

Expert support for a growing company's first quality steps



About ViQi

Californian start-up ViQi emerged from UC Santa Barbara and develops cloud-based image analysis software powered by AI and machine learning.

Their technology is used by life science organizations to accelerate drug discovery by modeling treatment and cell behavior, and has even been applied by the Bureau of Ocean Energy Management to perform oil spill risk modeling.

The challenge

The company's continued evolution into the life science sector, and their software's use as a medical device data system (MDDS) for preclinical work, prompted the ViQi team to begin planning a quality and regulatory pathway for the future.

Co-founder and CTO Dmitry Fedorov wanted to set a solid, proactive quality baseline for the organization in line with their digital, cloud-based 'mindset'.

It was important for the business to embrace modern eQMS technology early, before 'progressively more difficult' regulatory demands started to slow company growth.

Critically, the organization had no internal quality expertise. Any quality software vendor they found would need to offer a highly supportive and collaborative relationship.

We looked a lot at how Qualio worked, its user interface, and the technology behind it. It was by far the freshest, most logical eQMS system out there."

— Dmitry Fedorov
Chief Technology Officer, ViQi

Industry	Medical device data system (MDDS)
Regulations	FDA 21 CFR 820
Uses Qualio for	- Documents - Training - Suppliers

12 weeks

To construct an eQMS from scratch

35

Key quality documents built with Qualio support

\$20,000

Of consultancy spend mitigated



The solution

Dmitry and Project Manager Hallie Greene began to search for the perfect eQMS platform and the close QA/RA support they needed. A call with Sumatha Kondabolu on Qualio's quality success team 'sealed the deal'.

Going into September 2022, the ViQi team had the ambitious goal of getting the fundamentals of a quality management system in place and getting registered with the FDA by December.

They became Qualio customers at the end of the month and let themselves be guided by Qualio's expert onboarding team.

Sumatha's knowledge, warmth, and kindness made us instantly want to work with her and learn from her!

We could also tell early on that Qualio's software was the loveliest to work with as well.

As a software company, we care about that."

— Hallie Greene
Project Manager, ViQi

The results

Qualio provided both software and support to help ViQi quickly build their quality fundamentals from scratch

★ Quality expertise by their side

The ViQi team received both a brand new, fully digital **quality management system and expert quality and regulatory guidance** from Sumatha to help them build and populate it, from document and SOP creation to managing workflows and development lifecycles.

Sumatha even prepared a special presentation on MDDS regulatory strategy. Her targeted support allowed ViQi to forego an additional **\$20,000** in planned consultancy spend.

ViQi's Qualio investment therefore armed the business with both **quality tools and knowledge** they simply didn't have before.

🛡️ Quality fundamentals in just 12 weeks

Onboarding completed right on time in December 2022. ViQi could register with the FDA with a **fully operational QMS** in place for the first time, comprising:

- 35 new quality documents, created with Sumatha's help
- Digital training functionality underpinned by FDA-compliant e-signatures
- Supplier management with risk matrix functionality

😊 Making the impossible possible

For Hallie, the combined impact of Qualio's software and support hasn't been a question of accelerating ViQi's quality journey, but the difference between **possibility and impossibility**:

"I can tell you right now, it wouldn't have happened. I think that's pretty clear. I don't think we would've been able to pull it off if we didn't have a partner that could provide us guidance and templates. There's just no way. It's not even a time saving. It's a go-no go situation."

📁 Confidence for the future

The new system has helped ViQi prove their quality credentials to new customers, too, with their new eQMS a '**powerful talking point**' in sales conversations.

The team has even begun **coaching business partners** on their own quality management systems, adding one partner as a user in their Qualio system and working through quality documents in collaboration with them.

With both **quality system and know-how** in place, ViQi are perfectly poised to expand further into the life science sector and execute their future plans of developing Class II SaMD products.