5x return on investment with Qualio Compliance Intelligence



About LogixX Pharma

UK-based <u>LogixX Pharma</u> specializes in the commercialization of life science products, marketing and distributing a range of innovative pharmaceuticals, nutraceuticals and medical devices.

The company has two main divisions: one handling distribution of drugs for pharmaceutical manufacturers, and one offering DNA fragmentation diagnostics for fertility clinics.

The LogixX Pharma team is small but ambitious, with CEO Michael Close and IT Project Manager Andrew Smith responsible for quality and other primary business functions.

The team have been happy Qualio customers since 2020, and were keen to try Qualio's <u>new Compliance Intelligence product</u> shortly after it launched.

The tool

Qualio's launch of Compliance Intelligence, an AI-powered compliance management tool, came at a great time for LogixX Pharma.

The company was maintaining ISO 13485 compliance and preparing for a recertification audit, as well as investing in a new London laboratory — making ISO 15189 accreditation a top priority.

The tool's ability to automatically flag life science compliance gaps, and guide users to closing them, would be invaluable for mapping LogixX Pharma's current compliance health and supporting them to their desired state.

The team added Compliance Intelligence to their Qualio subscription.

Industry Pharmaceuticals, nutraceuticals, medical devices

Regulations • GDP

• ISO 13485

60%

Of consultant spend mitigated

80%

Reduction in new standard readiness time

5×

Return on investment in first 2 months

"In terms of both time and money, for what you spend on Compliance Intelligence you get it back at least fivefold."

— Michael Close
CEO, LogixX Pharma



The results

LogixX Pharma's CEO identified rapid and clear ROI from his Compliance Intelligence adoption

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Consultant spend sliced by 60%

To support their multiple certification and accreditation goals, LogixX Pharma were relying on a paid life science regulatory consultant.

Compliance Intelligence was immediately recognized as a 'far more effective' alternative, completing a full, end-to-end QMS scan and identifying gaps in just 40 minutes — then providing continuous, 24/7 monitoring afterwards for a fraction of the cost of a human.

And unlike a consultant who requires time and guidance to understand the business, Compliance Intelligence was ready to launch at the touch of a button.

Michael identified 60% of his consultant spend instantly mitigated, an impact that could save 'tens of thousands of pounds' annually for other scaling life science organizations.

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Acceleration of company strategy

Automating compliance processes had a dramatic acceleration effect on Michael's strategic plans for LogixX Pharma.

With the company preparing for UKAS ISO 15189 accreditation for their new laboratory, the team have already activated the ISO 15189 framework in Compliance Intelligence and begun to evaluate their operational controls against the standard's requirements.

The tool has already flagged every SOP and process the company needs in place, and its continuous monitoring functionality means work can be instantly checked and rechecked as the team makes its preparations — saving vital time.

Michael pinpointed an 80% reduction in his original planned accreditation time frame, with the company no longer reliant on the time frames of external consultants for building new documents and processes and getting audit-ready.

"Our ISO auditor complimented our approach, and how the tool is keeping the business safe and effective.

And because we can do things ourselves now, we can get ready for our next standard 80% faster."

— Michael CloseCEO, LogixX Pharma



Audit trust

Before LogixX Pharma's ISO 13485 audit, Compliance Intelligence flagged a series of required updates to the company quality manual: rework wasn't explicitly specified as not applicable to the company's operations, while the company's supplier reevaluation process was documented differently to ISO 13485 best practice.

Michael was pleasantly surprised to see their ISO 13485 auditor make the same findings and recommendations — a clear indicator of Compliance Intelligence's trustworthiness — and compliment LogixX's use of the tool as well.

After the audit, the team used the tool's guidance to make the necessary updates to their quality manual, strengthening their quality system for future inspections.



Upskilled and independent

Like many growing life science companies, dedicated in-house quality and regulatory expertise was limited for the LogixX Pharma team.

Michael was therefore pleased to see the expert-built Al within Compliance Intelligence delivering targeted, clause-by-clause recommendations immediately, guiding Michael and his team to close out compliance gaps with precise explanations.

The tool therefore 'upskilled' the team and made them independent, educating them on how to scale and shape their QMS with complete ISO adherence — and without the need to rely on any external parties in future.

