Procedure: Design Control

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Table of Contents

[1. Purpose 3](#_Toc406076438)

[2. Scope 3](#_Toc406076439)

[3. Responsibilities 3](#_Toc406076440)

[4. Procedure 3](#_Toc406076441)

[4.1. Design planning 3](#_Toc406076442)

[4.2. Design input 5](#_Toc406076443)

[4.3. Design output 6](#_Toc406076444)

[4.4. Design reviews 8](#_Toc406076445)

[4.5. Design verification 9](#_Toc406076446)

[4.6. Design validation 10](#_Toc406076447)

[4.7. Design transfer 11](#_Toc406076448)

[4.8. Design changes 12](#_Toc406076449)

[4.9. Project book 12](#_Toc406076450)

[4.10. Design History File 12](#_Toc406076451)

This procedure is for companies that design products. It is not relevant to companies that do not design products and are excluded from ISO 13485 clause 7.3.

The procedure describes the basics of a design control process. Edit this document to suit the company’s requirements and practices but ensure that all the standard’s requirements are met. The processes described in this document are not the only way to achieve the required result and level of control. Alternative methods that achieve this are acceptable.

This procedure applies to:

a) the design of new devices

b) the design of changes to existing devices

For larger companies or more complex devices, this may need to be two separate procedures.

# Purpose

This procedure describes a system, provides instructions and identifies responsibilities for product design, design changes, design verification and validation activities at [Company].

# Scope

The scope of this procedure includes:

* design and development of new medical devices, including packaging and labelling
* modifications and upgrades of existing devices

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Project Manager |  |
| Production Manager |  |
| Quality Manager |  |
|  |  |

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

# Procedure

## Design planning

(Refer ISO 13485 clause 7.3.1.) The main requirements of this clause are to:

a) determine the key design stages or activities

b) define review, verification and validation requirements for each design stage

c) assign responsibilities and authorities

d) manage interfaces between different groups involved in the design

Where the company’s design procedure is fairly constant, this procedure can be more specific and provide more detail. Edit as appropriate.

This template is suitable for smaller companies. In a larger company, the organisation may be more complex with different groups specialising in different engineering disciplines or a multidisciplinary project group managed by a Project Manager.

A Project Manager is responsible for managing product design projects. The Project Manager has authority for final approval of design plans, design inputs and outputs, design changes and release of the final design. The Project Manager also reviews and approves design verification and validation results and chairs design review meetings.

All personnel assigned to the design project, including external consultants, report directly to the Project Manager.

Prior to commencement of design activities, the Project Manager establishes a project plan. This plan is based on Form FM703-1: Medical Device Design Project Plan, and its purpose is to:

* identify and schedule design activities including verification, validation and design transfer
* assign resources to carry out these activities
* schedule design reviews

Start and finish dates for each activity are identified on FM703-1, so the requirement for scheduling the project is technically satisfied. However, the schedule would be much more convincing if it was also presented graphically, for example, as a simple bar chart or a Gantt Chart.

For more complex projects or projects with tight schedules, the Project Manager should prepare diagrams or flowcharts showing the interrelationship of activities. (e.g. Program Evaluation and Review Technique (PERT), Critical path Method (CPM), Gantt Charts or other such techniques.)

Delete the above clause if the company’s design projects are not complex. Alternatively, list only those techniques that are used. For larger, more complex design projects, more detailed planning will be expected showing the interrelationship between phases and timing for each critical step.

Groups and functions involved in a design project are identified in the Design Project Plan. These groups include:

* specific engineering skills and disciplines
* department representatives (e.g. Marketing, Engineering, Production, QA)
* external consultants and contractors

Functions with advisory or review responsibilities may not be identified in plans but their role and input must be documented.

Information transfer between groups should be through the Project Manager or via a formal document transmittal system. Review and approval may also be required for critical documents.

ISO 13485 require approval of the plans.

The Design Project Plan is evaluated and, if satisfactory, approved by the design review committee. The approval of the plan is recorded in the minutes of the design review meeting.

Design plans are updated as the design evolves. Key changes undergo review and may result in modification of the plan. The Project Manager is responsible for ensuring that Design Project Plan is updated, reviewed and approved and that it reflects the current status of the project.

At each design review, changes made are evaluated and, if satisfactory, approved and incorporated. Approval is recorded in the meeting minutes.

## Design input

ISO 13485 clause 7.3.2 and CFR 820.30(c) require that design inputs must include:

a) functional, performance and safety requirements that address the intended use and the needs of the user and patient

b) applicable statutory and regulatory requirements

c) information derived from previous similar designs

d) outputs of risk management studies.

In addition:

e) incomplete, ambiguous, or conflicting requirements must be resolved

f) design input requirements should be reviewed and approved and the approval documented, including the signature of the person approving the requirements.

Design input requirements must be specific and comprehensive (though not as detailed as product specifications). They must be sufficiently specific to focus on the needs of users and patients and serve as acceptance criteria for design verification.

Design input requirements are developed by design engineering from product concepts such as product briefs, sketches, models, prototypes, etc. Specific engineering and product specifications are developed from these general concepts and desired characteristics. Design input requirements must be sufficiently specific to provide acceptance criteria for verification of the design.

When requirements are found to be ambiguous, incomplete or in conflict, the Project Manager, or delegate, contacts the person(s) who specified the requirement in order to obtain additional information to resolve the issue.

Design input requirements are documented (e.g. in data sheets, drawings, specifications, photographs, samples, references to standards, etc.). The documents constituting design input are assembled or referenced in the design project file.

In this procedure the design input is reviewed and approved within the framework of the first design review meeting. The first design review should also approve the Design Project Plan. Other procedures may be acceptable and still satisfy the requirements of ISO 13485 clause 7.3.2 and CFR 820.30(c).

The initial design input requirements are evaluated by the first design review meeting. The purpose of the review is to ensure that:

* functional, performance and safety requirements for the device are appropriate and complete and that they address the intended use of the device, including the needs of the user/patient
* experience and lessons learned from similar designs are identified and used in the design input
* applicable statutory and regulatory requirements are defined
* risk assessments are carried out throughout product realisation
* requirements are clearly defined and are not in conflict with each other

Results of the input review are recorded in the minutes of the design review meetings. The record clearly identifies those requirements that are acceptable, those that are not and those that are missing. It initiates actions necessary to rectify and complete the outstanding requirements.

This allows the flexibility to accept some input requirements while others are still under review or are missing. It is important to identify what is questionable and what is missing and to initiate appropriate actions. This allows for more effective project monitoring.

Design input requirements that are accepted by the design review panel are formally approved by the Project Manager (with the date and signature). Only approved documents may be used as design inputs.

Giving final responsibility to the Project Manager avoids having to gather signatures from each member of the design review panel. The above Clause meets the CFR 820.30(c) requirement that approvals be documented. If compliance with CFR 820 is not required, the above clause can be deleted.

As the design matures, design input may be refined with more detailed and quantitative specifications. Such changes are reviewed and formally approved by the Project Manager. (Prior evaluation and approval by the design review panel may not be required.)

Significant changes or additions to an approved design input should be evaluated by the design review panel before approval by the Project Manager. The review may be carried out by the panel members independently if it is not practical to call a formal review meeting.

The notes and signoffs form are record of review but are not the formal approval. The formal approval required in CFR 820.30(c) is provided by the Project Manager (or whoever is delegated).

## Design output

Design output documents are basically the same as those required in the DMR (Device Master Record). Make sure that this section matches procedure QP402 Device Master Record.

Design outputs must:

a) be defined in terms that allow verification against design inputs

b) be comprehensive (include device specifications, packaging, labelling, purchasing, manufacturing, installation and servicing)

c) include or reference product acceptance criteria

d) specify characteristics that are essential for proper and safe use

e) be approved prior to release. The record must include the date and signature of the person approving the design output.

Product design outputs consists of documents, samples, models, mathematical data, software, etc, that precisely describe the device and how it is manufactured.

The following types of specifications form this design output:

Delete references to installation and servicing if not applicable.

* device specifications
* purchased product (raw material) specifications
* manufacturing process specifications
* packaging specifications
* labelling specifications
* installation specifications
* maintenance and servicing specifications
* acceptance criteria (raw material, in-process and final product)

Ensure this list is coordinated with the types of documents listed in the DMR (refer to QP402).

Design output documents are included in the Device Master Record (DMR). Procedure QP402: Device Master Record defines in greater detail the types of documents included in each category of design output specifications.

Design output is expressed in terms that can be verified against design input requirements. (Verification of design is addressed in section 4.5 of this procedure.)

Design output documents are reviewed in three phases before approval and release.

|  |  |
| --- | --- |
| Design output review phases | Description |
| Phase 1 | Overall evaluation of the design output package by the design review panel. This is to ensure that the package specifies those characteristics of the device that are essential for its safe and proper use. Design outputs must be quite comprehensive and cover the device, its manufacture, packaging, labelling, installation, servicing and acceptance criteria. |
| Phase 2 | The review panel then carries out verification that design output satisfies the design input requirements. When this verification involves calculations or other engineering methodology, it is carried out as a formal design verification (refer section 4.5). When it is a more qualitative evaluation, it may be conducted in a design review meeting. |
| Phase 3 | Final check that individual design output documents are complete, correct and do not conflict. This document check is carried out by a design engineer.  Results of reviews carried out at design review meetings are documented in the minutes. Results of other reviews and verifications are documented by way of notes or signoffs on the relevant documents, as they are reviewed. |

Regardless of how and by whom the design output is reviewed, the Project Manager is the only person authorised to approve and release design output documents. Before approval, the Project Manager must verify that the required reviews have been carried and that the documents are satisfactory.

The Project Manager signing and dating design output documents, provides evidence of review and approval. Where inappropriate or impractical (e.g. software or mathematical data), the approval can be documented by signing a memo, meeting minutes or other appropriate record.

ISO 13485 requires that design output be approved while CFR 820.30 (d) explicitly requires that the date and signature of the person approving the design be documented.

The establishment, review, authorisation, issue, distribution and revision of design output documents must be controlled in accordance with Procedure QP401: Control of Documents and Procedure QP402: Device Master Record.

## Design reviews

ISO 13485 clause 7.3.4 and CFR 820.30(e) require that:

a) design reviews should be planned and conducted at appropriate stages of development

b) reviews should be conducted by personnel independent from the design process and with skills relevant to the step under review

c) the review examines the appropriateness of the design in meeting the product’s requirements

d) any (potential) problems are identified and resolved

e) those participating in the review and the review results are documented.

This design review process can also be accomplished within the design review meetings

In addition, in this procedure design reviews are responsible for reviewing design input, performing design verification (for qualitative requirements), and reviewing design output. As these activities are required anyway, it is more efficient to get them done within the framework of design review meetings, rather than creating yet another committee or calling yet another meeting.

Design reviews are scheduled in the Design Project Plan and occur at the end of each key step in the design process.

Minor upgrades or changes, where specifications remain substantially unchanged, require only a single review at the time of the change.

For a simple new device or more substantial upgrades to an existing device, generally three reviews are required.

|  |  |
| --- | --- |
| Design Reviews | Description |
| Review 1 | Occurs early in the project. It evaluates and finalises design input requirements and reviews early design solutions. |
| Review 2 | Follows the design and verification phases. Its purpose is to ensure the design meets the input requirements and to review the design output. |
| Review 3 | Occurs after completion of trial production runs and design validation. Its purpose is to ensure the device meets both production and user requirements.  **Note:** When design verification and device validation are similar, or closely integrated (and no new production processes are being developed), the second and third design reviews may be combined. |

Additional reviews may be scheduled for more complex design projects.

The Project Manager draws up the agenda for each design review meeting. The agenda identifies:

* the project and phase being reviewed
* the date, time, duration and place of the meeting
* the required participants (or their delegates)
* the main topics of the review

The agenda is distributed to participants about a week prior to the meeting.

Design review meetings are chaired by the Project Manager. The Manager’s role is to provide an independent view and to represent the needs and expectations of customers, users and patients.

CFR 820.30 requires a participant who is independent of the design activities. To comply with CFR 820, an independent must be included.

|  |  |
| --- | --- |
| Design Review Meeting | Requirements |
| Participants or functional representatives | * the Project Manager * a design engineer * a process engineer * product specialist * production * sales and marketing * the QA Manager * any other relevant disciplines. |
| Purpose and objectives | * evaluate the evolving design and assess its ability to meet requirements * review outputs of the design phase and ensure that they meet design input requirements * identify problems, propose solutions and initiate the required actions. |
| Minutes | * a copy of the agenda * the place, date and times (start and finish) of the meeting * a list of participants and their functions (include any apologies received) * a summary of discussions and the results and conclusions from each item reviewed * corrections, changes and actions necessary to implement them * approvals and consents * a list of documents presented during the review (preliminary drawings, draft specifications, etc). |

All records resulting from each design review are placed into the Design History File.

## Design verification

Whilst design verification has a specific meaning, in practice there is a degree of overlap between design output review (4.3), design review (4.4), design verification (4.5) and design validation (4.6). For simple designs and changes, these four can be incorporated into the one activity.

Edit this section to reflect the company’s procedures and products. Nominate the verification methods relevant to the company and devices manufactured. Specifically identify the methods used.

The purpose of design verification is to ensure that design outputs meet design input requirements. Design verification is carried out at different phases of design and may be applied to components, subsystems or the total design. This process ensures that design outputs from one phase are verified before it is used as a design input in the next phase.

Identify those techniques or verification methods actually used in the company.

In consultation with appropriate experts, the Project Manager decides which verification methods are used to verify the design outputs. Common methods include:

* calculations
* studies
* analysis
* tests
* simulations
* reviews
* checks
* comparison with similar proven designs

Design review meetings are used for qualitative reviews of the overall design and for design verification requiring input from a multidisciplinary team of specialists (refer Section 4.4). Verifications are a primary reason for design reviews. Results are documented in the meeting minutes.

Design verification activities may include:

* Configuration Management
* Tool Validations
* Protocol Generation
* Readiness Reviews
* Protocol Execution
* Problem Reporting
* Regression Testing
* Requirements Traceability and Test Coverage Matrix

Design verification activities are scheduled in the Design Project Plan. Results are usually documented in special reports.

Simpler and routine verifications are integrated into the review and approval process (refer Section 4.3). Approval and release signatures on design output documents become the verification record.

Inadequate designs are corrected. Corrective actions are documented and their implementation recorded in minutes of design reviews, special reports, studies, notes or mark-ups on design output documents. All changes and corrections are recorded in the Design History File.

All design verification records include the date of the verification and the name(s) of the individual(s) performing the verification. Design verification records are maintained in the Design History File.

## Design validation

Design verification is used to manage design through the life of the project. It verifies each step in the design process. Design validation provides documented proof of the suitability of the final product. From a regulatory perspective, design validation is important and must be executed as an independent activity with a clear focus on final product testing rather than of each step in the design process.

Edit this section to specifically identify the actual methods of design validation that apply to the devices and the technologies used (e.g. biocompatibility testing, integrity testing).

Design validation ensures the actual device is safe to use and is able to completely meet the user’s requirements.

Design validation is performed on production units and should include device packaging and labelling. The product is tested under simulated or actual use conditions.

Design validation activities are scheduled in the Design Project Plan. All validation activities must be completed satisfactorily prior to delivery of the device to the customer.

Designs are validated in accordance with documented validation protocols. Validation protocols should at least specify:

Modify this list, as required, to reflect the type of device manufactured and the tests required. The list should be relevant to the technologies used.

* operating environment and/or conditions
* cleaning/sterilisation requirements
* modes of use
* setup procedure
* operating parameters
* test methods
* acceptance criteria

The Project Manager is responsible for establishing validation protocols.

Regulations (local or international) may require that design validation includes clinical evaluations or evaluation of performance of the device.

Design validation results are documented in design validation reports. Where practical, forms for recording data and reporting results are included in protocols. All design validation records must include the person and date when the verification was carried out.

If validation results do not meet specifications, the design must be reviewed through the established design review process. Corrective actions are documented in review meeting minutes, validation reports, notes or mark-up of design output documents.

Design validation records include:

* validation methods (validation protocols)
* validation results
* validation report
* non-conformances
* corrective actions
* identification of personnel performing the validation

These records are maintained in the Design History File.

## Design transfer

This section is only relevant to CFR 820.30 and is not required by ISO 13485. It is non-specific but refers instead to QP701 Production Planning and Risk Management and QP401 Control of Documents.

Design output documents (refer Section 4.3) form the basis for developing manufacturing specifications. Procedure QP701: Production Planning and Risk Management defines how these documents are established. The types of documents required in this phase are listed in Procedure QP402: Device Master Record.

The Production Engineer is responsible for producing manufacturing specifications from the device design documents. Design transfer activities interface with product design activities. Cooperation is facilitated by consultation between design engineering and production engineering. This relationship is reinforced by the requirement for both functions to participate in design review meetings (refer Section 4.4).

Manufacturing specifications, whether in the form of documents, software, data or templates, are reviewed and approved by the Production Manager before being used in production. Manufacturing specifications and changes are controlled in accordance with Procedure QP401: Control of Documents.

Some manufacturers include a design review step at this transfer stage. There is no requirement in ISO 13485 but it may be inferred from CFR 820.30.

## Design changes

Prior to production, design changes are controlled within the project’s design review process (refer Section 4.4).

Once the design is released to regulators for pre-market approval, is undergoing clinical trials or is released to production, design changes are controlled in accordance with Procedure QP704: Control of Design and Process Changes and Procedure QP401 Control of Documents.

## Project book

Documents and records related to the management of the design project are organised and kept in the Design Project Book. This is usually a three-ring binder (or binders) with tabs to organise the content into appropriate categories. The Design Project Book is maintained by the Project Manager.

The Project Book typically includes such documents and records as:

* product briefs and other such early documents conceptualising the product
* Design Project Plan
* design input requirements
* studies, calculations and analysis (or lists of these documents)
* lists of design output documents and their approval and release status
* minutes of design review meetings
* design verification and validation data and reports (or lists and status of these documents)
* emails, memos, minutes of meetings and other such records of communicating with and interfacing between design teams (internal and external), consultants, suppliers, etc.

## Design History File

A “Design History File” is a specific requirement of CFR 820. ISO 13485 calls for similar records but does not give it a name. To comply with ISO 13485 only, any name can be given to this file.

When the design project is complete, documents used for managing the project are gathered in maintained in a Device History File. The following documents and records are included in this file:

* the Design Project Plan and its revisions
* design input requirements
* records of design input reviews (minutes) and approvals
* conceptual and preliminary versions of design documents
* studies, calculations and analysis supporting the design
* protocols, reports, studies and other records of design verification and validation
* design output review records and approvals
* agendas and minutes of design reviews
* documents and records necessary to demonstrate the design process was carried out in compliance with requirements and procedures

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 |
| QP401 | Control of Documents |
| QP402 | Device Master Record |
| QP701 | Production Planning and Risk Management |
| QP704 | Control of Design and Process Changes |
| FM703-1 | Medical Device Design Project Plan |

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