

An FYI Case Study

FYI's business process and inventory control system allows Xerimis to help its clients bring therapies to patients faster: FYI solution — exactly what Xerimis needed to dramatically improve operations.

The Client

Xerimis is a privately held clinical packaging firm serving major pharmaceutical, bio-technology, and clinical research organizations of all sizes. It serves a growing base of customers that seek FDA approval for drug products, which entails successful completion of highly regulated clinical trials. Xerimis is committed to achieving profitable growth while maintaining its reputation for world-class products and customer service.

The Challenge

Knowing that every one of its clients' clinical trials has zero margin for error, Xerimis is dedicated to delivering the highest quality products when and where they are needed. This requires effective and efficient management of the complex business processes and materials associated with delivering 100% accurate product packaging for medications in clinical trials.

To maintain its ability to quickly respond to market demands and at the same time meet its growth objectives, Xerimis needed to streamline and automate business processes. In addition, the firm sought to dramatically improve its inventory management system. Among the inventory control issues Xerimis faced:

- Production managers needed more timely access to the status of the inventory items in order to optimize the scheduling of production resources
- The inventory discovery turnaround time took far too long and sometimes led to costly interruptions in the production process
- Employees needed to quickly and accurately produce inventory usage reports to generate the data needed to effectively order packaging supplies and materials

The Solution

In order to develop and implement a flawless business process and inventory control system, Xerimis needed

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*- Tom McLoughlin, Vice President
Quality Assurance*

an IT professional services partner to support its in-house team. After a comprehensive assessment of leading providers, Xerimis selected FYI Business Solutions to lead this important initiative. "FYI was by far the best of the vendors we met with. They clearly took the time to learn what we do, understood what we needed, and knew how to get us there," said Tom McLoughlin, Vice President of Quality Assurance at Xerimis.

FYI began by devoting significant time and resources to understand Xerimis' business and specifications for the new system. "FYI worked with our staff and learned about our business and processes," said McLoughlin. "Then they came in with a prototype of what they had in mind and it was right on the money."

In the ensuing four months, FYI and its offshore entity worked behind the scenes to develop and program the very complex system. Once the specifications were approved, FYI installed the alpha version and conducted user acceptance testing. Since the pharmaceutical industry is highly regulated, every change or enhancement to the system had to be flawless in order to get approved.

FYI solution - exactly what Xerimis needed to dramatically improve operations

During this critical period, FYI placed a full-time consultant onsite at Xerimis who conducted quality assurance and testing activities, supported Xerimis' project team, and created a master change document that tracked all changes and ensured they were successfully completed. The master change document proved so beneficial it was adopted by Xerimis and is still in use today.

The business process and inventory control system developed by FYI is a powerful, flexible and scalable solution that now serves as a central repository for all Xerimis projects and directly maps to each of the business processes that support the execution of clinical trials throughout their entire cycle. The system also automates the entire inventory management process, enabling fast and accurate inventory tracking and report generation.

Most importantly, Xerimis' new system will enable the firm to expand its customer base, support larger clinical studies, simultaneously handle a greater number of projects and ultimately increase the rate of revenue generation.

The Results

All aspects of Xerimis' operations have been positively impacted by the implementation of the business process and inventory control system. It has enabled the company to increase operational efficiency throughout the production cycle, consolidate all business information into one central database, and quickly access meaningful data that enables more effective planning and decision making. The system also allows Xerimis to:

- Electronically track and record the progress of all materials assembled, packaged and shipped, allowing for the generation of detailed and fully auditable documentation that exceeds FDA compliance requirements

- Access more precise costing information needed to determine future pricing strategies
- Automatically alert users when actions are required, eliminating considerable time required to manually monitor events in the supply chain
- Provide management, quality assurance and production employees with the exact status of every clinical trial so they can immediately react if an issue arises
- Provide all users with unique IDs consistent with their roles in the organization. This eliminates confusion about which functional area of the organization is authorized to undertake certain actions
- Significantly boost staff productivity
- Accurately schedule internal resources based on production schedule and inventory requirements
- Improve quality control levels

Xerimis now has the foundation in place that will enable the firm to complete phase two of the project, which will provide its customers with a secured link to the system. This will give Xerimis' customers immediate and direct access to the information they need and reduce the amount of time spent by Xerimis employees responding to project status inquiries, freeing them up to work on other initiatives.

"Working with FYI was a very positive experience," Loughlin concluded. "They were very up front, provided a very personal level of service and delivered exactly the product we had in mind. Based on this experience, we plan to engage FYI for phase two of the project."

For more information on our services, please visit www.FYIsolutions.com or contact us at (973) 331-9050.

