

TRIAD-AI: Purpose-Built Regulatory Intelligence

The Definitive Solution for Life Sciences Quality, Compliance, and FDA Remediation

Life sciences companies face unrelenting regulatory pressure. The FDA's September 2025 release of 89 previously unpublished Complete Response Letters (CRLs) reveals the stark reality: facility inspection failures and CGMP issues dominate at 56%, product quality and CMC deficiencies hit 47%, and clinical/statistical gaps exceed 30%. These are not isolated events. They expose systemic weaknesses in quality systems that traditional document repositories simply cannot address. Form 483 observations, warning letters, CRLs, recalls, import alerts, CAPA backlogs, complaint failures, MDR gaps, and data integrity findings are no longer standalone issues — they signal an inability to prove control, traceability, effectiveness, and inspection readiness across the entire quality ecosystem.

The industry no longer needs another storage system. It needs intelligence that understands regulatory meaning, connects fragmented evidence, distinguishes immediate fixes from true prevention, and delivers defensible proof to the FDA.

TRIAD-AI is that solution.

Purpose-built from the ground up for pharmaceuticals, biologics, medical devices, SaMD, AI-enabled device software functions, diagnostics, and combination products, TRIAD-AI is a multi-model, classifier-driven regulatory intelligence platform. It does not summarize documents — it classifies, interprets, links, and governs regulated content to accelerate analysis, expose gaps, and support human-led decisions that withstand scrutiny.

Unlike generic generative AI chatbots that risk hallucination, data leakage, or unvalidated outputs, TRIAD-AI operates with regulated-industry rigor. It reads FDA Form 483s, warning letters, CRLs, recalls, CAPAs, complaints, MDRs, validation records, SOPs, change controls, risk files, supplier records, and submissions — then delivers actionable, evidence-cited intelligence.

How TRIAD-AI Delivers the Solution You Need

- 1. Classifies Regulated Content with Precision:** TRIAD instantly identifies document type, quality-system domain, risk category, affected site/product, jurisdiction, and regulatory significance. It maps a CRL deficiency directly to CMC, facility, clinical, labeling, data integrity, or bioequivalence gaps — exactly the top issues in the FDA's latest CRL data.
- 2. Interprets Regulatory Meaning:** TRIAD goes beyond keywords. It recognizes whether a finding implicates weak complaint triage, inadequate root cause analysis, poor CAPA effectiveness, uncontrolled design changes, supplier failures, software validation gaps, or management oversight lapses.
- 3. Links Evidence Across Silos:** TRIAD connects observations to source records, CAPAs, complaints, recalls, validation evidence, training logs, and prior commitments — eliminating the “evidence somewhere but unfindable” problem that plagues most remediation efforts.
- 4. Enforces the Critical Fix/Prevent Model:** TRIAD separates immediate containment (patient safety, field action, deadline-driven response) from systemic prevention (root cause correction, process revalidation, effectiveness monitoring, recurrence detection). This is the exact discipline FDA demands — and the one most companies struggle to demonstrate.

Built for Trust and Regulatory Compliance

TRIAD-AI was engineered around FDA's own expectations for AI in regulated environments, including the January 2025 draft guidances on AI for regulatory decision-making and AI-enabled device software functions, plus Good Machine Learning Practice (GMLP) principles from FDA, Health Canada, and MHRA.

It features defined context of use, risk-based credibility assessment, lifecycle risk management, human-in-the-loop review, explainable outputs with full evidence citation, audit trails, change control, and performance monitoring. Every output includes the issue, cited source, implicated domain, confidence level, recommended fix, preventive action, and human reviewer disposition.

Data protection is non-negotiable. Customer data is never used to train any shared model. Customer information may be processed, indexed, classified, embedded, or tenant-tuned only inside the customer's secure isolated tenant, under customer control, for that customer's use only. No cross-customer training. No commingling. No vendor reuse. Each deployment lives in its own secure, isolated tenant. Your regulatory records, quality data, CAPAs, complaints, and submissions remain yours alone — governed by your controls, accessible only by your authorized users.

Proven Use Cases Aligned to Your Highest-Priority Pain Points

- Form 483 and warning letter remediation
- CRL deficiency classification and resubmission readiness
- CAPA backlog triage and effectiveness verification
- Complaint/MDR linkage and trend analysis
- Recall and open-action governance
- CMC/facility-readiness evidence mapping
- QMSR / ISO 13485 compliance acceleration
- Supplier quality and validation gap detection
- Executive regulatory risk dashboards
- Inspection-readiness intelligence

These are not future concepts. They directly address the manufacturing, facility, product quality, data integrity, and clinical gaps dominating FDA enforcement today.

Why TRIAD-AI Is Different — And Why It Matters

Generic AI answers questions. TRIAD governs regulatory meaning. Generic AI produces text. TRIAD produces citeable, reviewable, explainable, inspection-ready proof.

Generic AI may commingle data. TRIAD enforces absolute tenant isolation and zero cross-customer learning. Generic AI is difficult to validate. TRIAD is designed for defined context of use, lifecycle oversight, and human authority.

TRIAD does not replace your Quality, Regulatory, Legal, or Executive teams — it equips them to see the truth faster, cite evidence accurately, prioritize remediation, and prove sustained control.

The Strategic Outcome

At the operational level, teams work from one evidence-based view. At the executive level, leadership gains real-time visibility into exposure, overdue actions, weak CAPAs, and recurring risks. At the FDA-response level, companies deliver clearer, more defensible submissions that demonstrate not just correction — but prevention and oversight. FDA is not asking for more documents. FDA is demanding proof of control. TRIAD-AI turns your fragmented quality and regulatory records into that proof.

TRIAD-AI is the solution the industry has been waiting for. It is the regulated-industry AI architecture purpose-built to help life sciences companies move from reactive remediation to proactive, inspection-ready quality systems — exactly when FDA scrutiny has never been higher.

If your organization is facing Form 483s, warning letters, CRLs, or the broader challenge of proving systemic control, TRIAD-AI delivers the intelligence layer you need to succeed.

Ready to turn regulatory pressure into demonstrated compliance excellence?

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