

Unlocking a new quality approach with Compliance Intelligence



About AGADA Biosciences

AGADA Biosciences provides expert assistance with drug development programs from its base in Halifax, Nova Scotia.

The company’s objective is to accelerate the route to market for drugs which tackle rare diseases, particularly neuromuscular afflictions.

AGADA offers an array of regulatory testing and research, and is a highly regulated CRO audited by both sponsors and regulators. The team was therefore naturally excited to try Qualio’s compliance management tool as one of its very first users.

Industry	CRO
Regulations	• Good Clinical Practice (GCP) • Good Documentation Practice (GDocP) • FDA 21 CFR Part 11

The challenge

As an early adopter of Compliance Intelligence, Chris Rice, AGADA’s Senior Quality Assurance Manager, was tasked with exploring the tool and its organizational impact.

Chris and his team looked to test its capabilities in identifying compliance gaps and improving audit readiness using the tool’s pre-built compliance frameworks.

“My confidence in being audit-ready is dramatically improved.

Feeling like you're not missing anything going into an audit is always a nice thing.

Getting all the pieces in place with evidence and documentation, getting everything ready ahead of time — you just feel good about it.”

— Chris Rice
Senior Quality Assurance Manager, AGADA Biosciences

The results

Compliance Intelligence freed the AGADA quality team's time to shift to continuous improvement



Centralized compliance approach

Before Compliance Intelligence, Chris and the team relied on a 'fragmented', 'siloed' and manual approach to regulatory compliance that involved manually checking for compliance gaps across records.

Compliance Intelligence's **constant, real-time monitoring of the entire company QMS**, from SOPs to attached PDFs, ended that approach. Instant visibility of the entire company's compliance health allows **every gap to be targeted and closed** with designated tasks — and without manual searching.



Redirected energy

For busy quality teams, cutting admin and compliance burden to free up continuous improvement opportunity is one of the best ways to maximize organizational impact.

Chris saw **his team's time freed up by Compliance Intelligence's automation**. That time, in turn, can now be reallocated to value-add activities such as process improvements and deeper focus on individual sponsor trial contracts.

Chris was pleased to see his team now focusing on building an even more 'robust' QMS, maintaining audit readiness while also being able to **maximize sponsor satisfaction, 'look to the future', and plan new certifications** as a result.

"Compliance Intelligence cuts the stress out.

It really has cleaned up that aspect of having to find pieces all over the place, and moved us to one organized system that's a lot easier to maintain audit readiness with.

We now monitor everything at once."

— Chris Rice

Senior Quality Assurance Manager,
AGADA Biosciences



Gaps flagged and fixed

Recommendations for **documentation tweaks and terminology changes** were actioned by Chris' team from suggestions raised by Compliance Intelligence, and were then satisfyingly absent from the tool's subsequent gap analyses after completion.

Compliance Intelligence also **prompted the creation of new documentation** for some of AGADA's quality management processes, making these areas more clearly defined for both staff and auditors.



Audit readiness — without the stress

Chris saw a **clear reduction in audit preparation time** from the team's use of Compliance Intelligence. Both 'compliance and confidence' are at an all-time high for the company, and the proactive approach unlocked by the tool means **every audit ingredient is ready well ahead of time**.

This optimized preparedness has **'cut the stress'** from the team and means AGADA can now face their audit schedule with total control.