Embedding TGA and ISO compliance for a wellness pioneer

Industry	Wellness
Regulations	• ISO 9001 • ISO 13485 • ISO 17025 • TGA (essential principles)
Uses Qualio for	• Documents • Training • Events • Suppliers

About Drop Bio Health

Drop Bio Health is an Australian at-home health technology company that delivers personalized, evidence-based health and wellness insight by combining lifestyle data with biomarker analysis from fingerprick blood samples collected at home.

Laboratory testing of these small blood samples, collected with Class IIa *in vitro* diagnostic kits, takes place at Drop Bio Health's accredited laboratory at the University of New South Wales in Sydney, Australia.

The challenge

Central to the successful delivery of blood test and analysis services is consumer and clinician trust.

Co-founder and CEO Phil Hayes-St Clair knew that a strong quality and compliance focus was essential for the company to succeed.

But to complicate matters, the organization's 'wellness' product doesn't fit neatly into either an *in vitro* diagnostic medical device *or* therapeutic category.

In the absence of clear wellness-specific guidelines, Phil and the company were left to try and 'thread the needle' through a largely grey, complex regulatory area combining both TGA and ISO requirements.

85%

Of documents migrated into a purpose-built eQMS

1

New wellness product launched in first year of using Qualio

1

Dedicated cloud-based quality platform

"Everything you see in our new WellBeing experience is built off the back of our quality system in Qualio. It's a great manifestation of what sits behind to make that kind of product work."

— Phil Hayes-St Clair

CEO, Drop Bio Health



The solution

Digital medical device expert Dr. Lee Walsh was engaged by Drop Bio Health soon after he departed the TGA to establish his advisor business, Platypus MedTech Consulting.

Dr. Walsh recommended that the company replace the online workflow system they were using for quality management and upgrade to a dedicated eQMS.

Dr. Walsh helped Phil and the team to review the eQMS market for the perfect vendor, keeping Drop Bio Health's unique requirements in mind.

Adaptability and scalability were both crucial, since the company plans to offer a range of wellness and medical device products in the future.

Qualio was identified as the optimal choice, and Drop Bio Health went live with their new quality system in August 2022.

"It was obvious Qualio would let us do things bespoke. Other platforms were like a LIMS with a bit of quality on the side. That wouldn't work for us.

And because we use so many SaaS tools, we had to think carefully about integration with everything else we're doing."

— Phil Hayes-St Clair

CEO, Drop Bio Health

The results

Phil and his company adopted a purpose-built tool to put quality front and center

Controlled roll-out

Phil and the Drop Bio Health team started small with Qualio, then began to roll it out business-wide as its impact became clear. 9 of the 13 members of the team now access the system, with full adoption around the corner.

85% of legacy documents and **100% of supplier records** have been migrated from the company's legacy QMS into their new eQMS. Phil is now rolling out Qualio's new **Training Plans functionality** and enjoying watching a '**base level of compliance**' infuse across the company with automated tracking and roll-out of training requirements.

Product launch

Centralizing documentation, training, quality processes and even supplier management has given a **new level of quality control** and visibility to the organization. Within a year of going live with Qualio, Drop Bio Health were ready to **launch Version 2** of their WellBeing at-home healthcare experience. Phil credits Qualio with providing the 'critical layer' of quality management which **made the launch possible**.

Consumer & partner trust

Tracing and fixing quality issues at source wasn't possible with Drop Bio Health's legacy QMS. Qualio unlocked **full traceability** and **root cause regression analysis** of quality events from a single cloud-based source of truth, empowering Drop Bio Health with the ingredients for **confident, continuous improvement**. In turn, Phil knows that his customers and partners have '**confidence in what we're doing in quality**' – crucial as the company expands into 'game-changing' contract research work for fertility and cardiovascular treatments.

Ownership and input

Phil spotted a **positive cultural shift** in the first year of using Qualio, with SOPs, processes and quality elements now **owned and supported by the entire organization**.

"I'm in every quality meeting. I've never heard anyone say, "oh, that's Tahseen's SOP. That's Connor's SOP". This is the quality manual, this is the SOP. People look at them at a cultural level as key to what we do. I'm pretty proud of that."