

An Arena Solutions case study



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Novare Surgical Systems



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Novare Surgical Systems Uses Arena to Help Deliver the World's First Full-Range-of-Motion Handheld Surgical Instruments—Taking Minimally Invasive Surgery to a New Level

SITUATION

Minimally invasive surgery is one of the biggest trends in medicine, offering patients less trauma and pain, minimal scarring, shorter hospital stays and speedier recoveries. With its sophisticated instrumentation, Novare Surgical Systems (www.novaresurgical.com) is one of the companies at the forefront of the industry, advancing this emerging field and helping make minimally invasive surgeries more widespread.

This groundbreaking company is behind an entirely new category of high-dexterity (HD) instruments for minimally invasive surgery, RealHand®HD instruments. RealHand HD products are the world's first full-range-of-motion handheld laparoscopic instruments that are making it possible for physicians to perform advanced laparoscopic procedures such as colectomies, hysterectomies and gastric bypass in a minimally invasive way—sometimes with only a single point of entry through a belly button—with exceptional precision control.

THE CHALLENGE

Novare Surgical is part of a continually transforming healthcare industry that requires companies to innovate quickly, speed product development, decrease costs and maximize efficiency—while meeting all regulatory compliance and quality requirements.

As a growing medical device company, Novare Surgical had always worked to optimize its resources, performing research and development in-house while outsourcing manufacturing. For outsourcing to be effective, the company needed to effectively manage supplier relationships while tightly controlling the information distributed to each partner. It had to be certain the right information was reaching the right people at the right time, while keeping its intellectual property secure.

To be able to consistently hit product launch dates, Novare Surgical sought to more effectively manage the evolving definition of its products—and ensure that the latest information could be accessed by everyone who needed it. This was particularly true of data modified by engineering change orders (ECOs), which could lead to costly errors if outdated versions were used. Because the company relied on a manual approach based on spreadsheets, email and phone calls, and frequently saw travel schedules interfere with approvals and handoffs, Novare Surgical was experiencing unnecessary bottlenecks in its product development process.

“With Arena as a central repository for all of our data, our suppliers will find what they need—when they need it. Change orders that take up to a month now can be approved in a week or less. Ultimately, Arena will greatly improve our time to market.”

-Donna Nelson
Document Control Specialist
Novare Surgical Systems



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"A typical change order may have many different documents, associated drawings and bills of materials. Each supplier needs different pieces of the information, and up until now, I've had to manage everything manually," said Donna Nelson, document control specialist at Novare Surgical Systems.

In addition, Novare Surgical Systems had to comply with a continually increasing number of medical standards and regulations. Compliance had become critical to maintaining its competitive position—and to staying in business—but had come with the challenge of being able to efficiently manage requirements and compliance data, perform accurate and consistent conformity assessments, reduce supply chain transition risks and provide instant compliance reporting. Ultimately, using even the most orderly paper-based system would have meant filing cabinets and storerooms full of documentation.

"We've got to go digital. We can't throw any paper away for compliance reasons, and we're running out of space. A typical review of our device history means 50 pounds of paper. Distributing documents to our vendors involves more than 400 drawings. If I miss just one it's a problem—there's just too much risk for human error when the process gets that large," said Nelson.

Like other medical device manufacturers, Novare Surgical Systems realized that to streamline its processes, stay ahead of the competition and maximize growth, it had to proactively take advantage of a modern technology solution.

ARENA DELIVERS

Novare Surgical Systems selected Arena to improve control of its product development process, more easily comply with medical industry standards and regulations, boost productivity, and enhance collaboration with suppliers. The robust functionality, a high return on investment and the on-demand delivery model of Arena also played into Novare Surgical's decision.

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"We're very excited about Arena. Because it's web-based, we get a high-quality solution for much less money than a standalone system that would require investment in additional servers and IT support. With Arena as a central repository for all of our data, our suppliers will find what they need—when they need it. Change orders that take up to a month now can be approved in a week or less. Ultimately, Arena will greatly improve our time to market."

Novare is employing Arena to electronically control engineering changes, track and store the vast quantities of data that enable the company to comply with medical standards and regulations and share files for 24/7 access from anywhere in the world. The anytime, anywhere access is particularly significant for the company, which frequently saw approval cycles slowed by the heavy travel schedules of several key employees.

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Now those employees can use the Internet to log into Arena from anywhere, gain instant access to a single and accurate version of the product record and keep the product development process moving efficiently along.

As all of its data is hosted by Arena and protected by financial-grade security, Novare Surgical also gains peace of mind knowing its data is safer than when it was stored internally and distributed through mail and email, which are neither secure nor controllable.

"Now I won't be at risk of sending the wrong documents to the wrong people. Instead the suppliers will access the latest revisions in Arena, and we'll also eliminate the security risks associated with mailing and emailing our key product data," said Nelson. "This is a high-stakes product. Particularly in medical, people's lives are depending on us getting it right. Arena will make that easier."

STRATEGIC BENEFITS

By adopting Arena, Novare Surgical Systems gains a single, centralized product record that is accessible at anytime, from anywhere in the world. It decreases the risk of human error, significantly reduces bottlenecks, and increases security and productivity. Better management of engineering changes and supplier activities are other significant benefits.

"Just being able to go one place and find everything, without digging through paper, is so valuable to us as we move ahead. Using Arena levels the playing field for us," said Nelson.

RETURN ON INVESTMENT

Novare Surgical Systems expects to see significant savings from its investment in Arena, including:

Fewer process-related errors and faster time to market. Reducing reliance upon manual processes like spreadsheets, emails and phone calls and removing travel-related barriers that interfere with approvals and handoffs will virtually eliminate potentially costly human errors and help Novare Surgical Systems speed time to market by 10%.

Quicker ECO cycle times. With automated routings, electronic status notifications and the ability to update all relevant parts with a single change, Novare Surgical expects to reduce ECO implementation cycles by 70% or more.

Reduced cost of compliance. Compliance management functionality in Arena allows Novare Surgical Systems to generate a compliance report with a single click, reducing compliance reporting time by more than 90%—and eliminating the need to keep filing cabinets full of paper.

Affordable total cost of ownership (TCO). Because Arena is delivered on-demand, Novare Surgical Systems did not need any additional IT infrastructure to support its initiative. Over a five-year period, the TCO of Arena is 30% of the cost of traditional client/server software.

SALES CONTACT

sales@arenasolutions.com
p.1.866.937.1438

CORPORATE CONTACT

Arena Solutions
4100 East Third Avenue
Suite 300
Foster City, CA 94404
p. 650-513-3500
f. 650.513.3511