




Sidekick Health chooses Qualio for audit-readiness

About Sidekick

[Sidekick Health](#) is a software company founded by medical doctors and specialists that operates a gamified digital care platform designed to help people manage chronic conditions, overcome illnesses, and make lifestyle-related changes to enjoy happier and healthier lives. Due to the nature of its work, some of the content the company makes is considered software as a medical device. Sidekick Health — which was founded in 2014, has 60 employees, and is headquartered in Iceland — closed a [\\$20 million Series A round](#) in October 2020.

 **Time with Qualio / Plan**
20 seats, Qualio Plus

 **Vertical**
Software as Medical Device (SaMD)

 **Favorite features**
Audit-readiness

 **Impressed by**
Onboarding

 **Targeted regulatory submission**
CE marks; upcoming FDA submissions

The Challenge

At a very high level, Sidekick has two different kinds of products: those that are regulated and those that are not. For example, a program designed to help patients manage diabetes effectively by telling them to go for a walk and eat healthier isn't considered a medical device. On the other hand, apps designed to treat patients with chronic heart failure and peripheral artery disease are classified as medical devices.

Recently, Sidekick decided to increase the number of products in their portfolio that required a CE mark. Lacking a purpose-built electronic quality management system (eQMS), the Sidekick team saw that they would need to fill out a ton of paperwork and create a lot of documentation over and over again with each new product.

"We quickly realized that we were going to drown in paperwork," explains Kristinn Gylfason, Sidekick's Compliance Officer. "We saw in the near future that we would have to write all of these policies, procedures, and SOPs again and again and again."

Sidekick had been using another software to maintain and manage all documentation. While the platform might have done the job well enough at a smaller scale, the company was looking for a long-term solution that could keep pace with their growth.

"What I was mostly afraid of was the ever-changing nature of the software," Gylfason continues. "It could change two or three times a week — or twice a day even."

The Solution

Sidekick needed a new solution for quality management. Since they were particularly interested in automating the process as much as they could, the company knew it needed an eQMS. After looking at quite a few eQMS vendors, the Sidekick team ultimately selected Qualio as their final choice.

"Qualio was chosen because it focused on what we were doing — maintaining regulatory compliance for medical devices."

— Kristinn Gylfason, Compliance Officer,
Sidekick

Also of note is the fact that a potential investor recommended Qualio to the company's COO and CEO, while Sidekick was in the process of raising its Series A. "That confirmed our belief in Qualio," Gylfason explains.

The Results

While Sidekick is just getting started on its journey with Qualio, the software as a medical device company is eager to see where that journey takes them. With Qualio taking care of their quality management needs, Sidekick is excited at what the future has in store. With that in mind, here are some of the ways Sidekick is already benefiting from its decision to invest in Qualio.

1. Ready to Scale

Currently, Sidekick is growing rapidly; the company has grown from 20 to 60 people recently, and plans to continue to scale in 2021. Suffice it to say that this explosive growth has kept the team busy.

2. Well-Positioned to Enter the U.S. Market

Looking ahead, Sidekick has its sights set on tapping into the U.S. market. To do that, they will need to secure FDA approval on some products as a software as a medical device organization.

"Being a European company, a lot of U.S. policies and procedures are quite foreign to us," Gylfason explains. "This is a strong selling point for Qualio; the platform helps you through the process step by step. I can't recommend that enough. It was a real burden off of our shoulders."

3. High-Touch Onboarding

Shortly after Gylfason was onboarded by the Qualio staff, the Sidekick team hired a key position on the Quality team, and the company decided to hand over Qualio ownership to that individual.

"Her onboarding process was the same as mine," Gylfason continues. "Someone from the Qualio team onboarded her instead of me having to train her. That way, she was more confident in the system."

4. Audit-Readiness

One of the main selling points of Qualio is the fact that it enables Sidekick to operate from an audit-ready stance at all times.

"That helped us get the sign off from our CFO," Gylfason explains. "We haven't been audited yet, but it's only a matter of time. During the summer or fall, we're planning on contacting auditors and asking them to audit us proactively."

Thanks to Qualio's audit-readiness, the Sidekick team is confident those audits won't be an issue.



Learn how your SaMD company can use Qualio to achieve audit-readiness

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