syncroness
innovative product development

INNOVATION = ENSURING YOUR PRODUCTS ARE RELIABLE AND LONG-LASTING

INNOVATION AT A GLANCE

Client:
Various

Industry:
Medical & Aerospace

Syncroness services:
» Verification
» Risk Management
» Test Plan and Protocol Development

Objectives:
» Maximize device quality
» Minimize product risk
» Meet all regulatory requirements

Approach:
» Formalize Verification Plans
» Document Defect Tracking
» Traceable Action Plan

RESULTS

» Reliable Designs
» Enhanced Functionality
» Reduced Risk

For highly-regulated industries, development of the product is only half the battle. A complete, documented verification plan and execution leads to reliable product in the field and reduced risk.

LEVERAGING FORMAL VERIFICATION METHODS AND RUGGED TRACEABILITY FOR COMPLETE VISIBILITY AND CONFIDENCE.

When you're developing products being introduced in the medical device industry, the design and functionality are important, but reliability and confidence in the design are an absolute must. In a heavily-regulated environment, simple failures can lead to significant consequences, including the complete shutdown of your product line, or worse, your organization. Moreover, you need to be able to clearly illustrate how you've addressed these concerns and mitigated risks to both internal QA/RA groups and the FDA.

Verification and Validation are likely the most critical steps in the development process and Syncroness is well-versed in how to perform V&V completely, protecting you from future product issues. By developing, reviewing and releasing a formal Verification Plan, we are able to ensure all stakeholders are in tune with how verification will be performed, including the applicable individual verification procedures which either already exist from prior efforts and are developed as part of the plan.

As you move into the actual execution of the plan and procedures, having an experienced staff that knows how to 'abuse' the system ad-hoc, prior to formal verification, allows you to identify errors and anomalies that may not come to light in the standard V&V execution while also providing the opportunity to redline the formal procedure for more in-depth testing. Tracking and documenting all identified bugs and failed steps accurately in a formal tracking system (TFS, Bugzilla, Serena etc) provides a clear trail of what occurred during testing. Following the completion of initial testing, it is necessary to hold a review with product stakeholders and discuss each entry into the tracking system and score it according to impact and consequence and determine if the entry A) works as designed, B) must be resolved or C) may be deferred to future release due to acceptable risk level. Updates to the product are made and the testing is once again performed, following similar steps.

Once testing is complete, using this process, you can be confident that the end product is reliable and indeed ready for release.

LET'S KEEP INNOVATING.

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