

Turning Regulatory Readiness into an AI Advantage

How a MedTech OEM cut audit preparation time by 63% and raised documentation accuracy to 95%



Business challenge

For a European medical technology OEM, quality was not simply an operational requirement. It was the foundation for market access, patient trust, and product continuity. Yet fragmented systems and manual reviews were slowing documentation checks, delaying defect resolution, and increasing pressure across regulated product lifecycles.

As audit and compliance demands grew, internal teams needed to improve speed and consistency without adding workload or weakening governance. The business needed to:



Reduce the time and effort required for audit preparation and documentation review



Accelerate defect resolution and CAPA workflows



Improve the accuracy and consistency of regulated documentation



Create a scalable model for extending AI across quality and compliance operations

The Cyient solution

Cyient established an AI Center of Excellence and embedded intelligent assistants into everyday regulatory and quality workflows, creating a governed model for faster, more consistent execution.

- Automated documentation checks against regulatory procedures
- Applied AI-augmented defect analysis to speed root-cause assessment and resolution
- Streamlined CAPA documentation, PMO governance, and DevOps workflows
- Embedded procedure and regulatory alignment into every automation step
- Used continuous feedback loops to improve reliability and audit readiness
- Created a structured foundation for scaling AI into additional regulated processes

Business benefits

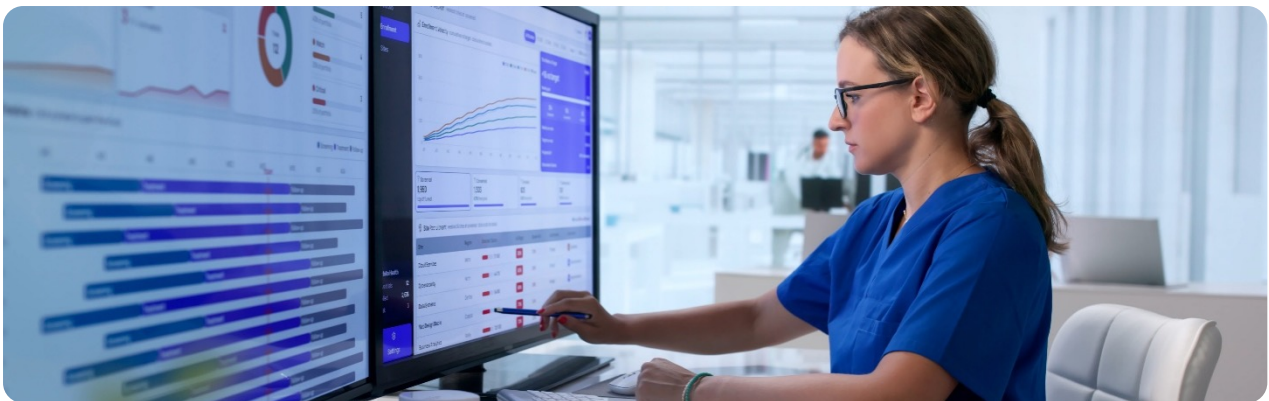
The AI-augmented operating model reduced manual effort, improved quality performance, and made regulatory readiness more predictable across the product lifecycle.

- Reduced audit preparation time by **63%**
- Decreased documentation review hours by **80%**
- Raised documentation accuracy from **78% to 95%**
- Accelerated defect resolution by **65%**
- Shortened CAPA cycle time by **50%**

Engineering excellence. Nothing Less.

Regulatory confidence did not come from automating more tasks. It came from embedding intelligence within governed workflows, so every gain in speed also strengthened accuracy, consistency, and readiness.

Make regulatory readiness a continuous advantage.
Speak with our experts today.



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North America Headquarters

USA
T: +1 860 528 5430

Europe, Middle East, and Africa Headquarters

UK
T: +44 118 3043720

Asia Pacific Headquarters

Australia
T: +61 2 8887 8600

Global Headquarters

Hyderabad
T: +91 40 6764 1000