FDA Regulated Software Validation Process

What does software validation mean?

In order to produce FDA compliant COTS (Configurable Off-the-Shelf) software, a vendor must:

1. Add a series of features that ensure data continuity, integrity and security
2. Complete a software validation process
3. Enhance security, recovery and training procedures (SOPs)

When all requirements are completed, a third party consultant provides a Compliance Letter to the vendor. A new Compliance Letter is obtained for each new major version release.

What do manufacturers have to do to validate their software is working as intended for their unique processes?

When FDA regulated manufacturers adopt software they are required to further validate that the software is working as expected for their specific quality processes. Manufacturers are required to create a list of "jobs" the software is to complete and then test to confirm the jobs are completed correctly. The process looks like this:

Step	Validation Requirement
1	Identify the software requirements based on specific quality processes.
2	Detail how the software will deliver against these requirements (specifications).
3	Create a testing protocol that outlines how each specification will be tested.
4	Test each specification and confirm the findings.
5	Keep the documentation in the event of an FDA audit.

What do manufacturers we need to do if the software is reconfigured or a new version is released?

Whenever the application is reconfigured (i.e. updates to forms or new processes) or a new version of the software is released the customer must revalidate the software. This process involves the following steps:

1. Create new versions of the validation documentation and update the specifications and test cases
2. Execute new test and report the results

How can Weever Apps help?

Weever Apps can provide fill-in-the-blank templates that include the required information for validation, including configuration settings, requirements, specifications and test cases. As a result, the manufacturer only needs to:

1. Ensure the specifications and tests are applicable to their unique environment
2. Execute the tests to complete the report

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Process MANAGER

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