

AI-Driven Audit Intelligence

Numa Audit: The Definitive Solution for Life Sciences Compliance and Audit Readiness

In today's fast-paced life sciences and medical device industries, staying ahead of regulatory requirements often feels like a fragmented, uphill battle because traditional audit methods are manual, time-consuming, and prone to error. Managing compliance across disparate systems adds complexity to operations, leaving organizations vulnerable to systemic gaps where Form 483 observations, warning letters, and quality management system failures signal an inability to prove control and traceability across the quality ecosystem. Ultimately, life sciences companies do not need another static storage repository; instead, they require active, domain-specific intelligence that streamlines the entire audit process, connects fragmented evidence, and delivers defensible proof of compliance.

Numa by Ailethea is that solution.

Purpose-built for life sciences and medical device companies, Numa is a comprehensive, AI-powered audit assistant specifically trained on the regulations that matter most: Title 21 CFR, QMSR, and ISO 13485. Numa standardizes observations, automatically generates real-time audit reports, and delivers instant regulatory references to engage every stakeholder and ensure complete inspection readiness.

How Numa Delivers the Solution You Need

Standardizes Compliance Observations

Numa instantly analyzes audit findings and maps them directly to specific clauses within FDA Title 21 CFR, QMSR, and ISO 13485. Eliminating subjectivity from the observation process ensures that every documented issue is rooted in a strict regulatory context.

Generates Real-Time Audit Reports

Numa automatically generates comprehensive, action-ready audit reports in real time, cutting total report generation time by more than 25% and freeing your quality team to focus on resolution.

Provides Instant Regulatory References

Auditors no longer need to waste time manually digging through global regulatory texts. Numa delivers immediate, citation-backed references during live audits, solving the "evidence is somewhere but unfindable" problem that plagues complex quality environments.

Enforces Predictive Fix/Prevent Models

Numa moves your organization from reactive remediation to predictive compliance. Its advanced predictive capabilities analyze data patterns to help auditors detect non-compliances before they result in a Form 483 and to identify recurring systemic issues early.



Built for Trust and Regulated-Industry Rigor

Unlike generic generative AI tools that risk hallucinations, data leakage, or unvalidated outputs, Numa operates with enterprise-grade precision engineered around strict regulatory expectations.

- **Absolute Data Protection:** Customer data is never used to train any shared or public model. Your regulatory records, quality data, and audit histories remain inside a secure, isolated tenant under your absolute control.
- **Human-in-the-Loop Authority:** Numa does not replace your Quality or Regulatory teams; it empowers them. It equips human auditors with explainable outputs, full evidence citations, and confidence-level insights to accelerate human-led decision-making.
- **Inspection-Ready Audit Trails:** Every output generated by Numa clearly aligns with global standards, creating a transparent and highly defensible layer of evidence for internal stakeholders and regulatory inspectors.

Real-World Impact Across Your Quality Ecosystem

Quality Management (QMSR / ISO 13485)

Automatically flags critical compliance gaps from minor logs and aligns system workflows with international quality standards.

Pre-Inbound Inspection Prep

Reviews historical data and current operational logs to identify and remediate vulnerabilities before regulators arrive at your facility.

Risk Mitigation

Predicts compliance exposure and recurring operational trends, drastically reducing the likelihood of receiving an FDA Form 483.

Why Numa Is Different

Numa governs regulatory meaning. Numa produces citable, reviewable, inspection-ready proof.

Numa eliminates the need to manage a patchwork of expensive, specialized regulatory tools. At the operational level, your teams work from a unified, evidence-based view. At the executive level, leadership gains real-time visibility into systemic exposure, overdue actions, and compliance risks.

Want to learn more?

Reach out to schedule a demo or speak with a compliance expert.

hello@ailethea.com | <https://ailethea.com>

