

Intuitive Surgical

Eliminating Obstacles to Explosive Growth with SAP

Challenge

As the undisputed global leader in the emerging field of robotic-assisted, minimally invasive surgery, Intuitive Surgical has been growing at the rapid rate of more than 25% annually. However, the company's existing systems for handling critical business functions like manufacturing operations, quality management, complaints management, and service repairs—a combination of an out-dated, heavily customized legacy system and paper-based records—presented obstacles to sustaining this explosive growth.

Solution

Intuitive Surgical recognized it needed a fully integrated, scalable solution that was not only capable of supporting the company's continued growth, but that would also help improve efficiency, streamline processes, and enhance compliance controls. The company turned to Clarkston Consulting, known for its extensive experience in the medical device industry and its widely recognized SAP expertise, for help with the effort. Clarkston's team of skilled and dedicated consultants helped Intuitive bolster its performance by making major enhancements to its existing SAP system and transitioning remaining critical business functions to the SAP platform.

Benefits

By eliminating the out-dated legacy system and transferring these processes to its scaleable SAP platform, Intuitive Surgical realized immediate benefits, including improved system reliability, better visibility of production, repair and complaints status, higher quality data, and greater operational efficiency. Most importantly, Clarkston delivered a solution that supports Intuitive Surgical's high growth potential well into the future.

"The collaboration between the team members on this project was so strong it was nearly impossible to differentiate between Intuitive people and Clarkston people. That said, Clarkston's presence—with its detailed knowledge of our business and industry, its strong project management skills, and its deep knowledge of SAP—was felt throughout the effort and played a major role in our success."

Steve Lucchesi
Vice President, Information Systems
Intuitive Surgical

World's first, only "surgical robot" fuels record growth

Intuitive Surgical, Inc. is the recognized global technology leader in robotic-assisted, minimally invasive surgery. In 2000, the company's da Vinci® Surgical System became the first and only surgical robot to be cleared by the U.S. Food and Drug Administration (FDA). Since then, the system has helped surgeons perform hundreds of thousands of complex procedures such as open-heart surgery through incisions as small as one to two centimeters.

The advantages of such minimally invasive surgery are substantial. Faster recovery, less pain, fewer complications and shorter hospital stays are a plus for patients and good for a hospital's bottom line as well.

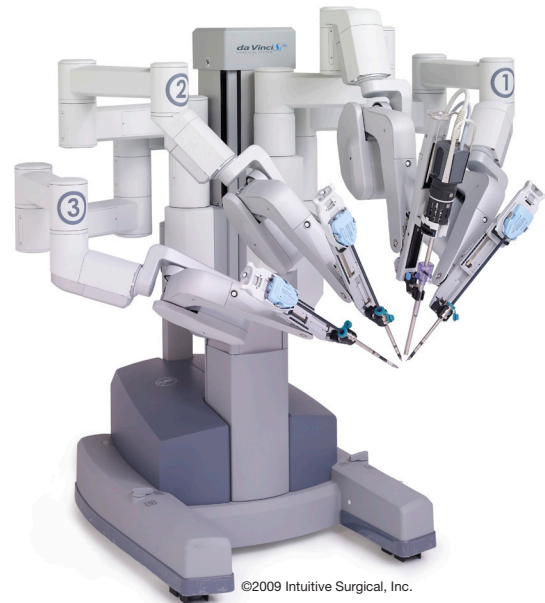
With so many benefits to offer—and as the only technology of its kind in the world—it's no surprise that the da Vinci System is in high demand. Since the system gained approval, Intuitive has expanded its installed base to more than 1,000 hospitals around the world, generating sustained growth in excess of 25% per year. In fact, fiscal years 2007 and 2008 saw revenue growth of 61% and 46% respectively.

Rapid growth brings challenges

This tremendous growth was a boon for the company and its investors. However, Intuitive Surgical's leadership team recognized that its existing infrastructure could not keep up with the growing volume and complexity of its products, and therefore was an obstacle to continued growth.

Thanks to prior work by the company's Information Systems group, financials, sales order, and inventory management functions were already operating on SAP. However, a number of the company's other critical business processes, including manufacturing operations, quality management, complaints handling, and service and repair management, were supported by a combination of an out-dated, heavily customized legacy system and paper-based records.

Although their legacy system had served the company well, it no longer met the demands of a rapidly growing and evolving organization. Challenges included system instability, high maintenance costs, lack of visibility into key data, and the inability to accommodate additional functionality—at least not without great difficulty. System maintenance required specialized knowledge that was becoming in-



creasingly difficult to find. In addition, many quality management processes were managed outside the system, creating the need to maintain extensive paper records

Scaleable solution provides platform for future growth

The company knew it needed a scaleable solution that would drive efficiency, streamline processes, minimize costs, enhance quality and offer greater control without losing flexibility. It also wanted to work with a partner with deep expertise in implementing SAP for life sciences organizations, as well as a company known for its collaborative approach. Intuitive selected Clarkston Consulting for help with the design and implementation of its solution.

The overall goal of the 2-phase, 12-month effort was to replace their legacy application with SAP in 4 key areas: manufacturing operations, quality management, service repair, and complaints management. Clarkston led the implementation of SAP's Production Planning (PP), Quality Management (QM) and Business Intelligence (BI) modules, as well as the enhancement of the existing Materials Management (MM), Financial Accounting and Control (FI), and Sales and Distribution (SD) functionality.

The effort also required further integration of SAP with the company's existing Agile PLM engineering design software. The Agile system was enhanced to align with SAP's

variant configuration data model to support the growing complexity of the company's products. Immediately upon release of relevant engineering documents, the appropriate master data is created/updated automatically in SAP.

Clarkston and Intuitive worked collaboratively to develop and introduce a number of new business processes in the areas of: complaints processing; service repair processing; manufacturing execution and product configuration; recording of quality results; inventory management; product costing; and processing of engineering changes.

A key focus throughout the project was achieving the right balance between control and flexibility. Some customization was added to streamline user interfaces in areas where Intuitive Surgical wanted to provide greater ease-of-use for its employees.

As with many large-scale implementations, a critical success factor was the incorporation of effective training. Clarkston provided hands-on navigation training, and helped Intuitive develop and deliver detailed transaction training to more than 300 users in affected departments.

Innovation in complaints management

One of the more innovative aspects of the initiative was the use of SAP to automate Intuitive's complaints management process. Clarkston helped Intuitive integrate their existing front-end customer relationship management (CRM) application, Clarify 9.0, with SAP. Now when service representatives enter complaint information from customers or field service representatives into Clarify, the data is automatically transferred and stored in SAP, where the remainder of the complaint investigation and documentation is carried out. Required regulatory reporting can be generated quickly and easily by the system.

"A key project challenge was in the design of the complaints management solution," said Rich Feller, associate partner, Clarkston Consulting. "While customer service departments are driven by how quickly they can address customer issues, internal regulatory departments are concerned with gathering as much data as possible related to the incident. Since these drivers can often be incompatible, Clarkston worked closely with both groups to define their requirements and find a balanced solution that met everyone's goals."

Key solution deliverables

- *Established fully automated manufacturing quality tracking and device history record (DHR) documentation*
- *Created customized user interface to streamline entry of key manufacturing and component data*
- *Automated the creation of SAP master data upon engineering release of parts, BOMs, production operations and inspection criteria*
- *Automated the creation of complaints and RMAs by integrating SAP with CRM call center system*
- *Implemented process to capture all data required to determine complaint reportability, as well as automatic generation of U.S. FDA medical device reports (MDRs) and E.U. Vigilance reports*
- *Streamlined return and repair processing with all functions directly accessible via the RMA document*
- *Enabled real-time integration of service parts inventory transactions between SAP and field service system*
- *Standardized categorization of defects and failure analysis results*
- *Implemented SAP BI for tracking complaint- and quality-related metrics*

Delivering immediate results

The solution designed and implemented by Clarkston Consulting provides Intuitive with operational improvements and cost savings now, as well as the foundation to enable accelerated growth.

Some of the business benefits Intuitive Surgical has already experienced include:

- Greater control and improved documentation of manufacturing activities. The system is capable of preventing manufacturing defects by ensuring the right parts are used on the production line at the right time. In addition, all production records are now automated and consolidated, giving the company a single point of access to key data.
- Ability to independently process complaints and RMAs. Intuitive gained better flexibility and process control, as well as a foundation to support fully automated electronic complaint filings in the near future.
- Improved inventory and repair visibility. The company can track and value service parts inventory much more accu-

rately. Similarly, repair cycle time—a key measure of internal performance—is now easily tracked and reported.

- Better stability of infrastructure system. Strong interfaces to the field service and engineering document management systems yield better overall system reliability. As a result, Intuitive spends less time troubleshooting and repairing broken interfaces and managing data between systems.
- Streamlined processes for the regulatory and RMA groups. The deployment of SAP QM improved Intuitive's ability to manage complaints and returns around the world, as well as to capture and analyze data on product defects.
- Significant reduction in need for paper-based records. The consolidation of electronic device history records (DHRs) minimized the need for cumbersome files that are time-consuming to maintain and difficult to search. It also presented significant opportunities to streamline processes while providing higher quality data and better controls.
- Improved efficiencies. The system has reduced time associated with processing complaints, production orders and device history records.
- Manufacturing expansion. In conjunction with the implementation, Intuitive was able to leverage the SAP platform in order to bring a new Mexican manufacturing plant online quickly.

In addition to these immediate benefits, the system provides a foundation for future enhancements. For example, it provides the necessary groundwork to support fully electronic medical device reporting (eMDR) in anticipation of the FDA's complete transition to electronic filings in the near future. While many companies are taking a wait-and-see position with eMDR, Intuitive anticipates significant time and cost savings will be achieved by converting to it.

Supporting the mission

While the primary driver behind this effort was improving the company's internal operations, at the end of the day Intuitive is focused on two things: serving its customers and improving the lives of patients. By optimizing its systems and processes, Intuitive can continue to meet this mission. Improved RMA handling means customers receive the parts they need when they need them. Better integration of front-end and back-end systems means field support has better access to the information they need. And less time maintaining routine data means more time to focus on what Intuitive Surgical does best: enhancing surgical capability and improving clinical outcomes.

Business benefits

Intuitive's expanded SAP system provides a robust platform to support its explosive growth and evolving business needs by:

- Automating complaints processing
 - Improving visibility into key business functions and data
 - Reducing time spent generating regulatory reports
 - Providing a foundation for future electronic MDR submissions
 - Providing for systematic documentation of quality-related data
 - Reducing processing time for customer credits and repair purchase orders
 - Providing opportunities for cost savings by decommissioning legacy systems
 - Supporting added functionality as it's needed
-

CLARKSTON CONSULTING

Headquarters
Research Triangle Park
1007 Slater Road, Suite 400
Durham, NC 27703
Phone: 800-652-4274
Fax: 919-484-4450

www.clarkstonconsulting.com

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 7-year average client satisfaction rate of 97%.