

Regulatory Knowledge, Finally in the Workflow

Regulatory evidence is never static. Whether you're building a risk file for a new device or updating one already on the market, it's a living record: revised every time a customer complaint comes in, a new test result lands, or an engineer flags a foreseeable harm following a design change, then weighed again in a risk-benefit analysis to confirm the benefit still outweighs the harm. Supplier records carry the same ongoing burden: build records, inspection results, and lot-level traceability all need to stay current, and a supplier's ISO certification can lapse quietly until an auditor goes looking for it.

Pensato's document management system tracks that evidence as it accumulates and surfaces it directly inside your regulatory, quality, and engineering workflows, so risk files, equivalency assessments, and supplier documentation are already current and audit-ready whenever a submission calls for them.

Where AI Changes How A Regulatory Function Operates

Document search and summarization are a good starting point, but the deeper opportunity is the assembly work that consumes senior regulatory time and produces no strategic value. Use cases include:

- Substantial Equivalence Research
- Design and Development File Assembly & Gap Detection
- Test Report & Protocol Cross-Referencing
- Risk Management File & Hazard Analysis Traceability
- CAPA Documentation & Trend Review
- Supplier Qualification File Review
- Regulatory Change Impact Assessment

Why Pensato

We create a secure intelligence layer that embeds your device's design and development file, test data, and quality records directly into AI workloads, without moving data or exposing proprietary design information. Design controls and quality system requirements are structural in this business. Every claim in a submission has to trace back to a source, and that source has to hold up years later when someone asks how the conclusion was reached. The result is submission packages that read the same way regardless of which specialist prepared them, and a review process that starts from a traceable source.

What Your Team Gains

Embedded Intelligence

Organizational context is embedded directly into document workflows.

Deterministic Outputs

Same document, same query, same answer.
Output tied to source data.

No Prompting

Document Management System surfaces intelligence native to the workflow.

Source Linked Trail

Every output traces back to its source document, so internal review starts from confirmation.

A single design change rarely stays contained to one document. It touches the risk file, the DHF, the supplier qualification record, sometimes the original 510(k) itself, and each of those usually gets reassessed by a different person, working from a different starting point, often without knowing what the others have already concluded.

This is what the four capabilities above look like in practice: **Pensato surfaces what a change actually touches across the design and quality system**, so the impact assessment starts from the full picture instead of one document at a time.