

Proscia Uses Qualio to Bring High-Quality Medical Device Software to Pathologists around the World

Time with Qualio / plan

1 year, 30+ users

Vertical

Software as medical device
SaMD

Favorite feature

History management and search

Impressed by

Customer support, responsiveness to customer requests

Recent regulatory submission

Achieved MDSAP certification

Since 2014, [Proscia](#) has been building software solutions for pathology and cancer research. The company recently decided to apply their software to a clinical setting to enable pathologists to work more effectively by moving from microscope-based workflows to a slide image management system that imports and reads digitized slides from multiple scanning sources, making it easier for doctors to store, retrieve, manipulate, and annotate them from any location where there is internet access.

To ensure the transition to the new market was a smooth one, Proscia needed a complete and compliant electronic quality management system (eQMS) that was cost-effective and could be implemented rapidly. After researching their options, they chose Qualio and were able to achieve Medical Device Single Audit Program (MDSAP) compliance shortly thereafter, allowing them to bring powerful software as a medical device to pathologists around the world.

The Challenge

To sell their medical device software to healthcare customers, Proscia needed a quality management system that would enable them to enforce high quality standards to ensure compliance with all relevant regulations.

Since they wanted to sell their product internationally, the company needed a solution that would help them [achieve MDSAP certification](#) thereby ensuring compliance with FDA and ISO regulations and allowing them to sell to organizations in Australia, Brazil, Canada, Japan, the European Union, and the United States.

“We needed a simple but comprehensive solution to document management for a small company that was cost-efficient, Part 11 compliant, flexible in configuration, but still easy to use and with reliable tech support,” explains Barbara Young, senior quality manager at Proscia.

The Solution

As they searched for a new solution, the team at Proscia demoed three products, including Qualio. Ultimately, they chose Qualio as their eQMS because of its simplicity and intuitive user interface.

“We especially liked Qualio’s history management that tracks changes to procedures and documents, and the configurable organization of documents that could be applied to demonstrate regulatory compliance,” Young continues.

Proscia has many young designers on staff who aren’t used to working in regulated environments; Qualio has made these employees’ transition to this kind of work setting much easier, Young explains.

In particular, Proscia enjoys Qualio's search function, which enables them to quickly find documents by keyword and reference IDs that appear either within the documents themselves or in document properties. They also enjoy Qualio's tag function which enables multiple documents to be grouped into sets that are created as needed and allows documents to belong to more than one group.

"We use it to show parent-child relationships with procedures and records, and also for creating file folders, such as a design history file," Young continues.

The Results

Since moving to Qualio, Proscia hasn't looked back. Already, they're on the market with their CE-mark Concentriq Dx product.

With Qualio, Proscia gets a robust eQMS that has already delivered a number of benefits to the organization.

1. A trusted system

More than 30 Proscia employees are using Qualio every day to help bring medical device software to the global healthcare market. With Qualio, the team has access to a trusted system that serves as a single source of truth for documentation.

"We're using it for all of our internal training, document access, document approval, storage and records, and maintaining our files," Young says. "We also have our audit schedules in there and all the files that have to do with our products are maintained in Qualio, too."

2. Audit preparation

Proscia used Qualio to prepare for and ultimately achieve MDSAP certification by ensuring that all necessary documentation was available, up-to-date, organized, and approved.

"The configuration for documents that the Qualio system supports made it easy to find documents, establish status, and implement corrections where needed," Young says.

3. Top-shelf customer support

While Qualio's intuitive design made adoption easy, organizations often run into issues when implementing any new software solution, including an eQMS. Thanks to Qualio's top-tier customer support offerings, the Proscia team was able to quickly get past any problems they encountered.

"I used the chat feature frequently when I had questions or needed to address problems," Young continues. As Proscia has scaled, customer service has stayed the same. "Customer support has been really interactive. I've gotten to know pretty much the whole team by name now."

3. A future-proof QMS

Looking ahead, Proscia is confident that Qualio gives them an eQMS they can use as they continue to scale—even while working remotely. Currently, the company plans to integrate AI apps and software that are provided from other sources into their own solutions, which would enable pathologists to work even faster.

"After witnessing Qualio's continuous improvements and their ability to incorporate recommendations and address problems as they surface, we know we made the right choice for Proscia," Young concludes. "Looking at the new functions that are in progress and the support we've received to date, we are very confident that Qualio will continue to grow with us as we evolve as a small business."

To learn more about how your medical device company can bring compliant products to market faster, [schedule a demo of Qualio today](#).