next sequential number (001 to 999)
* X is the next sequential number for related documents e.g. one procedure may have multiple associated forms

Numbering format may be amended to suit company systems/preference.

A template is provided for each type of document to facilitate ease of use, but it is the responsibility of the author of a controlled document to ensure that it contains this required information.

## Controlled notebooks

A notebook (or workbook) used for the development or manufacture of product is to be controlled. Notebooks used must be bound so no pages can be removed or added and each page must be numbered sequentially in indelible ink or print. The notebook must be identified prior to first use with (as a minimum):

* a unique identifier, for example the name of the person who primarily uses it; and
* a sequential number in the format 000.

Notebook numbering format may be amended to suit company systems/preference.

## Creating and revising controlled documents

Document revision is managed via the change control system (Procedure QP703 :Change Control).

A revision of a controlled document is required when any part of the content becomes inaccurate. The document must be updated in a timely manner.

Time requirements for revision may be specified in the change control procedure if require.

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

The initiator may write a draft of the proposed new document or revise an uncontrolled copy of the current one at any time. As the objective of this is to ensure that the document accurately reflects the company’s requirements and that the procedure is effective and efficient, the editing process can be undertaken as many times and utilising as many personnel as necessary to obtain a document that is correct.

A company may require limited access to electronic versions of controlled documents and so revisions/updates can be drafted using hardcopy mark ups. This should be specified in the change control procedure if required.

## Document approval and issue

When the document is correct and in the appropriate format it is signed in blue or black permanent ink by the author and a second subject matter expert.

Form FP703-1: Change Request is then completed and the document submitted together with this form to the quality manager for:

* checking, approval and issue of the document
* approval of the change via change control.

When approved by change control, the document is formally issued by the quality manager who ensures:

* the Change History section of the document is completed and has a valid reference to the Quality system (change control, CAPA, etc) raised to revise the document in accordance with site procedures.
* the document is approved
* the front page stamped in red “Controlled copy”
* it is issued to a document location and the details recorded on Form FP401-1: Controlled Document Master List
* it is signed and dated by the person issuing it to the document location
* the previous version of the document (if relevant) is withdrawn/superseded.

## Emergency revision

A controlled document may be reviewed for an emergency change 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. The document must be formally revised and reissued as soon as practicable.

## Storage and access

The original of an approved controlled document is stored in a secure location together with all other controlled documents.

Controlled documents must be available for use where they are required to complete an activity.

Copies of controlled documents may be made and stored in secondary locations within . Each secondary location is assigned a unique identifier and each copy of a controlled document is stamped in red “Controlled Copy” and the document location recorded on the document.

The identity of each copy is verified by a second person.

Controlled documents, including copies, must be legible and clean.

## Document master list

A list of all controlled documents is maintained in Form FP401-1: Controlled Document Master List. The list identifies each issued document by its code/number, title, approval/issuing authority, effective date, author, revision level and distribution of controlled copies made. Superseded documents are removed from the list.

The master list is updated on the same business day as when the updated document is issued.

Remove this next sentence if it does not apply to you.

A separate list of superseded documents may be maintained at the discretion of the quality manager.

## Uncontrolled copies

Documents issued for information only are stamped “Uncontrolled copy - Not to be used to control company processes” on each page. These are not followed up with revisions.

In order to remove the risk of carrying out procedures using out-dated documents, uncontrolled copies of documents are not be used to manage any process.

This next sentence may be required if very close control of a document is required. Detail specific requirements for your company.

At the discretion of the quality manager, the issue of any uncontrolled copies of a controlled document (for example, master batch documents) may be prohibited.

A draft of a controlled document must not be used to control a company process.

## Superseded documents

To ensure an accurate method of manufacture is available for the life of a product, the master copy of all superseded controlled documents must be retained. Copies are stamped “Superseded” and kept separate from active documents in a centrally available and secure environment.

Superseded controlled documents are retained according to procedure Procedure QP403: Control of Records.

## Control of electronic documents

Electronic versions, including scanned copies of originals may be held. However, as electronic systems have not been validated, electronic copies are considered uncontrolled and Section 4.8 applies.

Amend as appropriate if the company electronic systems are validated according to PIC/S GMP/ISO9001:2015 -published Sept 2015,previously 2008

ISO 9001:2015 significantly differs from the 2008 edition, with:

* A stronger focus on risk management and customer satisfaction
* A new structure to align management systems Standards
* More emphasis on leadership and commitment
* Fewer prescriptive requirements
* More requirements on communication and strategic alignment
* Formal introduction of ‘interested parties’.

## Review period

Each controlled document must have a defined review period.

Usually this is based on a risk evaluation, for example first revision documents are not likely be perfect, so a one year review may be appropriate, second revision documents a two year review period and third revision onwards, set at a maximum of 3 years.

The quality manager is responsible for reviewing controlled documents that have not been revised to assure that:

* the procedure is still correct
* the document adequately reflects the quality manual requirements.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
| Specification | Describe in detail the requirements with which the products or materials use or obtained during manufacture have to conform. They serve the basis for quality evaluation. |
| Manufacturing Formulae, Processing, Packaging and Testing Instructions | Provide detail all the starting materials, equipment and computerised systems to be used and specify all processing, packaging, sampling and testing instructions. In-process controls and process analytical technologies to be employed should be specified where relevant, together with acceptance criteria. |
| Procedures (SOP) | Give instructions for performing and recording certain discrete operations |
| Protocols | Give instructions for performing and recording certain discreet operations. |
| Technical Agreements | Are agreed between contract givers and acceptors for outsourced activities |

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 |
| QP403 | Control of Records |
| QP703 | Change Control |
| FP401-1 | Controlled Document Master List |
| FP703-1 | Change Request |

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