Ready for 510(k) in 90 days

About SimBioSys

SimBioSys is the developer of an innovative Class II software as medical device (SaMD) platform designed to revolutionize computational oncology.

By digitally modelling breast MRI scan data, including tumor growth and medicinal impact, SimBioSys' TumorSight platform unlocks precise, pre-simulated cancer care that saves lives.

Industry	Medical device
Regulations	• FDA 21 CFR 820 (510(k)) • cGMP • ISO 13485 • IEC 62304 • MDSAP
Uses Qualio for	• Documents • Training • Events • Design controls

The challenge

SimBioSys faced the typical challenge faced by any life science start-up: the blank slate.

The company in its fledgling state had no internal regulatory expertise or a functioning quality management system. Besides a handful of documents in a OneDrive folder, the company lacked a real quality structure or documented basics like a quality manual.

When VP of Regulatory & Quality Hilary Baldwin joined the team, she brought some valuable eQMS experience with her and recognised the powerful business benefits of going straight to a digital eQMS and sidestepping paper altogether.

The remote, software-focused and pro-digital culture of the business supported this decision.

Hilary's first task was therefore to position the company for success by implementing a suitable, trusted eQMS platform to build the company's digitized quality system into. Along with VP of Software & IT Michael Hallock, she began the search.

20 hours

Of quality admin time reclaimed every single week

1 month

Cut from marketization prep time

110

QMS documents linked and controlled in a centralized library

"Being able to assemble our risks, traceability matrices and documents in real time saves us so much work.

Normally, regulatory has to compile all that at the end. We're going to get it straight from Qualio. That's a saving of months and weeks."

— Hilary Baldwin

VP of Regulatory & Quality, SimBioSys

The solution

Hilary had implemented MasterControl in a previous role and hadn't enjoyed the experience.

It was critical she found a system that was easy to use, could be quickly validated, and would accelerate SimBioSys' journey to market.

A colleague from a previous role, Becki, had implemented Qualio at her own company Synthego and passed their first ever FDA submission with flying colors.

After a glowing endorsement of Qualio and its ease of use, Hilary wanted to try the system herself.

> *"I feel 100% ready in our 510(k) and ISO 13485 preparations. I honestly think our success is in the bag.*
>
> *If we didn't have Qualio, it'd be something we'd struggle through. But having the tool and the support from the Qualio team has let us bring quality in-house in a way that will make us successful."*
>
> **— Hilary Baldwin**
> VP of Regulatory & Quality, SimBioSys

The results

The fast, easy eQMS set-up Hilary needed was delivered by Qualio - and regulatory approval quickly followed

Trusted industry support

Hilary worked with Sumatha in the **Qualio+** team for targeted QA/RA support that accelerated SimBioSys' quality and compliance preparations.

Sumatha used her **20 years** of medical device industry expertise to help populate SimBioSys' shiny new eQMS with **templated content**, and to advise Hilary and the team on their **510(k) and ISO 13485 journey**.

A digital tool to match the culture

As VP of Software & IT at an SaMD technology company, Michael was keen to make **efficient, digital work** as widespread as possible.

After widespread frustration within the team caused by Excel-driven design control work, Qualio provided an integrated, **built-for-purpose eQMS platform** that provided 'the missing piece of the puzzle' and makes quality and compliance **natural, enjoyable and automatic**.

Successful 510(k) clearance

The company's first Qualio users logged in **within a month** of purchase, and a complete QMS was built into the software in just **90 days**.

Everyone in the team, from staff to contractors and consultants, now use Qualio for document access and training activities, from HR and HIPPA to privacy, day-to-day SOPs and ISO 13485 readiness.

Most critically of all, Qualio helped SimBioSys clear their first major regulatory hurdle, with Hilary and the team successfully securing a **right-first-time 510(k) clearance** for TumorSight in December 2023.

Quality as enabler, not blocker

Qualio allowed Hilary and team to sidestep the time-sapping admin work of a manual QMS.

Hilary estimates the software has saved her **20 hours a week**, in turn **shaving months** from SimBioSys' 510(k) timeline.