



How Cogstate cut ISO audit prep in half and **is tripling its compliance coverage with Qualio**

Cogstate, a neuroscience endpoint company serving global biopharma sponsors, cut ISO 9001 surveillance audit prep by 50%, predicted more than 70% of auditor opportunities for improvement in advance, and is now achieving compliance readiness across three more standards simultaneously, with the same QA team.

50%

faster ISO 9001 surveillance
audit prep

>70%

of auditor findings predicted
before the audit

3x more

compliance frameworks
pursued in parallel

"Qualio gives us a clear picture of where we stand. It saves time on the initial work so we can focus on more strategic things."

Allison Iles, Quality Engineer, Cogstate

Results

Qualio replaced Cogstate's manual, sequential compliance process with always-on gap visibility, enabling a lean QA team to prep faster, predict more, and achieve compliance readiness with more standards at once.

Activity	Before Qualio	After Qualio
Audit prep	Manual, clause-by-clause review of hundreds of documents	50% faster; Qualio scans the full document library automatically
New framework gap analysis	~1 month per standard; limited to ~1 new standard per year	Monitoring multiple frameworks (ISO 13485, ISO 27001, 21 CFR Part 11, ICH GCP E6 R3) in progress simultaneously; ISO 13485 already 83% mapped via cross-standard overlap
Cross-team compliance	QA and IT coordinated ISO 27001 prep via spreadsheets and Jira; technical staff often unaware of relevant procedures	Qualio surfaces gaps with remediation recommendations; non-QA teams act independently

How Cogstate is transforming its compliance approach

Cogstate serves clinical trial sponsors who regularly audit their vendors against ISO, FDA, and GxP requirements. Before Qualio, the team tracked every requirement in spreadsheets, mapping hundreds of documents clause by clause to regulatory requirements. A full gap analysis for a single framework could take several weeks.

Qualio accelerated audit prep for Cogstate's ISO 9001 surveillance by 50%, with AI-supported gap analysis and mapping of SOPs, procedures, and records to clause-level 9001 requirements. "Before Qualio, the level of manual effort required to pursue new certifications meant we could only take on one standard per year," said Allison Iles, Quality Engineer, Cogstate. "Now, we're managing multiple frameworks simultaneously and staying ahead of them."

Next, Cogstate is focused on demonstrating compliance with ISO 13485 and preparing for an ISO 27001 surveillance audit with Qualio, while simultaneously using the system to assess and monitor compliance with ICH GCP E6 R3, 21 CFR Part 11, and ISO 9001. This is allowing Cogstate to manage dozens of annual customer audits more effectively, replacing audit prep sprints with continuous visibility of compliance against regulatory requirements. Qualio's cross-standard document mapping showed that Cogstate is already meeting more than 80% of their ISO 13485 requirements, saving the team months of groundwork. Qualio's remediation recommendations have also extended QA's reach: the IT team managing ISO 27001 can now act on gaps independently, without relying on QA for every question.

As Cogstate manages quality and compliance processes in Qualio, their risk analysis updates in real time.

About Cogstate



Headquarters: Melbourne, Australia (HQ), with offices in New Haven, CT, USA and London, UK



Size: 50-200



Industry: Neuroscience Endpoint Company



Frameworks: ISO 9001, ISO 27001, ISO 13485 (in progress), 21 CFR Part 11, ICH GCP E6 R3

For more information please visit
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