

[Organization logo]

[Organization name]

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PROCEDURE FOR DOCUMENTATION AND VALIDATION OF COMPUTER SOFTWARE

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Change history

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	0.1	Advisera	Basic document outline

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1. Purpose, scope and users

The purpose of this Procedure is to describe the activities for the documentation and validation of computer software used in the Quality Management System (QMS).

Users of this document are [job title] in [organization name].

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E.g., Validation Manager and validation team

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2. Reference documents

- ISO 13485:2016 standard, clauses 4.1.6 and 7.5.6
- MDR 2017/745 Annex IX – Chapter I

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

3. Documentation and validation of computer software

This Procedure covers the validation of two types of software:

- purchased software products that are not standard or configurable software packages
- self-developed or purchased software products where the source code is available and tested

3.1. Validation team

[Job title]: manages the operation of software validation.

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[Job title]: uses the systems on a day-to-day basis. [Job title] provides the user for the hardware design and supports the testing and documentation effort for software.

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[Job title]: develops, tests, and supports the ongoing operation of systems. [Job title] development, testing, and support support documentation for software.

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[Job title]: reviews and approves validation documentation. [Job title] must be independent of the QMS.

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3.2. Software lifecycle model and validation

[Organization name] uses a lifecycle model approach to organize the validation process. [Job title] develops the software product and is required to provide all the inputs for the development of requirements to the software.

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3.2.1. Requirements specification

The requirements and intended use of the software are provided by [job title] to the validation team and are the basis for the development and validation process.

The requirements should encompass issues concerning the use of the software, like:

- Version of requirements. The actual version of the requirements specification, and the changes applied to it, must be properly communicated.
- Input. All inputs for the software product, including specification of ranges, limits, defaults, etc., must be provided.
- Traceability. Activities taken to enable recording and tracing every critical event of the user.
- Hardware control. All equipment and device interfaces.
- Default settings. All settings that will apply automatically with the first start of the software product. Default settings include default input values and options, default instrument or program control settings, etc. Also, the information on maintenance and managing default settings must be provided.
- Version control. A set of measures and controls to enable distinguishing between different versions and outputs from different versions of the software product.
- Special requirements. Requirements arising from applicable international standards.

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[Job title] must ensure that items of the software necessary for its proper use are defined in requirements for the software. Such items include:

- Documentation. All relevant information about the software product, including the mode of operation, needs to be documented.
- User manual. How to use the software product.
- Service and maintenance. Documented information on the level of support regarding maintenance, updates, resolving problems, etc.
- Special agreements. Agreements with the end user that can affect the software product development and use, e.g., special editions, additional features, etc.

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3.2.2. System acceptance test specification

[Job title] is responsible for ensuring that the system acceptance test specifications are based on objective criteria for how the software product should be tested, to demonstrate that the

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3.2.3. Version identification

[Job title] must ensure that software is identified by unambiguous version identification. For example, this could be a three-digit version number,

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3.2.4. Documentation

[Job title] shall ensure that software application is correctly documented so that all relevant information is provided to the user, enabling him to utilize the software product properly.

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All documentation from the validation of the software needs to be maintained.

3.2.5. Installation and system acceptance test

[Job title] must ensure that purchased software products are normally supplied with an installation kit to ensure that the entire software product is installed correctly.

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If the software product to install only contains small, well-known updates, it may be sufficient to conduct only a partial test of the areas being updated. Partial testing can be performed only if validation of the entire software product was conducted previously.

3.2.6. Performance, servicing and maintenance

During this phase, the customer uses the software and all support that is included. The decisions about the changes, revalidation, and phase out occur during this phase.

[Job title] must ensure that maintenance activities for software products developed may be classified as follows:

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- **Problem / solution.** This involves detection of software problems causing operational troubles.

[organization name]

- **Functional maintenance.** If the software product was developed according to international standards, the software must be updated every time the standards change in order to remain conformity to the standards.
- **Functional expansion and performance improvement.** Records should be made about end user suggestions and requests in order to improve the product software. These records will represent one of the inputs for future development and evaluation of new versions of the software product.
- **New versions.** Once a new version of the software is available for use, analysis and verification must be performed to determine the effects of the new version on the existing system.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Record of Software Validation	PR16.1	1 year	Information Management	Information Management

Commented [AES26]: If the record is in electronic form, write the retention time in years.

5. Appendices

- Appendix 1 – Record of Software Validation

[job title]

[name]

[signature]

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