Global Key Solutions Launches KeyPedia Predictive Risk Intelligence

The first platform to connect and score regulatory enforcement history across FDA and major global health authorities. KeyPedia Predictive is live.

KeyPedia Predictive, the first platform to connect and score regulatory enforcement history across FDA and major global health authorities.

NEW YORK, NY, UNITED STATES, April 28, 2026 /EINPresswire.com/ -- Global Key Solutions (GKS), the company behind the KeyPedia platform, announced the launch of KeyPedia Predictive, a comprehensive system that surfaces recurring regulatory citation patterns across any pharmaceutical manufacturing facility in the world.

KeyPedia aggregates enforcement actions and data from the FDA and other major global health authorities, including EMA, NMPA, Health Canada, and more, into a unified regulatory knowledge graph ontology. The platform's proprietary KeyPedia Risk Analysis (KRA) Score assigns risk ratings to facilities based on historical citation frequency, severity, vulnerability, and trend direction, giving quality and regulatory affairs teams a structured risk picture that previously required days of manual research to assemble.

> “What is the cost of a poor outcome? Recalls, delays, drug relabels, and even smaller events that have a real impact, not just on the business, but on the patient. And that’s why we’re here.”
>
> *Daniel Baretto, Ex-FDA, CEO PharmQ Global*

KeyPedia Predictive offers a range of capabilities, that include, but are not limited to;

KRA Score: Proprietary facility-level risk scoring across five operational dimensions, including manufacturing type, product form, geographic jurisdiction, compliance history, and trend analysis.

Predictive Risk Analysis Reports: Ranked violation categories with historical citation evidence, inspector pattern analysis, and regulatory correspondence probability scoring at 1-month, 6-month, and 1-year horizons.

Regulatory Knowledge Graph: Connected data linking facilities, inspections, observations, inspectors, and enforcement actions across the FDA and major global health authorities.

Inspector Profiles: Individual investigator track records, including citation frequency, observation category preferences, and active regional assignments
Global Coverage: FDA, EMA, MHRA, Health Canada, and additional authorities.

Three Problems KeyPedia Solves;

What Will an FDA Investigator Cite Me For?

KeyPedia assesses 21 CFR Parts 210 and 211 and matches observations with resolutions and long-form citations, bridging the gap between what gets cited, by whom, and since when. Query 483 and warning letter observations by product type, facility country, and inspection year, in the exact language FDA uses. Stop preparing for the last inspection. Prepare for the next one.

Which of My Foreign Suppliers Is Operating in a Blind Spot?

Surface the full enforcement history for any foreign facility across FDA, EMA, MHRA, Health Canada, and more in one search. Mapping any API or finished dose supplier against FDA inspection frequency by country and year before you sign a qualification contract. The oversight gap is not hidden. If it is quiet, silence is also telling.

What Is the Next Thing FDA Will Cite the Industry For?

Trend-assess any keyword across the full enforcement corpus. AI references in FDA Warning Letters have increased more than twofold in recent months. Using KeyPedia Predictive, teams can detect when new regulatory topics enter guidance and model how fast they migrate into enforcement. By the time the headline Warning Letter drops, the signal has been visible for many months.

Pharmaceutical quality teams face a fundamental information imbalance when preparing for inspections, qualifying suppliers, or even just monitoring their regulatory environment. Regulatory enforcement data is publicly available but fragmented across dozens of health authority databases, published in inconsistent formats, and requiring significant manual effort to analyze at scale.

Research published by GKS in the Journal of Pharmaceutical Innovation in 2026 found that FDA inspects foreign drug manufacturing facilities at roughly half the rate of domestic facilities, creating structural blind spots for quality teams whose supply chains span multiple jurisdictions.

KeyPedia addresses this gap by aggregating, normalizing, and scoring regulatory data across jurisdictions, giving quality teams a single platform for comprehensive regulatory intelligence.

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