Building a new digital quality approach

Zalgen

Industry	Medical device
Regulations	• FDA 21 CFR 820 • ISO 13485 • EU IVDD (CE marking)
Uses Qualio for	• Documents • Training • Design Controls • Suppliers

About Zalgen Labs

Zalgen Labs manufacture diagnostic kits for the detection of deadly diseases, from Lassa and Ebola to SARS-CoV-2.

Their diagnostic division spun out of a larger predecessor in 2016, and needed their own quality management system to operate.

The challenge

The company's formation from a larger, pre-existing company created an unusual inverted start-up dynamic: a team of fewer than ten staff serving around thirty separate medical device products to a handful of dedicated research customers in West Africa.

Their parent company's complex and mature QMS couldn't be easily translated into Zalgen Labs because of their much smaller headcount.

And as the company began to plan FDA 21 CFR 820, EU IVDD and ISO 13485 compliance to expand market presence, it was clear that their legacy, manual and highly paper-based QMS couldn't be efficiently run with a small team.

cGMP requirements like production records and SOPs could be met only with maximum effort, leaving little time for other key medical device quality management activity like design controls.

Director of Diagnostics Development Matt Boisen was spending over 80% of his working time on quality and regulatory, leaving him little time for his core work of product development.

100+

Legacy documents digitized and migrated into Qualio

90%

Of quality documents managed in Qualio

1

System for long-term ISO, FDA and EU compliance

It's so much easier to work in the Qualio workspace, find what you need, edit it, reference it.

It's a cultural change that's been really helpful."

— Matt Boisen

Director of Diagnostics Development, Zalgen Labs



The solution

Matt knew that an electronic quality management system (eQMS) wouldn't only give Zalgen Labs an agile and efficient system that could be easily run by a small team.

It would provide a more nimble, scalable system that could more easily keep up with regulatory developments and the latest best practice. Matt and the Zalgen team homed in on Qualio for 3 reasons:

1. Qualio's competitive, value-based pricing fit Zalgen's budget
2. Qualio's training functionality was identified as the most mature on the market
3. Qualio's customer support, with strong US presence, was the most comprehensive, offering the perfect solution for migrating and digitizing Zalgen's complex document stack

We've got our documents migrated over. We're filling the gaps, fixing the procedures that weren't correct.

The expertise of Qualio has helped too. There were areas where we were behind the state of the art – but we've had Qualio to fall back on and ask questions."

— Matt Boisen

Director of Diagnostics Development, Zalgen Labs

The results

Qualio gave Zalgen Labs a fully digitized quality system to stand behind for the future

A quality system for a start-up budget

The growing pains of trying to adapt Zalgen Labs' parent company's legacy QMS to a team of 10 have been eliminated.

Qualio empowered Zalgen with a **cost-effective, agile digital framework** for managing quality more effectively and, in Matt's words, 'firing on all cylinders' without breaking the bank.

Headcount expansion, including a director-level quality hire, was mitigated, delivering immediate return on investment.

And Zalgen Labs are now approaching the tipping point of maximizing their Qualio ROI, positioning themselves for their next phase of growth with a compliant eQMS firmly in place.

Redirected time and effort

Matt no longer needs to allocate four-fifths of his time to quality and regulatory upkeep.

Automated system guardrails and digital workflows set repeatable, unshakeable quality processes, freeing Matt to focus on his primary role of R&D for Zalgen's next wave of products.

Paperless control

With close support from the Qualio team, Matt could adapt and optimize Zalgen Labs' stack of over **100 documents** as it was digitized and fed into Qualio.

More than **90%** of the company's documentation is now securely handled in Qualio, ending what Matt called a 'Wild West' of uncontrolled legacy documents.

Digital medical device eQMS

Internal company training is now trending in the right direction, for 'Matt cleaning up the gaps' of internal competence and compliance with fully traceable cloud-based training.

Qualio Design Controls, meanwhile, has given Matt and the Zalgen Labs team a central area for **boosting control of device risks** and building fresh Design History Files, taking the company a big step closer to their next objective of preparing key devices for **CE marking and 510(k) submissions**.