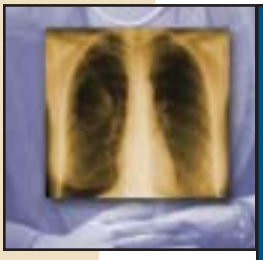
NetRegulus™

report

IssueExpert's Drill-Down Capabilities Let Company Monitor Product Quality, Including Vendor-Supplied Subcomponents



Company Background

This manufacturer is a leader in open-heart surgery technology. The company has a strong market position in its field, with about 950 employees and worldwide sales of about $150M. The company's product areas include autologous blood-recovery products and cardiopulmonary products, such as oxygenators, heart-lung machines, and bloodlines.*

Formerly owned by one multinational medical products manufacturer, the company was acquired by another a few years ago. Based in Europe, the new parent company is a major supplier and manufacturer of cardiovascular and autotransfusion products.

The Challenge

The decade of the 90s was an expansion period for this cardiopulmonary products manufacturer. With the help of its previous owner, the company launched a number of new and innovative products, all of which required careful postmarket monitoring. The acquisition by a different European parent added another dimension to the surveillance situation. Under the terms of the acquisition agreement, the corporation had to discontinue use of the previous owner's proprietary information systems. In short, the company was in urgent need of a software solution that could track complaints, product malfunctions, and the like. To compound the difficulty, the manufacturer needed to track its products down to the subcomponent level, where many of the parts were supplied by outside vendors. The company wanted to monitor the quality and compatibility of the vendor-supplied components. In addition, management was concerned with 21 CFR Part 11 compliance. They hoped to find software that met all their requirements.

analyze

Was there a system that could do all this – and make the relevant information available company-wide, so any authorized person could access the data any time from the company's European facilities as easily as from the United States?

The Solution

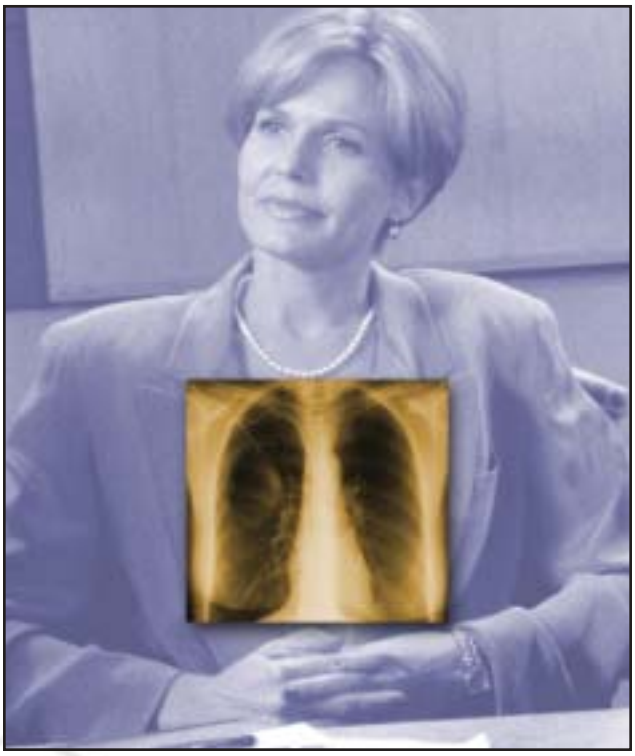
The cardiopulmonary products manufacturer chose NetRegulus software because it was the only solution that could meet all their requirements. For their needs, company executives selected the IssueExpert™ module of the PQIntelligence™ Software System. The company was pleased to find that IssueExpert was all they needed for postmarket monitoring in their areas of interest: product quality of their own components and those of their vendors; complaints; and product malfunctions. The fact that the software is 21 CFR Part 11-compliant gave them an added measure of security. In addition, because the company could no longer use its previous proprietary information system, NetRegulus transferred all the corporation's product data to the new system so they wouldn't lose any information they already had. To complete the package, NetRegulus developed a series of custom report forms to meet the corporation's unique needs.

share

information

The Benefit

The NetRegulus package of software and services benefited the company in several ways. First, NetRegulus' conversion of the firm's existing database was a money-saver compared to hiring an outside consultant. Then, with IssueExpert's drill-down capabilities – even to the subcomponent level – it became much easier for key personnel to determine whether problems were with their own components or their vendors'. Troubleshooting moved faster, and the company could establish a vendor quality trail that now weighs heavily in the selection of appropriate vendors.



And, should there be a major problem or equipment failure at the subcomponent level, the manufacturer can make contact with the appropriate supplier immediately. This is an invaluable capability that helps to minimize liability in the event serious problems or potential recall issues arise.

Opting for customized report forms has paid off too: now employees can complete their documentation faster, so they have more time to devote to company business that impacts the bottom line.

As for FDA compliance: During their last FDA inspection, the company felt confident about 21 CFR Part 11 compliance for this critical component of their quality system, and since they had ready access to product-quality data, it was easy to provide further information whenever they needed to clarify or resolve an issue.

*Actual company names have been omitted to protect the privacy of the customer.

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NetRegulus™

collect

IssueExpert™, RegistryExpert™ and TrackExpert™ Provide Complete Package for Tracking and Contacting Patient Database

Company Background

Located in the Rocky Mountain area, this nonprofit institution was established to research and monitor ongoing issues related to a recall of certain components of heart pacemakers that failed after implantation. The manufacturer of the flawed components was forced to withdraw the product after failures caused a series of injuries and several deaths. However, 40,000 devices containing the defective components had already been implanted worldwide, and patients with the potentially faulty pacemakers required monitoring for a period of years. The institute was established to provide ongoing monitoring of the patient database and to conduct follow-up studies of those patients.*

The Challenge

Because the consequences of product failures were potentially so severe and even life-threatening, the institute's principal need was for a software solution that would provide extremely accurate tracking of the patient base, along with readily accessible contact information. Initially, there were discrepancies in the available data that made it impossible to tell how many patients had the defective products (or who they were). Mindful that the original manufacturer got into trouble in the first place because the company didn't have a system to track the product, the organization wanted to redo their whole data-tracking system to ensure that no patients were lost to the system. In addition, the institute needed software that would help with reporting follow-up studies to the FDA.

The Solution

The institute chose the IssueExpert™, RegistryExpert™, and TrackExpert™ modules of the PQIntelligence™ Software System from NetRegulus, and they chose to have NetRegulus serve as their Application Service Provider (ASP), so that the institute could access the software from the secure NetRegulus server, rather than installing it on their own system. This option freed them from all maintenance chores, and it saved them money.

RegistryExpert and TrackExpert provided staff with the ability to keep track of both patients and their implanted devices. The institute can follow up data on the defective product by product number, date, location, manufacturing site, or other categories specified by personnel.

IssueExpert's configurable "trees" allow staff to classify types of injuries, specific events occurring with the problem components, and other information relevant to patient follow-up. In addition, they can integrate the institute's own reporting tools with IssueExpert, so that they can quickly prepare uniform reports.

track

trend

The Benefit

With IssueExpert's versatility and drill-down capabilities, the institute can monitor virtually all issues related to the defective components. Trending is easy too, so staff can look for patterns in either product failures or the characteristics of patients who experience them. At the institute's website, either patients or physicians can fill out product failure and injury reports. Information from these reports is added to IssueExpert's database as product failure or adverse consequences from such failure are reported. In the long run, when monitoring is completed, the institute will have well-organized data that will greatly reduce the time – and improve the accuracy – of the final report-writing process.

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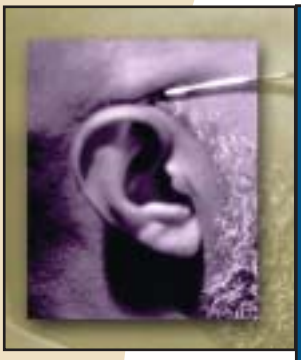
NetRegulus™

StudyExpert™ Helps Bring Product to Market in Record Time With 21 CFR Part 11 Compliance Assured



Company Background

This corporation's principal product is an implantable hearing device for profoundly deaf children and adults. The company also manufactures ancillary products, including a speech processor and other enhancements to the company's implantable devices.*

The company's history began with the first successful implantation of a hearing device in 1979 at the University of Melbourne, Australia. Shortly thereafter, the university formed a consortium with the Australia government and a group of companies that manufactured highly developed medical equipment to develop a commercially viable implant. To carry on commercial operations, the present corporation was subsequently established as a spinoff of the original group. Later, the company and its parent became a wholly owned subsidiary of a giant multinational conglomerate. About five years ago, the corporation was sold, and it is now an independent publicly listed company.

The enterprise has been successful from the start. Today there are more than 30,000 devices implanted worldwide, and the company does business in more than 50 countries. Second-half sales were up 34 percent in 2000, and sales revenue totaled $A103M. Before-tax profits were $A24M for the same period. About half ($A51M) the company's sales revenues came from North America. U.S. headquarters are in the Rocky Mountain region, while world headquarters remain in Australia.

The Challenge

Market share was slipping in the Americas, and the company was eager to gain regulatory approval for a new device, which among other innovations, was available in a smaller implantable package, especially suitable for children. New hearing screening programs for children had been introduced in several key U.S. markets, and the manufacturer wanted to target these potential customers early. First, however, they needed to conduct clinical trials to gain FDA approval. For previous trials, staff had used Microsoft Access to manage their data. However, Access was cumbersome, and the company found that it took weeks at the end of a trial to clean up their data and then to put it into a form suitable for submission. Time to market was critical: the manufacturer was in a race to the finish with several aggressive competitors. In addition, they needed software that met FDA guidelines for computerized systems used in clinical studies and 21 CFR Part 11, which Access did not.

study

The Solution

Executives chose to work with NetRegulus, not only because the PQIntelligence™ Software System was designed specifically for the medical device industry, but also because NetRegulus' professional staff could offer biostatistical consulting to help the company prepare for FDA submission. The module they chose was StudyExpert™, which was developed by industry professionals as well as IT experts. The industry-savvy design meant that data would be clarified and verified properly on an ongoing basis throughout the clinical studies, so there wasn't the need for time-consuming clean up at the end. This was extremely important to top management because time to market was critical. And the software was designed with regulatory compliance in mind.

The Benefit

Staff found that work that had taken weeks with Access was accomplished in hours with StudyExpert. Clinical studies went smoothly, and the manufacturer received FDA approval for the new device in record time. Since that approval late last year, the corporation has already regained its U.S. market share.

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Meeting Unique Needs: NetRegulus™ Expertise and Study Expert™ Get Clinical Trials Up and Running

Company Background

This West-Coast manufacturer of sophisticated heart-mapping equipment resulted from a merger of two companies noted for their cardiac-care products. One of the original companies was a manufacturer of products for endocardial diagnosis and therapy, while the other had a long history of advancing the design of diagnostic and therapeutic cardiac catheters. Late in the 1990s, one party to the merger became a member of a large healthcare products conglomerate, and the present corporation remains a part of that family.*

Since the merger several years ago, the manufacturer has become a world leader in software and hardware systems for three-dimensional cardiac mapping and navigation. The company manufactures equipment that provides real-time data on three-dimensional color-coded maps of the heart. Other products include catheters and sheaths.

The Challenge

Executives thought they had their clinical data management software situation well in hand. The company used a proprietary system developed by one of their own employees. However, when that employee left the business, the company found it couldn't maintain the system, let alone make needed changes to support a new clinical trial. Management was extremely concerned about meeting FDA validation requirements for the necessary changes. Without an appropriate software system to help with this and other clinical trial issues, the company was stalled.

The company had other requirements too. Personnel needed a system that was easy to use and adaptable, as well as one that could interface with other computer systems.

The Solution

Executives met with several large software vendors, and in the end, the company chose to go with the study management provided by NetRegulus' StudyExpert™, which is a part of the PQIntelligence™ Software System. Decision-makers felt that StudyExpert – and the NetRegulus professionals – had the best understanding of their validation issues. Plus, the software had an extremely user-friendly interface and considerable flexibility and configurability.

Since the company had been left in the lurch previously by the departure of a key IT person, they took no chances with the new installation. Management opted to have all relevant personnel receive training from NetRegulus so they would have a number of "experts" on board.

manage

validate

study

The Benefit

Management had some very specific issues they wanted to address, and they were pleased with the all-out commitment from NetRegulus to work closely with them to ensure that the software met their unique needs. They felt the other software companies would not provide such full support. Indeed, the company and NetRegulus have an ongoing collaboration to add improvements to StudyExpert. Administrators are pleased that the software meets both the ease-of-use and adaptability criteria. Also, with the comprehensive validation of the corporation's StudyExpert implementation, the company can proceed with its clinical trials with confidence.

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NetRegulus™

automate

Working Smart on a Budget: StudyExpert's Automated Features Keep Small Company Competitive

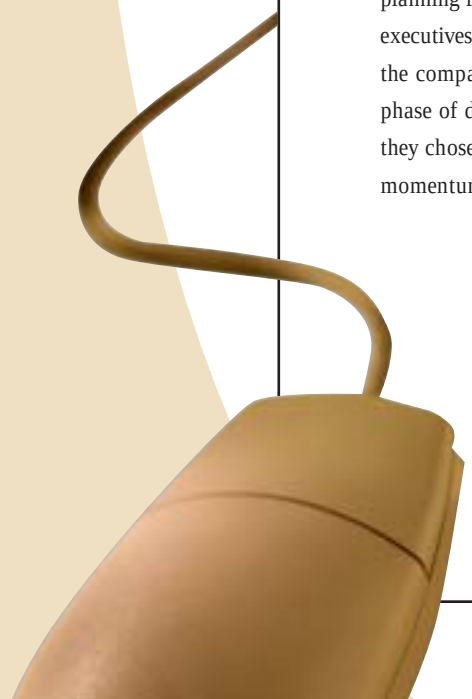
Company Background

This corporation is a young, growing medical device manufacturer based on the West Coast. Formed in the fall of 2000 as a spinoff from another manufacturer, the company is a pioneer in the development of a new method to treat atrial fibrillation, an arrhythmia (abnormal heartbeat) that affects 5 million people worldwide. The company's core technology is a system capable of producing freezing temperatures at the tip of an intravascular catheter. Initially, the device will be used to treat only atrial fibrillation, but the company reports that the technology is also applicable for treatment of other cardiac arrhythmias, such as tachycardia, and Wolf, White, and Parkinson's syndromes. Clinical trials are currently underway for the company's flagship product.*

The corporation recently opened a European office in to oversee clinical trials and European operations. The office will eventually manage the company's European sales and distribution.

The Challenge

As a newly independent company, the corporation was in the final stage of pre-clinical testing. They were planning for the clinical trial of their cryoablation system. With limited resources and staff to manage this effort, executives recognized the need for efficient systems that could perform many activities automatically. In particular, the company needed a software system to manage the clinical trial and to monitor product quality during this phase of development. With no in-house IT support, the staff also needed external support for whatever system they chose. Since the company was in the forefront of cryotechnology, management's hope was to maintain that momentum and get to market quickly. Because they lacked staff, they needed systems to help with this effort.



coordinate

organize

The Solution

Executives felt that StudyExpert™ from the NetRegulus PQIntelligence™ System was the software package that would get them up and running on their current and upcoming clinical trials. A company spokesperson said that NetRegulus offered the best pricing option on a package that met their needs.

NetRegulus worked with the company to help set up the system and to develop case report forms and protocols. Because the corporation wanted external support for their system, they elected to go with NetRegulus' Application Service Provider (ASP) client-server configuration, in which NetRegulus provides the server and network support. This setup relieved staff from maintaining the software system, and it saved them money. One of the decision-makers indicated that availability of the ASP arrangement helped their firm decide to go with NetRegulus.

The Benefit

With StudyExpert's Study Setup features and the Case Report Form Wizard, projects were organized quickly, despite the lack of personnel. Since the company partners with an organization in Europe to conduct trials there, StudyExpert's capability for multiple-study data management will make it easy to coordinate multiple trials on two continents. Plus, once the trial is complete, the manufacturer can proceed to FDA submission with confidence, since StudyExpert meets the requirements of FDA Guidelines for Industry: Computerized Systems Used in Clinical Trials and 21 CFR Part 11, Electronic Records and Signatures. This feature is important to all users, but it is especially helpful for small companies who may not have the staff to provide support on FDA requirements for computerized systems.

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NetRegulus™

Overcoming CAPA Management Problems with IssueExpert™

Company Background

This corporation is the U.S. subsidiary of a large European company that was itself formed by the merger of two other firms. The group manufactures medical devices for the operative treatment of bone fractures and for artificial joint replacements. They also manufacture power tools for use in orthopedic surgery. Their latest products include implant coatings, biodegradable implants, synthetic bone replacement materials, and products for computer-assisted surgery. Annual sales are around $587 million, with medical implants accounting for 97 percent of revenues. The company and its parent employ more than 3,000 people worldwide. They have manufacturing sites in Europe, North America, and South America. Headquarters are located in an eastern state.*

The Challenge

After undergoing an FDA audit, in which the company received an "observation" with respect to CAPA management, executives realized their business needed help. Their problem stemmed partly from having many different manufacturing sites, each with its own CAPA software system. In some cases, there were even different systems within the same site. As a result, the company had no means of viewing data across the entire organization. It was impossible to get a 360-degree view of information in any given area. The corporation knew it couldn't correct the CAPA management problem without obtaining a system-wide software solution that could be used by anyone in any location. In accordance with the plan they submitted to the FDA, the company went shopping for such a system.

track

The Solution

NetRegulus had the answer to the manufacturer's dilemma. Decision-makers chose the IssueExpert™ module of the PQIntelligence™ Software System because it supports a broad spectrum of sources of CAPA information – including complaints, product returns, adverse events, and product recalls – and it is easily adaptable to a variety of needs.

With IssueExpert, the company was able to put all its employees on the same page, regardless of their working site. "After an extensive search and analysis of several software applications, we came to the conclusion that NetRegulus had the only application and was the only company that could meet our total needs," said the firm's manager for business applications. "We needed an application that could work in the clinical studies arena and also solve our requirements for complaint handling and corrective and preventive actions (CAPA) gathering," he added. "NetRegulus met all these needs and more by giving us the application plus the development and training personnel to get it implemented on time."

report

analyze

manage

The Benefit

By using NetRegulus software, the corporation was able to get the company-wide 360-degree view they needed to tackle their CAPA management situation, and they had all the tools to monitor product quality for the future. Having the same software system in all facilities saved time and greatly improved efficiency as well. The manufacturer is apparently on the right track: in the year 2000, sales exceeded expectations, and the strong revenue growth – again exceeding expectations – continued during the first quarter of 2001.

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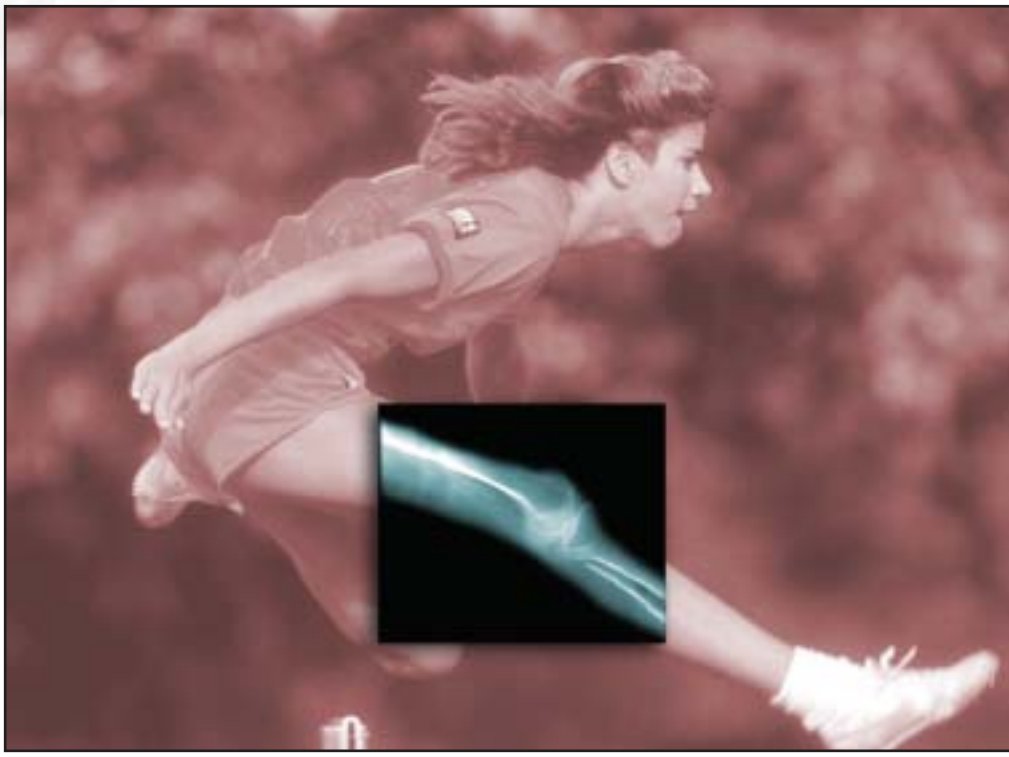

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