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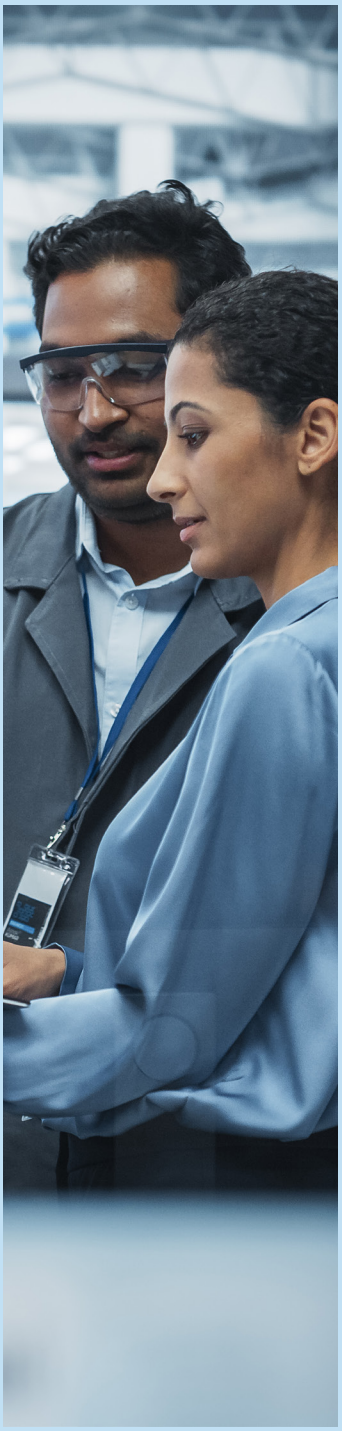


FROM REGULATORY NOISE TO AN AI NATIVE INTELLIGENCE AGENT

TRANSFORMING COMPLIANCE MONITORING WITH AI

Infosys | CONSULTING

1) Executive Summary

Regulatory change used to arrive in cycles. Today it arrives as **stream** guidance, safety notices, recalls, and consultations across multiple authorities.

Most teams still work the old way:

Scan sites	Read PDFs	Paste into Spreadsheets	Forward Emails

It's slow, inconsistent, and difficult to audit.

This paper lays out a different path: an **AI-native, agentic Regulatory Intelligence platform** that **listens to official sources, explains changes in plain language with citations back to the source, prioritizes by business impact, maps effects to dossiers and labels,** and **pushes work into RIMS/DMS** with controls that match a regulated environment.

Early Value Realization:

- **Speed:** median time from publication to "on the dashboard with provenance" ≤ 24 hours.
- **Coverage & freshness: ≥ 90%** of priority sources polled on schedule; latest versions surfaced with versionbyversion comparisons.
- **Consistency & traceability:** AI proposes the **likely dossier/label impact; human reviewers** confirm; every decision leaves a **clean audit trail.**

The outcome isn't "more alerts." It's **fewer, clearer, and actionable** updates delivered with the **assurance** and **traceability** your QA teams, auditors, and future self will rely on.

2) The Problem Landscape

Challenge	Current Reality	Why It Matters
A. Fragmented regulatory truth	Updates are scattered across Q&As, PDFs, and announcements with no authoritative view.	Teams act on different "versions of truth," increasing inconsistency and compliance risk.
B. Nonscalable manual handoffs	Critical updates are shared via emails and attachments, not decisions.	Effort shifts to reading and forwarding, driving duplicate work and missed actions.
C. Invisible timelines, weak traceability	Effective dates and decision history are hard to find or reconstruct.	Late discovery triggers fire drills and undermines audit readiness.
D. No structured path to dossier impact	Regulatory changes lack clear linkage to eCTD modules, labels, or SOPs.	Affiliates interpret impacts differently, leading to divergent product updates.
E. Adhoc safety triage	Safety alerts rely on spreadsheets and afterhours manual coordination.	Version conflicts and delays erode speed, alignment, and confidence in response.

Summary: Together, these issues increase compliance risk, slow decision making, and dilute accountability.

3) End-to-End Process Flow

Design intent: Replace "scan & scramble" with a **transparent pipeline** that turns official updates into **prioritized, dossier-aware work** with provenance end-to-end.

Before diving into architecture and modules, it is essential to understand how the platform works from the perspective of a regulatory affairs professional on a typical day. The following end-to-end process flow illustrates the complete journey from regulatory change publication to organizational action.

Figure: End-to-End Regulatory Intelligence Process Flow

PHASE 1 | DISCOVER & INGEST			
RSS Feeds Auto-Poll	**Web Search Discovery**	**URL Crawling & Extraction**	**Content Cleaning**
FDA Drugs, Biologics, Law & Device blogs polled continuously	DuckDuckGo multi-regulator search with date range filtering	Playwright browser automation fetche full HTML content	BeautifulSoup extracts clean text, metadata, and file attachments

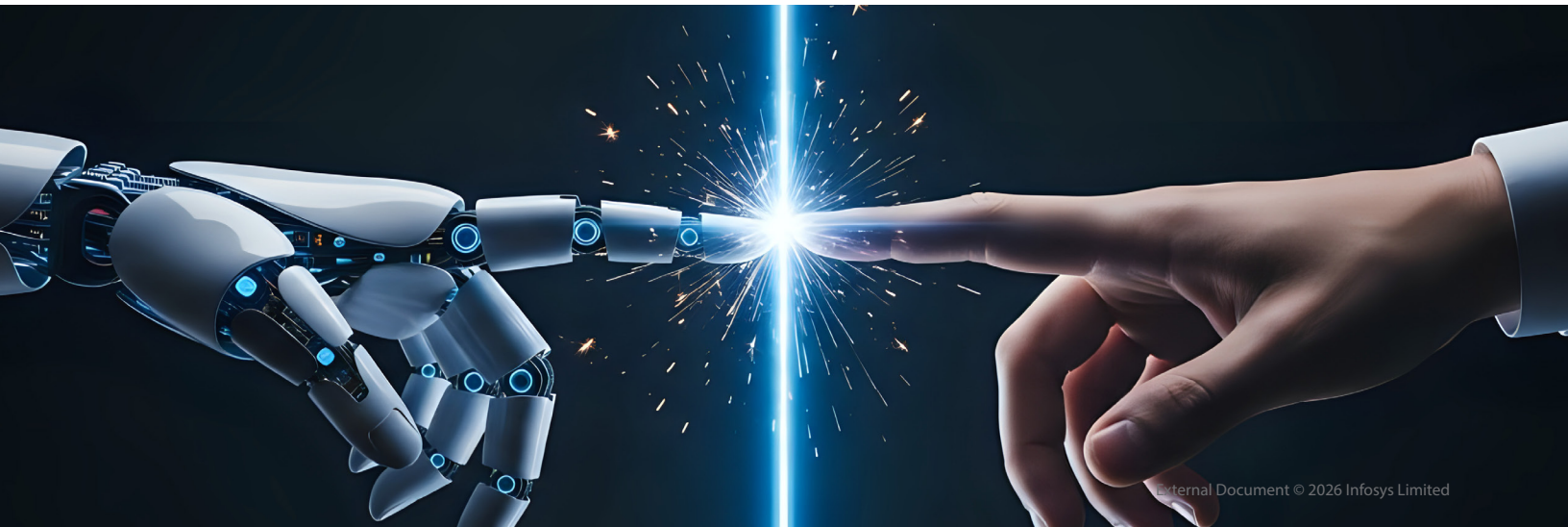
PHASE 2 | AI-POWERED ANALYSIS & CLASSIFICATION			
Smart Classification	**Impact Scoring**	**Deep AI Interpretation**	**Compliance Mapping**
Auto-tag document type, product type, pathway, therapeutic area	AI assigns Critical / High / Medium / Low with rationale	GPT-4 generates exec summary, key changes, action items, dates	Requirements mapped to dev stages: Pre-clinical → Commercial

PHASE 3 | ACT, TRACK & REPORT			
Workflow Assignment	**Gap Analysis**	**Compliance Questionnaire**	**Report & Export**
Route to analyst queue, assign priority, set deadlines	Upload SOP → AI matches regulations → identifies critical gaps	AI generates targeted questions, team tracks responses	Analytics dashboard, Excel/CSV export, trend monitoring

30 Minutes vs. 4-6 Hours

In under 30 minutes, the analyst discovered 12 new regulations, triaged by impact, performed deep AI analysis on critical items, completed a gap analysis against an internal SOP, assigned actions to team members, generated compliance questionnaires, and exported a formatted weekly report. The same workflow previously took an entire morning — and often resulted in incomplete coverage.

This flow **ensures** every regulatory update is c**aptured, understood, acted upon, and auditable** without manual handoffs



4) Current Capabilities & Modules

Cross-Cutting Capabilities Powering the Platform

Capability	What It Enables	Illustrative Outcome
AIPowered Intelligence	Extracts key regulatory signals, produces plainlanguage summaries with citations, and proposes likely dossier and label impacts.	"Guidance clarifies stability data reporting for temperature excursions. High impact for Product Z; likely eCTD Module 3.2.P.8."
Discovery & Storage	Continuously monitors authoritative sources, captures full text and PDFs, and preserves timestamped, versioned records.	"Guidance Y published March 1; revised March 12. View a sidebyside comparison of the two modified paragraphs."
C. Invisible timelines, weak traceability	Effective dates and decision history are hard to find or reconstruct.	Late discovery triggers fire drills and undermines audit readiness.
D. No structured path to dossier impact	Regulatory changes lack clear linkage to eCTD modules, labels, or SOPs.	Affiliates interpret impacts differently, leading to divergent product updates.
E. Adhoc safety triage	Safety alerts rely on spreadsheets and afterhours manual coordination.	Version conflicts and delays erode speed, alignment, and confidence in response.

User-facing capabilities

The following modules/phases **represent capabilities that guide an update from discovery to implementation:**

REG RADAR Discover & scan regulatory articles	**HORIZON SCANNING** Multi-source discovery & workflow	**INTERPRETATION & SCOPING** AI-powered deep analysis & workflow	**IMPACT ASSESSMENT** Line-by-line regulatory translation
MY QUEUE Personal workflow management	**COMPLIANCE TRACKER** AI-generated questionnaires	**REPORTING & ANALYTICS** Charts, trends, exports	**GAP ANALYSIS** SOP vs. regulatory comparison

5) Architecture, Standards & Controls

5.1 Agentic orchestration

Behind the scenes, the platform uses an **agentic orchestration** pattern: small, specialized "workers" handle **discovery, analysis, classification, compliance questions, gap checks**, and **reporting.** They share a common data layer, so each worker can **scale, pause, or retry independently** without losing the **single record of truth.** Prompts and AI outputs are selectively cached to ensure results are reproducible and defensible during audits, while **maintaining clear human review and approval at every decision point.**

DISCOVERY AGENT RSS Monitor Web Search URL Crawl	**ANALYSIS AGENT** LLM-powered Regulatory Interpreter	**ANALYSIS AGENT** LLM-powered Regulatory Interpreter
SHARED DATA LAYER - SQLite (structured) + ChromaDB (semantic)		
COMPLIANCE AGENT Generates questions Tracks responses	**GAP ANALYSIS AGENT** SOP vs Reg comparison Identifies gaps	**REPORTING AGENT** Analytics & trends Export & distribution

6) Value & Success Metrics

The success of the Regulatory Intelligence capability is **measured not just by speed, but by clarity, reliability, and confidence.** The following indicators are designed to be simple, transparent, and meaningful for both operational teams and senior leadership.

- **Speed of awareness**
  Regulatory updates are visible in the system within **24 hours of being published**, along with a clear record of where the information came from.
- **Breadth of coverage**
  At least **90% of important regulatory sources** are monitored consistently, so critical updates are not missed.
- **Information accuracy**
  Teams always see the **latest official version** of a regulatory update, verified daily, avoiding confusion caused by outdated or conflicting documents.
- **Quality of interpretation**
  In most cases, regulatory experts agree with the **AI-suggested impact** on dossiers or labels showing that the system is reliably supporting expert judgment and improving over time.
- **Compliance confidence**
  The regulatory monitoring process stands up to audits, with **no findings related to missing records, unclear decisions, or insufficient validation,** supported by clear documentation and evidence.

Conclusion:
From Compliance to Confidence through AI

Regulatory intelligence is no longer a peripheral activity carried out in the background of the organization. In an environment defined by accelerating regulatory change, heightened scrutiny, and increasing operational complexity, it must operate as a core enterprise capability.

The approach described in this PoV is intentionally human-centered. Artificial intelligence is not positioned as a replacement for regulatory expertise, but as a force multiplier. It absorbs the scale and noise of the regulatory ecosystem continuously discovering updates, explaining what has changed in clear language, organizing information, and proposing likely impacts so regulatory professionals can focus on what truly matters: judgment, decision-making, and execution.

Equally important, this capability is built on a foundation of trust. Controls, traceability, and accountability are designed in from the start, not added later.

- Every regulatory update can be traced back to its source.
- Every interpretation has a rationale.
- Every action has a clear owner.

This ensures that speed and automation never come at the expense of compliance or confidence.

The value is both immediate and tangible: faster awareness of regulatory change, more consistent impact assessment, reduced operational friction, and stronger inspection readiness. Over time, this foundation enables organizations to move beyond reactive compliance toward a more proactive, informed, and resilient way of operating.

For CEOs and senior leaders, the message is clear. The question is no longer whether regulatory intelligence can be improved, but whether the organization is equipped to navigate an increasingly complex regulatory landscape with clarity, control, and confidence.

Those that invest in this AI capability today will be better positioned to lead not just comply tomorrow.

Authors

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Sapna Bhardwaj is a Senior Consultant at Infosys Consulting with over 11 years of experience in life sciences, specializing in R&D, pharmacovigilance, clinical research, and regulatory affairs. She works closely with pharmaceutical organizations to drive innovation, improve operational efficiency, and strengthen capabilities across the drug development lifecycle. With expertise in project and quality management, data analysis, and computer system validation (CSV), she has delivered impactful outcomes in safety, clinical, and compliance domains. She is particularly passionate about leveraging Artificial Intelligence to enable responsible, data-driven transformation and accelerate innovation in the life sciences industry.

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Sayan is an Applied AI Engineer and consultant at Infosys Consulting, specializing in Generative AI and agentic AI solutions for the healthcare and life sciences industry. He has designed and delivered AI-powered proofs-of-concept for leading global pharmaceutical and medical device clients, with a focus on regulatory intelligence, document automation, and multi-agent workflow orchestration. Passionate about responsible AI adoption in regulated environments, Sayan brings hands-on expertise in Azure Cloud, LangChain, LangGraph, and intelligent document processing pipelines

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Jayadhar Gundu is an AI expert and builder at IC-LS with 9+ years of experience across life sciences and manufacturing. He specializes in delivering AI-driven solutions that transform supply chain and business operations. He has a proven track record in process optimization and end-to-end transformation, driving measurable efficiency gains and performance improvements. Known for bridging strategy and execution, he translates complex challenges into scalable, practical AI solutions.

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