last modified: November 13, 2020

* [Introduction](#Introduction)
	+ [Subject](#Objet)
	+ [Recipients](#Destinataires)
	+ [Guides, Standards and Regulations](#Guides_Normes_et_Reglementations)
	+ [Abbreviations](#Abreviations)
	+ [Definitions](#Definitions)
* [General](#Generalites)
	+ [Planning](#Planification)
	+ [Magazines](#Revues)
* [Project input data](#Donnees_dentree_du_projet)
* [Associated templates](#Templates_associees)
* [Design](#Conception)
	+ [General](#Generalites-2)
	+ [Design output data](#Donnees_de_sortie_de_la_conception)
* [Development](#Developpement)
	+ [General](#Generalites-3)
	+ [Development output data](#Donnees_de_sortie_du_developpement)
* [Audits](#Verifications)
	+ [Planning](#Planification-2)
	+ [Conducting Audits](#Realisation_des_verifications)
	+ [Audit output data](#Donnees_de_sortie_de_la_verification)
* [Production transfer](#Transfert_de_production)
	+ [General](#Generalites-4)
	+ [Output data of the production transfer: Initiation of manufacturing file](#Donnees_de_sortie_du_transfert_de_produ)
* [Validations](#Validations)
	+ [General](#Generalites-5)
	+ [Device Validation](#Validation_du_dispositif)
		- [Planning](#Planification-3)
		- [Realization of the validations](#Realisation_des_validations)
	+ [Specific validations](#Validations_particulieres)
	+ [Validation output data](#Donnees_de_sortie_de_la_validation)
	+ [Meeting regulatory requirements](#Reponses_aux_exigences_reglementaires)
* [Device certification](#Certification_du_dispositif)
* [Post-Marketing Surveillance](#Surveillance_Apres_Commercialisation)
* [Modifications](#Modifications)
* [Appendices](#Annexes)
	+ [Flowchart](#Logigramme)
	+ [Requirements definition and traceability](#Definition_des_exigences_et_tracabilite)
	+ [Measurement, Analysis, Improvement](#Mesure_Analyse_Amelioration)

**procedure - Design & Development**

# Introduction

## Subject

This procedure describes the steps taken to meet the regulatory and normative requirements for the **design and development of** a medical device or group of medical devices.
This procedure frames the activities of the design office: from the beginning of the design to the CE marking. The pre-study phase is not covered by this procedure.

## Recipients

* Design office;
* Service tests, trials, control, validation;
* Project manager;
* Management;
* Production manager;
* Quality manager;
* Responsible for CE marking.

## Guides, Standards and Regulations

* Regulation (EU) 2017/745;
* Standard ISO 13485:2016;
* Handbook for ISO 13485:2016 \*

# General

## Planning

The planning is carried out according to the PLN.C& D document.

## Magazines

The journals are managed according to REV.C& D.

# Project input data

**Input data** are initiated at the beginning of the project, they are updated according to the evolution of the project and the new information detected and reported, notably relative to the technical, regulatory and clinical context.
The documents expected in input data are listed below:

Example :

|  |  |  |
| --- | --- | --- |
| **Document** | **Utility** | **Associated Templates** |
| Planning of C&D activities. | Definitions of human resources, material resources and the main stages of C&D. | PLN.C& D |
| Planning and recording of C&D reviews. | Input data and checkpoints for the various C&D reviews. | REV.C& D |
| Action Plan | Action plan associated with the project: for the follow-up of the actions decided during the reviews (or even outside). | DOC.SDA |
| Specifications | Marketing/commercial specifications and identification of customer requirements. | PRO.GEC, PRO.MKT |
| Responses to General Requirements | Applicability and means of meeting regulatory requirements. | OTL.REG |
| Lists of applicable standards and regulations | Standards and regulations associated with the project. | OTL.LRA; OTL.LNA |
| State of the art | State of the art, competing products, alternative solutions, clinical alternatives, previous designs, ... Clinical aspects are addressed in the clinical evaluation process, see PRO.EVL.CLI. | DOC.DGR (can also be a separate file) |
| Risk Management and usability engineering | Control of risks, benefit/risk ratio and usability.  | PRO.GDR; PRO.IAU; DOC.DGR |
| Electrical safety requirements | Functional requirements, requested certificates, IFU content, ... | PRO.60601-1 |

# Associated templates

* PRO.GEC and PRO.MKT to define customer requirements;
* OTL.REG to define the general requirements for the device;
* DOC.DT to define the expected content of the technical documentation;
* OTL.INS to define the requirements on the instructions for use;
* OTL.ETQ to define labelling requirements;
* PRO.60601-1 for safety requirements for medical electrical equipment;
* PRO.CVL for the software associated with the device;
* PRO.GDR and PRO.IAU to manage risks and user errors;
* PRO.EVL-CLI for clinical validation activities;
* PRO.SAC and PRO.SCAC to monitor the critical parameters identified during the C& D and the evolution of the context.

# Design

## General

**Input data** are taken into account to realize the "Requirements Specification(s)".
This **specification** addresses in particular the :

* Functional requirements,
* Performance requirements,
* Security requirements,
* Requirements from risk management and usability engineering,
* Security requirements.

The specification contains the necessary design information about :

* Medical **device**,
* Possible **accessories**,
* **Information provided to** the user: instructions for use, labelling, training

## Design output data

Example :

|  |  |
| --- | --- |
| **Document** | **Content** |
| XXX | General functional specification of the device |
| SAL, SAL, SUL | Software specification |
| XXX | Mechanical Specification |
| XXX | Specification of electronics |
| XXX | Specification of operating instructions |
| XXX | Labelling specification |
| XXX | Specification of the device packaging(s) |
| XXX | Specification of user training |
| XXX | Input Elements for Defining Post-Market Surveillance |
| XXX | Non-clinical bibliography  |
| … | … |

# Development

## General

The development is carried out **according to the specifications** resulting from the design phase. Design **reviews** are regularly conducted to assess the ability to meet the requirements and identify necessary **actions**, they are recorded according to REV.C& D.
Development may lead to changes in design requirements, **changes are** managed according to PRO.MDF.
The design office takes into account the problems related to **manufacturing,** by collaborating with the production department to validate the planned processes.

## Development output data

Example :

| **Ref.** | **Specifications** |
| --- | --- |
| XXX | Map |
| XXX | Nomenclature |
| XXX | Diagram |
| XXX | Source code |
| XXX | Installation Instructions |
| XXX | Purchase Specification |
| … | … |

# Verifications

## Planning

Verification activities are **planned** in the " Verification Planning", specifying :

* The field of verification;
* The methods;
* Acceptance criteria;
* If applicable: statistical techniques / justification for sample size.

Verifications are carried out taking into account the intended use (in particular: connected devices, accessories, interfacing, etc.).

## Conducting Audits

Verifications are **recorded**, specifying :

* Associated planning ID
* Justification of any discrepancies
* Results
* Conclusions
* If applicable: access to raw data
* Person in charge, date, means used, ...

Verifications may require the use of testing laboratories (electrical *safety*, environmental testing, *EMC,* biocompatibility, etc.).

## Audit output data

Example :

| **Ref.** | **Reports** |
| --- | --- |
| XXX | Software test report |
| XXX | Test report for electronic boards |
| XXX | Electrical safety report lab XXX |
| XXX | Biological assessment report, biocompatibility |
| XXX | Declaration of conformity to a standard |
| XXX | Certificate of conformity to a standard |
| … | … |

# Production transfer

## General

The design office collaborates with the departments concerned to define the information for **purchasing**, **production** and **after-sales service**. The
manufacturing processes are **validated** during the manufacture of pre-series (see PRO.VAL.PRD).
If the pre-series uses a different manufacturing process than the series, the deviations must be studied to validate the quality of the validation data.

## Output data of the production transfer: Initiation of manufacturing file

Example :

| **Ref.** | **Specifications** |
| --- | --- |
| XXX | Maps |
| XXX | Nomenclatures |
| XXX | Purchase Specifications |
| XXX | Methods of operation |
| XXX | Checklist of controls |
| XXX | Traceability requirements |
| XXX | Process, equipment, ECM, ... |
| … | … |

See also PRO.PRD.

# Validations

## General

The final validations are carried out on **pre-series** whose characteristics are **identical** to those of the final products.
Any deviations are justified.

## Device Validation

### Planning

Validation activities are planned, specifying :

* The validation field
* Methods, equipment...
* Acceptance criteria
* If applicable: statistical techniques / justification for sample size
* When useful: modifications and planned actions following validation results

Validations are carried out taking into account **the intended use** (e.g. connection to other devices, use of accessories, etc.).

### Realization of the validations

Validations are recorded, specifying :

* The ID of the validation;
* Justification of any discrepancies;
* The justification of the choice of the product;
* The results;
* If applicable: access to raw data;
* The name of the person in charge, the date, and the means used.

## Specific validations

Validation requires to realize :

* An assessment of usability according to the PRO.IAU procedure
* A clinical evaluation according to the PRO.EVL.CLI procedure
* A validation of the software
* A validation of the SEMP

## Validation output data

Example :

|  |  |
| --- | --- |
| **Ref** | **Reports** |
| XXX | Summative Evaluation Report (IAU) |
| XXX | Clinical Assessment Report |
| XXX | Software validation report |
| XXX | Installation Validation Report |
| … | … |

## Meeting regulatory requirements

Responses to the general safety and performance requirements of the regulation are reviewed, with regard to the completeness of the **evidence** provided.

# Device certification

See PRO.RDM and DOC.DT.

# Post-Marketing Surveillance

The critical parameters of the device relative to safety and performance are identified during the design.
If necessary, **criteria**, **thresholds** and methods for **data** collection and analysis are defined in order to feed the post-market monitoring process.
See also PRO.SAC and PRO.SCAC.

# Modifications

**Changes to** the device or its intended use are managed in accordance with PRO.MDF.