

Peace of mind and a quality-first strategy for a medical device company CEO



About EvoEndo

EvoEndo is the developer of a single-use gastroscope system which allows transnasal upper endoscopies to be performed without sedation or anesthesia. The company relies on a third-party contract manufacturing organization (CMO) to make its Class II medical device product.

The challenge

EvoEndo relied on a different contract manufacturing organization (CMO) to build its initial eQMS from scratch. But the on-premise nature of that eQMS, coupled with a significant level of paper, quickly became clunky and unfit for purpose.

CEO Heather Underwood didn't want to keep flitting between physical files and on-premise devices, and soon found that efficiency and document control were beginning to slip and hamper the company's FDA 510(k) preparations. Reviewing and approving documents required a drawn-out process of printing, signing and scanning, and accessing vital QMS info wasn't easy.

As EvoEndo changed to a fresh CMO, they also began to look for a purpose-built, pre-existing and cloud-based eQMS to better serve their needs.

In particular, Heather wanted to flesh out EvoEndo's internal quality management system, including elements like document control and training management without relying solely on the product-based data in her CMO's QMS.

“No-one used our old system. Everyone uses Qualio. The UX is intuitive and everyone's used to logging in and checking their Dashboard. Everyone's comfortable using it. Night and day is the only way to describe it!”

— Heather Underwood
CEO, EvoEndo

Industry	Medical device
Regulations	• FDA 21 CFR 820 (510(k)) • ISO 13485
Uses Qualio for	• Documents • Training • Events • Design controls

510(k)

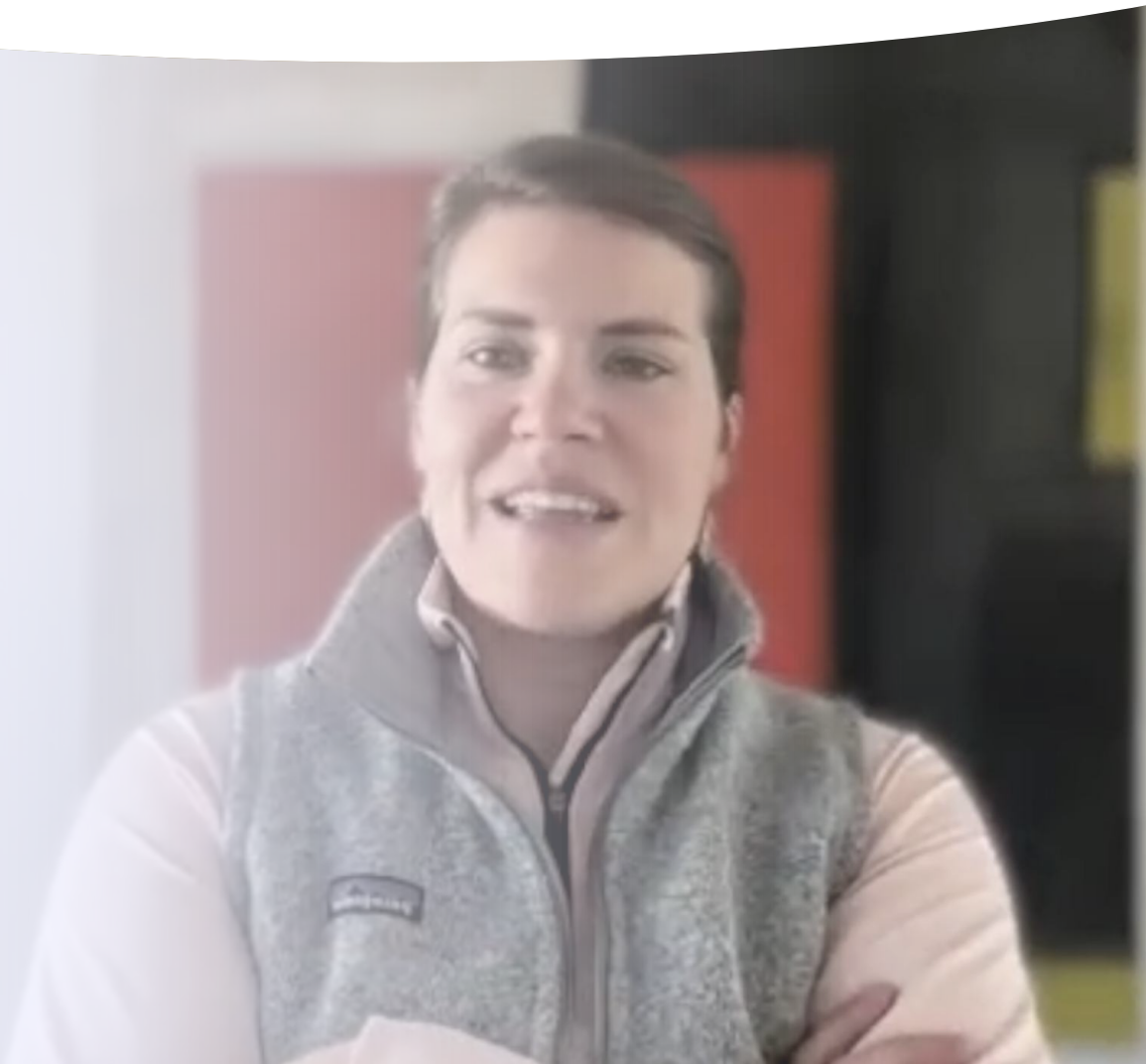
Clearance achieved

100%

Remote cloud-based eQMS

60%

Faster quality processes



The solution

Heather needed an intuitive, easy-to-use eQMS platform which could knit EvoEndo's operation together with that of her CMO (based in Florida) and the company's distribution partner (in Ann Arbor, Michigan).

After reviewing a string of potential vendors, it was the extra customer support which made Qualio stand out as Heather's partner of choice.

EvoEndo became Qualio customers in mid-2020.

As someone who'd never performed an eQMS validation exercise before, Heather was pleasantly surprised by how straightforward, simple and fun the process was.

With targeted training from the Qualio customer success team, and pre-built Qualio document templates allowing EvoEndo's new system to be quickly populated, Heather could start using her new eQMS in a matter of weeks.

"Qualio helps me sleep better at night. It gives everyone a roadmap in this time when we're having to move very quickly."

Having that structure for everyone to work within is essential for us to really succeed this year in getting onto the market and staying compliant.

I have only good things to say!"

— Heather Underwood
CEO, EvoEndo

The results

Qualio gave EvoEndo a remote, cloud-powered eQMS which made 510(k) preparation easy

Regulatory success

With a connected cloud-based quality system, the company has been free to grow and pass through **Series A** funding without compromising on compliance. New team members can be onboarded and trained quickly, and quality information can be shared and accessed at the touch of a button from a **single source of truth**.

And crucially, EvoEndo has been able to demonstrate its quality and compliance credentials to the FDA, who **cleared the company's 510(k) submission** in February 2022. With **Series B** funding on the horizon and the company's first market launch arriving this year, Heather believes Qualio's flexible scalability can only deliver even more value.

Extra help from the Qualio team

Heather leveraged Qualio's unique quality service support to accelerate EvoEndo's market readiness.

"Initially, we didn't have anyone on the quality side. The support Kelly and the team gave us at the beginning was great, and we were really leveraging them to build out our QMS from scratch with templates and everything. That's exactly what we needed — and that's why we went with Qualio."

'Night and day' engagement difference

Core quality tasks like digital document signatures, review processes and training can now be done at a **fraction** of the previous time and effort, while engagement with the quality system has **skyrocketed**.

Heather and her team now access a complete cloud-based eQMS within Qualio, spanning documents, training, design controls and quality events.

Quality everywhere

Heather notes that:

"I can review and sign off on documents on my phone as I travel. I can complete training or take a look at an SOP. It's really easy and it's allowed us to grow our business."

With a trusted, **remotely accessible** quality system connecting all her staff for the first time, Heather has now been able to step away from day-to-day quality management as the business grows, comfortable in the knowledge that her team has an intuitive eQMS behind them.