Procedure: Change Control

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# Purpose

The purpose of this procedure is to describe the system to control and manage all changes that can impact product quality and safety both developed and manufactured under the Quality Management System (QMS) at [Company].

It ensures these changes are clearly identified, documented, reviewed and approved.

# Scope

The scope of this procedure includes all changes with the potential to impact product quality or GMP, including (but not limited to) changes associated with:

* controlled documents of the Quality Management System (QMS)
* any specification, in-process control, critical quality attribute (CQA) or critical process parameter (CPP), or any other criteria with GMP impact
* utilities, infrastructure or parts of the facility with GMP impact
* software and other IT assets/hardware
* equipment within manufacturing, laboratories or other areas with GMP impact
* regulatory submissions/amendments, notifications or impact to the marketing authorisation
* manufacturing processes and supporting processes (cleaning, environmental monitoring etc.)
* suppliers of active pharmaceutical ingredients (APIs), excipients, primary packaging, critical consumables

Excluded from this procedure are:

* administrative or facility changes not described by the QMS (for example, administration /Human Resources documentation, installing a water cooler in the office area)
* like-for-like changes (replacing a part that does not affect the validated state of the equipment)
* consumables (stationery, laboratory chemicals/solvents/glassware etc.).

# Responsibilities

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| --- | --- |
| Role | Responsibility |
| Department Managers | Identify and follow up actions to be taken to justify any change within their area of responsibility. |
| Quality Manager | * Independent evaluation of proposed change controls. * Approve changes to the company QMS. * Management of the change control system. |
| All staff | Raise a change control request. Personnel are encouraged to make changes that improve product quality, or reduce or remove the risk of non-conforming product or processes. |

Amend to reflect company structure.

# Procedure

Any change to the following must be approved before the change is made:

* changes affecting company procedures and systems, referred to as the QMS
* changes affecting manufacturing equipment performance
* changes affecting product quality not managed by batch or process documentation.

The change control procedure has the following distinct elements:

1. **Proposing a change** – Reason and description of the proposed change.
2. **Evaluating the effect of a change on product quality** – Evaluation or impact of the change on product quality, including the documents affected and actions proposed.
3. **Approval of a change before implementation** – Independent approval of the change before implementation.
4. **Implementing a change** – Description of actual change made.
5. **Storing of completed change controls** – Change control forms must be stored for traceability.
6. **Trending change control metrics** – ongoing management and trending of change controls.
7. **Emergency change control** – raising emergency change controls.

## Proposing a change

All changes are recorded and managed using Form FP703-1: Change Control. The change form is a controlled record once completed.

The initiator describes the proposed change and the justification for the change in the Description of Change section. All documents and equipment affected must be listed on the change form. Attach copies of all impacted documents, highlighting the proposed change.

Send the change form to the Quality Assurance department so that a unique identifier can be assigned to the change request and then forward to the responsible manager(s) for approval to initiate the change control.

Changes are not to be made until they are approved except for emergency change control (see Section 4.7).

## Evaluating the effect of a change on product quality

The responsible manager or delegate assesses the effect of the change and lists the actions required to complete the change.

The initiator must complete a risk assessment for the proposed change.

The level of Quality Risk Management (QRM) should be commensurate with the level of risk involved with the change.

## Approval of a change before implementation

The Quality Manager (or delegate) reviews the change request and proposed actions; amending as necessary.

Depending on the significance of the requested change, a meeting may be held with stakeholders to discuss and assess the merits of the change. Minutes of this meeting are recorded and form part of the change control package.

The actions cannot be implemented until the Quality Manager has reviewed and approved the change request and the proposed actions.

## Implementing a change

The initiator records on the change form when the actions have been implemented.

The responsible manager (or delegate) and the Quality Manager review the change form and associated evidence.

If the change actions:

* have been completed satisfactorily, the change control is approved as implemented and is closed out.
* are not satisfactory or further actions have been required and assigned to the responsible manager, then the change request remains open. Changes are reviewed until satisfactory progress has been made and the change control is closed out. If the scope of a change control is modified, or actions are added or removed, it is necessary to gain approval from the Quality Manager.

Change controls may be extended or cancelled by the Quality Manager upon request by the Department Manager if a documented justification is provided and approved.

Wherever possible, timescales for completion of work is to be specified. Changes must be made in timely manner.

Specify frequencies for change control types if required by your company.

## Storage of completed change controls

Completed change requests are controlled records according to Procedure QP403: Control of Records. All associated documentation must accompany or reference the completed change request.

## Trending change control metrics

The Quality Manager should report to executive management the following metrics on a monthly basis and the trends for each metric over a rolling 12 month period:

* number of open change controls
* number of approved to implement changes
* number of closed changes
* number of changes past the expected close-out date (expired change controls).

Ongoing expired change controls should be escalated to executive management.

## Emergency change control

Emergency changes may be made to controlled processes or equipment or controlled documentation when the responsible manager or delegate decides that failure to make the change would threaten the:

* occupational health, safety or environment of company personnel
* quality of raw materials, labelling and packaging materials, container closures, finished product.

If an emergency change control is proposed, this must be approved by the responsible manager and a Quality representative. Actions may then be implemented immediately without further evaluation of the change control request. In all other respects, emergency change control must be managed in an identical way to other change controls.

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. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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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. |
| FP703-1 | Change Control Form |

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

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

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