

FISCHER IMAGING



CUSTOMER CASE STUDY

IMPLEMENTING A PROACTIVE ENTERPRISE-WIDE QUALITY SYSTEM

AssurX



FISCHER IMAGING: IMPLEMENTING A PROACTIVE ENTERPRISE-WIDE QUALITY SYSTEM

When you are engaged in the battle against breast cancer second-best just won't do. "Everyone at Fischer Imaging takes great pride in our firm's history of contributions in the fight against breast cancer, but we know good intentions are only part of the solution," says Gary Turner, Vice President, Quality & Regulatory Affairs. To bolster its good intentions, Turner and his Fischer Imaging team recently implemented a quality control system that tracks nonconformances and corrective action requests as part of a broader proactive corrective and preventive action (CAPA) program. That effort has already helped the firm streamline operations, improve efficiencies, and demonstrate to the Food & Drug Administration (FDA) that Fischer has a secure handle on its quality control.

"We want to be part of the ultimate victory over breast cancer," Turner says. "Quality assurance in our operations is making our firm stronger on many levels – including the bottom-line – to strengthen our work in the good fight."

Since January 2004, Fischer has been enjoying the benefits of AssurX's CATSWeb, a proven leader as the industry's enterprise quality tracking software of choice. CATSWeb is used at FDA-regulated and ISO/QS 9000 certified companies around the world. Fischer also leveraged CATSWeb to achieve compliance with 21 CFR Part 11, the FDA's electronic record integrity and archive history requirements.

FASTER, BETTER ELECTRONIC SIGNATURE CAPABILITIES

To get a sense of the significant improvements Fischer Imaging has already experienced, just ask Supplier Quality Engineer Frank Strupeck about electronic signature approvals. "It's a night and day improvement since we installed AssurX's CATSWeb," he says. Strupeck, the person who led the CATSWeb implementation at Fischer, says that before CATSWeb, employees at Fischer had to physically walk around hunting for other personnel to get signatures on forms, averaging 15 minutes or more to collect each signature. He estimates that where they once spent at least 50 hours per month chasing down signatures, CATSWeb has helped cut that down to a click of a button. "That alone is a tremendous benefit

to our company," Strupeck says. "There's almost no chasing down now for signatures," agrees Turner. Turner joined Fischer after AssurX had been selected for the quality assurance upgrade project but before it had been installed. As he describes it, one of his first tasks after coming on board was to take a second hard look at AssurX and CATSWeb to make certain it was as good as advertised and demoed. "Passed with flying colors," he says. So in October 2003, Fischer and AssurX began to work together closely to implement CATSWeb, and three months later the nonconformance system was fully validated and operational.

FISCHER'S QUEST

Founded in 1910, Fischer Imaging is the United States' oldest manufacturer of x-ray medical equipment, and a world leader in imaging solutions. In recent years, Fischer Imaging has focused its expertise in medical imaging toward the early detection of breast cancer. Through a wealth of experience and industry recognition in breast imaging and biopsy, Fischer is proving itself to be an ongoing pioneer and leader in the fight against breast cancer.

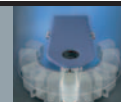
Fischer's two main products, SenoScan® Digital Mammography and MammoTest® Breast Biopsy System are shaping the future of breast care. With cutting-edge technology, the highest quality images, innovative designs, and total system connectivity, each of these systems lives

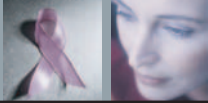
FISCHER IMAGING SELECTED CATSWeb OVER ALL OTHER VENDORS BECAUSE:

IT'S EASY TO CONFIGURE
AND ADMINISTER

CAN ADAPT TO THE
COMPANY'S GROWING
NEEDS

HAS POWERFUL QUERY
FUNCTIONALITY FOR
EASY HISTORICAL
TRENDING AND
ANALYSIS





Fischer's reputation as being Clearly Better™. Between these two products, all aspects of breast cancer detection and diagnosis are covered.

Fischer Imaging recognizes that digital technology is the present and future of mammography – and it remains committed to digital. Fischer has developed technology to capture the highest quality images possible, and will continue to push digital imaging as far as it can go in its race to defeat breast cancer.

INSPECTING VENDORS

When Fischer Imaging investigated vendors, the firm wanted to find a quality product that did what it said it could do, showed the ability to grow and adapt with the firm and its needs, and was easy to use. "Two of the biggest reasons we picked CATSWeb was that it was so easy to configure ourselves and so simple to manage," Strupeck says.

Fischer Imaging has also used CATSWeb to help it identify operational bottlenecks that had slowed everything down in the past. For example, before CATSWeb, Fischer's quality assurance team had to process about 400 nonconformance forms per month. In their old manual paper system it took at least ten minutes to re-enter each form into the legacy system. "In a paper-laden system that's a lot for a company our size," Turner points out. "We used to get bogged down, but CATSWeb has allowed us to identify bottlenecks, report issues and actions assigned to various people, quantify where bottlenecks are and get help to that area." That wasn't happening in a paper world, he says. Before CATSWeb, those bottlenecks "just got bigger and bigger."

In addition to speeding and streamlining, CATSWeb has helped in the important area of electronic record archiving, too. "We're not losing forms anymore," Strupeck flatly states.

"With CATSWeb we have better tracking, better visibility and resource allocation, and better use of personnel."

GOOD SURPRISE

Strupeck says one of his greatest surprises in the CATSWeb environment is that the electronic signature program is much faster and efficient. "My biggest surprise is that now our signature requests really happen in a two day period." He attributes that success to a combination of Fischer's management commitment to the program and CATSWeb's E-mail notification capabilities. For example, on the now rare occasions when someone does not get a signature back within two business days, CATSWeb alerts the appropriate staff to follow-up. "It's like clockwork," Strupeck says.

Even better, if a document is higher priority and requires a faster signature response, CATSWeb allows Fischer's team to "speed it up easy," Strupeck says. "We can put a hyperlink in the document and it has been a tremendous improvement."

USING OLD DATA IN A NEW WAY—TRENDING AND ANALYSIS

After implementing the new automated system, Fischer wanted to have access to their legacy data for historical trending and analysis. By using an out-of-the-box feature, Frank Strupeck was able to link his table of legacy records into CATSWeb, giving him direct access to 30,000 records in his legacy database. By not having to import the legacy data into the new automated quality system, validation and test activities were virtually reduced to zero. Confirming that the link worked properly was all the validation that was required.



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Gary Turner
Vice President
Quality & Regulatory Affairs
Fischer Imaging



“Now we’re able to perform trending and analysis on archived data, as well as new data all within CATSWeb without having to perform two separate queries,” said Strupeck. “I can perform queries that go back a couple of years to data that was entered today,” adds Strupeck. The built-in Query Tool allows users to run queries that join external data with internal data, giving a complete picture that includes active and historical records.

WIDESPREAD USAGE

Fischer is utilizing CATSWeb largely in its operations, quality regulatory group and engineering departments, but other departments are brought in as required by job. Fischer’s operations group includes purchasing, receiving, inspection, and production. “It is truly a corporate wide usage,” Turner says. The product’s ease of use and flexibility facilitates the addition of new users and finding new ways to take advantage of its capabilities, adds Strupeck.

As of mid 2004, almost half the company regularly uses the system, Strupeck says. When CAPA goes online soon, Strupeck estimates usage will increase further to two-thirds of Fischer’s employees.

Training on CATSWeb is easy. “Those with basic computer skills easily master CATSWeb and they are able to quickly get their colleagues up to speed as well,” notes Strupeck. “As more people

learn the system they can then speed up the learning curve for everyone else.”

He keeps his training groups small, uses screen shots and goes through a two-week trial validation period. After that is completed, Strupeck goes over the process with trainees. “I’m confident if a new employee comes in with basic computer skills they can pretty much get it going with our procedure document,” he says. CATSWeb is even easier for managers and younger staff to master, he adds.

Fischer doesn’t have plans to open up the system to outside vendors, but feels it already reaps its benefits with vendors. Frank gives an example, “With product nonconformances, we can E-mail the CATSWeb screen to them as “read-only” so vendors can instantly get a clear idea of the problem.” It helps suppliers to see the problem, shows them the specific product order number, and helps them to more quickly identify the issue and fix it. “This is a lot easier now,” Strupeck says. “Now it takes one click, enter the vendor’s E-mail address, and they’ve got it!”

CONCLUSION

Those charged with quality assurance at Fischer Imaging appreciate the importance of their task to rid the world of breast cancer. Working with CATSWeb to improve their quality assurance program, they believe they’ve made important new strides toward that ultimate goal.

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