An eQMS that builds client trust

Industry	Life science industry provider (software and services)
Regulations	• ICH E6(R2) • FDA 21 CFR Part 11 • EU Annex 11 • FDA/EMA/PMDA clinical trial regulations • ISO 27001/27701 • SOC 2
Uses Qualio for	• Documents • Training • Events

About eClinical Solutions

eClinical Solutions provides a cloud-based clinical data software platform which makes truly digital clinical trials possible.

eClinical Solutions empowers its clients in the clinical trial space with sharper insights and complete visibility of their trial journeys, from clinical analytics and biostatistics to data control.

The challenge

eClinical Solutions could get by with a paper-based quality management system while they were still a small, single-site operation.

Things began to change as the company expanded its growth (including its India operations), widened its hiring radius and embraced more remote work, and as COVID-19 arrived.

The company moved to a trial master file-based content management platform but found it lacked the extra QMS functionality they needed, such as full CAPA and training management. It was clear eClinical Solutions needed a holistic, purpose-built eQMS.

VP of Quality & Compliance Evan Grunbaum and his team started to search for a tool which would eliminate their manual ceiling and free up the company to scale.

50

Remote customer audits a year handled in Qualio

3x FTE

Spend mitigated by eQMS investment

25%

Company growth since implementation

"To not have a major hiccup when you're hosting a remote audit, where they can get in and see the entire QMS – that's worth its weight in gold."

— Evan Grunbaum

VP of Quality & Compliance, eClinical Solutions



The solution

The team were immediately drawn to the intuitiveness and ease of use offered by Qualio. Evan could access the company QMS at a glance and drill into a web of connected quality information in seconds.

Internal Training Manager Aminah Brelvi knew the system would be easy for new hires to grasp, with functionality like Qualio's Training Overview providing snapshot visibility of company compliance.

And QA Manager Angel Baez Vega could use electronic system workflows to manage quality events to completion and continuously improve the company's operation. With its balance of functionality, price and ease of use, Qualio was selected as eClinical Solutions's new eQMS, and the team went live in 2021.

> *"As we grow and expand into new areas, I have no doubt Qualio can support us. I didn't have that level of comfort with any of our prior eQMS platforms.*
>
> **— Evan Grunbaum**
>
> VP of Quality & Compliance, eClinical Solutions

The results

The eClinical Solutions team gave themselves a controlled, compliant and continuously improving eQMS to show excellence to clients

Demonstrable quality

eClinical Solutions face over 50 customer audits a year, as well as *ad hoc* quality information requests from customers and prospects. Qualio delivered a clear step-up from their old systems, which worked with clunky shared logins and SSO functionality.

The team can now quickly **share external access to a single, controlled source** of quality truth, proving their quality credentials, satisfying regulators and winning new business.

Consultants advising eClinical Solutions can also log in and see the entire QMS in a **matter of clicks**, accelerating gap assessments and helping them deliver more targeted support.

Lifting the lid with a scalable eQMS

Evan and the eClinical Solutions quality team recognised that their manual, spreadsheet-based QMS wasn't scalable and was holding back company growth.

Replacing spreadsheets and emails with digital documentation and workflows has **cut hours** of admin time from the working week and allowed the QMS to keep pace with the business. **100 new users** have been onboarded and trained in Qualio in the first year, as the company headcount expanded by **25%**.

Quality culture

The ease of use of Qualio has allowed Aminah to introduce new hires to the eQMS and train them quickly, helping a **quality culture to coalesce**.

System roles have been **devolved across different eClinical Solutions departments**, allowing team leads to step back from day-to-day quality work like document approval while still enjoying complete visibility. Best of all, Evan notes no complaints or resistance to Qualio, testament to its **frictionless** addition to the company.

Long-term partnership

Evan wanted to partner with an eQMS provider like themselves: technology-driven, customer-centric and rapidly expanding.

Qualio delivered that partnership. Evan, Aminah and Angel appreciate Qualio's **continuously evolving product roadmap** and the fresh functionality which continues to be unveiled a year after they went live.

With ambitious international expansion in the works, the team are confident they have the **long-term quality platform** they needed for success.