Making quality software work for the business, not the other way around

Industry	Medical device
Regulations	• FDA 21 CFR 820 • ISO 13485 • MDSAP • MDD CE marking
Uses Qualio for	• Documents • Training • Events

About TriMed

TriMed is a California-based medical device manufacturer. Their upper and lower extremity orthopaedic implants help patients recover from musculoskeletal damage.

The challenge

TriMed went through two previous quality management set-ups:

1. A paper-based system

Though sufficient at first, TriMed's manual paper-based approach was unsuitable as the company began to grow past 10 heads, with clunky manual searching and suboptimal control. Manually moving documents from desk to desk, and information going missing as it routed around the business, forced TriMed to consider a stronger option.

2. A competitor eQMS

TriMed then moved to a medical device eQMS to replace their paper system. Although the inflexibility of this system was initially a perceived advantage, allowing TriMed to get a regimented digital quality approach in place very quickly, it began to cause ‘widespread frustration’.

Inefficiency, and an inability to scale, configure and evolve to match TriMed's growth, prompted Quality Assurance Director Michael Holcomb to search after just 18 months for a more suitable eQMS platform.

98%

Company training completed on time

29%

Reduction in customer feedback cycle time

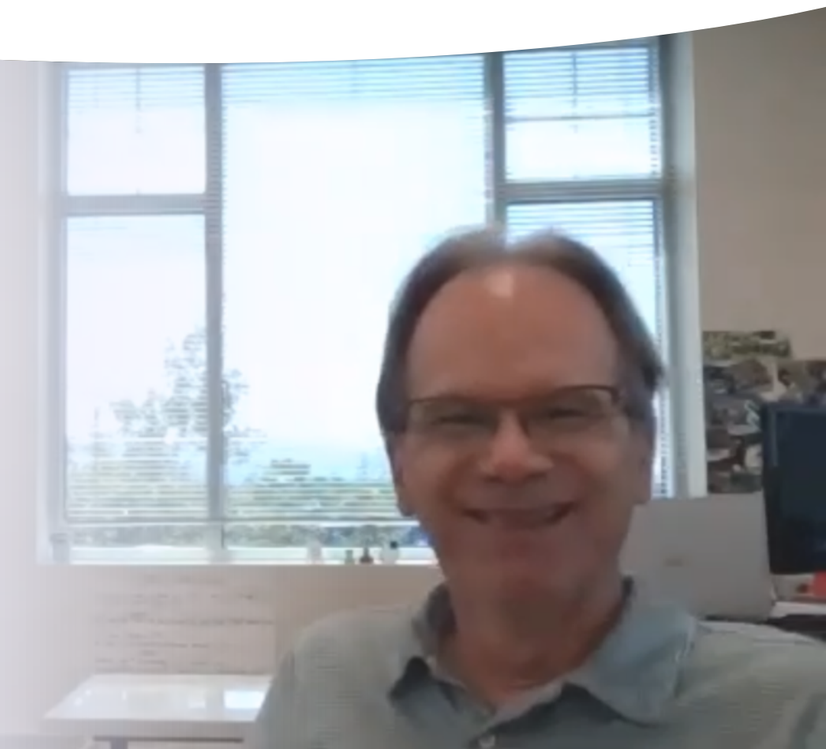
100%

Engagement with the quality system

“Once you have more than 10 people, paper-based just doesn't work. Qualio is far superior to other systems I've worked with in the past. The limitless configuration is truly beneficial.”

— Michael Holcomb

Quality Assurance Director, TriMed



The solution

TriMed had no in-house IT team capable of writing validation protocols, and so a trusted vendor who could ‘spoon-feed’ validation and perform the heavy lifting of validation activity was a key criterion.

Mike and the team used a hands-on approach of demos and vendor calls to whittle down their choices, before the 'lightbulb' moment happened with Qualio.

TriMed became Qualio customers in November 2021. The expert validation approach Mike was looking for was completed in a matter of days, and TriMed was live and ready to use the system by early December.

> *“I realized, ‘oh my God, this is fantastic!’ We could configure Qualio within its validated state almost unlimitedly. I realized I could set up any process flow that matches us, rather than having to adapt to a system. The flexibility has been mind-boggling.“*

— Michael Holcomb

Quality Assurance Director, TriMed

The results

TriMed were ‘third time lucky’ with Qualio, enjoying a highly configurable and scalable quality system for the first time.

Business-wide engagement

The contrast in engagement between Qualio and TriMed’s previous eQMS was instant. Where previous eQMS implementation was half-finished and engagement was limited to content and quality owners, Mike saw an instant **100% engagement** with Qualio, with trainees, quality staff and even consultants actively logging in.

Return on investment

Qualio has helped to **pay for itself** by:

1. Removing the need to expand the quality team into an ‘an army of document control specialists’, and...
2. Accelerating TriMed product development, by aligning staff around clearly documented right-first-time processes

A configurable, flexible eQMS

Unlike TriMed’s previous eQMS, Qualio can be **configured to match TriMed’s exact quality process preferences**. Mike praises the ‘limitless configuration’ as his main reason for selecting Qualio, freeing the company from having to work within the straitjacket of their old system.

Quality culture

98% of scheduled training is now completed on time, keeping the TriMed team compliant, competent and audit-ready. Mike’s favorite Qualio feature is its search functionality, which gives him at-a-click access to any document with a quick keyword search.

Qualio has also simplified and smoothed notified body audits, allowing Mike to quickly collate and present information to auditors.

Faster, sharper quality

Thanks to the remediation workflows within Qualio Events, TriMed can close out quality processes around **30% faster**. Customer feedback cycle times have drastically reduced by **22 days each**. And Mike and the team can add real-time comments to system activity within Qualio, allowing them to collaborate and share information faster than ever.