A supportive vendor for a rapid eQMS timeline

vectorbiomed

Industry	Biotech
Regulations	• GDocP • GMP
Uses Qualio for	• Documents • Training • Events • Suppliers

About Vector BioMed

Vector BioMed is a Maryland-based manufacturer of lentiviral vectors used in gene therapies and medicines.

As a biotech manufacturer, cGMP compliance and a strong, integrated quality management system are crucial operational requirements.

The challenge

Vector BioMed's quality team, led by Quality Assurance Specialist Bennett Klusas, wanted to adopt a fully digitized quality approach, leapfrogging the limitations and eventual operational ceiling of their paper-based set-up.

Embedding ALCOA++ data integrity was a key consideration, as was eliminating the physical footprint and manual demands of paper.

Critically, Vector BioMed wanted to digitize fast - setting themselves an implementation deadline of just 3 months to balance their project with the start-up and commissioning of their manufacturing facility.

An easy-to-use platform with rapid validation was therefore critical.

400

Live, fully paperless documents

30

Suppliers onboarded & managed

>95%

On-time training

"Qualio gave us the ability to move quickly, and we don't have to break things.

We accomplished our goals while complying. That's the real promise of a platform like Qualio that's well implemented and well planned for."

— Bennett Klusas

Quality Assurance Specialist, Vector BioMed



The solution

The Vector BioMed team conducted a detailed search of the eQMS market, led by some key scoping questions:

- How flexible is the system?
- How responsive and supportive is the vendor?
- Does the software meet all our operational requirements?
- What does the future product roadmap look like?

Qualio answered these questions and more.

Crucially, becoming a Qualio customer would also allow Vector BioMed to access a range of pre-built, ready-to-go system content which would accelerate their go-live speed even further. The company signed on the dotted line in mid-2023.

"We had no shortage of skeptics about Qualio's CSA validation approach.

But once they'd dug into the documentation, there was nothing else for them to really say.

They were like, 'wow, it's actually all here!' There was nothing else to do, and we had a clear pathway."

— Bennett Klusas

Quality Assurance Specialist, Vector BioMed

The results

Effective company-wide rollout ahead of schedule

Deadline success

Vector BioMed's **3-month implementation deadline** was a key factor in selecting Qualio - and Qualio's expert implementation team got to work straight away to meet the customer's required set-up timeframe.

With just a **single internal sponsor** in Bennett, Vector BioMed successfully upgraded their existing paper-based system and established a **fully functional paperless quality system** in just 3 months. Bennett credits this feat to Qualio's ease of use, best-practice validation approach and clear collaborative roadmap.

Accelerated quality build

Becoming Qualio customers allowed Vector BioMed to access a range of **pre-built, biotech industry-specific document templates** to feed into their new eQMS.

When coupled with hands-on support to migrate valuable legacy documents, Qualio gave Vector BioMed an **accelerated route to a robust, fully documented digital quality system**.

This vital groundwork allowed the company to proceed quickly to full GMP production, with the company's **first manufacturing kicking off in November 2023**.

Validation sweet spot

GAMP Category 3 eQMS platforms offer rapid set-up and light validation but limited configuration capability to mold and evolve.

Category 5 platforms offer vast amounts of customization, at the cost of huge validation burden and testing demands.

Qualio's Category 4 set-up offered the sweet spot for Bennett and the team, acting like a 'box of Lego' with pre-tested functionality adaptable to their specific business needs. The Vector BioMed team - even its cautious skeptics - reviewed and accepted Qualio's **in-depth and fully compliant validation documentation** to save themselves weeks of time and effort.

Complete quality approach

Vector BioMed's legacy paper-based eQMS was replaced with a paperless approach that **centralized quality processes for documentation, training, supplier qualification, CAPAs, deviations, change requests and more**.

Bennett came away fully happy with his Qualio experience, with a right-first-time roll-out that required no major reworks or backtracks. **Company engagement with quality has rocketed**.