

Alphazyme Uses Qualio to Produce Molecular Enzymes at Scale for Biotech Companies

Time with Qualio / plan
1.5 years, 30+ users

Impressed by
Exporting PDFs for external collaboration

Vertical
Biotechnology manufacturing

Targeted regulatory submission
ISO 13485:2016
medical device certification

Favorite features
Single source of truth for all experiment data

Alphazyme is a biotechnology manufacturer headquartered in Jupiter, Florida that produces custom enzymes that are used by large-scale biotech companies to read, write, and edit DNA molecules. Founded in 2018 by CEO Christopher Benoit—a serial entrepreneur and expert in the enzyme development and production space—Alphazyme has grown steadily over the last 18 months as it helps biotech firms accelerate cutting-edge applications in DNA literacy technologies.

To facilitate this growth, Alphazyme implemented Qualio as its electronic quality management system (eQMS) when the company initiated its first R&D experiments.

The Challenge

In 2005, Benoit founded a life sciences company called Enzymatics, which has since been acquired by QIAGEN. After an early customer sent over an 18 page supplier evaluation form and asked for a site visit to further explore their products and processes, Benoit realized the company needed to rapidly implement a robust quality management system.

At the time, electronic QMS systems were rare, not user friendly, and costly, so the Enzymatics team established a paper-based system—a decision that turned into a learning experience.

“We rued the day we chose paper,” Benoit says. “Everytime we wanted to change a document, we needed five signatures. Papers would get lost on someone’s desk. It was a cumbersome process that slowed us down.”

Seeking to avoid a similar problem in his new venture, the Alphazyme business plan called for a paperless, ISO 13845-compliant quality system architecture from the get-go.

The Solution

Right after Stephana Petrino was hired as the Vice President of Quality at Alphazyme, she was tasked with finding an eQMS that met these requirements. Because the young company needed to operate with agility, the right system would also need to be flexible.

Petrino examined roughly 15 solutions and had sales discussions with eight vendors. After thoroughly assessing the options, Alphazyme selected the Qualio product and embarked on a process of building its quality system inside the system - from the ground up.

“We needed something that was user friendly, easy to on-board new team members, and easy to get up and running,” Petrino says. “Qualio has surpassed our expectations on those metrics.”

The Results

Alphazyme's decision to use Qualio as the foundation of its quality system has helped the Company accelerate innovation while enabling them to quickly move through the development cycle, work more effectively, and prepare for the future. More specifically, here are some of the direct benefits Alphazyme has experienced by using Qualio for quality management.

1. Streamlined, Rapid Product Development

First and foremost, Alphazyme has been able to bring numerous products and development processes online rapidly, thanks to Qualio.

"We barely had a lab when we started using Qualio," Benoit explains. "Once we set up a process for designing, recording, and reviewing experiments in lab notebooks in Qualio, we were able to move through the development of a number of enzymes in a matter of months. Using Qualio allowed management to review the work-product in real time, mentor our team, and build towards 'design-lock ready' processes far more quickly than with a paper-based experimental tracking system."

2. Streamlined Collaboration

Qualio has enabled Alphazyme to streamline collaboration across the organization. Currently, all categories of team members—from C-level executives to scientists, quality engineers, and more—use Qualio to document, review, and approve their work.

"By using Qualio to track all of our experimental records, we can review scientists' data and advance projects from anywhere. This has been of particular benefit during the pandemic, and has allowed us to maintain fast-paced development while navigating work-from-home and split schedule strategies to keep our staff safe."

Using Qualio enables the Alphazyme team to collaborate more effectively with external clients, too.

"Much of our work is directed by individual clients, and experimental records are easily exported via PDF from Qualio lab notebook entries," Benoit continues. "We are always two mouse clicks away from sharing important data with clients, which drives project progress and transparency."

3. Improved Productivity

Qualio's intuitive design has helped the Alphazyme team to work more productively together.

"We started with three people in the system a year-and-a-half ago and have grown to 15 people right now, with steady participant growth planned," Petrino explains. "It's easy for people to grasp the system concepts and start navigating Qualio immediately upon hire."

Since Qualio helps the Alphazyme team collaborate more efficiently, they're able to get more done.

"It really is a good system to keep all information in one place—including documents, images, and other supporting information," Petrino continues. "Qualio keeps us paperless, it keeps us all on the same page, and it keeps us on track with meeting timelines and deliverables."

4. Future-Proofing Processes

For Alphazyme, Qualio is more than just a stagnant product. It's a robust solution that they are able to influence with their feedback and suggestions.

"We appreciate the feeling we get from Qualio that the team is highly welcoming of our feedback," Benoit says. "We actually see the product evolving according to the feedback we've provided."

In this light, Qualio's customer-centric approach gives Alphazyme an eQMS that can grow alongside them. Looking ahead, the company aims to become certified to the ISO 13485:2016 standard and is also looking to achieve compliance with certain federal regulations for diagnostic and therapeutic products.

5. Customer Validation

Qualio has also impressed Alphazyme's clients.

"We've been able to show certain clients what we've accomplished with Qualio, and they were very impressed," Petrino continues.

Recently, a publicly traded company conducted a "light" audit of Alphazyme's facilities and was impressed by the role Qualio played in the Company's operations.

"The VP of Quality for this client said, 'If I could build from the bottom up, I'd do it exactly the way you guys did it,'" Petrino concludes. "Qualio was a key system feature they would look to incorporate."

To learn more about how your biotech company can rapidly implement an eQMS and move groundbreaking research forward faster, [schedule a demo of Qualio today](#).