Laying the groundwork for simple quality success

EnaraBio

Industry	Biotech
Regulations	• GCP • GDocP • GMP
Uses Qualio for	• Documents • Training

About Enara Bio

Enara Bio is a UK-based biotech start-up pushing the boundaries of cancer immunotherapy. The company is keen to position itself for simple, right-first-time success when quality and compliance demands begin to arrive.

A number of regulatory and compliance benchmarks have to be considered and mastered early.

The challenge

Prior to Qualio, Enara Bio operated a largely manual system to oversee documentation and training activity.

This system operated effectively while the company was very small. But managing and tracking Word documents in SharePoint, and relying on spreadsheet-based training processes, meant a loss of time to administration and duplicated effort as headcount and internal activity grew.

Above all, Head of Business & Portfolio Optimization Kate Nicholson was keen to take a proactive approach to quality and compliance - weaving best practice into day-to-day operations before they became mandated by external regulatory requirements.

500

Documents and training records managed with ease

92%

On-time training

1

Cloud-based eQMS connecting the company

"If our pre-Qualio training was anywhere close to 92%, I'd be very surprised.

People are very comfortable using it. Everyone sees the benefit. It's now so easy to demonstrate who's trained on what, and to locate and trace our documents."

— Kate Nicholson

Head of Business & Portfolio Optimization, Enara Bio



The solution

The Enara Bio team wanted to pursue an eQMS investment to optimize quality - while not recreating past experiences from other roles of large, clunky platforms with layers of superfluous functionality.

A simple, focused platform was required, and this need structured the eQMS search. Kate led a detailed procurement process which saw multiple eQMS platforms evaluated.

As complicated pricing and confusing modular set ups caused other platforms to be taken off the table, the team focused in on Qualio as their preferred system.

Enara Bio became Qualio customers in April 2022.

"There's so much complexity with other eQMS platforms.

At vast expense you can have all sorts of bells and whistles you'll either never use or you'll feel compelled to use, thus overcomplicating your processes.

My favorite thing about Qualio is its simplicity. It's reassuring to know there's nothing I've missed."

— Kate Nicholson

Head of Business & Portfolio Optimization, Enara Bio

The results

A futureproof quality approach supported by everyone

Simple validation for a busy team

The Enara Bio team had anticipated a long, complex validation process based on past experiences.

But Qualio's **best-practice CSA approach**, with pre-built validation and testing documents provided to the Enara Bio team, brought a pleasant surprise. The detail, focus and airtight compliance of the documents meant the team felt comfortable proceeding **without the need for further testing and validation activity themselves**, saving hours of work.

No more wasted time

Kate couldn't quantify the amount of time lost to quality admin and upkeep before Qualio, with the company's manual training management system resulting in traceability gaps and duplicated effort.

Qualio's automated prompts and reminders and its complete traceability, underpinned by **audit trails, change histories and incorruptible training records**, has changed all that, unlocking a lean, fast and right-first-time approach that frees the team to focus on priority activities.

Targeted functionality

Enara Bio didn't want to waste budget, time or headspace on layers of eQMS functionality they didn't really need.

Qualio's focus on life science start-ups and scale-ups meant a **lean, uncluttered system** which matched Enara Bio's requirements as a growing biotech operation, and **maximized internal engagement** after deployment.

Doing the groundwork early

Kate wanted to give Enara Bio a proactive, industry-leading approach to quality and compliance - making 'small-q quality' automatic before they begin to encounter formal 'big-Q quality' requirements.

Qualio gives the company a **simple, accessible quality tool engaged with across the organization** - on-time training completion **has hit 92%** and colleagues actively approach Kate to expand their system usage.

Quality is now a natural, automatic part of the day-to-day, giving Kate **confidence** in their ability to face document and training questions in future audits.