



How Distica aced its ISO 13485 audit with Qualio

A newly unified quality team brought six sister companies, spanning pharmaceutical marketing authorization holders and medical device distribution, onto a single Qualio platform. With Qualio, they cut software validation from months to weeks, and passed their first ISO 13485 surveillance audit without a single comment.

Key results

6 companies

1,500+ documents migrated
into one platform

ISO 13485 audit success

Zero auditor findings or
comments

Validation reduced

from months to weeks

"The auditors said it was very rare that we passed our ISO 13485 audit without any comments. I think Qualio helped a lot in that process."

Sigurbjörn Jónsson, Quality Systems Lead, Distica

Results

Distica took on the group's newly unified quality function as each of the entity's previously separate quality units merged into one team. Each company had been managing quality differently, with some on paper and others using SharePoint tools. This meant every audit meant digging through physical archives to reconstruct training records and historical evidence.

As a distributor, Distica is regularly audited by the marketing authorization holders it serves, on top of maintaining multiple ISO certifications across six entities. As they searched for a replacement, the team prioritized audit readiness and validation, plus a UI simple enough that every process owner across all six entities could adopt it. Qualio gave them a single platform to standardize on, with the audit readiness and validation rigor to back it up.

Activity	Before Qualio	After Qualio
Software validation	Validation packages took months to compile and verify from scratch	Qualio's pre-built validation evidence package cut the process to weeks. No repeat testing needed.
Audit & inspection readiness	Records scattered across paper archives; audits meant manually digging through historical files	Auditors get instant access to documents, approval history, and timestamps. Passed first ISO 13485 audit with zero comments.
Quality system unification	6 sister companies ran on a mix of paper and an aging, end-of-life SharePoint tool	All 6 companies now run on one platform, managing 1,500+ documents and 9 event types under a single quality culture

"This really feels like a partnership. Qualio holds our hand, and we feel like our feedback is actually listened to."

Sigurbjörn Jónsson, Quality Systems Lead, Distica

Qualio delivers a strong foundation for growth

As the group's shared quality unit, Distica was tasked with merging previously separate quality functions into one team. They needed a single system that could serve every entity's distinct regulatory needs (ISO 9001, 13485, and the parent company's ISO 27001) without losing the ability to segregate access by company.

Distica used tags in Qualio to segregate documents and events by entity while keeping a single, harmonized quality system underneath. Qualio's pre-built validation package enabled Distica to map its own requirements directly to evidence Qualio had already tested, eliminating repeat work. The payoff came quickly: Distica now manages more than 1,500 documents and nine event types across the group, with supplier management and ERP integration next on the roadmap.

Distica is also testing Qualio's agentic AI capabilities to move faster and reduce manual processes. The quality team is leveraging Qualio's AI copilot to initiate complaint flows, populate them, and route for approval. "The organization is using the copilot quite heavily, and we can see great potential in asking it to perform tasks, not just search content," said Sigurbjörn Jónsson, Quality Systems Lead. Distica has connected Qualio to key business systems like Microsoft via Qualio's Developer API to enable more connected processes across the organization.

Looking forward, Distica plans to connect quality and regulatory data with more tools across the business via Qualio's MCP server. This will enable staff across all six sister companies to trigger quality tasks they're authorized for, surface live KPIs, and query training data without leaving their everyday tools. Distica's next priorities for their Qualio deployment also include ERP integration for better end-to-end supplier management.

"We've seen Qualio evolve significantly, and with our experience so far, we take it as a given that the system is going to keep growing alongside us."

Sigurbjörn Jónsson, Quality Systems Lead, Distica

About Distica



Headquarters: Garðabær, Iceland



Size: 11-person quality team, spanning a group of 6 sister companies



Industry: Pharmaceutical and medical device distribution



Frameworks: ISO 9001, ISO 13485, ISO 27001 (parent company)

For more information please visit
www.qualio.com/product