

Total audit confidence for a medical device manufacturer



About Tamer Mölnlycke Care

Tamer Mölnlycke Care is a joint venture between the Swedish Mölnlycke Healthcare and the Tamer Group, based in the latter's native Saudi Arabia.

The venture, launched in 2021, represents an ambitious mission to bring a host of new medical devices and healthcare products to the GCC and MENA regions.

Tamer Mölnlycke acts as a contract medical device manufacturer, making a range of devices for clients from wound care and operating room products to surgical gloves.

The challenge

After launch in 2021, it was clear that Tamer Mölnlycke required both ISO 13485 accreditation and certification from the Saudi Food & Drug Authority in order to commence its work.

But as a brand-new operation, the company had no established quality system or processes in place.

QEHS and Regulatory Manager Omran Falemban knew from previous experience that suboptimal document and quality processes could make his day-to-day work much more difficult - and he was keen to start the new company off on the best possible footing.

"We're confident to receive any audit at any time.

If anyone wants to review our documents, we always use Qualio. Very beneficial, flexible, robust."

— Omran Falemban

QEHS and Regulatory Manager, Tamer Mölnlycke Care

Industry	Medical device
Regulations	<ul style="list-style-type: none">• ISO 13485• Saudi Food & Drug Authority
Uses Qualio for	<ul style="list-style-type: none">• Documents• Training• Events

10x

Document approval speed vs. paper

1 month

To build a fully audit-ready ISO 13485 eQMS

100

Employees, all Qualio users



The solution

It was recognized by company leadership that an integrated electronic quality system offered the best, fastest route to regulatory compliance and optimal operational quality, and the company began the search in early 2022.

Qualio soon emerged as the clear winner, based on price, flexibility, and Qualio's deep specialization in the medical device sector.

After becoming a Qualio customer, Omran and the team enjoyed a fast, guided expert implementation built around the company's ISO 13485 accreditation plans.

Tamer Mölnlycke received [pre-built content and templates](#) to accelerate their ISO 13485 compliance, and were up and running with their new medical device eQMS in just a month.

"We took document templates from Qualio. We also gave them our existing ones and got a gap analysis.

They uploaded them and did a full migration, and our implementation was completed with our validation in around one month."

— Omran Falemban
QEHS and Regulatory Manager,
Tamer Mölnlycke Care

The results

Rapid ISO 13485 certification — and ongoing audit readiness for the future

Ready for certification at speed

As an ambitious new company, Tamer Mölnlycke wanted to prepare for **ISO 13485 certification as quickly as possible**.

As well as receiving Qualio's eQMS software platform, targeted support from the Qualio team, including pre-built medical device QMS templates and expert advice, allowed Omran and his team to construct a mature, audit-ready eQMS set-up in **just one month**.

Audit success

Tamer Mölnlycke **sailed through their ISO 13485 audits** with Qualio, giving them the certification they needed to begin production.

Subsequent audits, from the Saudi FDA and from the company's sponsor, have all gone smoothly, with auditors **singling out Qualio for its speed, ease of use, and ability to clearly and simply demonstrate compliance**.

Omran now feels totally confident for future audits, too!

Faster, nimbler quality processes

Omran had worked with paper-based quality systems in the past, and was keen to avoid their headaches as Tamer Mölnlycke got ready for production.

Cloud-based document access now connects everyone in the company, accelerating key processes like approval from **a full week to less than a day**.

Digital quality workflows for events like CAPAs and complaints also live in Qualio, giving Omran a single repository for his day-to-day work.

Quality at the core

All of the company's 100 staff now engage with Qualio for key compliance activities like document access and training.

The company now plans to expand its Qualio usage to new levels by bringing all documentation into the platform. And as Tamer Mölnlycke begins to distribute its products to customers, pre-built workflows for processes like complaints and CAPAs are standing by, giving the company a **quality-centric set-up for the future**.