SOP Software Validation

Summary

This SOP ensures that the organization only works with validated computer/software systems to avoid erroneous systems affecting the safety and performance of its medical devices. The process outlines requirements for validation before use.

Process Owner	QMO
Regulatory References	ISO 13485:2016 Sec. 4.1.6 and 6.3 and 7.6IEC 62304:2016 Sec. 9.8

Process Steps

1.1 Collecting Information and Preliminary Assessment

- Employee notifies QMO of the new system and provides the minimum information required for preliminary assessment, such as intended use description and preliminary risk estimation.
- QMO documents the intended use and determines whether the system is relevant for the QMS or the organization's medical devices as part of the computerized system validation form.
- If quality-relevant: continue to fill out the computerized system validation form (assessing criticality and risks).
- If not quality-relevant: document the system in the list of computerized systems and release the software system for use.

Responsible
Employee intending to work with the new system QMO

Input	Output
Information about the system Software Validation Form List of Softwares	Preliminary Software Assessment

1.2 Plan Validation

- QMO continues to fill out the computerized system validation form by planning the validation and documenting the requirements for expected validation results.

Responsible
QMO

Input	Output
Software Validation Form	Updated Software Validation Form

1.3 Perform Validation

- Perform the validation based on the validation plan and fill out the validation report as part of the software validation form.
- Where appropriate, save additional proof of validation (e.g. screenshots) and add them to the validation report.

Responsible
Employee working with the system

Input	Output
Software Validation Form	Updated Software Validation Form

1.4 Release

If validation was not successful:

- Document the validation results in the list of computerized systems and classify the system as “blocked” / “not released for use”.

If validation was successful:

- Document the validation results and sign the validation report as part of the computerized system validation form.
- Release the computerized system by adding it to the list of computerized systems.
- Inform relevant staff about the approval of the system.

Responsible
QMO

Input	Output
Software Validation Form Software List	Completed Software Validation Form Updated List of Software Notification sent

1.5 Monitoring of Softwares

- User feedback and error reports by developers are monitored for relevant occurrences that may affect the organization or its medical devices.
- New version updates are implemented and the list of computerized systems is updated accordingly. If necessary, a revalidation is carried out.

Responsible
QMO in collaboration with employee working with the system

Input	Output
Error reports by users / developers	Updated List of Software If required: new record of Softwares Validation Form created

1.6 Decommissioning of Software

- In case it is decided to decommission a computerized system, evaluate possible effects and document the actions in the List of Software.

Responsible
QMO

Input	Output
Software Validation Form Software List	Updated List of Software

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