# PURPOSE

This procedure defines software validation requirements for GT Medical Technologies.

# SCOPE

This procedure applies to software used to automate any part of the device production process or any part of the quality management system

This procedure does not pertain to software used as a component, part or accessory of a medical device or software that is itself a medical device. Reference the Software Decision Tree to determine if a software validation is required, Appendix A.

# DEFINITIONS

## Off-The-Shelf (OTS): Ready-made and available for sale to the general public.

## Software Validation Plan (SVP): Document that typically covers the scope of the effort, the required activities and the order in which activities must be completed.

## User Requirements Specification (URS): Specification document that defines the intended use of the software, the operating environment, the essential performance requirements and high-level control requirements. URS requirements are typically written as if the solution is not yet developed and focus on what the software is required to do, rather than how that will be accomplished. For solutions sourced externally, the URS is often used as the basis for the request for quote.

## Functional Requirements Specification (FRS): Specification document representing a decomposition of the URS requirements to a higher level of detail and specificity. The FRS therefore identifies how the software solution will be required to function to meet the user requirements.

## Software Design Specification (SDS): Specification document detailing the design approach to the software, which may include block diagrams defining architecture, selection of programming language(s), definition of interfaces between software modules, etc. The SDS is typically developed and used by the software supplier and will only rarely be a part of the GT Medical Technologies document structure.

## Software Validation: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. In a software development environment, software validation is establishing through objective evidence that all software requirements have been implemented correctly and completely and are traceable to system requirements.

## Software Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In a software development environment, software verification is confirmation that the output of a particular phase of development meets all of the input requirements for that phase.

## Traceability: The ability to link between design inputs and customer requirements, design specifications, risk analyses, verification and validation protocols and reports.

# RESPONSIBILITIES

QA/RA:

1. Review and approve software validation plan, protocol, and report.

Quality Engineering:

1. Establish software validation plan.
2. Establish software validation protocol.
3. Document software validation report.

Executive Management:

1. Review Master Validation Plan periodically.
2. Ensure software used for medical device processes is validated appropriately.

# PROCEDURE

## This procedure is based on a lifecycle model, with four phases:

### **Concept Phase**. During the concept phase, the opportunity to automate a process is evaluated, an initial URS is (typically) drafted, and potential suppliers are consulted. If the stakeholders determine that a viable solution is available and the costs, benefits and risks are favorable, the effort proceeds to the project phase. Alternatively, the opportunity may be dropped at this phase, with no further action required.

### **Project Phase**. The project phase involves planning, supplier assessment and selection, specification development, purchase, configuration and installation (when required), validation and release. Complex projects involving development of custom software may require an iterative process, with the evaluations performed on each iteration used to refine the specifications, the solution and the test plan. Prior to release of the software solution for the intended use, all supporting activities shall be complete, including release of any required procedures and work instructions.

#### Scaling according to risk

##### Activities in the project phase, particularly those related to specification and validation, should be scaled according to:

* The potential system impact on patient safety, product quality or data integrity
* The novelty and complexity of the system
* The outcome of the supplier assessment

##### The risk associated with OTS software is frequently considered to be lower than comparable custom software, because the history of use has increased the probability that defects have been identified. However, GT Medical Technologies is responsible for ensuring that the product development methodologies used by the OTS software developer are appropriate and sufficient, and that the software meets the intended use. The supplier’s life cycle documentation can be used as part of an internal process to establish that the software has been validated. However, any supplier documentation leveraged for validation shall be reviewed for adequacy, and the review documented within the GT Medical Technologies Quality Management System.

#### Software specifications

##### Every new software solution within the scope of this procedure shall be defined by an approved URS document.

##### FRS and SDS documents may be generated as well, depending on the risk considerations identified in the previous section, and the extent of documented evidence available from the software supplier. In particular, when the solution requires installation, specific hardware, or verification of detailed functionality that will not be managed and documented by the supplier, an FRS should be generated and used as a basis for validation, along with the URS.

##### Each specification line item shall be unique, unambiguous, verifiable, and shall not conflict with any other requirements.

##### Each specification should be singular, so that verification cannot result in a partial pass and partial fail.

#### Software Validation

##### Every new software solution within the scope of this procedure shall be validated prior to release for the intended use.

##### An SVP shall be established and maintained.

##### At least one validation protocol and accompanying report shall be generated to document evaluation of the system with respect to the established requirements. Typically, one set of protocol and report should be generated for each specification document (URS or FRS).

##### A final software validation report shall be generated, individually identifying the results of all activities required by the SVP and providing a conclusion about the readiness for service of the software solution.

#### Release

##### When the final validation report is approved, and indicates that all requirements were met, the system is considered released for its intended use.

### **Operation and Maintenance Phase.** When changes are made to a software system post release, the following activities are required, at a minimum:

##### An assessment of the proposed change shall be documented through the change management process.

##### A revision to the associated SVP, appending a description of the change, revalidation requirements, and any additional requirements such as changes to supporting procedures or work instructions.

##### A revision to the associated validation report(s), appending the outcome of each requirement added to the SVP.

### **Retirement Phase.** Retirement of software systems within the scope of this procedure shall be performed per a documented plan including the following at minimum, as applicable:

Data archiving

Data migration (if replaced by another system)

Ensuring that references to the software in active procedures or work instructions is corrected to reflect the new status

Deactivating credentials

Uninstalling the software.

# RECORDS

Records and documents required by this procedure shall be retained and controlled in accordance with the established document control and change management procedures.

# APPENDICES

Appendix A: Software Decision Tree

# DOCUMENT HISTORY

|  |  |
| --- | --- |
| Functional Area | Signature & Date |
| Operations |  |
| Quality |  |
| Regulatory |  |

|  |  |  |
| --- | --- | --- |
| **REVISION HISTORY** | | |
| Rev. # | Released Date  (YYYY-MM-DD) | Author |
| 1 | 2019-07-22 | Haidy Henes |

**APPENDIX A: Software Decision Tree**

