# 0 to 13485 in 6 months

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|---|---|
| **Industry** | Medical device / Pharmaceutical |
| **Regulations** | • ISO 13485<br>• ISO 14155<br>• Medical Devices Regulations 2002<br>• UK Statutory Instruments<br>• FDA and EU Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) |
| **Uses Qualio for** | • Documents<br>• Training<br>• Events<br>• Design controls |

## About 30 Technology

UK-based developer of therapeutic nitric oxide products. With a medical device in development and laboratory-driven pharmaceutical products as well, 30 Technology has a complex double regulatory landscape to navigate.

## The challenge

30 Technology has two products in development for the market. A quality culture of continuous improvement means the business is constantly looking to:

- Challenge existing processes
- Embed a right-first-time go-to-market approach
- Unlock faster, smarter ways of doing things

Above all, a largely remote team required digital access to, and training on, the latest and greatest operating procedures with strict version control.

But a heavily paper-based QMS meant a slew of time-heavy manual processes which cluttered and complicated compliance, as Head of Quality & GxP Compliance Karen Hue discovered when she joined the business.

Karen wanted to implement a simpler electronic way of managing the 30 Technology QMS, that matched the company's size.

Speed, agility, cost-effectiveness and ease of use were the primary requirements.

**97%**

Reduction in quality task completion time

**ISO 13485**

Stage 2 certification unlocked in 6 months

**3x**

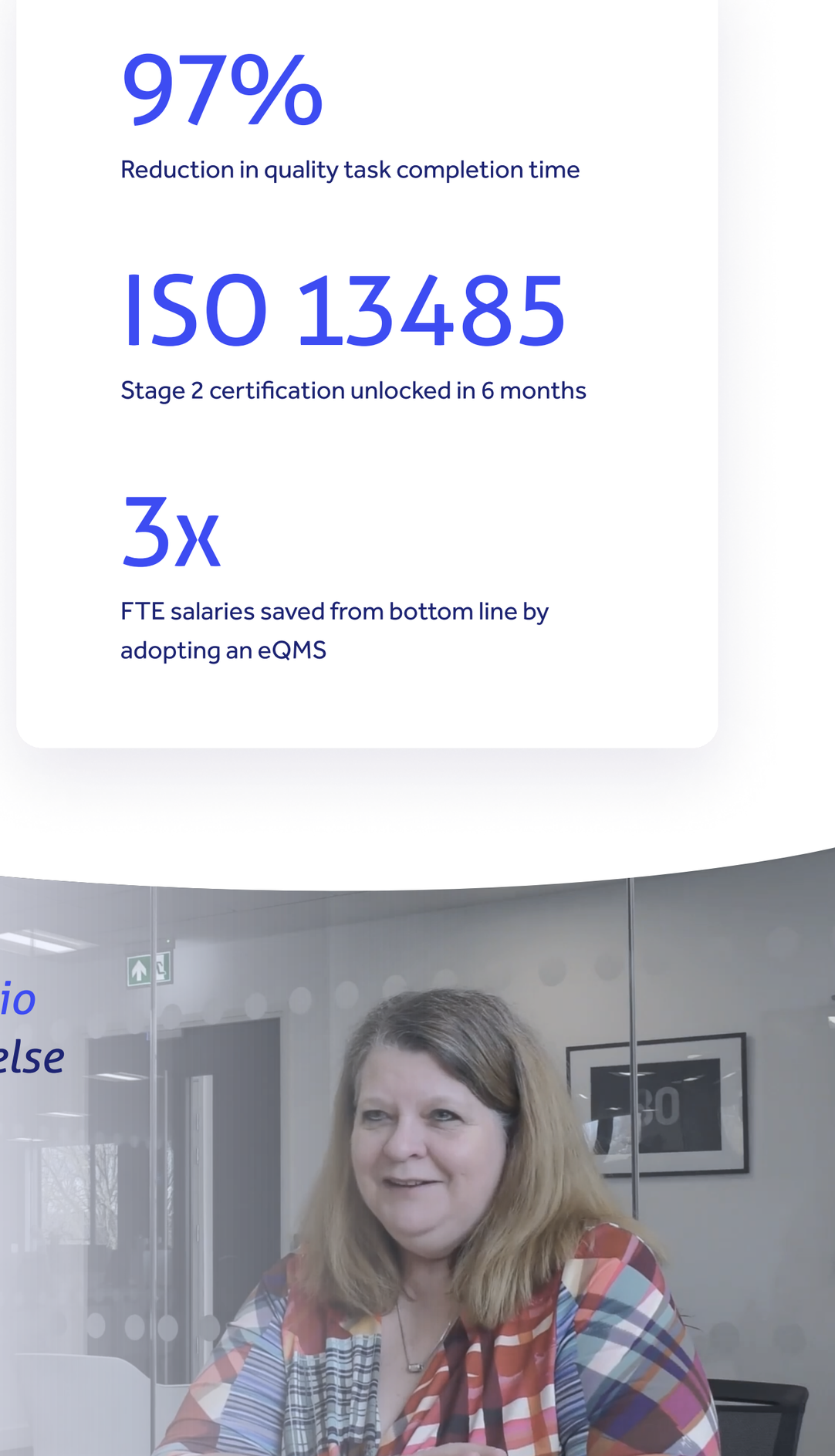
FTE salaries saved from bottom line by adopting an eQMS

*"My colleagues always go, 'You just talk about Qualio the whole time!' I think half the reason everybody else likes Qualio is because I get such a buzz out of it."*

— **Karen Hue**

Head of Quality & GxP Compliance, 30 Technology

Watch case study video



# The solution

Two weeks after joining 30 Technology in November 2020, Karen led the search for an electronic quality management system (eQMS) and approached three vendors after a Google search.

Karen was impressed by Qualio and had a detailed discussion about how Qualio's software would fit into 30 Technology's operation, including cost, users and scalability potential.

After a rapid implementation and validation process, Karen and 30 Technology's Qualio system went live in mid-December and was christened Fort NOx: a nod to Qualio's security credentials and 30 Technology's nitrous oxide product base.

By January, all users were fully trained and accessing Qualio on a daily basis – less than two months after Karen's search began.

> *"I joined in November 2020. I contacted Qualio 2 weeks later. We went live mid-December. We had all users working in the system by January. And we had our Stage 2 certification by July. Without Qualio, we'd never have done that."*
>
> **— Karen Hue**
>
> Head of Quality & GxP Compliance,
> 30 Technology

# The results

## Qualio delivered dramatic operational results for Karen and the 30 Technology team.

### Time savings

Karen estimates that core quality management tasks which previously took **half a day** can now be completed in **five minutes**.

### Strong return on investment

Karen quantified the ROI of her Qualio system by comparing its cost with the manual personnel work that would have been required without it, and estimates a saving of at least three FTE salaries from the company's bottom line. Karen estimates that she'd need **5 assistants** to match the level of document control she enjoys with Qualio.

*"I'm not saying you can't do things by paper. What I am saying is that in order to really be in control and free up your time to do the real quality work, you need something that helps you in the background. I've employed an e-system to be my administrator. I don't need people and I can still do quality, because the computer is doing the work for me."*

### Confidence & compliance

Karen now enjoys complete control and oversight of her QMS, while her colleagues access a single source of truth for documents, training records and more. With centralized quality data, unified processes, and the headache and risk of manual paper management gone, Karen can now leverage her eQMS to support 30 Technology's market ambitions and drive a **continuously improving quality-centric approach**.

### Faster route to market

Karen identifies the rapid set-up of an **ISO 13485-compliant quality system**, supported by the entire business, as the standout benefit of becoming a Qualio customer. Their fully certified, quickly achieved medical device QMS has unlocked new markets for 30 Technology and will allow them to win new business into the future.