






About VitaCyte

[VitaCyte](#) is a biotechnology company that manufactures high-purity tissue dissociation enzymes and cell recovery reagents, including collagenase. The company's product portfolio is designed to correlate optimal enzyme activity with specific cell and tissue types to maximize viable cell yields. VitaCyte, which was founded in 2004 and is headquartered in Indianapolis, has 11 employees.

-  **Time with Qualio / Plan**
11 users
-  **Vertical**
Biotechnology
-  **Favorite features**
Versatility, version management
-  **Impressed by**
Collaborative partnership
-  **Targeted regulatory submission**
ISO standard certification

[Visit VitaCyte website to learn more >](#)

VitaCyte uses Qualio to manufacture highly purified cell recovery reagents

The Challenge

VitaCyte began as an early-stage startup funded by an NIH grant as it pursued a commercialization path for reagents used for the recovery of cells used in human transplant therapies.

From the outset, the VitaCyte team knew they would need a robust quality management system to achieve their goals. But with limited resources, that wasn't really practical. So they built a paper-based system from the ground up knowing that they'd have to eventually migrate to something more sophisticated.

VitaCyte manufactures ancillary reagents that are used in the preparation of cells, operating in an evolving, yet-to-be-fully defined regulatory space. Recently, the company was audited by a customer's quality team, and the experience led VitaCyte to begin the process of searching for a new quality management system.

The Solution

As VitaCyte began looking for a new solution, they examined a few eDoc platforms and found that most of them were feature-heavy and rigid, catering to established pharmaceutical businesses and manufacturers of already-certified materials.

"We're a small group here, and we needed something that was a little more versatile, a little simpler, a little more approachable," Breite continues.

After exploring their options, VitaCyte ultimately decided that Qualio, the electronic quality management system (eQMS) built for medical device, biotech, and pharma companies, was best-suited for their needs.

"Qualio addressed exactly what we needed."

— Andrew Breite, Director of Quality Assurance,
VitaCyte

The Results

VitaCyte has found a powerful and adaptable quality management system in Qualio. Since there's a lot of risk in the niche regenerative medicine and cell therapy space, Qualio gives VitaCyte the peace of mind that comes with knowing their quality challenges are solved — which enables the team to accelerate their R&D efforts with confidence. Here are some of

the benefits VitaCyte enjoys by trusting Qualio for quality management.

1. Seamless Onboarding

Thanks to high-touch support from the Qualio team, VitaCyte was able to get up and running on the platform quickly. "Qualio offered to migrate all our existing documents," Breite continues. "We had some concerns about the numbering convention we had in place. But the Qualio team helped me understand how their system would adopt that same type of numbering and organization very quickly."

2. Immediate Impact

VitaCyte started using Qualio concurrently with the migration — and the ROI was immediate. Today, the company manages policies, SOPs, test procedures, and master batch records through the eQMS.

"The impact was immediately felt in terms of version management and training."

– Andrew Breite, Director of Quality Assurance, VitaCyte

Within three months, VitaCyte integrated 200 effective documents into Qualio, and they've since added 100 additional documents.

3. Streamlined Training

Qualio has also helped Vitacyte ensure employees are up to speed with the newest policies, procedures, and objectives.

"People are responsive to training requests and review and sign off," Breite continues. "We've had two new people join our team since we've had Qualio, and both of them were able to undergo the initial training period very quickly."

4. Exceptionally Secure and Reliable

As a small shop, VitaCyte doesn't currently own any patents. Everything they do is a trade secret, which means they can't afford to compromise on security.

Since Qualio encrypts data in transit and at rest and takes a proactive stance toward protecting customer

data, VitaCyte is able to secure its intellectual property. Additionally, thanks to Qualio's high-availability architecture, VitaCyte has a reliable eQMS that enables them to work productively whenever inspiration strikes.

5. A True Partnership

VitaCyte has found a true partner in Qualio. Not only did Qualio help Vitacyte seamlessly transition to the eQMS, they also regularly solicit feedback from Breite, who's particularly excited about the new Design Controls module.

"When I interfaced with the team, they asked me for feedback," he says. "It's great to know the platform is evolving in line with our needs."

Breite also enjoys the steady stream of helpful content that Qualio publishes — ebooks, guides, and webinars.

"The content is so helpful because it provides a tangible connection to others who are working in that space."

– Andrew Breite, Director of Quality Assurance, VitaCyte



Qualio can help your biotech company accelerate product development while maintaining regulatory compliance

[Schedule a demo today](#)