

HUTCHINSON TECHNOLOGY



CUSTOMER CASE STUDY

FROM PAPER TO EFFICIENCY:
STREAMLINING A
BIOMEASUREMENT DIVISION'S
CAPA AND NCRs

AssurX®



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STREAMLINING BIOMEASUREMENT DIVISION CAPA & NCRs

For a company like Hutchinson Technology (HTI), getting the job done right is never left to chance. Their commitment to quality excellence, continuous improvement and a relentless focus on the fundamentals has transformed a small company founded in 1965 by two young entrepreneurs in a former chicken coop into an international leader with more than 5,500 employees.

HUTCHINSON
TECHNOLOGY
SELECTED ASSURX
OVER ALL OTHER
VENDORS FOR ITS:

HIGH
CONFIGURABILITY

USER FRIENDLY
DASHBOARDS

EASY QUERY
CAPABILITIES THAT
ELIMINATE THE NEED
FOR IT SUPPORT

Yesterday, today and tomorrow, one thing never changes at HTI: everyone and every facet of its business must be on a path of continuous improvement. HTI employees are committed to finding the best way to get the job done and then doing it better than anyone else. By improving at a faster rate than the competition, HTI can maintain its leadership position. In this case study, we'll examine how a team of HTI employees identified an area of inefficiency and found the tools to help them get the job done right.

The Company

Hutchinson Technology is a global technology leader committed to creating value by developing solutions to critical customer problems. The company's Disk Drive Components Division is the world's leading supplier of suspension assemblies for disk drives. Suspension assemblies are precise electro-mechanical components that hold a disk drive's recording head at microscopic distances above the drive's disks.

The company's BioMeasurement Division is filling a critical information gap in the monitoring of trauma patients with the introduction of the **InSpectra™ StO2** Tissue Oxygenation Monitor. Launched in 2006, the device gives hospital trauma teams the ability to noninvasively and continuously measure tissue oxygen saturation (StO2) and monitor it during resuscitation.

The Challenge

The BioMeasurement Division had a cumbersome paper-dominated system where CAPA and NCR were not linked, explained Mike Bates, quality engineering supervisor. "We essentially kept a log of NCR and CAPA events in separate spreadsheets," he said. They also tracked each that way—separate and on paper.

Bates and his colleagues recognized this was not the most efficient way to operate and also knew they wanted to improve it. "Our biggest motivation was the integration of NCR and CAPA," he said. Specifically, HTI sought a better way to manage escalations and track the status of NCR and CAPAs.

Their focus on CAPA was wise, experts agree. In fact, many current and former FDA inspectors have remarked publicly that the first thing they look at during an inspection is a company's CAPA capabilities. If you are strong there, an inspector proceeds with a greater degree of confidence in the rest of your operation. If you are weak there, it sets off alarm bells, many inspectors have said.

The Search

The search for a better solution began in earnest about a year ago, said Lynn Jacobson, systems analyst.



After doing some initial Web searching and networking with others, HTI settled on three prospects, including AssurX CATSWeb®, a flexible, all-in-one platform that automates quality management & regulatory compliance related processes so issues can be globally managed—from detection to corrective action to trend analysis. It helps collect, organize, analyze and share information to better manage and improve quality and compliance performance everywhere in your enterprise. “We brought two suppliers in for a demo, and held a conference call with the third,” Jacobson said.

The Solution

It was before, during and especially after the demo that AssurX separated itself from the pack, Jacobson commented. During the demo “we were very happy with AssurX’s configurability, easy to use dashboards, and the ease with which users could do their own queries without relying on the IT department,” she said.

She said AssurX also scored highest marks for being responsive when any issues came up “before we picked them, while we installed it and afterward.”

The Installation

“It was pretty painless to install,” said Jacobson. They now have about 20 regular users on the system, but that number may climb.

In fact, during the installation and training process, HTI, with the help of the AssurX team, saw that the tool was more powerful and useful than they had thought. “Other users will be able to design their own system and forms in the future,” she added.

And Jacobson said she’s living proof as to the ease of configuration. “I did it, and I’m not a developer,” she said. “I was able to do it with a very limited programming background,” she said.

HTI installed CATSWeb on a test server in late February/early March, and was live by September. Jacobson said part of the secret to HTI’s success with the installation and launch was their decision to leverage AssurX’s Fast Start Program.

The Fast Start Program

This exclusive program allows for a faster deployment by setting up a private database for a period of time on AssurX servers in the secure data center. This allows the customer to immediately start configuring their system with the assistance of a process expert.

This program significantly reduces deployment times because the installation process can be run in parallel to the configuration and training activity. When ready, all of the processes developed on the AssurX server can easily be moved to the customer’s system.

This includes:

- Hosted system setup
- Up to 5 concurrent users hosted for 90 days
- 8 hours of remote consulting for on-line training, best practices, and automation with point and click administration and configuration
- One-time transfer of hosted processes (forms, lists, rules, etc.)

“WE HAVE SUCCESSFULLY ELIMINATED THE PAPER SYSTEM AND MANUAL LOG, REPLACING IT WITH LINKED NCR’S AND CORRECTIVE ACTIONS IN CATSWEB. THIS HAS MADE INFORMATION SIGNIFICANTLY MORE ACCESSIBLE, VISIBLE, AND THUS MORE VALUABLE.”

Colin McGraw
Operations Manager
Hutchinson Technology
BioMeasurement Division

The Impact

Simply put, CATSWeb helps to make the administration of non-conformance MRBs (Material Review Boards) “much nicer,” notes Bates. “It’s quick now, we get together in a room with a computer and a projector, put it up there and have discussions in real time,” he added. “We type in dispositions and sign them as we go in a wireless environment. That works really well and we like it a lot.”

Bates likes the visibility of CAPA with CATSWeb and the ability to query the database as needed. “As the CAPA Coordinator, I need to make sure all pending actions are getting the needed attention,” he said. “CATSWeb is a great tool for keeping tabs on how well the organization is responding to correcting problems.”

With CATSWeb, readability of records is no longer an issue. “I can type a lot faster and more legibly than I can write,” he said. Bates thinks that, if he is typical of most users, this equates to a 50% efficiency increase.

“We have successfully eliminated a paper system and manual log, replacing it with linked NCR’s and Corrective Actions in CATSWeb,” said Colin McGraw, operations manager. “This has made information significantly more accessible, visible, and thus more valuable.”

That has meant faster signatures, too. McGraw: “Time to disposition has been reduced with the ability to approve via HTI’s Intranet rather than relying on physically routing a paper copy for manual signatures.”

The Future

The future is as bright as CATSWeb is configurable, the HTI team agrees.

“We could improve our configuration on selectable items—such as reasons for a non-conformance—and improve how we use the product down the road,” Bates said.

“Based on early success with the NCR and Corrective Action process, we are evaluating the use of CATSWeb to support our complaint process,” McGraw said.

For the team at HTI, the commitment to continuous improvement continues. It’s a never-ending quest for excellence.

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