

QuadRite helps Topcon Medical Laser Systems save time and improve quality

Objective

Increase efficiency by streamlining design control, document control, quality control, and many business processes companywide.

Improve quality by replacing paper-based processes with automated software-controlled processes.

Save time and money by implementing comprehensive, automated processes.

Approach

Implement QuadRite RitePro software to achieve operational excellence.

Companywide solution must be available to and used by the entire organization.

Business benefits

Key processes companywide changed and automated, significantly improving efficiency and quality.

Time savings: 80 percent when dealing with complaints, 20 percent with NCRs and 10 percent on service calls.

Regulatory inspectors and auditors appreciate the reporting excellence, saving time and ensuring smooth inspections.

Laser eye surgery has made tremendous advancements in the last twenty years. One of the global leaders of laser medical devices is **Topcon Medical Laser Systems (TMLS)**. Located in Santa Clara, California, TMLS has developed a radically new technology for the treatment of ocular disease. Initially developed at Stanford University and exclusively licensed to TMLS, the PASCAL® lasers are used to treat a variety of retinal conditions including diabetic retinopathy, age-related macular degeneration, and retinal vascular occlusive disease. PASCAL lasers provide physicians more control of the lasers, which leads to improved outcomes for patients.

Like any medical device company, TMLS must meet stringent regulatory requirements. Prior to 2011, they were using a product lifecycle management (PLM) software to track engineering processes. Although the software performed these basic duties, it was not doing everything TMLS wanted. Because it was so limited in its functionality, TMLS decided to explore other options. The breaking point was when the existing PLM software company tripled their rate, sending TMLS to immediately look for a better solution.

After a year looking at different solutions, they discovered QuadRite's RitePro software. RitePro helps medical device companies streamline design control, document control, quality processes and training management to achieve operational excellence while being regulatory compliant.

TMLS was thrilled with RitePro's advanced capabilities, standing head and shoulders above competing software solutions. An added bonus was the cost – coming in significantly lower than comparable solutions.

According to Dwayne Meyer, Senior Quality Engineer, RitePro is a simple and comprehensive program that works well and meets all of their needs. "RitePro was also the most cost-effective solution—and it was easy to understand. QuadRite's straightforward approach was impressive; it was difficult to get answers from some of the other vendors we contacted," continued Meyer. Also in RitePro all the functionalities are fully integrated; you do not have to buy additional modules.

Simple, comprehensive solution deployed companywide

Since 2012, all employees at TMLS use RitePro for a variety of processes. According to Dwayne Meyer, Senior Quality Engineer, RitePro is a simple and comprehensive program that works well and meets all of their needs. RitePro manages training, documents, work instructions, assembly instructions, quality procedures/ processes, schematics, drawings, project planning, service logs, complaints and meeting notes.

For example, whenever a complaint is filed, a medical device company must respond due to regulatory requirements. “Prior to RitePro, this process generated a huge amount of paperwork, and we had trouble keeping track of everything,” Meyer explained. “With RitePro, everything is simpler because we don’t have to deal with paperwork at all—no filing, no losing papers. It’s all done electronically. We’re always just a couple of clicks away from accessing any information. It’s a big time and cost savings for us.”

Analysis
[Back to top](#)

Section 1: Supplier History

<input type="radio"/> Critical <input type="radio"/> Important <input type="radio"/> Non-Critical	<input type="checkbox"/> Service Provider <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Consultant <input type="checkbox"/> Component/ Product Related <input type="checkbox"/> Distributor <input type="checkbox"/> Other Description of Product or Service: <input type="text"/>
Current Disposition <input type="radio"/> Approved <input type="radio"/> Conditional Approval <input type="radio"/> Inactivated <input type="radio"/> Disapproved	
Certification <input type="checkbox"/> 13485 <input type="checkbox"/> 9001 <input type="checkbox"/> Other <input type="text"/>	Agreements <input type="checkbox"/> Regulatory <input type="checkbox"/> NDA <input type="checkbox"/> Purchasing <input type="checkbox"/> Manufacturing <input type="checkbox"/> Supplier Agreement <input type="checkbox"/> Contract <input type="checkbox"/> Quality Agreement

Section 2: Evaluation

Review Period:

Evaluation:

Supplier Corrective Actions? No Yes

Section 3: Conclusion

Final Disposition: Approved Conditional Approval Inactivated Disapproved

RitePro saves time and money

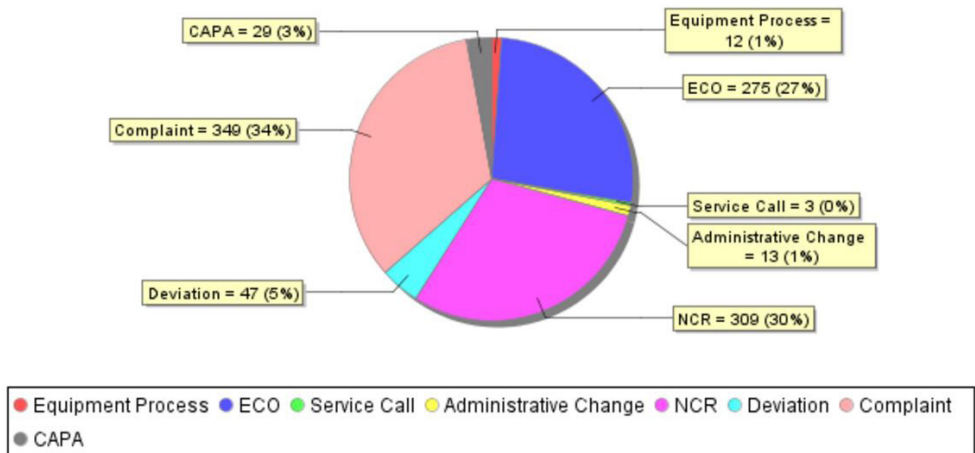
Meyer estimates that RitePro has cut the time by more than half for dealing with complaints. “We went from it taking us more than 6 months down to about 30 days to deal with a complaint—that’s an 80% time-savings. We also cleared away our huge backlog,” said Meyer. “The biggest advantage though is that our auditors love it – so much so that they have recommended RitePro to many of the other companies they audit.”

Accountability and traceability within TMLS have definitely improved using RitePro. TMLS must keep track of non-conforming reports (NCRs), which are any discrepancies they find during manufacturing of the devices. As materials come in, TMLS inspects them and some parts don’t meet inspection criteria; when that happens they log the information. They also must manage corrective action, preventative action plans (CAPAs), which are improvements to their processes to eliminate these non-conformities.

“Previously, both processes were paper-based, and we were losing approximately ten percent of the paperwork,” Meyer explained. “The NCRs and CAPAs were kept in binders, and human error could cause the reports to be misfiled or lost.”

Reports Management Reports

Process Orders by Process Type Created Since Sun Nov 22 15:26:12 PST 2015



Improves efficiency and product quality

Matthew Fortson, (Quality Engineer), is the main person who manages the CAPA program at TMLS, and he has seen a tremendous improvement in this process using the RitePro software. “As with all paper processes, we were having lots of problems—such as missing deadlines, extension requests, etc. RitePro has completely eliminated those issues. We now have more efficient processes in place that improves efficiency and product quality.”

Fortson went on to explain that another important aspect of the software is the ability to create an automated decision tree. “When we get a complaint, it goes through an automated process to determine how to handle the issue. We added investigations for frequent complaints, along with trend analysis,”

According to Fortson, TMLS couldn’t even begin to implement this amount of sophistication prior to RitePro. “The end result is higher quality and less scrutiny from the auditing bodies. We can now identify small issues before they become bigger problems. And better processes give us improved quality.”

TMLS also appreciates the flexibility of the software. “We are constantly looking for ways to eliminate paper redundancies – to streamline and automate processes,” continued Fortson. “RitePro’s flexibility allows us to do just that. It has an infinite amount of configurability, allowing us to pretty much do anything we need for any purpose.”

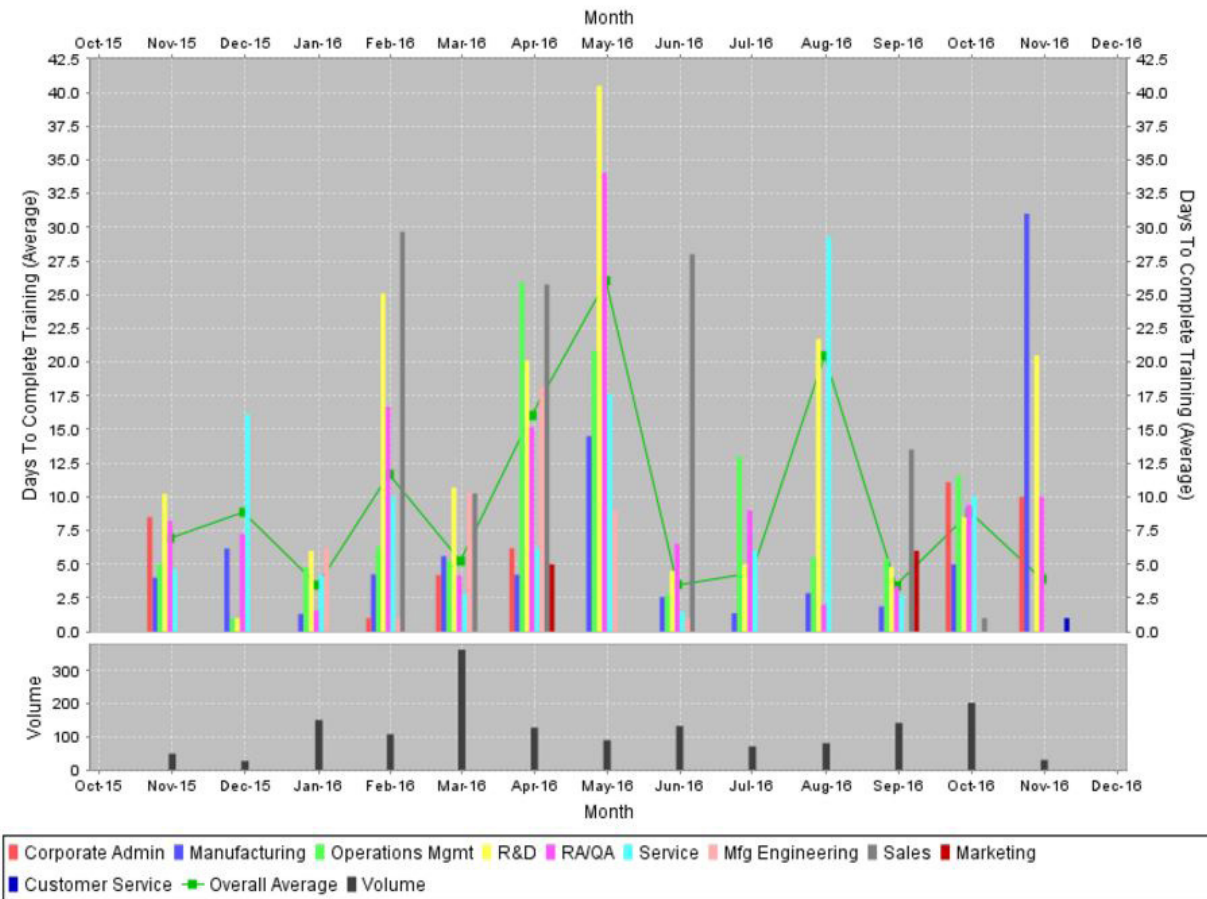


Inspectors love it

Overall, TMLS has seen substantial improvements in time savings and quality control by using RitePro. They estimate it provides them with an 80 percent time savings when dealing with complaints, 20 percent with NCRs and 10 percent on service calls.

When asked his overall impression of the product, John Talarico, Vice President of Regulatory Affairs at TMLS concluded, “It definitely saves us time and provides objective evidence that we have everything under control. And the regulatory people and inspectors absolutely love it. And because they love it, we love it.”

Trend Report for Training Completion Time



About QuadRite, Inc.

QuadRite enables technology and medical device companies to streamline engineering, manufacturing, and quality processes to achieve operational excellence--from product concept and design to planning, production and support. Simple to deploy and easy to use, RitePro™ software is a cost-effective solution that improves collaboration throughout the product lifecycle. Compared to traditional PLM solutions that focus primarily on the activities of the engineering groups, QuadRite packs significantly more features into a single integrated solution, improving all aspects of product development and management. RitePro is a powerful yet simple and affordable alternative that replaces or complements today's traditional PLM solutions.

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