CASE STUDY

# LEADING US ORAL HYGIENE SUPPLIER SELECTS RALTUS FOR SYSTEM VALIDATION

**"ProcedureCapture provided a complete risk based validation solution which was faster, easier and cut our validation cycle by 50%. A huge saving...."**

**M. A.**
**VP, Operations**

## *The Challenge*

The customer is the leading US producer of dental materials and equipment. They manufacture a wide range of products for the global market.

As part of their CSV effort they needed to create approved documentation of practices and procedures that are consistent with CFR Part 11. The company had relied on manual systems which they found particularly time consuming and inefficient as documents where needlessly recreated and tedious manual tasks performed on a routine basis.

In particular they had struggled to identify what where the important things that needed validated. They had therefore ended up validating everything in case they missed something that was later found to not have the documented evidence that the regulators might expect.

The company had previously looked at adding a manual risk assessment process into their validation efforts to reduce this workload however on reviewing the results of some internal audits this had proved to be ineffective and had missed multiple high priority cases.

The customer uses the AX product range from Microsoft so any product or tool used in the final solution must interact fully with this product and demonstrably be able to handle updates and changes.

## *The Solution*

Raltus's ProcedureCapture® is a Risk based Application Lifecycle Management solution which covers Requirements, Risk, Testing, Traceability and Defects, all from one integrated, affordable and easy to use tool.

For their System and Requirements, ProcedureCapture® allowed them to select different GAMP Risk assessment models in terms of Risk priority levels and also Risk Detectability that best suited their assessment.

From this Risk assessment, they where able to ensure that the Tests created where of the necessary scope and rigor to reflect the risk level. This enables the amount of testing to be appropriately scaled to the risk.

By running the real time Traceability view, they could see, by Risk Priority, the relationship between Requirements and the Test scripts that satisfy them. This allowed them to then allocate their scarce resource to testing against the things that actually had an impact on patient safety.

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They then created test scripts in ProcedureCapture® with different test scope types based on the Risk Priority of the Requirement they satisfy. This meant that they could directly check that for a specified Risk priority that a Requirement had been properly tested.

When these Test scripts where executed paperlessly within ProcedureCapture®, and if a deviation was found, they where able to Manage and Track the defect throughout the lifecycle. For these Defects, they could see their Risk priority as they where linked directly back through the Test Scripts to the Requirements they affect. This meant they could focus on fixing the most important Defects first.

ProcedureCapture® allowed them to assess Risk and then trace this assigned Risk priority throughout the whole lifecycle of Requirements, Testing and Defects. This enabled them to concentrate their resources on finding and fixing the things that mattered.

## *The Benefits*

The customer found that the validation project was finished in half the time taken previously (8 weeks instead of 16):

- One Risk based tool only required for Requirements, Testing and Defects, no add on or APi's needed.
- Real time Traceability between all these elements of the validation lifecycle, linked by Risk Priority, and allowing the customer to focus their resources on the things that are important.
- Test scripts where run 100% paperlessly within ProcedureCapture with 30% of these run using the built in automation engine.
- Test results are 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.
- Reducing the time taken to complete the validation project from 16 weeks to 8 weeks directly translated into a cost saving of over $48,000.

**"Buying this tool has turned out to be an absolute 'no brainer'. The ease of use, quality of output and validation specific output were invaluable. I would have bought it just to do the trace matrices alone."**