


## Fix the Mask turns to Qualio Plus to bring a medical device to market during the pandemic


### About Fix The Mask

[Fix the Mask](#) is a medical device organization with a simple mission: helping everyone stay healthy during the pandemic by wearing well-fitting masks. The group, which is based in California, makes a brace that is worn over a surgical mask that ensures the mask stays tightly affixed to the individual's face so that germs don't get through.

 **Time with Qualio / Plan**  
1 year

 **Vertical**  
Medical Devices

 **Favorite features**  
Qualio Plus support

 **Impressed by**  
Seamless onboarding

 **Targeted regulatory submission**  
510(k) certification  
ISO 13485: 2016  
FDA 21 CFR 820  
ISO 14971:2019  
NIOSH 42 CFR Part 84

### The Challenge

Fix the Mask was created in response to the COVID-19 pandemic. As the virus began shutting everything down, people around the world started scrambling to get masks to protect themselves and their communities. Unfortunately, many of these masks were loose-fitting, which gave virus droplets a path to potentially spread.

Seeking a way to give everyone an N95 fit, Sabrina Paseman, CEO of Fix the Mask, and her sister, Katherine, put their brains together and invented the Essential Mask Brace, the nonprofit's flagship product. As they began trying to bring the product to market, Paseman quickly realized how difficult it was to check every box and get the FDA's blessing.

### The Solution

Since time was of the essence, Paseman couldn't afford to wait any longer than was absolutely necessary to get the mask brace to market. So, she began searching for a quality management system (QMS) that would make the process of securing FDA approval much easier.

"Recognizing that there were a lot of regulatory hurdles that needed to be done well and correctly the first time made me realize I needed some outside help," Paseman says.

After doing her due diligence and exploring her options, Paseman ultimately decided that Qualio, the cloud-based electronic quality management system for life sciences companies, was the best fit for her nonprofit's needs.

As someone new to FDA approval processes, Paseman opted to go a step further by investing in Qualio Plus, Qualio's quality as a service offering that couples the company's powerful eQMS with expert Quality Assurance support.

### The Results

Thanks to Qualio, Fix the Mask was able to bring their medical device to market quickly in an environment where every minute mattered. Thanks to her experience with Qualio Plus, Paseman is confident she's ended up with a QMS that can grow with her company.

## 1. A Purpose-Built Qms

Before Qualio, Fix the Mask didn't have any type of QMS in place. Thanks to expert support from the Qualio team, the decision to trust Qualio Plus for quality management enabled the med device company to create a QMS that met their exact specifications.

"Qualio has created my QMS and really guided me along the way to make sure I'm hitting all the requirements," Paseman explains, adding the platform is easy to use with a "well-designed and intuitive" interface.

## 2. Seamless Onboarding

With the friendly, approachable Qualio Plus team holding weekly check-ins to see how things were going, Paseman felt "incredibly supported" during onboarding, which was as smooth as could be.

## 3. Streamlined Processes

Qualio's expert guidance enabled Fix the Mask to implement smart and efficient processes that made it easy to ensure compliance.

*"I was genuinely impressed by the Qualio Plus team. Not only was everyone very professional, they really went above and beyond to help me understand the more difficult concepts you need to know when building a QMS from scratch."*

– Sabrina Paseman, CEO,  
Fix the Mask

"We didn't have any streamlined processes prior to Qualio," she says. "Not only did Qualio help us define our processes, it's made it a lot easier to adhere to them because everything is clear and intuitive."

## 4. A True Partnership

In Qualio Plus, Fix the Mask has found a true partner that is committed to the company's success.

For example, right off the bat, Qualio's experts recognized that Paseman was new to quality management and were able to guide her team in the most important direction first.

"If I tried to figure it out on my own, I would have been too overwhelmed and confused," Paseman explains.

When the relationship was just starting out, the Qualio Plus team answered all of Paseman's questions and explained how the different parts of the QMS interrelate with one another. Right away, Qualio's commitment to its customers was evident.

"The team really cares about the success of the companies they work with," she says. "That was a huge differentiating factor for me."

If your medical device company is in the market for a QMS, Paseman advises you to take a look at Qualio Plus.

"I'd highly recommend it — particularly for companies that are new to quality management," Paseman concludes. "If you're ready to do it right the first time, it's an excellent program to get started with."



**Learn more about how Qualio can help your medical device company bring products to market safely and quickly**

[Schedule a demo today](#)