

[Organization logo]

[Organization name]

**Commented [16A1]:** All fields in this document marked by square brackets [ ] must be filled in.

## PROCEDURE FOR DESIGN AND DEVELOPMENT

**Commented [16A2]:** If you want to find out more about the design and development process, see:

The ISO 9001 Design Process Explained  
<http://advisera.com/9001academy/blog/2013/11/05/iso-9001-design-process-explained/>

**Commented [16A3]:** Adapt to your organization current practice.

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

### Distribution list

**Commented [16A4]:** This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

## Change history

Date	Version	Created by	Description of change
	0.1	16949Academy	Basic document outline

## Table of contents

<b>1. PURPOSE, SCOPE AND USERS .....</b>	<b>3</b>
<b>2. REFERENCE DOCUMENTS .....</b>	<b>3</b>
<b>3. DESIGN AND DEVELOPMENT PROCESS.....</b>	<b>4</b>
3.1. PROCESS FLOW .....	4
3.2. FORMING PRELIMINARY DESIGN .....	4
3.3. DESIGN AND DEVELOPMENT PLANNING .....	5
3.3.1. <i>Planning design and development stages and activities</i> .....	5
3.3.2. <i>Authorities and responsibilities in design and development</i> .....	5
3.4. DESIGN AND DEVELOPMENT INPUTS .....	6
3.4.1. <i>Functional and performance requirements</i> .....	6
3.4.2. <i>Statuary, regulatory and other requirements</i> .....	6
3.4.3. <i>Information gathered from previous similar projects and / or competitor products</i> .....	7
3.4.4. <i>Other requirements important for design and development</i> .....	7
3.5. DEVELOPING THE PROJECT PLAN AND REVIEW.....	7
3.6. DESIGN AND DEVELOPMENT EXECUTION .....	8
3.7. DESIGN AND DEVELOPMENT CONTROLS .....	8
3.7.1. <i>Verification of design and development process</i> .....	8
3.7.2. <i>Validation of design and development process</i> .....	8
3.8. DESIGN AND DEVELOPMENT OUTPUTS.....	9
3.9. RELEASE IN PRODUCTION/MARKET .....	10
3.10. DESIGN AND DEVELOPMENT CHANGES .....	10
3.11. PROJECT REVIEW .....	11
<b>4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT .....</b>	<b>11</b>
<b>5. APPENDICES .....</b>	<b>12</b>

## 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, product change projects and customer projects.

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

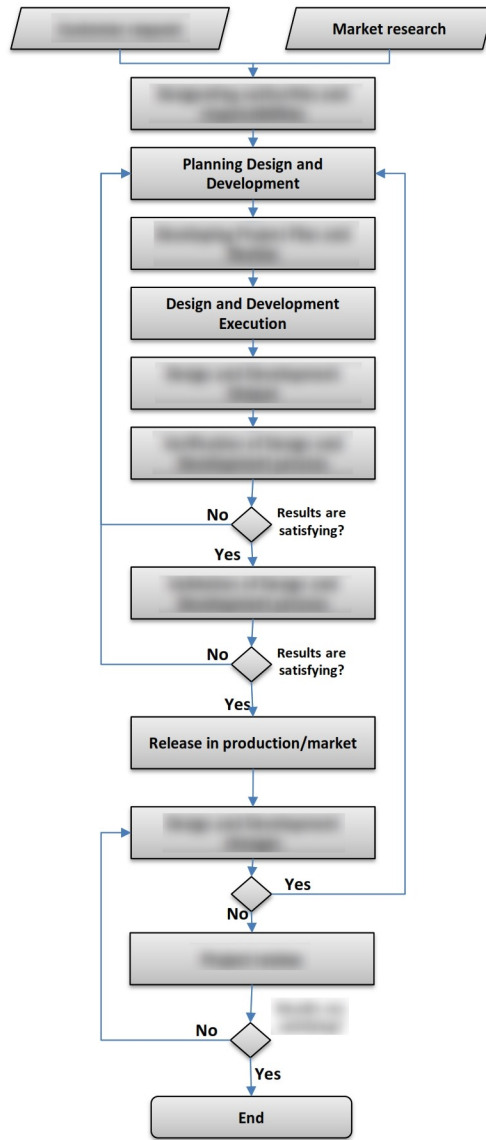
**Commented [16A5]:** Adapt to organization's needs.

## 2. Reference documents

- IATF 16949:2016 standard, clauses 8.3.1, 8.3.2, 8.3.2.1, 8.3.2.2, 8.3.3, 8.3.4, 8.3.4.1, 8.3.4.2, 8.3.4.3, 8.3.5, and 8.3.6
- FMEA procedure
- Production Part Approval Process Procedure
- [other legal and contractual requirements]

### 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 [redacted] or process will be focused on prevention, rather than detection of failure modes and their effects according to the FMEA procedure.

### 3.3. Design and development planning

#### 3.3.1. Planning design and development stages and activities

[Job title] plans stages and controls for the design and development process, by taking into account:

**Commented [16A6]:** E.g., Design and development team leader.

- [redacted]
- [redacted]
- The required design and development verification and validation activities
- [redacted]
- [redacted]
- The requirement for subsequent provision of products and services

Documented information needed to demonstrate that design and development requirements have [redacted]

#### 3.3.2. Authorities and responsibilities in design and development

The design and development team is responsible for:

**Commented [16A7]:** Adapt responsibilities to organization's needs.

- Implementing design control
- Generating project schedule and plan
- [redacted]
- [redacted]

**Commented [16A8]:** Control that ensures compliance with legal and regulatory regulations or standard.

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
- [redacted]
- [redacted]
- [redacted]
- Managing relationships between different groups involved in design and development
- Resolving conflicting design and development inputs
- [redacted]
- [redacted]

**Commented [16A9]:** Design History File is a compilation of documentation that describes the design history of a realized product or service. It is specific to a particular design; therefore, it should be provided by the organization itself.

**Commented [16A10]:** E.g. customers, suppliers, third parties, etc.

[Job title] must ensure that the design and development team has the following competences:

- Knowledge and experience in appropriate design tools
- [redacted]





[organization name]

[Job title] must ensure that legal requirements from the customer-identified country of destination are analyzed and integrated into product data.

**Commented [16A19]:** Typically, this is the development leader; however, you need to adapt to your organization.

### 3.4.3. Information gathered from previous similar projects and / or competitor products

The design and development team leader must take into consideration the previous similar projects information exists, [job title] enters it into the Project Task.

**Commented [16A20]:** E.g., if instrument clusters for a car that will be delivered in "X" country has to be compatible with national standard "X," then this compatibility must be defined as a product requirement.

If there are available products manufactured by a competitor, a benchmarking analysis will be establishing product quality targets. [Job title] is responsible for this.

**Commented [16A21]:** 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, such as internal and of products and services, requirements for packaging and delivery, safety requirements, etc.

**Commented [16A22]:** Typically, it will be the quality manager, project manager, or development leader; however, you need to adapt to your organization.

Validation Plan as inputs for product test planning.

**Commented [16A23]:** Adapt to organization's needs.

**Commented [16A24]:** Adapt here to your organization; typically, Product Engineer /or Development Leader.

## 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 (as defined below)
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- Start of new phase

**Commented [16A25]:** Note: Appendix 2 – Project Plan and Review is created according to these elements; if organization needs to change these elements, Project Plan and Review must be adapted also.

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

**Commented [16A26]:** E.g. Legal and regulatory requirements (environment, health, safety), industrial practice and standards, previous experience, requirements for packaging and shipment, etc.

**Commented [16A27]:** Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, product, product parts, etc.

Project phases in [organization name] are:

- [Redacted]
- [Redacted]

**Commented [16A28]:** E.g. Human resources, finance, equipment, raw materials, etc.

[organization name]

- Product design and development
- Process design and development
- [redacted]
- [redacted]

### 3.6. Design and development execution

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

The design and development team conducts a review in appropriate project phases. People included in the review are determined in accordance with the project plan and the project phase. All participants in the project review of the design and development team make their contribution.

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 [redacted] is responsible for the review. The effect of the measures taken is the subject of the next review.

[redacted] signs the Project Plan and Review.

### 3.7. Design and development controls

[Job title] ensures that design and development results to be achieved are defined, and reviews are conducted to ensure the fulfilment of the results of design and development to meet requirements.

#### 3.7.1. Verification of design and development process

The design and development team leader conducts verification in project phases where necessary. The design and development team leader signs the appropriate box in the Project Plan and Review.

#### 3.7.2. 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. Results are recorded in the Project Plan and Review.

If making a prototype is not needed, the product is sent to market.

The design and development team conducts validation before release of product in production or market.

[redacted] signs the Project Plan and Review.

**Commented [16A29]:** This is a list of the most common phases implemented in project management within the automotive industry. You must adapt this content to your organization or refer to your customer manuals, procedures, phases...

**Commented [16A30]:** If you want to find out more about design verification and validation, see:  
ISO 9001 Design Verification vs Design Validation  
<http://advisera.com/9001academy/blog/2013/11/12/iso9001-design-verification-vs-design-validation/>

**Commented [16A31]:** Adapt to your organization; typically, this is the reliability manager or product engineer.

**Commented [16A32]:** E.g. Software, services, etc.

**Commented [16A33]:** In some cases, validation can be conducted by computer simulations and animation. Validation can be conducted by customers, who must inform Design and development team leader about result. E.g. in design bureau.



[organization name]

[Blurred text]

### 3.8. Design and development outputs

[Job title] must ensure that the following product design outputs are available for process development:

- Drawings or CAD data, geometric dimensioning and tolerances, 2D drawings, product definition, product manufacturing information
- Bill of Material
- [Blurred]
- [Blurred]
- [Blurred]
- [Blurred]
- [Blurred]
- [Blurred]
- [Blurred]
- Process ergonomic requirements, product handling
- Design for manufacturing / assembly
- [Blurred]
- [Blurred]

**Commented [16A34]:** Develop here according to what your organization uses or receives from the customer.

**Commented [16A35]:** These are the most common items met within a typical development.

**Commented [16A36]:** Adapt here to your organization – typically, this is the development leader or quality manager / project manager.

[Job title] is responsible for monitoring the deliverables and accepting the process design.

[Blurred text]

- Specifications and drawings, including special characteristics for product
- Error-proofing methods based on risk analysis
- Plant and line layout
- [Blurred]
- [Blurred]
- [Blurred]
- [Blurred]
- [Blurred]
- Control Plan
- Process approval acceptance criteria
- SPC (Statistical Process Control) and capacity analysis
- [Blurred]
- [Blurred]
- [Blurred]

[Blurred text]

according to the Production Part Approval Process Procedure.

[organization name]

[Job title] is responsible for monitoring of the deliverables and accepting the product design deliverables as the beginning of the new development phase.

**Commented [16A37]:** Adapt here to your organization.

members, enters in Design History File additional information, related to deliverables of design and development, such as:

**Commented [16A38]:** Deliverables can be in different form. E.g. engineering documentation, drawings, calculations, product, product parts, etc.

- Information about purchasing, production and services provision once it's launched
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- Requirements of subsequent processes for the provision of product and service

**Commented [16A39]:** E.g. Specification of materials for purchasing, requirements for equipment and management of production process.

**Commented [16A40]:** E.g. Instruction Manual for Product; or safety regulation for product e.g. type of material used for baby toys, label for inflammable products, etc.

**Commented [16A41]:** Instruction for handling product in a way that preserves its intended use and condition. For example: "Keep the Product in dry and dark place out of reach of children."

[Job title] must approve these output elements of design and development before acceptance of

**Commented [16A42]:** E.g. CEO or Design and development team leader.

### 3.9. Release in production/market

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

**Commented [16A43]:** E.g. Production manager

After creating a prototype, the design and development team leader conducts verification in order to done by development and use of a prototype Control Plan. Once the Control Plan is established, [job

**Commented [16A44]:** Remove if proto is not requested by customer.

### 3.10. Design and development changes

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

- Changes of product specification on customer request
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- Project review
- Verification activities
- Validation activities

**Commented [16A45]:** Organization can add or delete listed reasons in order to adapt to organization's needs.

All changes proposed by suppliers, the organization itself, and its customers are assessed by [job

**Commented [16A46]:** Adapt to your organization.

(deviation) from the customer.



[organization name]

			team leader]	
Control Plan	PR.08.7	EOL + n years	[office of design and development team leader]	[job title]
List of Alternate Controls	PR.08.8	EOL + n years	[office of design and development team leader]	[job title]

**Commented [16A54]:** If the record is in electronic form, write the name of the folder on the design and development team leader's computer.

**Commented [16A55]:** If the record is in electronic form, write the name of the folder on the design and development team leader's computer.

**Commented [16A56]:** If the record is in electronic form, write the name of the folder on the design and development team leader's computer.

## 5. Appendices

- Appendix 1 – Project Task
- Appendix 2 – Project Plan and Review
- Appendix 3 – Change Review Record
- Appendix 4 – Design Review Minutes
- Appendix 5 – Plant and Lines Layout
- Appendix 6 – Validation Plan
- Appendix 7 – Control Plan
- Appendix 8 – List of Alternate Controls