Cascading quality from a Qualio customer to their own clients

EFFECTUM MEDICAL

Industry	Medical device
Regulations	• EU MDR • EU IVDR
Uses Qualio for	• Documents • Training • Events • Design controls • Suppliers

About Effectum Medical

Switzerland-based **Effectum Medical** acts as a legal manufacturer, QMS consultant and Swiss Authorized Representative to accelerate access to the European markets for its diverse range of medical device clients. The company is highly engaged in the start-up field and aims to promote innovation and best practice early in the development of client companies.

By offering a mixture of consultancy and a 'plug-and-play' digital QMS document set, the Effectum team of medtech experts helps their customers hit the market and embed lasting compliance with the EU's MDR and IVDR.

The challenge

The Effectum Medical team is small, but combines a complex grouping of administrative, quality, regulatory, supply chain and product design/ development departments.

Prior to the move to an eQMS, the company's quality management system was largely manual, driven by wet signatures, email, and manual training record generation.

The company wanted to strengthen and accelerate Effectum's operation. A small improvement was achieved by switching to DocuSign for electronic signing of documents, but the execution of DocuSign processes remained time-consuming and further digitization was desired.

It was clear that a dedicated electronic quality management system (eQMS) was required - and increasingly requested by Effectum's tightly regulated medtech clients.

6 hours

Saved every week managing documents

6 months

Cut from Effectum Medical clients' go-to-market time

50%

Faster quality event processes

"We saw that a lot of eQMS systems are really not so user-friendly, and that was making us hesitant to introduce them. But with Qualio, we've not had a single customer saying it was difficult to use the system, or that they didn't understand it — that's very satisfactory for us."

— Karina Candrian

CEO, Effectum Medical



The solution

As a small company, Effectum Medical needed a cost-effective eQMS designed for SMEs.

They also had a unique use case: they wanted an eQMS to optimize their own quality activities, but also to share with and offer on to Effectum clients to help them get to market with a robust quality set-up of their own.

Several solutions were assessed by usability, cost and functionality. A clean, user-friendly eQMS, which could let Effectum Medical clients manage quality but not see the private information of other clients, was vital.

Effectum underwent a thorough vendor search to find the most suitable solution.

Qualio emerged as the clear platform of choice, and the company went live with the system in July 2023.

"We're really seeing the whole benefit of everything being able to communicate together. Our internal risk is reduced by increasing collaboration between our teams.

And our clients can pull what they need for management reviews straight from Qualio Analytics, which is a great aid for them.

I also like our collaboration with the Qualio team. Everyone's been brilliant."

— Camilla Messerli

Head of QM & RA, Effectum Medical

The results

A collaborative quality system for Effectum Medical and their customers

Parent-child quality set-up

Qualio's configurable view and access permissions gave Effectum the flexibility to construct the **connected, digital quality environment** they wanted to share with their clientele.

Shared information, including SOPs, can be accessed by clients from Effectum's main 'parent' system – while individual client 'child' systems house **confidential documents** relevant only to that client, such as technical product information.

Effectum clients enjoy **instant access** to a holistic, market-ready quality set-up – while Effectum use their own Qualio system to coordinate with clients, share information and guide their clients to **market success**.

Higher-quality service

Since implementing Qualio, Karina and Camilla report both faster and easier quality processes – free of the manual admin demands of their old set-up.

Training, supplier and document management have been largely **automated** and quality event and design control processes **centralized**, saving the team at least **6 hours every week** to commit to continuous improvement and extra client support.

Accelerated speed to market

Effectum Medical's clients want to hit marketization and profitability as soon as possible. But the complex regulatory demands of the EU's MDR and IVDR represent a significant hurdle.

By leveraging the **pre-built quality document templates** in Effectum Medical's Qualio system, Effectum's clients can skip the time-consuming headache of constructing a QMS from scratch themselves. Camilla estimates **half a year of time savings** for each of their clients' routes to market.

Industry reputation

Karina was keen to keep Effectum Medical competitive and attractive to new clients by adopting a **best-in-class quality platform**.

As the medtech industry continues to digitize, potential Effectum clients increasingly preferred to work with industry partners who were using an eQMS to manage their quality.

By adopting an **easy-to-use, cost-effective and fully digitized quality platform**, Effectum Medical have boosted their competitiveness and ability to attract fresh clients.