

# Anesthesia Division of Global Life Sciences Leader Reduces Overhead and Risk with Seapine's TestTrack

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The potential for harm in medical gas delivery is high, and the industry is closely regulated. FDA and EMA compliance both require extensive, complex documentation of all designs, and demonstrations of claims. So when the anesthesia division of a global leader in life sciences needed to modernize their system of testing and tracking their medical device manufacturing process, they turned to Seapine Software.



A Forbes Global 2000 corporation, this life sciences company designs anesthesia machines to control the breathing of patients and modulate the delivery of gases. These are quality-critical situations where mitigating risk requires closely tracking all changes.

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The company had been using Microsoft Office-based tools to track their device testing. Test protocols and reports in Word and Excel documents catalogued the interdependencies, requirements, and the related levels of risk. This system depended heavily on staff to regularly review and manually update those relationships.

"The administrative burden was significant," said the electrical and systems engineer who was tasked with researching a new system. "Although we were producing satisfactory results, we needed a tool that could easily record and trace the requirements of tests; allow us to seamlessly edit, approve, and lock the information; and, ultimately, to prove that the data was in an acceptable state for compliance."

### **The Right Tool for the Job (and More)**

The company began its search by quantifying its requirements and performing a preliminary comparison of a number of different systems. Next, they completed an in-depth, hands-on evaluation of the finalists.

"We identified deal breakers, where a tool just couldn't support a need," said the systems engineer. "But from there, it was a qualitative judgment on which tool met most of our requirements at the best price. Seapine's TestTrack was one of the more expensive tools, but also the most highly qualified."

For easier and more cost-effective traceability, the company chose TestTrack to help streamline the administration of the complex life cycle of product tests. At least that was the initial plan.

It wasn't long before the company realized that other areas, such as quality assurance, could benefit from TestTrack. Management of the company's risk and defect analysis also suffered from the same administrative overhead as testing. Although automating and organizing risk and defect management weren't primary requirements when they were comparing tools, the workflow and relationship management capabilities of TestTrack seemed incredibly well-suited to the tasks.

"I wasn't tasked with implementing a risk management system for quality assurance," said the electrical and systems engineer, "but it was nice to have a solution right in my back pocket that I could offer our QA department. Having everyone use one seamless, integrated system is great. There's no need to figure out how to interface between two different tools."

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## **Targeted Customizability Saves Money, Reduces Risk**

TestTrack’s targeted customizability has been the most valuable part of the tool for this life sciences leader. Some of the tools they originally considered were so configurable, and the possibilities so limitless, that the effort to get up and running would have been overwhelming, inefficient, and far too costly.

“We didn’t want a blank slate that we basically had to build ourselves,” said the systems engineer. “Seapine has gotten the balance exactly right. They’ve built a foundational system that meets the basic needs of what most people will require, and then created an intuitive and efficient way to customize and configure it. And on a few occasions when we pushed the limits of customization, their technical support was convenient and responsive.”

Since completing the TestTrack installation in 2013, Seapine has released a number of software upgrades that have improved its already invaluable functionality. The company sees plenty of room to grow with TestTrack, too.

“The potential for harm in anesthesia gas delivery is high and our devices can be incredibly risky. The whole point is to take the risk away,” said the systems engineer. “TestTrack’s streamlined, secure, and detailed tracking system has reduced the considerable administrative costs associated with eliminating the possibility of paper trail oversights. TestTrack helps us reduce the risk.”



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## About Seapine for Life Sciences

Founded in 1995, Seapine Software is based in Mason, Ohio, with sales and support offices located in Europe, Asia-Pacific, and Africa. Hundreds of leading medical device, pharmaceutical, biotechnology, and clinical research organizations rely on Seapine to streamline their core development processes, drive innovation, and gain a competitive edge.

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