

Reaping the rewards of a new agile quality approach

About Wellcome-HRB

The **Wellcome-HRB Clinical Research Facility (CRF)** is a state-of-the-art clinical research partnership between Saint James' Hospital and Trinity College Dublin.

From its research pharmacy to its aseptic compounding suite, the Facility specializes in delivering clinical trials with optimal standards of quality and regulatory compliance.

The Facility sponsors its own trials, and works with external sponsors such as Pfizer and Novartis.

The challenge

Consistent Good Clinical Practice is of critical concern to Wellcome-HRB's quality team.

Kishor Santhosh and Sruthy Thoniparambil Vinesh are responsible for managing the organization's quality and compliance activity, and before Qualio ran monthly quality reviews to spot non-conformances and protocol deviations.

But their QMS was run entirely on paper, and these manual quality processes took up significant time, with activities like CAPAs difficult to build and close out.

Staff training was difficult to track, and there was no effective way to ensure that employees actually understood their operating procedures.

And with no centralized system for quality and compliance, the team found it difficult to prepare for audits and sponsor reviews, with some nonconformances and protocol deviations only spotted by sponsors.

Industry	Clinical research
Regulations	• GCP • ICH E6
Uses Qualio for	• Documents • Training • Events • Analytics

50%

Reduction in trial protocol deviations and non-conformances

1 week

Of admin time saved for every single new document

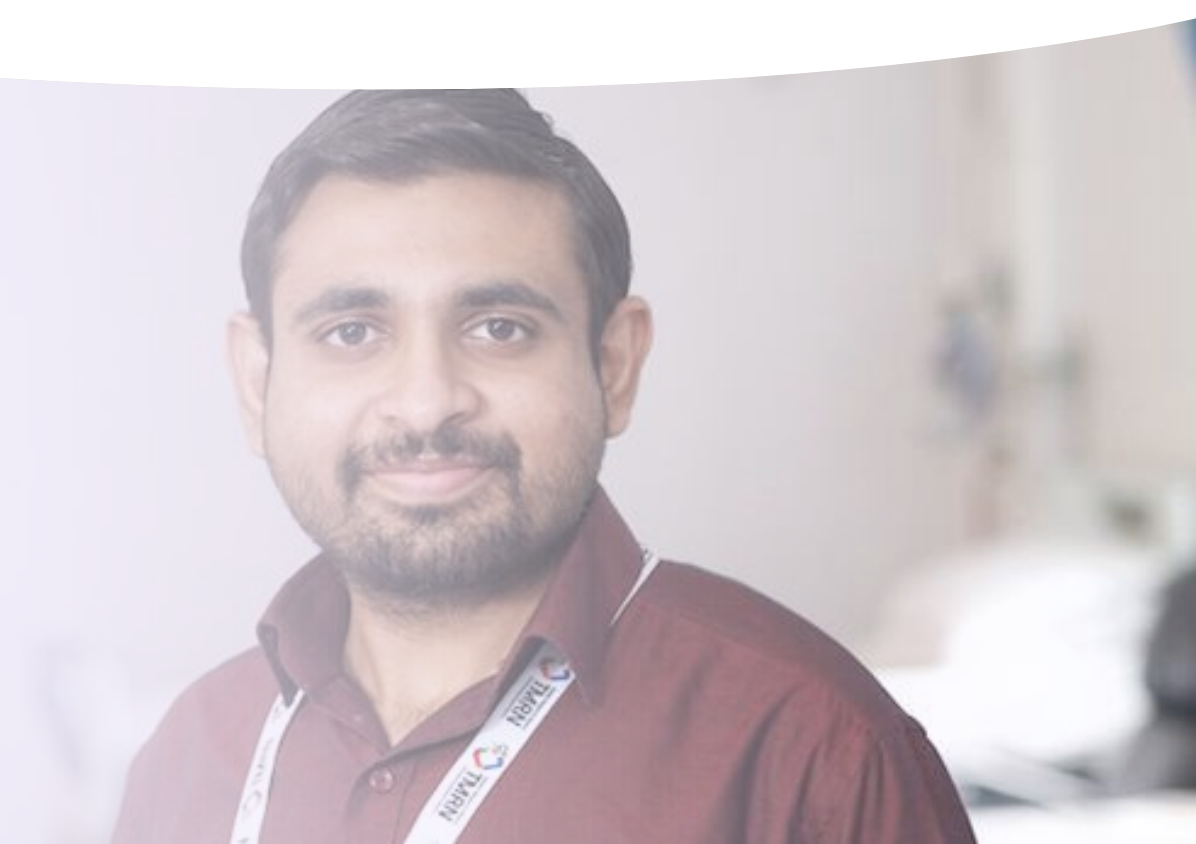
400%

Boost in trial request pipeline

"In terms of the amount of work that's now being done compared to the cost, Qualio is the most cost-efficient system we've ever had."

— Kishor Santhosh

Quality & Regulatory Affairs Manager, Wellcome-HRB CRF



The solution

It was clear that, as headcount expanded to over 40 employees, a more modern quality approach was required to keep up with the CRF's rapid growth and new trial expectations.

In 2023, Wellcome-HRB decided to transition to an electronic quality management system (eQMS).

After evaluating several vendors, including Q-Pulse and Veeva Vault, the team selected Qualio as the optimal choice due to its user-friendly interface, price, and its ability to meet the organization's specific needs through flexible configuration.

Wellcome-HRB became Qualio customers in late 2023, and went live with their new eQMS in January 2024.

"We're looking forward to extending our partnership with Qualio and using its new features, like AI.

That's the way forward.

We're looking forward to all of that."

— Kishor Santhosh

Quality & Regulatory Affairs Manager, Wellcome-HRB CRF

The results

A more proactive quality set-up to attract new sponsors

Daily quality reviews that hit the mark

Sruthy and Kishor couldn't keep up with the paper and admin demands that came with daily quality checks.

But the agility and efficiency unlocked by Qualio made this approach possible for the first time.

Moving to daily checks, powered by Qualio, allowed more protocol deviations to be detected, with faster resolution and better QMS visibility bringing the number of non-conformances and significant deviations **down by 50%**.

A quality system for the entire operation

Sruthy notes that **staff satisfaction and engagement have skyrocketed**, with Qualio's intuitive UI and high levels of automation removing the headache from quality and compliance and helping a collaborative quality culture take root.

All departments within the Facility — from quality team to pharmacy lab, nursing staff and doctors — can access Qualio in the cloud to contribute to quality tasks, and both Sruthy and Kishor are keen to expand their user numbers even further.

Faster processes

Back-and-forth document-building with the range of departments within Wellcome-HRB took huge amounts of time for Kishor and Sruthy to complete.

Quality process speed has taken a dramatic boost with Qualio's powerful collaboration functionality, with Kishor estimating a week saved for every single new SOP publication — **down to 3 days from 10**.

Murky, difficult-to-track wet-signature training processes have also been completely eliminated, with all Facility training now centralized within Qualio.

Higher quality = more sponsors

This optimized digital quality has paid off, with improved sponsor satisfaction bringing a jump in Phase I trials in the pipeline from **1 to 5**, and the Facility being widely recognized by key sponsors as an **optimal, GCP-centric** operation to trust with complex trials.

Kishor and Sruthy link this increased sponsor demand directly to the stronger quality approach they've implemented — and the positive feedback generated from sponsors as a result.