Software Validation for Medical Device Manufacturers

FDA requires software used in production to be validated, see FDA Title 21 CFR Part 820.70 (i)

Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

What needs to be validated?

According to a guidance paper by the FDA[1] the following software must be validated

- Software used as a component, part, or accessory of a medical device;
- Software that is itself a medical device (e.g., blood establishment software);
- Software used in the **production of a device** (e.g., programmable logic controllers in manufacturing equipment); and
- Software used in implementation of the device manufacturer's quality system (e.g., software that **records and maintains the device history record**).

Software that records and maintains the device history record must also follow Title 21 CFR Part 11 (ELECTRONIC RECORDS; ELECTRONIC SIGNATURES)

How much validation evidence is needed?

The amount of validation depends on the intended use and of course on the risk associated with the use of the software. The following documents should be produced:

User requirements including
- intended use
- operating environment

Validation plan including
- acceptance criteria
- test cases

Validation report including
- test results
- validation summary

How can Matrix Requirements help you?

Matrix Requirements shares with you the system requirements as well as our validation plans and results for your version of Matrix Requirements. We will inform you before we tend to upgrade your system and only do it if you wish so.

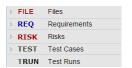Furthermore we can set up a specific project which helps you with tool validation in general.

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[1] http://www.fda.gov/RegulatoryInformation/Guidances/ucm085281.htm

Matrix Requirements Tools Validation Project

Matrix Requirements Medical has a standard project template which you can use to validate any tool you use in production of your medical device. The template is set up like this:

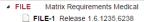|	
▷ **FILE**	Files
▷ **REQ**	Requirements
▷ **RISK**	Risks
▷ **TEST**	Test Cases
TRUN	Test Runs

It contains FILEs (where we will attach our own documents with one file item per release) as well as requirements (REQ), risks (RISK) and tests (TC, XTC).

It comes also with some pre-configured document templates: System Requirements Specification, Validation Plan and Validation Report.

How it works for Validation of Matrix Requirements Medical

1. For each release Matrix Requirements will upload the release documentation (e.g. release notes, requirements or validation report) into the FILE section

   ◢ **FILE** Matrix Requirements Medical
   　　📄 **FILE-1** Release 1.6.1235.6238

2. You review and update the REQ, RISK and TC which are pre-populated

   ◢ **REQ** Requirements
   　◢ **REQ** Matrix Requirements
   　　📄 **REQ-1** Off-the-shelf Functionality
   　　📄 **REQ-2** Software Updates
   　　📄 **REQ-3** Specific Setup: Categories, Fields, Traceability
   　　📄 **REQ-4** Specific Setup: Risk Management
   　　📄 **REQ-5** Specific Setup: Controlled Documents
   　　📄 **REQ-6** Specific Setup: Signed Documents
   　　📄 **REQ-7** Title 21 CFR Part 11

3. You create a new test run for the new release
4. You execute the tests
5. You review and sign the system requirements document
6. You review and sign the validation plan
7. You update the validation report to include the new test run and also review and sign it
8. You rename the 3 signed documents to include the version number

How it works for other tools

Just the same:

- For each tool you want to validate, you can create a sub folder in the FILE, REQ, RISK, TEST, TRUN, DOC and SIGN.
- You add files, requirements, risks and tests as needed
- You create the 3 new controlled documents for each tool using the default templates and enter the content.