0 NCRs. 100% audit readiness

About Restech

Restech produces a suite of medical devices for minimally invasive diagnosis and treatment of reflux disorders.

The company's impressive growth and its gastroenterological device range has demanded a carefully constructed QMS to support operations in multiple international territories.

Industry	Medical device
Regulations	• FDA 21 CFR 820 • ISO 13485 • cGMP • EU MDR • UK Medical Device Regulations
Uses Qualio for	• Documents • Training • Events

The challenge

Restech and its Director of Quality Assurance Lowell Hoffman ran a manual, paper-based quality management system.

Lowell knew strong document control was at the heart of the QMS, but their old ways of working included drawn-out, labor-intensive and time-consuming document processes.

These included:

- Local saving of document copies, preventing access to centralized up-to-date information
- The time demands of creating paper folders and collecting wet signatures desk-to-desk
- Natural human errors as documents were manually circulated and used

95%

Reduction in document control process time

2 weeks

Saved resolving each quality event

0

Non-conformances in ISO 13485 audits

"The amount of time and resources needed to maintain our old QMS was tremendous. We had too many hands in the cookie jar.

The hours lost trying to keep up with the paperwork were less than an eQMS system payment."

— Lowell Hoffman

Director of Quality Assurance, Restech



The solution

The adoption of an electronic quality management system (eQMS) to eliminate admin time and lift the lid on quality-centric growth had been a long-term Restech priority for several years. Well aware of the powerful business benefits offered by digital quality, Restech's senior management team tasked Lowell with sourcing the best medical device eQMS platform.

Since the systems Lowell found all offered broadly similar functionality, the deciding criteria had to be:

- Cost
- Ease of use
- Look and feel
- Ease of set-up and transfer from the old QMS
- Long-term customer support

Taking all these factors into account, Lowell pinpointed Qualio as the optimal choice, and Restech became Qualio customers in 2022.

> *"I've never been more confident in my 27 years of being audited."*
>
> **— Lowell Hoffman**
>
> Director of Quality Assurance, Restech

The results

Qualio demolished the burden of Restech's paper QMS, turning quality from admin exercise to continuous improvement tool

Efficient, paperless quality

Restech's quality and other department leads contributed multiple hours each week to manual document upkeep, a single Qualio administrator now orchestrates Restech's information with ease. **Document update processes** which took 2 weeks now take 4 hours. And by managing quality events like CAPAs and deviations with configured digital workflows, **10 days have been cut from each event close-out**.

A compliant, audit-ready medical device QMS

100% of the Restech team now complete their quality training on time, effectively positioning the company for regulatory scrutiny. In Restech's recent ISO 13485 audit, they received **0 non-conformances** – and Lowell knows his new eQMS is responsible.

"Qualio was a big factor in our audit. Getting everyone easily and effectively trained is one of the best benefits of the software. My admin smiles every time she goes to the training section of our Qualio system!"

Long-term success

Lowell felt supported by Qualio from Day 1. He credits the online Help Center as the **'shining star'** of the system in his early days of usage, and the only online help functionality he's found truly beneficial in his career. With full confidence in Qualio as a long-term business tool, Lowell now plans to roll the system out to Restech's San Diego facility.

He also plans to start using Qualio's **supplier and design controls management functionality**, as well as using Qualio's Salesforce integration to pull customer quality events straight into Qualio. With transition from the EU's MDD to the MDR next on the strategic list, Lowell sees Qualio as a 'big part' of Restech's future success.

Refocused energy

Free from the manual admin demands of a paper-based QMS, Lowell and the team now have time to focus on **continuous optimization** of Restech's products and processes. The cost of Restech's Qualio investment has been cancelled out by the **hours of value-add work** regained from the team's old ways of working.