[Organization logo]

[Organization name]

PROCEDURE FOR DESIGN AND DEVELOPMENT

Code:	
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Date	Version	Created by	Description of change
	0.1	Advisera	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this Procedure is to define the design control process used by [organization name] during the design and development of its products.

This Procedure applies to all product development, product modifications, line extensions, and product change projects. It covers the overall development of products and services.

Users of this document are members of the design and development team of [organization name].

2. Reference documents

- ISO 13485:2016 standard, clause 7.3
- MDR 2017/745, article 10(9), Annex I – Chapter II, and Annex IX – Chapter I
- [other legal and contractual requirements]

Commented [AES4]: Include the name of your organization.

Commented [AES5]: Adapt to the organization's needs.

Commented [AES6]: Include the name of your organization.

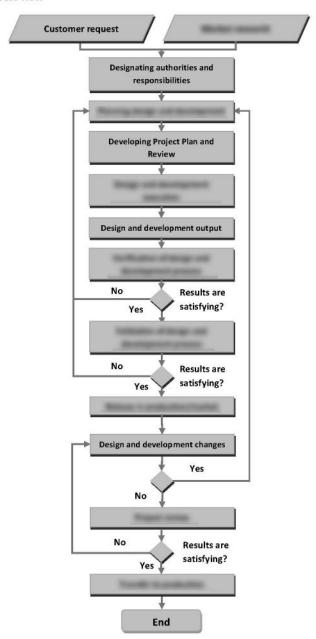**Commented [AES7]:** Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

3. Design and development process

3.1. Process flow

3.2. Forming preliminary design

According to the customer's request or determined needs of the market, [job title] defines the
~~preliminary design, designates design and development team and team leader and defines their
duties and responsibilities.~~

3.3. Authorities and responsibilities in design and development

The design and development team is responsible for the following:

- Implementing design control
- Generating project schedule and plan
- ~~Reviewing changes in product or service design~~
- ~~Defining activities of verification and validation for any phase of design and development~~

The design and development team leader has the following responsibilities:

- Assuring that all requirements are addressed, documented and approved as necessary including the rationale/justification for not performing certain activities
- Obtaining top management approval for any additional resources and/or funding
- ~~Assuring that all regulatory requirements are checked and documented~~
- ~~Maintaining the Design and Development File~~
- Approving changes in design
- Managing relationships between different groups involved in design and development
- ~~Defining design and development phases~~
- ~~Approving review, verification and validation of every phase and the start of a new phase~~

3.4. Planning design and development

According to the preliminary design, the team leader creates the project activities, which are part of the Design and Development File and Design and Development Inputs & Review, which contains input data that defines the requirements for product by including the following:

3.4.1. Functional and performance requests

The functional specification described in the Project Task by the design and development team leader according to the customer request for product addresses at least the following points:

- The performance objectives, operating conditions, and the requirements for reliability, availability, and maintainability
- Mechanical, electrical, cryogenic, radiation resistance, and other technological constraints to be respected by the design
- Safety and regulatory requirements constraints
- ~~Manufacturing and installation constraints~~
- ~~The basic technical interface requirements of the design~~
- ~~Requirements for calculations, tests and development work, including the construction of prototypes~~

- Demanded quality of service and timeframe

Commented [AES12]: Adapt to the organization's needs.

[illegible]

Commented [AES13]: E.g., design and development team [illegible]

3.4.2. *Legal, regulatory and other requirements*

[Job title] identifies legal and regulatory requirements and other normative documents used for dimensioning the product, selecting materials, defining manufacturing, assembly, testing and operation procedures defined in the design documentation. [illegible]

Commented [AES14]: E.g., design and development team leader.

Commented [AES15]: Adapt to the applicable corresponding regulations / standards in the organization.

[illegible]

Commented [AES16]: Adapt to the organization's needs.

Commented [AES17]: You can find the Official Journal of the European Union on the following link: [illegible]

Commented [AES18]: Common specifications are different [illegible]

3.4.3. *Information gathered from previous similar projects*

The design and development team leader must take into consideration the previous similar projects in order to prevent recurrent mistakes and to avoid exceeding the budget and time schedule. [illegible]

Commented [AES19]: E.g., design and development team leader.

3.4.4. *Other requirements important for design and development*

[Job title] must define other requirements related to design and development, [illegible]

Commented [AES20]: Adapt to the organization's needs.

3.5. Developing the Project Plan and Review

According to Project Task and input data for design and development, the design and development team leader, together with team members, creates the Project Plan and Review and defines:

- Project phases
- Responsibilities of team members for each phase
- Phase realization deadlines
- [illegible]

Commented [AES21]: Adapt to the organization's needs.

[illegible]

The design and development team member responsible for phase execution enters the following into the Project Plan and Review:

- All activities related to phase realization
- Input elements of the phase
- [illegible]

Commented [AES22]: E.g., legal and regulatory requirements [illegible]

Commented [AES23]: Deliverables can be in different form. [illegible]

Commented [AES24]: E.g., human resources, finance, [illegible]

[Job title] must ensure that the Project Plan and Review includes requirements of risk management [illegible]

Commented [AES25]: E.g., design and development team leader.

Commented [AES26]: You can find a template for this [illegible]

3.6. Design and development execution

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The design and development team member responsible for the project phase ensures that all activities of the phase are conducted and all necessary records about the phase are kept.

The design and development team conducts a review for all appropriate project phases. People included in production or service provision, as well as clients and suppliers, can participate in the project review if the design and development team leader finds it appropriate.

The design and development team leader convenes a formal meeting attended by all participants in design and development, and minutes for the meeting in free form represent a record of the review.

If the project phase review discovers problems, [Job title] suggests actions to resolve them and enters them into the minutes for the meeting. The effect of the executed action is the subject of the next review.

Commented [AES27]: E.g., R&D Manager, QA Manager.

After each phase review, the design and development team leader approves the start of the new phase by signing the Project Plan and Review.

3.7. Design and development output

After completion of the last phase, the design and development team leader, together with team members, enters in the Design and Development File additional information related to deliverables of design and development, such as:

Commented [AES28]: Deliverables can be in different form, e.g., engineering documentation, drawings, calculation, product, product parts, etc.

- Information about purchasing, production and services provision once it's launched
- Criteria for accepting the product before production
- Product characteristics needed for its safe and intended use
- Details about preservation of product

Commented [AES29]: E.g., specification of materials for technology equipment for equipment and management of production process.

Commented [AES30]: E.g., Instruction Manual for Product; or safety requirement for product e.g. type of material used for base, input, WATTS, inflammable product, etc.

Commented [AES31]: Instruction for handling product in a way that minimize its damage and minimize hot spaces. Those that produce in dry and dark place.

[Job title] must approve these output elements of design and development, contained in the Design Review Minutes, before acceptance of product. All output elements must meet all input requirements for design and development.

Commented [AES32]: E.g., CEO or design and development team leader.

3.8. Verification of design and development process

[Job title] conducts verification in project phases according to Design and Development Verification and Validation Plans where necessary, and determines whether the output elements address the input elements of the design and development process. After verification, [Job title] needs to prepare the Verification Report. If the results of the verification are satisfactory, then [Job title] approves the Verification Report. In cases when the results deviate from the requirements, [Job title] initiates corrective action.

Commented [AES33]: E.g., CEO or design and development team leader.

Commented [AES34]: E.g., test engineer, QA tester, design and development team leader, etc.

Commented [AES35]: E.g., CEO, QA Manager.

Commented [AES36]: E.g., R&D Manager, QA Manager, Sales Manager.

3.9. Validation of design and development process

Validation is a check-up process that determines whether the final product is capable of satisfying the needs of the customer in specified conditions of use.

The design and development team conducts validation before release of the product to production.

Commented [AES37]: In some cases, validation can be conducted by computer simulations and animation.

3.10. Release in production/market

[Job title], together with the design and development team leader, organizes a test production of the designed product.

Commented [AES38]: E.g., CEO, QA Manager.

Commented [AES39]: E.g., R&D Manager, QA Manager,

Commented [AES40]: E.g., Production Manager

3.11. Design and development changes

Changes in design and development can occur in every phase of design and development as a result of the following:

- Changes of product specification on customer request
- Evaluation of the effects of the changes on the product
- Problems during production
- Demand of market for improved product
- Validation activities
- Inputs or outputs of risk management and product realization processes

Commented [AES41]: Organization can add or delete listed

The design and development team leader must document all changes in the Change Review Record,

3.12. Project review and transfer to production

After completion of all phases of design and development, making a prototype and releasing to production or market, the design and development team leader conducts a review of design and development and delivers Design Review Minutes to [job title].

Commented [AES42]: E.g., CEO

Commented [AES43]: E.g., R&D Manager, engineer

Commented [AES44]: E.g., R&D Manager, Engineer

[Job title] must ensure that Design and Development Files contain all data about the product.

Commented [AES45]: E.g., R&D Manager

Commented [AES46]: E.g., R&D Manager and Production Manager

3.13. Design and development files

[Job title] must ensure that all files and records resulting from the design and development process are properly maintained. ~~These files must include all reference records generated to demonstrate conformity to the requirements for design and development, and records for design and development changes.~~

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Design and Development File	PR10.1	Equal to the lifetime of medical device, but not less than two years	[office of design and development team leader]	[job title]
Project Plan and Review	PR10.2	Equal to the lifetime of medical device, but not less than two years	[office of design and development team leader]	[job title]
Change Review Record	PR10.3	Equal to the lifetime of medical device, but not less than two years	[office of design and development team leader]	[job title]
Design Review Minutes	PR10.4	Equal to the lifetime of medical device, but not less than two years	[office of design and development team leader]	[job title]
Design and Development Verification and Validation Plans	PR10.5	Equal to the lifetime of medical device, but not less than two years	[office of design and development team leader]	[job title]
Validation Report	PR10.6	Equal to the lifetime of medical device, but not less than two years	[office of design and development team leader]	[job title]

		(not less than [not years])		
Verification Report	PR10.7	*Equal to the lifetime of medical device, but not less than [not years]*	*[office of design and development team leader]*	*[job title]*
Design and Development Transfer Record	PR10.8	*Equal to the lifetime of medical device, but not less than [not years]*	*[office of design and development team leader]*	*[job title]*

> **Commented [AES54]:** If the record is in electronic form, write the name of the folder of design and development team leader's computer.

> **Commented [AES55]:** If the record is in electronic form, write the name of the folder of design and development team leader's computer.

5. Appendices

- Appendix 1 – Design and Development File
- Appendix 2 – Project Plan and Review
- Appendix 3 – Change Review Record
- Appendix 4 – Design Review Minutes
- Appendix 5 – Design and Development Verification and Validation Plans
- Appendix 6 – Verification Report
- Appendix 7 – Validation Report
- Appendix 8 – Design and Development Transfer Record

[job title]
[name]

_____
[signature]

> **Commented [AES56]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.