Raltus
SOFTWARE

PHARMACEUTICAL MULTI-NATIONAL USES PROCEDURECAPTURE TO STREAMLINE VALIDATION

The Challenge

A US based Pharmaceutical manufacturer wants to run its worldwide validation processes using a single tool.

Their current validation approach, which relies on manual systems is time consuming and inefficient as documents are needlessly recreated and tedious manual tasks are performed on a routine basis.

They want a Paperless solution to remove the need for generating excessive paperwork while also using a Risk based model to help them concentrate on the areas which have most impact.

Test results also need to be recorded in such a way that an independent reviewer can compare the documented acceptance criteria against the Test evidence and determine whether the test met the relevant criteria.

In addition, the company had also acquired several product divisions through acquisition and hence has a mixture of old and new software and technology and this complexity of systems needed to be supported.

"ProcedureCapture helped us manage the whole lifecycle with a risk based approach This integrated, affordable and easy to use tool. covered everything including Requirements, Risk, Testing, Traceability and Defects."

J. V.
Operations Director

The Solution

Raltus Software has helped many companies validate their systems and their solution works across any software and technology.

The company wanted a Risk based Application Lifecycle Management tool which covered Requirements, Risk, Testing, Traceability and Defects with no add-ons. They also wanted the tool to be integrated, affordable and easy to use.

We also worked closely with the customer to utilize their already existing SOP documents and use these as input templates. Minimum modification of the original documents allowed approval ready documents to be output from the captured processes in a rapid and consistent basis. These template documents were easily shipped to the various subsidiary organizations to be reused in a country specific manner.

The low technical barrier to entry was a key factor in being able to transport this knowledge to distributed teams who were generally not either IT specialists or programmers. The simplicity and short learning curve meant that time was spent creating and executing assets and not on "tool training".

Contact

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As in all other Raltus projects the customer was able to see the real time traceability between Requirements, Test Scripts and Defects and this was key in understanding where they where in the project and how everything hung together in the lifecycle.

Initially the customer was using paper only validation but once the ease of use of the system was established and some familiarity was gained, paperless execution was begun with the output signed using the built in eSignature capability for multiple signatories and the documented evidence was then stored on a SharePoint server.

The Benefits

Within four weeks of introducing the ProcedureCapture® technology from Raltus Software the customer :

- Imported/created 150 User Requirements, reviewed them and then electronically signed them as approved and locked.

- Created 200 GxP impacting Test Scripts and linked these to the relevant Requirements that they satisfy

- Reviewed and pre-approved the 200 Test scripts and electronically signed them thus locking them and ensuring that the tests will be subsequently executed accurately and in their entirety.

- Each captured Test Script was truly 'shareable', and could be understood as a standalone asset without the need for clarification or open to interpretation or ambiguity (unlike using words only). This was of particular importance in locations were a common language was not shared.

Within eight weeks the customer had made additional important steps:

- Test scripts for execution where allocated to parallel teams within local staff whereas previously everything had been run serially due to the dependency on the HQ IT staff.

- Test scripts where run 100% paperlessly within ProcedureCapture with 30% of these run using the built in automation engine.

- Automatically produced Traceability report to show linkage between Test Script run and the Requirements showing the coverage and pass/fail results.

- Compared to previous manual validation, this solution reduced the time taken for similar effort to this point by 75%.

"Getting ProcedureCapture was a great decision. It covered everything, was easy to learn and we got our payback almost immediately…."