Software validation

History

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1. Subject

1.1 Purpose

The purpose of this procedure is to present the validation activities of software applications used in our company to ensure that each software meets the intended use (functional specifications).

1.2 Scope

This procedure applies to all software whose use is accepted in our company:

- production
- process validation
- design and development
- servicing
- monitoring and measurement
- management of the QMS
- documentation management
- management of electronic signatures

Software is bought or developed internally

1.3 Glossary

QMS – quality management system
Software application (or software): set of machine-readable sequence of instructions to automate an activity that may affect the ability of the product or service to meet requirements
Validation: confirmation by examination and objective evidence that the software specifications are in accordance with user requirements and intended uses and that the particular requirements implemented by the software can be continuously met (according to FDA)
Verification: confirmation by tangible evidence that the specified requirements have been met
IT: information technology

2. Responsibility

The IT manager has the authority to write and update this procedure. He is guarantor of its application. He has the support of the test manager and the quality manager.

3. Documents

3.1 Procedures

Risk management
Design and development
Purchasing
Process validation
Monitoring and measurement

Production

3.2 Instructions and records

Software list
Validation report

4. Requirements of ISO 13485: 2016 and ISO 17025 standards

ISO 13485 v 2016

4.1.6 Document procedures for the validation of the application of computer software used in the quality management system. Validate such software applications prior to initial use and, as appropriate, after changes to such software or its application.

Ensure that the specific approach and activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software.

Retain records of such activities.

7.5.6 Document procedures for the validation of the application of computer software used in production and service provision. Validate such software applications prior to initial use and, as appropriate, after changes to such software or its application. Ensure that the specific approach and activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Retain records of the results and conclusion of validation and necessary actions from the validation.

7.6 Document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Validate such software applications prior to initial use and, as appropriate, after changes to such software or its application. Ensure that the specific approach and activities associated with software validation and revalidation are proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Retain records of the results and conclusion of validation and necessary actions from the validation.

ISO 17025 v 2005

5.4.7.2 a Ensure that when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

5.7.4.2 b Ensure that when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that procedures are established and implemented for protecting the