[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

# PROCEDURE FOR VALIDATION

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

Commented [AES2]: The document coding system should be in line with the organization's existing system for document coding; in case such a system is not in place, this line may be deleted.

## Distribution list

Commented [AES3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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## Change history

| Date | Version | Created by | Description of change |
|---|---|---|---|
| | 0.1 | Advisera | Basic document outline |
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## Table of contents

## 1. Purpose, scope and users

The purpose of this Procedure is to define what validation is, which processes need to be validated in [organization name], and which records are necessary in order for all processes necessary for the manufacturing of the medical device to be kept under continuous control.

The goal of process validation activities is to ensure the quality, safety, and efficacy of the finished product.

The users of this document are all employees of [organization name] designated by [job title] to perform process validation.

This Procedure does not cover the software validation, which is included in the Procedure for Documentation and Validation of Computer Software.

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

**Commented [AES5]:** Include the name of your organization.

**Commented [AES6]:** Include the job title of the person in charge for designating the responsibilities for the validations in your organization.

Usually it is CEO or Quality manager.

**Commented [AES7]:** You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "16_Software_Validation".

## 2. Reference documents

- ISO 13485:2016 standard, clause 7.5.6
- ISO 14971:2019
- MDR 2017/745 Annex IX – Chapter I

**Commented [AES8]:** 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. Identification of special processes

[Job title] is responsible for reviewing all manufacturing processes to identify those that need to be designated as special processes, and for defining the validation team for each process.

[redacted]

In [organization name], the following processes need validation:

- [list processes that need validation]

**Commented [AES9]:** This should be someone from the top [redacted]

**Commented [AES10]:** Special processes are considered those [redacted]

**Commented [AES11]:** The validation team can be made up of [redacted]

**Commented [AES12]:** Include the name of your organization.

**Commented [AES13]:** List here all the processes in your [redacted]

## 4. Validation Master Plan

[Job title] must specify the schedule of conducting validations in the Validation Master Plan. Validation frequencies are determined using a risk-based approach, considering the potential risk to the end user. [redacted]

[redacted]

**Commented [AES14]:** This should be someone from the top [redacted]

**Commented [AES15]:** This should be someone from the top [redacted]

**Commented [AES16]:** This should be someone from the top [redacted]

**Commented [AES17]:** The best practice is to prepare the [redacted]

## 5. Conducting the validation process

[Job title] must evaluate which medical devices pose the greatest risk for the patient/user, and list those medical devices in the Validation Master Plan to be used for validation.

### 5.1. Process validation protocol

[Job title] must prepare the validation protocol that will include at least the following topics:

- Introduction of the process that needs to be validated
- Purpose and objectives of validation
- Scope of the protocol – identification of the medical devices manufactured using the process
- [illegible]
- [illegible]
- [illegible]
- Process description
- Equipment – all equipment shall be properly identified, and calibrations shall be performed and documented, if needed.
    - installation qualification (IQ)
    - [illegible]
    - [illegible]
- Tests – defining which test will be conducted, with criteria. The criteria by which the validation activities can be considered successful shall be fully described within the validation protocol. Basically, it is essential to identify the acceptability criteria for validation results, and clearly identify the results to be met for the process to be considered validated.
- Revalidation criteria
- [illegible]
- [illegible]
- [illegible]

### 5.2. Criteria for revalidation

[Job title] must revalidate the processes at least [frequency]. [Job title] is responsible for deciding if a process needs an unscheduled revalidation by using the following criteria for revalidation:

- changing the actual process in a way that may affect the quality of the product or its validation status
- design of a new medical device that has different content and dimensions than all previous ones
- changes or exchanges to a main part of the equipment that could affect one or more of the established parameters
- [illegible]
- [illegible]
- [illegible]

**Commented [AES18]:** E.g., head of the validation team

**Commented [AES19]:** The reason for validation can be any of the following:
- first-time validation
[illegible]

**Commented [AES20]:** Under reference documents, you need [illegible]

**Commented [AES21]:** Include a detailed description of who in [illegible]

**Commented [AES22]:** Describe the validation process, and include information about operators and equipment to be used [illegible]

**Commented [AES23]:** These are mandatory. Do not delete any.

[illegible]

**Commented [AES24]:** E.g., head of the validation team

**Commented [AES25]:** Include the period in which a [illegible]

**Commented [AES26]:** E.g., changing the paper/foil for the sterilization

**Commented [AES27]:** These are mandatory. Do not delete any of these bullets.

[illegible]

**Commented [AES28]:** E.g., appearance of more scraps than [illegible]

[Job title] is responsible for defining how extensive revalidation must be compared

Commented [AES29]: E.g., head of the validation team

Commented [AES30]: For example, if new equipment is purchased for a validated process, the IQ portion will need to be

## 6. Equipment qualification

[Job title] is responsible for defining which equipment needs qualification. In [organization name], the following equipment needs qualification:

Commented [AES31]: This should be someone from the top

Commented [AES32]: Include the name of your organization.

- [list equipment name]

Commented [AES33]: List the names of all equipment that

Each equipment that needs qualification must pass the following phases:

### 6.1. Installation qualification (IQ)

Commented [AES34]: Installation qualification ensures that

[Job title] is responsible for organizing installation qualifications

Commented [AES35]: E.g., head of validation team,

### 6.2. Operational qualification (OQ)

Once product requirements have been established, and equipment installation qualification activities are complete, [job title] is responsible for conducting the operational qualification.

Commented [AES36]: E.g., head of validation team,

### 6.3. Performance qualification (PQ)

[Job title] is responsible for conducting the performance qualification in order to demonstrate that the process will consistently produce an acceptable medical device under anticipated conditions. During performance qualification, [job title] must take into consideration at least the following:

Commented [AES37]: E.g., head of validation team,

Commented [AES38]: E.g., head of validation team,

- actual product and process parameters and procedures established in OQ
- acceptability of the product

Commented [AES39]: These are mandatory. Do not delete any.

[Job title] must ensure that, during performance qualification, the process simulates conditions that will be encountered during actual manufacturing.

Commented [AES40]: E.g., head of validation team,

## 7. Managing records kept on the basis of this document

| Record name | Code | Storage | Responsibility |
|---|---|---|---|

| | | [illegible] | [illegible] | |
|---|---|---|---|---|
| Validation Master Plan | PR15.1 | [illegible] | [illegible] | [illegible] |

## 8. Appendices

- Appendix 1 – Validation Master Plan

[job title]
[name]

_____
[signature]

**Commented [AES41]:** The mandatory retention time for the [illegible]

**Commented [AES42]:** If the record is in electronic form, write [illegible]

**Commented [AES43]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.