

# CGX Uses Qualio to Deliver Innovative EEG Headsets to Medical Researchers

**Time with Qualio / plan**  
1.5 years Growth; 15 users

**Impressed by**  
Quick validation

**Vertical**  
Medical device

**Recent regulatory submission**  
510(k) premarket for FDA

**Favorite feature**  
Document control

CGX is one of the world's leading manufacturers of dry electrode EEG headsets that are designed for researchers in the fields of simulation training and virtual reality, among other things. About 18 months ago, CGX decided that their innovative headsets would also be well-suited for clinical use.

To get their devices approved for medical research, CGX moved to Qualio as their quality management software system (eQMS). The decision has enabled them to get more devices to market faster with a robust system that scales alongside the company.

## The Challenge

For five years, CGX had been selling its products to researchers at universities exclusively. The company then decided to also start selling its products into the medical market, which meant they would have to adhere to a whole new slate of requirements.

"We needed to do internal adjustments to meet the needs of being a medical device company," explains Spencer Linton, Vice President at CGX.

CGX had been using an offline QMS that "got the job done." But it wasn't something the young company thought could grow alongside it. The system, for example, didn't support working from home. "It was creating a lot of roadblocks for us and slowing down development," Linton says.

Seeking a better way forward, the CGX team began looking for an eQMS.

"We wanted a flexible QMS system to develop products for a range of markets. It also had to be scalable as we grow with projects, personnel, and sales," Linton continues. "We needed software to meet the needs of a 510(k) filing and satisfy the FDA's expectations for a well-documented design and development process."

## The Solution

After surveying the market and demoing Greenlight Guru and MasterControl, the CGX team decided to implement Qualio as their eQMS.

As a smaller, agile company, CGX didn't need all the bells and whistles that ship with many QMS systems. They also didn't want to be forced to use another company's templates.

"We really needed a process we could make our own," Linton says. "Qualio is flexible, it's a great price compared to the competitors out there, and we can put all of our company inside the system."

## The Results

The decision to move to Qualio has proven to be a shrewd one. Not only did Qualio make it easier for CGX to file their 510(k), it has also given them the flexibility early-stage companies need to pivot quickly while helping them improve collaboration with many different stakeholders across distributed environments. Qualio also helps ensure regulatory best practices while easily building a QMS that meets CGX's unique needs.

Qualio delivered a number of other benefits to CGX, including:

### 1. Easy onboarding and easy validation

Onboarding was incredibly easy because the platform was self-explanatory and CGX didn't migrate anything to Qualio, Linton says. Today, there are 15 users on Qualio, including the quality team, engineers, contractors, and the president of CGX. Nobody's had any trouble figuring out how to be productive on the platform.

Linton also oversaw the validation process, which he wrapped up in two or three hours — something he credits to Qualio's robust documentation.

"Qualio helped us quickly build a system that was compliant for the medical device market," Linton says.

### 2. Improved collaboration

Before Qualio, CGX was using an offline Excel-based QMS for a very brief period. It wasn't a match for the company because they're a small team that works with many different vendors.

"You had to be logged into our server to pull an Excel sheet," Linton explains. "It quickly became a mess."

Now, CGX uses Qualio as a central hub where they store all of their processes, SOPs, and step-by-step how-to guides. As a result, all stakeholders — including contractors and consultants working remotely — can hop into Qualio and figure out how to do something right away.

"We run all processes across our entire company through Qualio. It's allowed us to reach beyond design and development," Linton says. "We want to work fast, and we want our own process so we can be our best. And that's what Qualio offered. Having that flexibility has really allowed us to find our best self as a company."

Simply put, Qualio has become a trusted, reliable system that enables CGX to move work forward faster.

### 3. Customer support and responsiveness

Linton says that whenever he's needed help — not often — and whenever he has any ideas for new features, the Qualio team always quickly provides top-notch support and incorporates feedback rapidly

"It's a software that's continuing to develop with us," Linton explains.

### 4. Scalability and increased output

During the first three years of the company, CGX released about 10 products, Linton says. In 18 months with Qualio, they've released 12 products and revisions.

"Our output has really gone through the roof since we adopted Qualio," Linton concludes.

With Qualio, CGX has a reliable eQMS that can keep pace with their speed and can be adjusted to meet their specific requirements—whatever they might be tomorrow, five years from now, or even further into the future.

To learn more about how Qualio can transform quality management at your medical device company, [request a demo today](#).