Qualio

IRISYS Uses Qualio to Help Biotech and Pharmaceutical Firms Secure FDA Approval

Time with Qualio / plan
3 years, 75 users (Growth plan)

Vertical
Pharmaceuticals - Contract development and manufacturing (CDMO)

Favorite features
Standardized document templates

Impressed by
Ease of use

Targeted regulatory submission
FDA Drug Establishment Registration

IRISYS is a contract development and manufacturing organization (CDMO) headquartered in San Diego that helps biotech and pharmaceutical firms manufacture clinical drugs, drug delivery technologies, and formulations for rare diseases and orphan drugs, and get them approved by the FDA. When IRISYS contracts with partner firms, they assist with R&D, manufacturing, and regulatory processes. In addition to this, the company also has a small product portfolio of its own that includes the SCOT-TUSSIN family of sugar-free and alcohol-free cough medicines.

Founded in 1996, IRISYS had been relying on a paper-based quality management system for many years. When the company started to scale rapidly a few years back, they quickly realized their paper-based system simply couldn't keep pace with their fast-growing operations. Seeking a better way forward, IRISYS sought to modernize their operations by moving to an electronic quality management system (eQMS). After doing their due diligence, they moved their quality management system to Qualio, and they haven't looked back since.

The Challenge

As a smaller operation, IRISYS relied on a paper-based system where everything—including all SOPs—were printed out and signed by hand. Eventually, these documents would be scanned and put on a shared network drive. But it was still a manual process that took a lot of time.

While this system worked well enough for a company with a handful of staffers, IRISYS started to scale rapidly. Between 2014 and 2017, the company expanded from 10 to around 50 full-time employees. With this growth came a lot more research and a lot more documentation.

> "It started to become a burden," explains Adolfo Ramirez, Director of Information Systems and Data Compliance at IRISYS. "QA was getting overwhelmed because everything was paper-based. This process in place was slowing us down."

The Solution

IRISYS quickly realized they needed a better solution for quality management that would enable them to move faster. To find a solution, Ramirez and his team conducted Google and LinkedIn searches to see what other folks in the industry were using for quality management. Eventually, Ramirez ended up with a list of 30 or so eQMS systems and began investigating them further.

Right off the bat, IRISYS realized that while platforms like MasterControl and Veeva offered a lot of features, the smaller CDMO didn't need all those bells and whistles. After testing a different solution in sandbox mode and finding it was full of bugs, Ramirez decided to test Qualio next.

“The Qualio sandbox worked as designed,” Ramirez says. “The UI is actually very user-friendly. I was able to go into a sandbox and immediately start using it productively. It’s very easy to use compared to a lot of the other systems we looked at, which required lots of training and sifting through documentation to figure out.”

Liking what they saw, the IRISYS team ultimately decided to invest in Qualio as their eQMS solution.

The Results

By ditching their paper-based system and moving to Qualio as an eQMS, IRISYS has experienced a number of benefits that have enabled them to develop more products and deliver more value to their clients.

1. Increased productivity

First and foremost, Qualio has enabled the QA team at IRISYS to keep up with their increased workload.

“The reason we were looking into an eQMS in the first place was to help QA be more efficient and keep up with everything because they were so far behind,” Ramirez says. “That was the main goal, and that has been fulfilled.”

Whereas other solutions require teams to upload files, download them, revise them, and reupload them—in a process Ramirez describes as unnecessarily “cumbersome”—Qualio enables IRISYS’ QA staff to move much faster.

“Everything is in the system,” Ramirez explains. “It’s just a lot easier.”

Additionally, Qualio has helped IRISYS collaborate effectively, even when being forced to work remotely due to COVID-19.

2. Standardization

IRISYS hoped that moving from a paper-based system to an eQMS would make it much easier to standardize all of their SOPs, and Qualio has delivered on that front.

“With Qualio, you have no choice,” Ramirez says. “Standardization is built in.”

3. Increased compliance

As a CDMO, IRISYS gets audited randomly by the FDA, FDB (California), and DEA; they don’t submit to be certified, Ramirez explains. Since moving to Qualio, the company hasn’t had any problems passing audits.

“We’ve never had an issue with it,” Ramirez says. “The changelog in Qualio has been particularly helpful. We can print it out and give it to the auditor to show we’re still compliant since we validated two years ago, for example.”

4. Excellent support

When migrating to Qualio, IRISYS had to upload more than 500 documents to the system. This process was arduous because all SOP numbers had to stay the same. To expedite it, IRISYS reached out to the Qualio team.

“I know that some of the things we asked for wasn’t what the engineering team is usually asked to do,” Ramirez says. “But they did it anyway. We were definitely grateful for that.”

According to Ramirez, the IRISYS team enjoys the fact that Qualio is a small business that sells to SMBs in the life sciences space. Due to Qualio’s smaller size, the support team is more accessible and responsive than larger companies might be.

“We knew Qualio was going to take care of us better than the bigger guys,” Ramirez says. “All of the feedback I’ve given has been taken into consideration.”

5. Simplified operations

Qualio has also enabled IRISYS to move away from clunky, bloated processes that were unnecessarily complicated.

“We changed our quality system to fit to whatever Qualio does,” Ramirez continues. “Truth be told, it’s a lot easier. The way we had it was a really old way of doing things. There were a lot of unnecessary steps and a lot of unnecessary signatures. Qualio simplified things a lot more for us.”

6. Future-proofing operations

By moving to Qualio, IRISYS is better positioned to scale even further in the future.

“Now that we’re electronic, we can grow to 500 employees or 1,000 employees,” he says. “Since we don’t need to grow the QA team as much, we can put more resources into employees who make us money—scientists, manufacturing personnel, people like that.”

To learn more about how your CDMO can use Qualio to accelerate R&D efforts and help clients secure FDA approval faster, schedule a demo today.