

Fujifilm Medical Systems USA becomes the picture of collaboration



Overview

■ **IBM Business Partner:**

Winchester Business Systems

■ **Customer:**

Fujifilm Medical Systems USA Inc. supplies products and services for capturing, communicating, displaying and archiving medical diagnostic images.

Business Challenge

Hospitals, radiology labs and imaging centers throughout the U.S. rely on a picture archival communications system (PACS) from Fujifilm Medical Systems USA called Synapse. Used for X-rays, MRIs, nuclear medicine and ultrasounds, Synapse provides immediate access to valuable patient care information to support timely decision making.

As demand has grown for the company's Synapse image and information management systems, along with its Computed Radiography and printer products, Fujifilm Medical Systems realized the paper-based processes it used to manage its operations were no longer adequate. Re-engineering these processes would help the manufacturer maintain competitive levels of customer service and support, ensure the quality of its

product lines, and better manage the imaging continuum of care.

Change management was a big issue. Any time a product, document, or specification is changed, the company needs to ensure that new versions will work with older models. The company also needs to manage issues such as obsolete parts inventory.

Regulatory compliance was another critical issue. As a manufacturer of medical devices, Fujifilm Medical Systems must comply with the U.S. Food and Drug Administration 21 CFR Part 820 Quality System Regulation and Part 11 predicate rule regulations, which govern access, control

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and use of electronic records and electronic signatures. In addition, Fujifilm Medical Systems must be able to guarantee the privacy of any patient data it possesses, due to the Health Insurance Portability and Accountability Act (HIPAA) regulations that went into effect in April 2003.

Inability to demonstrate compliance with FDA regulations can have disastrous effects on a manufacturer, which risks having to halt production until it can demonstrate that it has met FDA requirements.

“Our paper systems were no longer meeting our needs. We were maintaining reams and reams of paper that track the design history of every device, and we were constantly hand-delivering documents to five or six locations to obtain signatures,” says Rob Berry, director of quality assurance and regulatory affairs at Fujifilm Medical Systems USA.

Solution

Fujifilm Medical Systems believed a simple document management solution would do the job. Working with an independent regulatory consultant, Fujifilm Medical Systems narrowed its search to Winchester Business Systems, an IBM Premier member of PartnerWorld® for Software in Boston, Mass.

It quickly became apparent that Fujifilm Medical Systems would benefit from an enterprise-wide solution that went far beyond document management. To help the company get better access to critical business information, increase customer service and responsiveness, and be better positioned to comply with

government regulations, Winchester Business Systems implemented three Lotus® Domino® based solutions. The solutions are Engineering Change Control, adWATCH Product Complaint Management Systems (adWATCH-e) and paraFILE Document Management.

The Engineering Change Control Solution leverages the collaborative functions of Domino to quickly and efficiently analyze and process engineering change requests, using electronic management of bill of materials, manufacturing specifications, item masters, routings, drawings, manufacturing processes and equipment.

adWATCH-e helps Fujifilm Medical Systems capture, distribute, retrieve, and manage product complaints from any manual source, computer or application. Its ability to enforce an approval process for each product complaint that complies with regulatory requirements addresses a critical issue for the manufacturer.

Winchester’s paraFile is an EDM (Electronic Document Management) system that helps users capture, author, edit, distribute, retrieve, and manage electronic documents. The solution is Web-enabled to support both internal and external authors, reviewers, and approvers.

To address Fujifilm Medical Systems’ concerns about system security, Winchester Business Systems replaced the company’s existing Microsoft® Exchange system with more than 500 seats of Lotus Notes® V6. An IBM eServer™ iSeries™ was installed as the Notes server.

A Collaborative Effort

Fujifilm Medical Systems USA is using Winchester’s solutions to manage all of the FDA-regulated document libraries, computerized engineering drawings, manufacturing specifications, and quality assurance procedures for its products.

With the combined strength of Domino’s collaboration and Winchester’s industry expertise, Fujifilm Medical Systems is now able to work more efficiently through collaboration between its many business operations – sales, technical, customer service, regulatory, quality assurance, and engineering.

“The solutions from Winchester Business Systems, combined with Domino’s collaboration power, have made Fujifilm Medical Systems more competitive. We have shortened our time-to-market, increased our efficiency, and improved our customer service. The solutions have made our jobs easier,” Berry says.

The company has greater confidence now about its ability to demonstrate compliance with government regulations. “Moving from paper processes

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to these systems provides single-point record acquisition," notes Berry.

Winchester Business Systems

Fujifilm Medical Systems cites Winchester Business Systems' experience in the medical device products and pharmaceutical industries, as well as its professionalism, as contributors to the success of these solutions.

"Winchester Business Systems was very good. We put a lot of pressure on them and were constantly making adjustments. They were very accommodating," says Berry.

As an IBM Business Partner for more than a decade, Winchester has developed in-depth knowledge of Lotus Notes and Domino, and leverages IBM programs to help it deliver these solutions.

"Through our relationship with IBM via the Top Contributor Initiative and the You Pass We Pay Program, we continue to address customer driven initiatives by utilizing IBM's broad base of services and product offerings. These programs allow Winchester to more effectively address the needs of our customers as they grow and expand," says Michael Regentz, managing director of Winchester Business Systems.

For more information on Winchester Business Systems, visit:
<http://www.wbsnet.com/> and to learn more about IBM PartnerWorld go to **ibm.com/partnerworld**.



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