



TRANS1

MEDICAL DEVICE COMPANY IMPROVES INVENTORY CONTROL AND REGULATORY COMPLIANCE

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Greg Manson, Director of IT, TranS1 Inc.

QUICK FACTS

Company

- Name: TranS1 Inc.
- Location: Wilmington, North Carolina
- Industry: Life sciences
- Products and services: Medical devices
- Revenue: US\$11.5 million (3Q 2007)
- Employees: 62
- Web site: www.trans1.com
- Implementation partner: SoftBrands Inc.

Challenges and Opportunities

- Streamline inventory control and forecasting by improving data access
- Enhance visibility, integration, and efficiency by eliminating paper-based, manual business processes
- Decrease costs associated with regulatory compliance
- Optimize regulatory compliance reporting by providing real-time, automated identification and tracking of material lots
- Respond efficiently to new product development and business growth

Objectives

- Modernize enterprise resource planning (ERP) by implementing a comprehensive solution tailored to industry-specific needs and regulatory requirements
- Implement a scalable, flexible solution with audit trail functionality
- Automate and simplify lot tracing
- Enable comprehensive access to business data for improved reporting and analytics

SAP® Solution and Services

SAP® Business One application

Implementation Highlights

- Implemented SoftBrands FourthShift Edition for use with SAP Business One
- Configured workflow rules and user profiles to control role-based access
- Completed FDA validation of the solution as part of implementation

Why SAP

- Flexible, adaptable solution to meet current and future business needs
- Affordable, easy-to-deploy solution
- Highly integrated ERP foundation

Benefits

- Streamlined medical device tracking requirements via automated lot trace
- Reduced inventory costs by automating inventory reporting and forecasting for field sales reps
- Minimized risks by completing pre-implementation validation of solution
- Reduced compliance costs by improving business process efficiency
- Enabled comprehensive, real-time transaction processing

Existing Environment

Nonintegrated, legacy applications and manual processes

Third-Party Integration

- Database: Microsoft SQL Server 2000
- Hardware: Dell PowerEdge 860
- Operating system: Microsoft Windows Server 2003 R2



As a pioneer in the expanding field of minimally invasive surgery techniques to treat lower back pain, medical device company TranS1 Inc. was facing unprecedented business expansion and aggressive sales growth. In addition, increasingly complex regulatory requirements that the government imposes on medical device manufacturers had escalated, necessitating real-time product visibility across the supply chain. To keep pace with industry demands, TranS1 set its sights on strengthening its enterprise resource planning (ERP) backbone. To do so, the company turned to SAP's channel partner SoftBrands to implement a validated software solution tailored to the needs and requirements of the medical manufacturing community.

A Less Invasive Approach

Headquartered in Wilmington, North Carolina, TranS1 designs, manufactures, and sells products that treat degenerative disc disease of the spine's lower lumbar region. The company's new AxiaLIF System is a far less invasive approach to lumbar fusion. According to clinical studies, the system dramatically reduces patient recovery time in comparison to traditional lumbar fusion procedures. Rick Randall, president and CEO of TranS1, says, "We offer surgeons and their patients a 'two-stitch' lumbar fusion alternative to the more invasive fusion and disc replacement therapies currently employed."

Since the introduction of AxiaLIF in 2005, surgeons have treated more than 2,000 patients around the world with

this minimally invasive solution. As more surgeons are trained in the procedure, the rate of adoption is increasing. Today, spine surgeons from at least 37

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states and seven countries are using this advanced approach. In addition to increasing market share with its AxiaLIF product, TranS1 is on a growth path and has other innovative products in the pipeline.

ERP Challenges

Lacking an integrated IT infrastructure to support highly decentralized field operations, TranS1 was unable to manage inventory efficiently – particularly when it came to forecasting inventory requirements for sales representatives in the field. Paper-based processes resulted in inaccurate projections that typically erred on the side of too much inventory, rather than not enough. The result was ballooning inventory levels that in turn increased carrying costs (the costs associated with maintaining inventory in the company's warehouse). With nonintegrated, manual business processes, TranS1 suffered from insufficient access to data, poor operational visibility, and limited business intelligence. The lack of integration negatively affected not only inven-

tory management, but also resulted in inefficiencies in complying with complex regulatory requirements – including the traceability of material lots.

Unique Regulatory Requirements Drive Solution Selection

Numerous regulations in the medical device industry require meticulous management of business processes. Among them are current Good Clinical, Laboratory and Manufacturing Practices (cGxP) and the U.S. Food and Drug Administration (FDA) 21 CFR Part 11, which set down requirements for electronic record keeping, including audit trails. With compliance with Part 11 high on the list, TranS1 assembled a team of representatives from each of the company's competency centers to determine the requirements for a comprehensive ERP solution. Fundamentally, the team wanted a solution that mapped to the company's top priorities and, more broadly, provided an immediate and complete view of all business operations. The solution also had to match the size of the company's budget. TranS1 engaged SoftBrands Inc., a global supplier of enterprise application software and an SAP® software solution partner.



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Support for FDA-regulated manufacturing environments and related solution validation requirements turned out to be the key qualifiers for the candidate ERP solutions. “We needed a solution capable of modeling the FDA Quality System Regulation (21 CFR Part 820) to help ensure that the business system as implemented would meet the requirements for medical device companies. Not many vendors were able to demonstrate that,” says Greg Manson, director of IT at TranS1. From an initial field of 15 contenders, TranS1 selected the SAP Business One application as the foundation for its ERP solution. In addition, TranS1 decided on SoftBrands FourthShift Edition for use with SAP Business One. SoftBrands FourthShift Edition provides extended functionality for users of SAP software by enhancing auditing functionality, lot traceability, inventory serialization, and bar code-based processing.

SoftBrands Drives Implementation Success

The complete implementation took approximately five months to complete. The TranS1 team worked closely with SoftBrands consultants to review and adjust business processes in accordance with the capabilities of the new software. “We built business rules into the application and the application helped us create our business rules,” says Manson. For instance, team members configured SAP Business One workflow rules along with user profiles to enable role-based access control.

The team also defined preferred suppliers and supply schedules and assigned unique identities to outside partners such as suppliers, transportation providers, and government agencies. To ensure referential integrity, SoftBrands also applied business rules specific to records management and data handling. The objective was to implement a solution with easily accessible – and accurate – business data.

Solution Validation Before Go-Live

For TranS1, a key requirement of the implementation was ensuring FDA validation of the new solution in advance of deployment. The team of experts completed validation before the cut-over to the live system. Cheryl Wagoner, quality manager for TranS1, considers this essential for reducing risk during implementation. “SoftBrands worked with us to customize the scripts we needed to use and the process moved very smoothly,” Wagoner says. “Overall, we had to spend about 20 hours to review the scripts, rather than spending weeks and weeks writing and reviewing them.” The validation process and the support of the SoftBrands consultants gave TranS1 the peace of mind that its business solution was operating as intended.

TranS1 also found it important that the implementation process was “risk-managed.” From the start, the team identified the critical points at which FourthShift Edition for use with SAP Business One functions and data

records intersected with specific cGMP (current good manufacturing processes) regulatory requirements. In doing so, the team was able to focus documentation and audit coverage at those key intersections. As Manson explains, “The goal of the implementation was to start out right, reduce regulatory risk, and get to work immediately. And that was accomplished. We were pleased with the whole package.”

New Level of Inventory Control

“The SAP Business One application with the SoftBrands FourthShift Edition add-on has substantially reduced our inventory costs and levels,” reports Manson. A specific area of cost savings results from the way TranS1 manages field inventory. Before the implementation of SAP Business One, field sales representatives manually determined their inventory requirements and inventory was shipped to them accordingly – a generous but costly and inefficient approach.

Now, by using the SAP software, TranS1 is able to arm each sales representative with an electronic “stock and bin” that is not only virtually accessible, but also easily managed. The company replenishes inventory – quantity plus one – based on historical data derived from prior sales activity. “As an indicator of newfound simplicity, our reporting to track and monitor field inventory is typically down from 10 pages to just a single page – and manual processes and guesswork have been eliminated,” says Manson.

Automated Lot Trace

“SoftBrands FourthShift Edition for use with SAP Business One has the lot trace, security, and auditing features that we need from our ERP system,” says Randall. By implementing lot trace functionality, TranS1 no longer relies solely on manual, paper-based processes to fulfill complex regulatory requirements – including Part 11 compliance.

“In the past, when there were questions, we used to have to dig manually through records, which might take an hour or more if someone was available to dedicate the time. Now it takes just minutes to pull up pertinent information without leaving the desk,” explains Wagoner. In the event a device presents a risk, notification and retrieval are much more efficient as well.

Poised for Growth

By implementing an integrated, flexible ERP foundation, TranS1 has transformed its business operations. No longer constrained by manual, inefficient business processes and the lack of integrated business data, TranS1 has achieved its top priorities – improved regulatory compliance and inventory management.

Today, plans are in the works to implement additional features of the software, such as bar coding. And in terms of business analytics, TranS1 has only begun to take advantage of the comprehensive information that is now readily accessible to its key decision makers. Moving forward, the innovative manufacturer of less invasive lumbar fusion devices is poised for continued growth.



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