SOP-DND-012

Software Development Planning

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Approvals	Reviewer	Status	Date	Comment
Approval		PENDING		

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Current Version (v. x)	<Date>	QA Manager

Signatures required

Signature required / meaning (Prepared by, Reviewed by, Approved by, Read and understood)	Function of signatories	Name of signatories

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References

ISO 13485 – Clause 7.1 a
These clauses say that development activities, including those related to software, must be planned, controlled, and documented in a manner consistent with the quality management system and proportionate to the product and its risks.

IEC 62304 – Clause 5.1
Clause 5.1 says that software development activities must be planned before implementation starts, with a level of structure appropriate to the software safety classification, complexity, and intended use.

MDR / IVDR – Software lifecycle control
MDR and IVDR require manufacturers to demonstrate that software used in or as a medical device is developed under controlled conditions, with documented planning, traceability, and risk management throughout the lifecycle.

1. Summary

This procedure defines how software development planning is performed for software used as a medical device or intended for use in medical devices.
It ensures that software development activities are planned, documented, and aligned with product-level planning, risk management, and regulatory requirements.

2. Scope

This procedure applies to:

- software used as a medical device (standalone software),
- software embedded in a medical device,
- software that contributes to the safety or performance of a medical device.

This procedure applies to new software developments and to significant software changes.

Software maintenance activities after release are addressed in dedicated maintenance procedures.

3. Inputs

Inputs to the software development planning process typically include:

- an approved Product Realization / Development Plan,
- intended use and system-level requirements,
- preliminary software safety classification,
- applicable regulatory and standard requirements,
- initial software-related risk considerations.

4. Process Description

4.1 General principle

Software development planning shall be performed before software development activities start.
The planning shall ensure that software lifecycle activities are defined, coordinated, and proportionate to the software's role, complexity, and risk contribution.

Software development planning shall be consistent with:

- product-level planning,
- system design and development activities,
- risk management activities.

4.2 Software Development Plan

For each applicable project, a Software Development Plan shall be established and documented using FOR-DND-015 Software Development Plan `<Name of the Device>` v1.

The Software Development Plan defines, as applicable:

- the scope and purpose of the software,
- applicable software lifecycle model(s),
- processes to be applied during development and maintenance,
- expected deliverables and documentation,
- interfaces with system design, verification, and validation,
- configuration and change management principles.

The level of detail of the Software Development Plan shall be adapted to the software safety classification and project complexity.

4.3 Interfaces with design and development activities

The Software Development Plan shall be aligned with the design and development planning defined in SOP-DND-002 Design and Development Planning.

Software-related activities shall:

- support system and product requirements,
- contribute to the Design History File,
- be reviewed during design review activities.

Traceability between system requirements, software requirements, verification activities, and risk control measures shall be ensured.

The complete procedure is included in ReadySet

ISO 13485 QMS framework for Confluence – azbc.be