Dot Compliance

CASE STUDY

# Trial by Audit: How Omega Diagnostics Digitalized its Quality System

## The Challenge: A Legacy eQMS Going out of Support

Omega Diagnostics faced an operational transition as its old electronic quality system was scheduled to go completely out of support by November 2024. Backed by over 32 years of industry experience under ISO13485, the company needed to migrate data, update standard operating procedures (SOPs), and clear backlogs before the old system became obsolete.

Prior to the transition, a legacy nonconformance backlog required significant manual QA effort to drive down. Additionally, critical corporate training compliance was stalling, standing at just 67% complete for read and understood.

With the old eQMS reaching its end of support, the company prepared for its first regulatory audit under Dot Compliance, which was scheduled for February 2025.

## The Solution: Out-of-the-Box Digitalization

Led by Liam Dower, Head of Quality and Regulatory, Omega Diagnostics initiated its transfer process. To address the support deadline, the company established a clear objective: the configuration had to be deployed as "out of the box" as possible, with no customization.

The implementation began in July 2024. Before the old software became completely unsupported in November 2024, the team successfully migrated data, updated SOPs, and cleared legacy backlogs. Instead of a basic, one-to-one software swap, quality leadership viewed the project as a catalyst for cultural change. As Liam explained:

"We needed to change, and this was our chance to think beyond a direct replacement option. We wanted to shift the mindset for QA away from chasing up actions and checking documents and get them thinking critically about effectiveness checks and investigation quality. By helping the rest of the company take ownership of their tasks, we can foster a culture of quality where Quality is simply the most efficient way to do your job."

Following this philosophy, the team focused heavily on the workflow, deploying modules for Design Controls, Program Management, and Electronic Batch Records (eBR).

Omega Diagnostics

**Industry** Medical Device and In Vitro Diagnostics (IVD).

**Location** Cambridgeshire, United Kingdom.

## About

Omega Diagnostics manufactures and develops diagnostic products designed to enable fast, accurate, and reliable insights. The organization operates under a certified ISO quality system built on over 35 years of industry experience. Their product portfolio features microarray ELISA tests analyzing IgG responses to over 200 foods, professional use tests with results in 40 minutes analyzing responses to 59 foods, and biomarker stool tests that check inflammation, intestinal permeability status, and digestive efficiency.

## The Benefits: Passing the Audit and Launching AI

The plan to get the new software running smoothly before the official inspection faced its first real test. In February 2025, Omega Diagnostics underwent its surveillance audit, the first under Dot Compliance, successfully completing its "trial by audit".

Following the live launch, the company drove corporate training compliance from its historical baseline up to greater than 95% complete. To implement a less retrospective workflow and build a true quality culture, Omega established a "Hotel California" policy: The ability of Dot Compliance to manage workflow as well as control the documentation was used to make Dot Compliancethe system the default place for employees to manage their work. The desire is for employees to check into Dot Compliance in the morning and never leave.

With their core system validated, Omega Diagnostics launched its AI journey on September 23.

In the first three weeks of deployment, employees executed 275 queries within the system. "Similar" searches quickly emerged as a highly popular feature for the team.

## Looking Ahead

Omega Diagnostics continues to pursue continuous improvement and workflow optimization. Quality leaders recognized a core behavioral shift was needed to drive platform engagement deeper, with Liam noting: "If they wait for an email, they aren't in the Dot Compliance system."

To address these notification nudges, the company utilizes report subscriptions and homepage dashboards as a permanent replacement for standard email alerts. Internal user surveys show that this transition to proactive tracking is well-received; currently, 81% of surveyed users utilize the dashboard on the home page to track their actions, while a strong 43% of employees strongly agree that the system sends the perfect amount of emails and nothing should be changed.

The company's focus remains fixed on future continuous improvement milestones, and as stated by Liam: "We are not done yet."