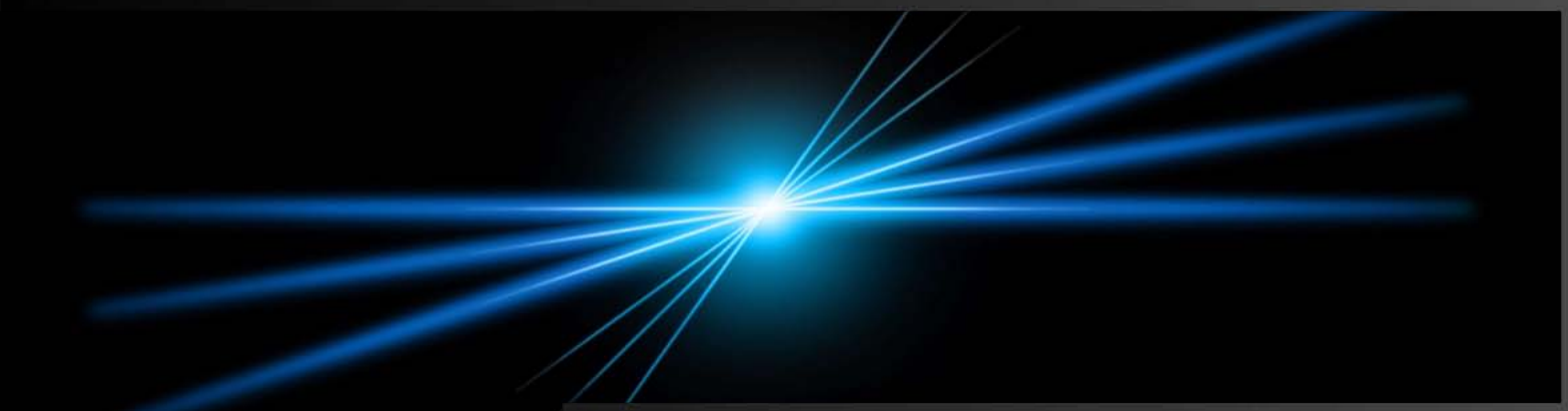
DLS SOLUTIONS

SUCCESS STORY

PRECISE LIGHT SURGICAL RELIES ON DLS SOLUTIONS FOR REGULATORY COMPLIANCE DOCUMENTATION



"My experience with DLS was terrific... DLS delivered the software on-time and on-schedule. They did exactly what they said they would, and they executed on it well. I would highly recommend DLS."

Ken Arnold

President and CEO

THE BACKGROUND

Precise Light Surgical, located in Campbell, CA, is a medical device start–up that has developed a new micro–surgical device that uses light to remove tissue. This breakthrough system, called OPEL for "Optical Scalpel," is the most precise tissue cutting tool available. Precise Light Surgical is targeting micro–surgeries where there are thin layers of healthy tissue and delicate anatomy that are to be preserved near an area that is being removed. OPEL provides the surgeon with a sub–millimeter control of targeted tissue removal without harming healthy tissue.

Ken Arnold, President and CEO of Precise Light Surgical says, "We have developed a very precise micro–surgery tool at a level that doctors have never had before." The complexity of OPEL required a substantial software development effort that had two components. One was the unit firmware that was developed by in–house engineers; and the other was the user–interface and application software which Precise Light Surgical elected to have developed by a third party. Just as important as the actual software was in–depth and specific documentation required by the regulatory agencies, which are the FDA and CE.

THE CHALLENGE

After an extensive search Precise Light Surgical found DLS Solutions. DLS had prior experience with medical device projects and was familiar with the regulatory standards. Ken says, "The way DLS described their business followed right along the lines of the regulatory requirements. DLS understood the importance of the documentation, that it had to be done completely and to the regulatory standards. When I met DLS I came away believing that they could well cover both the software development and the documentation."

Ken continues, "When you require approval by the FDA or CE the one thing you can count on is that auditors will go through your requirements, implementation and testing with a fine–tooth comb. "Documentation is critical. People can write code that works beautifully, but you will not get your product approved if you don't document the software as is required by the regulatory agencies. For someone to understand the need and importance of documentation and making sure they're delivering on it is key to saving us a lot of time, money and headaches down the road."

Continued on next page.

EXPERTISE

SUCCESS STORY

PRECISE LIGHT SURGICAL RELIES ON DLS SOLUTIONS FOR REGULATORY COMPLIANCE DOCUMENTATION

PRECISE LIGHT SURGICAL

Precise Light's Flash Vaporization technology provides unprecedented precision and control for the removal of delicate tissues to improve patient outcomes, reduce surgical risk and downtime while lowering the treatment costs.

THE SOLUTION

The documentation required by the FDA and CE is extensive. Each software module needs documentation on requirements, architecture, design and implementation. Then the modules have to run through a documented risk–hazard process. Finally, test plans need to be defined and executed, with all results documented with confirmation that all requirements have been met.

"I was very pleasantly surprised with the quality of the documentation that DLS delivered," says Ken." It was excellent and well organized. So much so, that we are now having DLS prepare the documentation for all the system software, even though they did not write the firmware code. DLS is pulling all the documentation together so it's consistent and fits together. Essentially, we will have comprehensive documentation of the firmware, application software and interface for the complete package."

IN CLOSING

Ken continues, "It's very difficult for companies that are doing medical products to find people that can both program well and document well. But, we found that DLS has the right combination of folks to cover those bases. I think DLS would be a great asset to any company that produces medical device software. For start–ups, or smaller companies, it's great to have a firm like DLS that you can use for outsourced projects. They get it right."

Ken concludes, "My experience with DLS was terrific, and I would state that others would be on the right path with these folks. DLS delivered the software on–time and on–schedule and, most importantly, on–budget. They did exactly what they said they would, and they executed on it well. I would highly recommend DLS."

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DLSSolutions, Inc.
46 Gatehouse Road
Trumbull, CT, 06611
e-Mail: info@dlssolutions.com
www.dlssolutions.com

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