

AKT Health Launches RegXtrakt, an AI-Powered Regulatory Operations Platform for Connected Regulatory Lifecycle Management

Developed from AKT Health's regulatory expertise, RegXtrakt unifies Regulatory Affairs, Quality, Safety, and Labelling for life sciences organizations.

TOKYO, JAPAN, July 28, 2026

/EINPresswire.com/ -- Regulatory operations have evolved far beyond managing submissions. Today's pharmaceutical, biotechnology, medical device, and digital health organizations must continuously manage regulatory information across multiple products, markets, health authorities, and post-market obligations.

While regulatory responsibilities continue to expand, many organizations still rely on disconnected spreadsheets, email chains, shared drives, and multiple software applications to manage information that spans Regulatory Affairs, Quality, Pharmacovigilance, and Labelling. This fragmentation creates duplicated effort, limited visibility, inconsistent data, and operational inefficiencies that can affect regulatory execution and compliance.

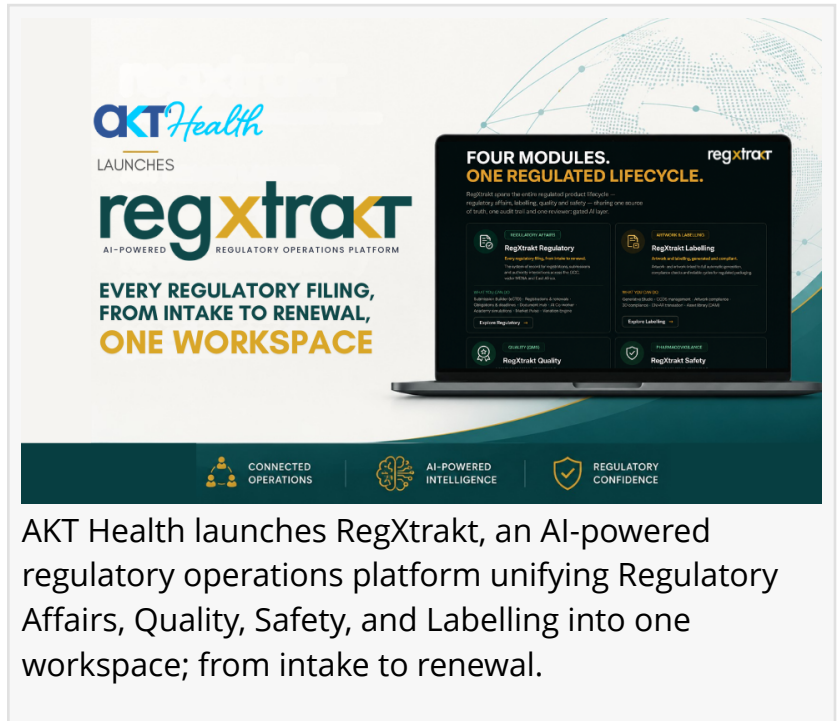
“

Regulatory teams shouldn't have to choose between speed and control. RegXtrakt brings both together through connected data, embedded AI, and built-in governance, closing that gap with confidence.”

Hema Dubey

Today, [AKT Health](#) Analytics, a global life sciences consulting and technology company, announced the launch of [RegXtrakt](#), an AI-powered regulatory operations platform developed to help organizations manage regulatory activities through a single connected operating environment.

Rather than functioning solely as a regulatory information



The image displays the RegXtrakt platform interface on a laptop screen. The interface features a dark theme with a grid of four modules: 'RegXtrakt Regulatory', 'RegXtrakt Quality', 'RegXtrakt Safety', and 'RegXtrakt Labelling'. Above the modules, the text 'AKT Health LAUNCHES regxtrakt AI-POWERED REGULATORY OPERATIONS PLATFORM' is visible. Below the modules, a banner reads 'EVERY REGULATORY FILING, FROM INTAKE TO RENEWAL, ONE WORKSPACE'. The bottom of the interface has three icons: 'CONNECTED OPERATIONS', 'AI-POWERED INTELLIGENCE', and 'REGULATORY CONFIDENCE'.

repository, RegXtrakt enables organizations to coordinate regulatory work throughout the entire product lifecycle, connecting people, processes, documents, and regulatory intelligence within a single integrated platform.

"Technology alone doesn't solve regulatory complexity. It must reflect how regulatory teams actually work," said Aditya Tallapragada, President of AKT Health Analytics. "RegXtrakt is the result of years of regulatory consulting experience across global markets. We've built a platform that connects information, workflows, and regulatory knowledge so organizations can operate more efficiently while maintaining compliance throughout the product lifecycle."

Built from Regulatory Experience

RegXtrakt was developed to address operational challenges AKT Health has repeatedly observed while supporting pharmaceutical and medical device companies across multiple regulatory environments.

Regulatory teams manage far more than submissions. They coordinate authority queries, product registrations, variations, renewals, safety reporting, quality events, labelling updates, commitments, inspections, and ongoing compliance activities throughout a product's commercial life.

These functions frequently operate across separate systems despite relying on the same regulatory information.

RegXtrakt connects these activities through a shared regulatory data model, enabling organizations to maintain a single source of truth across regulatory operations.

What RegXtrakt Delivers: One Connected Regulatory Platform

RegXtrakt brings together the core operational functions that support regulated products throughout their lifecycle:

- Regulatory Affairs: Manage submissions, registrations, variations, renewals, authority correspondence, commitments, and regulatory intelligence.
- Safety: Support pharmacovigilance activities, signal management, case workflows, compliance obligations, and ongoing product safety monitoring.



Technology alone doesn't solve regulatory complexity. It must reflect how regulatory teams actually work. RegXtrakt is the result of years of regulatory consulting experience across global markets. We've built a platform that connects information, workflows, and regulatory knowledge so organizations can operate more efficiently while maintaining compliance throughout the product lifecycle.

regxtrakt

ADITYA TALLAPRAGADA
PRESIDENT, AKT HEALTH INC

AKT Health

Aditya Tallapragada, President of AKT Health, on why RegXtrakt was built to reflect how regulatory teams actually work.

regxtrakt

RegXtrakt -AI-powered regulatory operations platform by AKT Health unifying Regulatory Affairs, Quality, Safety, and Labelling.

- Quality: Centralize quality management processes, controlled documentation, CAPAs, audits, supplier management, risk management, and inspection readiness.
- Labelling: Coordinate product information, artwork, multilingual labelling workflows, version control, and market-specific compliance requirements.

Because every module operates from the same regulatory data foundation, information flows across functions without manual duplication.

Built to Simplify Regulatory Complexity

At the core of RegXtrakt is [Hakase AI](#) Coworker, an AI-powered assistant embedded throughout the platform, designed specifically for regulated life sciences environments. Rather than functioning as a generic conversational AI, Hakase works across submissions, registrations, quality records, safety data, authority correspondence, controlled documents, and operational workflows to help regulatory teams retrieve information, generate insights, and accelerate day-to-day regulatory activities.

Hakase assists with a broad range of regulatory tasks, including retrieving regulatory knowledge, summarizing complex documentation, drafting submission content and authority responses, identifying dossier gaps, analyzing regulatory obligations, surfacing compliance risks, and supporting regulatory decision-making. It can also reference internationally recognized regulatory frameworks and guidance, including ICH, EMA, FDA, and WHO publications, alongside an organization's own regulatory records to provide contextual regulatory support. By connecting information across Regulatory Affairs, Quality, Safety, and Labelling, Hakase enables teams to work from a shared understanding of their regulatory landscape rather than isolated systems.

Designed with enterprise governance in mind, every AI-generated output remains grounded in the organization's own regulatory records, with recommendations fully traceable to their underlying sources and subject to human review before regulatory decisions are made. This approach enables organizations to leverage AI while maintaining the transparency, control, and governance expected in highly regulated industries.

Designed for Global Regulatory Operations

RegXtrakt is built to support life sciences organizations managing regulatory operations across multiple regions and regulatory authorities. Its configurable architecture supports country- and authority-specific regulatory processes and multilingual documentation, while maintaining consistency across a global product portfolio.

Designed to scale alongside organizational growth, RegXtrakt enables companies to extend regulatory operations across new markets while preserving standardized processes, connected data, and end-to-end visibility within a single regulatory operating environment.

Connecting Expertise with Technology

For AKT Health, RegXtrakt represents a shift from advising on regulatory operations to running them alongside its clients. Organizations increasingly need more than a system that stores regulatory information; they need regulatory knowledge to move efficiently across functions, support informed decisions, and hold up under inspection. RegXtrakt was built with that standard in mind, combining AKT Health's regulatory consulting practice with AI-enabled technology to help organizations modernize regulatory operations while maintaining the governance regulated industries require.

About RegXtrakt

RegXtrakt is an AI-powered regulatory operations platform powered by AKT Health to help pharmaceutical, biotechnology, medical device, and digital health organizations manage Regulatory Affairs, Quality, Safety, and Labelling within a single connected platform. By integrating regulatory workflows, AI-assisted intelligence, and lifecycle management, RegXtrakt helps organizations improve operational efficiency, strengthen compliance, and accelerate regulatory execution | Visit to know more: <https://regxtrakt.ai/>

About AKT Health

AKT Health is a data-driven global life sciences consulting and technology company founded in 2017, supporting pharmaceutical, biotechnology, medical device, and digital health organizations across the healthcare product lifecycle, with operations spanning India, Japan, the United States, and the UAE.

The company brings together expertise across Regulatory Affairs, Clinical Development, Pharmacovigilance, Medical Affairs, HEOR, Market Access, and Commercial Strategy, supported by in-house AI-enabled Digital Solutions that strengthen data quality, improve operational efficiency, and support informed decision-making. This integrated approach helps organizations navigate complex regulatory environments, generate robust clinical and real-world evidence, and accelerate regulatory readiness and market entry. From strategy and development through regulatory submission, approval, and patient access, AKT Health connects every stage of the product lifecycle, helping organizations bring innovative healthcare products to market with greater speed, regulatory confidence, and long-term compliance | Visit to know more: <https://www.akthealth.com/>

AKT Health

AKT Health

[email us here](#)

Visit us on social media:

[LinkedIn](#)

[Facebook](#)

[YouTube](#)

[X](#)

[Other](#)

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2026 Newsmatics Inc. All Right Reserved.