

From 'pain' to 'fun'



About Helix Biotech

Tennessee-based Helix Biotech, founded in May 2022, develops and manufactures lipid nanoparticles, liposomes and hybrid nanoparticles for customers, as well as producing manufacturing tools like extrusion and injection systems.

Robust quality and GMP processes are vital to support the company's work from R&D to manufacturing.

The challenge

Founder and President Graham Taylor began his career in quality as an associate quality engineer in 2007. Having spent over 15 years in the medical device and pharmaceutical worlds, he recognised the importance of an optimized QMS as he set up Helix.

At a previous role, Graham battled the time and effort demands of a paper-based quality system, which included constant circulation, completion and filing of paper documents.

A single FTE, a full 10% of labor costs, was swallowed up by quality admin demands.

With Helix as a blank slate, Graham wanted to sidestep the effort of paper and build an efficient, easy-to-run quality system from the company's first days.

Industry	Biotech
Regulations	<ul style="list-style-type: none">FDA 21 CFR Part 11FDA 21 CFR Part 210/211ICH Q10
Uses Qualio for	<ul style="list-style-type: none">DocumentsTrainingEvents

1x FTE

Of quality admin mitigated

3 days

Sliced from each quality event
close-out time

GMP

Embedded with a fully paperless
quality system

"We used paper in a previous company.

The biggest challenge was time: labor, filling out pieces of paper, passing them round, filing them. It was so painful you'd find ways to delay having to do things.

With Qualio, it's very easy. It's fun."

— Graham Taylor
President, Helix Biotech



The solution

Graham compared multiple eQMS vendors like [MasterControl](#) and [Greenlight Guru](#), and found it 'easy' to home in on Qualio as the most valuable and sensibly priced option on the market.

Graham was also swayed by Qualio's 'straightforward', 'refreshing' and 'easy-to-use' interface, particularly in relation to other, less intuitive systems he'd used in the past like [TrackWise](#).

Graham trusted Qualio with the future of his infant company's quality system and went live with the software in October 2022.

"Qualio is incredibly easy to use. We had our initial SOPs and procedures in place in a matter of weeks.

The Qualio+ set of documents was spot on, and boom: we have a dialled-in quality system. With the speed to get the base in place, and the ease of use to make changes, we feel like we're flying."

— Graham Taylor
President, Helix Biotech

The results

Qualio empowered Helix Biotech with a quality cornerstone to begin their journey

★ Rapid set-up of a quality foundation

The infancy of Helix Biotech meant Graham faced a double task of scaling the company and building a quality management system from scratch.

Starting with Qualio, and leveraging extra guidance and support from the Qualio+ team, made that task **rapid and simple**.

Helix's shiny new eQMS was populated with **industry-ready document templates** and augmented by **expert Qualio+ QA/RA guidance**. Helix established the structure of their biotech quality management system within a **matter of weeks** of becoming Qualio customers.

💻 An eQMS to connect the business from day 1

Graham wanted an **easy-to-use, collaborative** eQMS to build his company around. All Helix employees now use Qualio day-to-day, accessing a continuously expanding **single source of truth** for quality, manufacturing and more.

And as new employees are onboarded, they can be integrated into Helix's quality approach quickly and easily. **90%** of company activity is already housed in Qualio.

🛡️ Setting a lean and agile quality precedent

By **maximizing speed** and **minimizing clutter** with a fully digital eQMS, Graham and the Helix team have set a high-quality precedent to carry forward.

Quality events, such as deviations, can already be closed out a full **3 days quicker** than in Graham's previous organization.

95% of scheduled training is completed on time, with an average of **2 days'** completion time – a significant boost from what Graham experienced in other roles.

And the dreaded 'document dance' of manual paper-shuffling has been completely demolished, freeing up Helix staff to evolve the company **without time-sapping admin**.

👥 A 'marketing point' to win first customers

Showing off an optimal, electronic quality approach has allowed Helix to position themselves as a **quality-centric** organization embracing the latest digital tools. Graham's seen a clear effect:

"We can tell people we have our GMP systems, we're setting up our manufacturing facility, we have an eQMS, we're using Qualio. And then people say, 'Oh that's great, I've used Qualio in another project. That's really great.' We're leveraging it for sure."