Procedure: Control of Design and Process Changes

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This procedure applies to both product design changes and manufacturing process design changes.

Form FM704-1 Engineering Change Request is suitable for both of these. To separate the two types, this procedure and FM704-1 may both be split into two.

Control of product design changes is required by ISO 13485 and CFR 820 (sections 7.3 and 820.30 respectively). Control of the manufacturing process changes is explicitly required only in CFR 820.70(b). ISO 13485 is not explicit.

# Purpose

This procedure describes the system, provides instructions and identifies responsibilities for initiating, processing and controlling:

* device design changes
* manufacturing process design changes

at [Company].

# Scope

The scope of this procedure includes device and manufacturing process design changes after completion and approval of the design. Specifically, it applies once the design is:

* released to regulators for pre-market approval
* undergoing clinical trials
* released to production

During the device and the manufacturing process design phase, and before any of the preceding events take place, design changes are controlled in accordance with Procedure QP703 Design Control.

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Engineering Manager |  |
| Department Manager |  |
| Quality Manager |  |
|  |  |

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## General

Requests for product design and manufacturing process changes may be initiated by company personnel or by external consultants or subcontractors. Design and process change requests are documented and processed using Form FM704-1: Engineering Change Request (ECR).

The ECR system is intended for minor changes to correct design problems or improve the devices’ reliability or manufacturability, etc.

More comprehensive changes (e.g. modifying functional characteristics or significant performance upgrades) require revision of the original design input requirements. These are developed as a design project controlled by Procedure QP703: Design Control.

The ECR system must not be used to avoid design control requirements. Edit Section 4.1 to reflect the company’s practices and requirements.

## Engineering change request

The ECR meets the requirements of ISO 13485 clause 7.3.7 and CFR 820.30(i) and CFR 820.70(b).

The ECR form includes the following blocks:

a) effect of Change

b) engineering Disposition (with fields for defining verification/validation requirements)

c) authorisation (for referencing corresponding records).

This form may be simplified by removing blocks or information that is not relevant to [Company]’s procedures. All information on the form is required but not everything must be implemented through the form.

All company personnel are able to request a process or design change. An ECR form is ompleted and submitted to the relevant Departmentl Manager. The originator completes the first two blocks of the form:

* the first block of the ECR form is to identify -
* the product/process to be changed
* the relevant drawing, specification or other document that identifies the feature to be changed
* the second block is to describe the requested change and references documents that may be enclosed (e.g. photographs, sketches, marked-up drawings, etc.)

When the first two blocks are completed, it is signed (in the “Originator” box) and forwarded to the Department Manager.

The Department Manager evaluates the proposed change, and the possible implications, using the checklist provided in the *EFFECT OF CHANGE* block of the form. Consult with appropriate functions and subject matter experts (SMEs), review the evaluation and determine the status of the change request (approved or rejected). Only the Engineering/Quality Manager has authority to approve requests for product and process design changes.

Amend as required for your company structure.

* If the request is accepted, the space in the block is used to define how the design change is to be verified and/or validated and the applicable acceptance criteria.
* If the change request is rejected, the ENGINEERING DISPOSITION block is completed, with a short explanation. The form is then closed out.

The last block in the ECR form is to authorise implementation of the change in production. The Department Manager must authorise implementation of product design changes and/or manufacturing process changes. The authorisation may only be given after the design change has been verified, validated and all affected DMR documents updated.

The free space in the *PRODUCTION IMPLEMENTATION AUTHORISATION* block is to be used to list revised DMR documents and, where applicable, reference any verification or validation protocols and reports.

## Corrective action request

If a Corrective Action Request (CAR) is initiated to deal with wider, systemic problems related to the change, the *YES* box is checked on the ECR and the CAR number is recorded at the bottom of the last block.

If a CAR is not required, the *NO* box is checked.

(Refer to Form FM810-1: Corrective Action Request for information on the CAR process.)

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 |
| QP703 | Design Control |
| FM704-1 | Engineering Change Request (ECR) |
| FM810-1 | Corrective Action 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.

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