‘Lighting the fire’ of a real quality culture

AKADEUM LIFE SCIENCES

Industry	Medical device
Regulations	• FDA 21 CFR 820 • ISO 13485
Uses Qualio for	• Documents • Training • Suppliers

About Akadeum Life Sciences

Akadeum Life Sciences makes isolation products leveraging the gentleness of buoyancy to capture chemical and biological targets.

Their innovative flotation-based microbubble technology isolates samples of cells, proteins, exosomes, nucleic acids and more with complete integrity and quality.

The challenge

Quality Assurance Manager Angela Pinkston joined the Akadeum team in June 2022, just as the company was beginning to search for a better way to manage quality.

The early-stage company takes good manufacturing practice (GMP) and continuously improving quality seriously, but a paper- and spreadsheet-based QMS was demanding huge amounts of upkeep and admin time.

SOPs, forms and records were all manually managed by Angela in a process with lots of duplicated effort and stress.

Document revisions meant editing, converting to a PDF, sending to DocuSign for signatures, then saving the returned copy into the company's internal records.

Manually assigning and recording training, meanwhile, could take an entire day at a time.

99%

Reduction in quality admin time

100%

Improvement in job satisfaction

99%

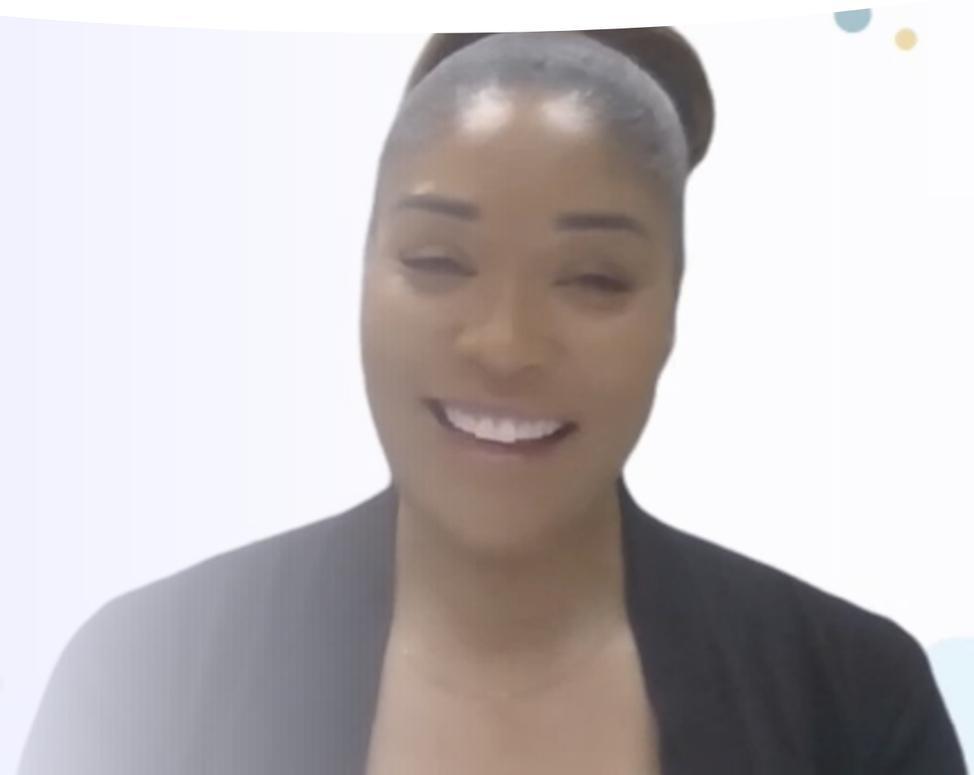
On-time training

“Document control took anywhere from 5 hours to 3 days. Now things get done in hours, even minutes. I can send training out in seconds now.

Qualio has made my life 100% better!”

— Angela Pinkston

Quality Assurance Manager, Akadeum Life Sciences



The solution

The Akadeum team had already begun scoping eQMS platforms as Angela joined, and had a frontrunner in mind. Since Angela had previous eQMS experience from other roles, she was tasked with taking over the search.

An easy-to-use system with fast implementation was her main criterion after going up against other clunky platforms in the past. Akadeum also wanted a cloud-based system to support its business continuity and disaster recovery objectives, and an audit-ready platform which could go under the microscope of an FDA inspection.

After performing her own search of the market, Angela identified the same frontrunner as the rest of the team: Qualio.

Akadeum became Qualio customers shortly after, and Angela and the team were guided through a 'seamless' implementation and training process which completed in a 'phenomenal' 3 months - much shorter than Angela was expecting after her previous eQMS experience.

> *"There's a new culture of ownership since we implemented Qualio. It's like a fire lit up under everybody.*
>
> *Everyone wants a piece of Qualio and of quality. That's the one thing I did not see happening. It's refreshing for me as a quality professional."*
>
> **— Angela Pinkston**
>
> Quality Assurance Manager, Akadeum Life Sciences

The results

Digitizing quality helped Angela build a collaborative culture of continuous improvement that was impossible with paper

Airtight medical device compliance

On-time company training has rocketed to **99%**. QMS gaps have been identified and **plugged**. And a complete **design history file** (DHF) has been built with ease and confidence within Qualio.

All have helped to shore up Akadeum's quality and compliance as the company rapidly expands and prepares to bring **new, innovative tools for cell therapy applications** to market. Angela now plans to expand system usage even further, embracing Qualio Events for the first time to manage CAPAs, equipment calibrations and more.

Full visibility

Angela now enjoys 'at-a-glance' insights of document, training and supplier management activity from a single cloud-based source of truth. **100%** of that activity is now managed within Qualio. Ditching filing cabinets and complex spreadsheets hasn't only made her life easier — it's boosted company ability to act with **confidence and control** during audits.

'Ownership' of quality

Angela didn't anticipate perhaps the main impact of Qualio: the infusion of a **collaborative culture of quality ownership**.

Rather than lone gatekeeper and performer of quality tasks, Angela's colleagues now **independently** build and revise documents and drive improvement opportunities across the organization.

'Angela's SOPs' are now owned and supported by everyone!

Refocused time

Angela was spending **hours** and even entire **days** on unavoidable quality admin tasks like document revisions and staff training. She estimates a **'90-99%'** cut in admin time thanks to Qualio's functionality. This in turn has allowed her to **refocus** on value-add, improvement-based parts of her role, like internal auditing, validation and calibrations.