Ditching admin tasks with the help of a supportive eQMS vendor

Industry	Medical device
Regulations	• FDA 21 CFR 820 • ISO 9001 • ISO 13485 • ISO 14971
Uses Qualio for	• Documents • Training • Design Controls

About NeuFit

NeuFit is the Austin-based manufacturer of Neubie, a neuromuscular electrical stimulation medical device. Neubie helps patients recover from neuromuscular damage, and can treat conditions from plantar fasciitis to strokes and spinal cord injuries.

The challenge

NeuFit relied on a manual paper- and Dropbox-based system to manage their quality activities. Documents required a cumbersome approach of downloading, editing and passing to DocuSign for every edit. Key document updates were easily forgotten, and searching for information in multiple logs and filing cabinets became overwhelming.

Director of Operations & Quality Management Ami Anderson spent ‘every day, all day, and a lot of overtime thrown in’ just completing quality admin tasks. Since her team of 2 were paid hourly and Ami was salaried, she would be first in line for after-hours work if things didn't get done.

And this excessive quality timesink meant the other half of her role – operations – didn’t get the same attention, causing issues in areas like supplier management. The issues with NeuFit’s manual system came to light when an FDA auditor arrived with a thumb drive, expecting to be able to load electronic quality documents and take them away with her. Her bag wasn’t large enough to hold the paper documents prepared by the NeuFit team.

$130K

Of employee and consultant costs saved

3x

Quality event resolution speed

5.5 days

Saved per audit

“We couldn’t have got set up as fast as we did without the Qualio team. There were no dumb questions.

All they wanted to do was set us up the best way for the company. And they did. It's incredible.”

— Ami Anderson

Director of Operations & Quality Management, NeuFit



The solution

Ami homed in on three potential eQMS vendors for closer inspection. One option still required lots of manual change control, including downloading system documents for revision then re-uploading.

The second option put Ami off with overly pushy sales tactics, which included putting down other eQMS vendors and over-promising functionality.

During discussions with Qualio, Ami felt comfortable to discuss and explore her operational requirements without pressure. On top of that, the system itself met all of NeuFit's needs. After NeuFit's CEO Garrett Salpeter was impressed by Qualio too, sign-off was given to become Qualio customers.

NeuFit took on additional Qualio+ support to accelerate their quality and compliance journey, and Ami was pleased by the entire onboarding and training experience.

> *"We're so streamlined now. It's amazing where we were, compared to where we are now. I hope we get the same auditor in future, so I can say, 'look how wonderful this is now!' My job is so much less stressful now."*
>
> **— Ami Anderson**
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> Director of Operations & Quality Management, NeuFit

The results

Qualio demolished the mountain of manual paperwork activity taking up Ami's working week

Happier customers

Moving the NeuFit quality management system into a digital platform unlocked oversight of areas invisible in a paper system. With Qualio's reporting functionality, Ami could spot and fix a part defect with the potential to decrease patient comfort. Ami notes a **clear uptick in customer reviews** since implementing Qualio, driven by NeuFit's ability to deliver a higher-quality product and service.

Stress-free, faster audits

NeuFit's pre-Qualio audit took 6 days, as the team scrambled to pinpoint and copy paper documents requested by their FDA auditor. Ami estimates that her audits now take **half a day**.

Accelerated close-out

Besides unlocking greater visibility of quality events and issues, Ami and the NeuFit team can now close them out faster too. Where events took around **6 months** to resolve pre-Qualio, they now take an average of **30-60 days**.

400% ROI

Before Qualio, Ami requested 2 additional staff to help her manage NeuFit's QMS. Instead of spending **$100,000** on these new employees, NeuFit spent just **$30,000** on Qualio to eliminate manual quality admin altogether.

And as a Qualio+ customer, Ami enjoys monthly touchpoint support meetings from Qualio's expert QA team – meaning she didn't need to accept a **$30,000** service offered by an external consultant.

Refocused time

Ami spent her entire working week just keeping NeuFit's paper QMS afloat. Qualio has allowed her to rellocate this lost time to value-add activity, including continuous improvement and planning work for a second product launch. Instead of a 5-year estimate, Ami estimates they can now **get their new device to market in just 2 years**.