



# THE FUTURE OF REGULATORY AFFAIRS

THE ROLE OF AI



# **MOVING TOWARD AN AI-AUGMENTED REGULATORY ECOSYSTEM**

The regulatory affairs landscape is entering a new era, with AI implementations at major health authorities globally, including the U.S. Food and Drug Administration's (FDA's) Elsa system and the European Medicines Agency's (EMA's) Scientific Explorer. These AI implementations are already demonstrating measurable improvements in regulatory review efficiency and consistency.

Simultaneously, pharmaceutical sponsors are exploring AI-enabled solutions to strengthen submission quality, reduce validation failures, and accelerate time to market across global jurisdictions. This report depicts the current state of AI adoption in regulatory affairs, documenting the tools, applications and governance considerations that define the transition from a paper-based to an AI- or intelligence-augmented regulatory ecosystem.

## **FOR SPONSORS: Potential role of AI in eCTD submissions**

### **1. Proactive technical compliance**

AI can identify submission risks before compilation by analyzing structure, metadata and content against authority-specific validation rules.

#### **Applications:**

- Early detection of XML, naming and structural errors
- Automated hyperlink and bookmark integrity checks
- PDF compliance verification

**Value:** Reduced technical validation failures and resubmissions

### **2. Content readiness and authoring support**

AI supports earlier eCTD readiness by evaluating documents during authoring.

#### **Applications:**

- Verifying heading structures for automated bookmarking
- Detecting scanned or non-searchable text
- Highlighting inconsistent terminology or references

**Value:** Higher-quality documents and smoother publishing

## **GOVERNANCE CONSIDERATIONS**

AI in regulatory submissions must operate within controlled, validated environments.

- Human-in-the-loop model: Human management and review remain essential
- AI outputs must be explainable and auditable
- Compliance accountability remains with sponsor

### **3. Intelligent life-cycle management**

AI can analyze prior sequences to guide correct life-cycle operations.

#### **Applications:**

- Recommending appropriate life-cycle operators
- Identifying duplicate content so that identical documents are not repetitively submitted to the application (e.g., investigator CVs and 1572 forms, labeling files, etc.), or modules and sections in the XML structure where copy links of existing content can be used (i.e., files throughout your previous sequences that can be reused in your current submissions)
- Identifying obsolete content to apply a life-cycle operator appropriately (e.g., old or draft versions of reports)
- Visualizing life-cycle impact across submissions

**Value:** Fewer life-cycle errors and clearer regulatory history

### **4. Authority-specific submission intelligence**

AI can adapt checks to regional technical requirements and evolving guidance.

#### **Applications:**

- Differentiating validation expectations across the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA)
- Supporting parallel global submissions
- Anticipating eCTD 4.0 technical requirements

**Value:** Faster, more consistent global submissions

### **5. Quality control beyond validation**

AI enhances QC by assessing reviewer usability, not just via pass/fail compliance.

#### **Applications:**

- Navigability and table-of-contents optimization
- Cross-document reference consistency
- Reviewer-effort scoring

**Value:** Improved review efficiency and sponsor credibility

### **6. eCTD 4.0 transition support**

AI helps organizations move toward data-centric submissions.

#### **Applications:**

- Mapping documents to structured content and metadata
- Validating data completeness and reuse
- Supporting hybrid eCTD 3.2.2/4.0 environments

**Value:** Lower transition risk and improved future readiness



## **FOR HEALTH AUTHORITIES: AI implementation has already begun**

### **U.S. Food and Drug Administration (FDA)**

#### **Elsa**

Elsa is a generative AI tool publicly launched and rolled out agencywide across the FDA in June 2025 to support agency staff, including scientific reviewers, investigators and inspectors, in handling large volumes of unstructured regulatory data. Elsa is built on a large language model (LLM) and designed to assist with reading, summarizing and writing tasks.

- Hosted within a high-security GovCloud environment, ensuring that all data used by Elsa stays inside the FDA's controlled systems
- Does not train on data submitted by regulated industry (e.g., sponsor dossiers), reducing risk of exposing proprietary or confidential information

#### **Primary uses within the FDA**

Elsa is designed to augment human reviewers (not replace them) by helping with routine, labor-intensive tasks:

##### **1. Summarizing and extracting information**

- Summarizes adverse event reports and safety profiles
- Assists with clinical protocol assessments and internal technical summaries

##### **2. Document comparison and synthesis**

- Compares drug labels/packaging inserts to highlight differences or inconsistencies
- Helps consolidate large packets of scientific evidence for quicker human review

With both Elsa and CDRH-GPT, the objective is to use AI tools to make review work more efficient and consistent, potentially speeding reviews for submissions like 510(k), De Novo, and PMA (high-risk) applications.

### 3. Internal workflow efficiency

- Helps generate code for internal database tasks (e.g., nonclinical data workflows)
- Supports identification of high-priority inspection targets and other compliance activities

#### Operational impact

According to FDA leadership, Elsa has dramatically shortened certain routine review tasks, e.g., tasks that took days to complete can now be completed in minutes, while the human reviewer retains decision authority.

#### Limitations and challenges

- **Accuracy and reliability concerns.** Internal staff have cited instances of hallucinated content where the AI confidently generates inaccurate or nonexistent references. Such behavior underlines the need for careful human verification.
- **Technical maturity.** Some early reviews describe Elsa as “clunky,” with constraints on document upload capabilities and integration with internal systems. It may not yet be able to handle complex regulatory formats or datasets without human support.
- **Scope of use.** Elsa is currently for internal use only and not part of the formal submission interface or external sponsor tools. Its use is focused on agency efficiency, not on automating regulatory determinations or submission acceptance.

### CDRH-GPT

CDRH-GPT is an internal AI tool in the early beta testing stage at the FDA's Center for Devices and Radiological Health (CDRH) to support regulatory review of medical devices.

The tool aims to help CDRH staff analyze large volumes of device-related documents and data such as clinical study results, engineering reports and safety information during premarket review cycles. It is intended as a decision-support aid for reviewers, not as an autonomous reviewer or decision maker.

CDRH-GPT complements Elsa, which, as noted earlier, has been rolled out for broader FDA use (e.g., clinical summaries, label comparisons).

## **AIM-NASH**

AIM-NASH (AI-Based Histologic Measurement of Nonalcoholic Steatohepatitis) is an AI-driven image analysis tool qualified by the FDA through its Drug Development Tools Qualification Program.

It is the first FDA-qualified AI tool intended to assist in drug development by standardizing the scoring of liver biopsy features used in metabolic dysfunction-associated steatohepatitis (MASH) clinical trials.

AIM-NASH helps reduce subjectivity and variability in histologic assessment, speeding up and enhancing consistency in MASH trial evaluations. It represents a formal step toward integrating AI into regulated clinical research workflows:

- Analyzes digital histology images to identify and quantify key disease features like fat accumulation, inflammation and fibrosis
- Generates standardized scores based on established clinical scoring systems
- Pathologists then review and interpret the AI outputs — humans remain responsible for final decisions

## **precisionFDA**

A secure, cloud-based collaborative computing environment, precisionFDA has been developed for FDA scientists, regulators, industry and external researchers to use in analyzing large biological datasets (e.g., genomics). The tool supports shared computational tools, workflows and data-analysis pipelines.

precisionFDA enables rigorous exploration of AI/ML models (including LLMs and automated analytics) under controlled conditions, advancing both regulatory science research and stakeholder collaboration ahead of real-world regulatory integration.

The tool serves as a **sandbox and development platform** for AI/ML research tied to regulatory science, including genomics, multiomics and drug safety analytics.

precisionFDA hosts challenges and pilot projects (e.g., AutoML and generative AI challenges) to advance innovative AI methods that may inform regulatory approaches.

The tool supports collaborative development/testing of AI applications in a secure, reproducible environment.



## **European Medicines Agency (EMA)**

### **Scientific Explorer**

An AI-enabled knowledge mining and search tool, Scientific Explorer was introduced by the EMA in March 2024 as part of the European Medicines Regulatory Network's (EMRN) broader AI strategy. It is designed to help EU regulators more efficiently access and extract scientific and regulatory information from internal regulatory data sources (i.e., extract key information from large volumes of regulatory and scientific documents).

### **AI-enhanced search and information retrieval**

Scientific Explorer uses natural language processing and other AI techniques to enable focused, efficient search across internal regulatory documents, especially scientific advice letters and related procedural data stored in EMA's IRIS system. Users can find relevant precedents, extract targeted information and see full source documents for context.

### **Knowledge mining**

The tool goes beyond simple keyword search, as its capabilities also include:

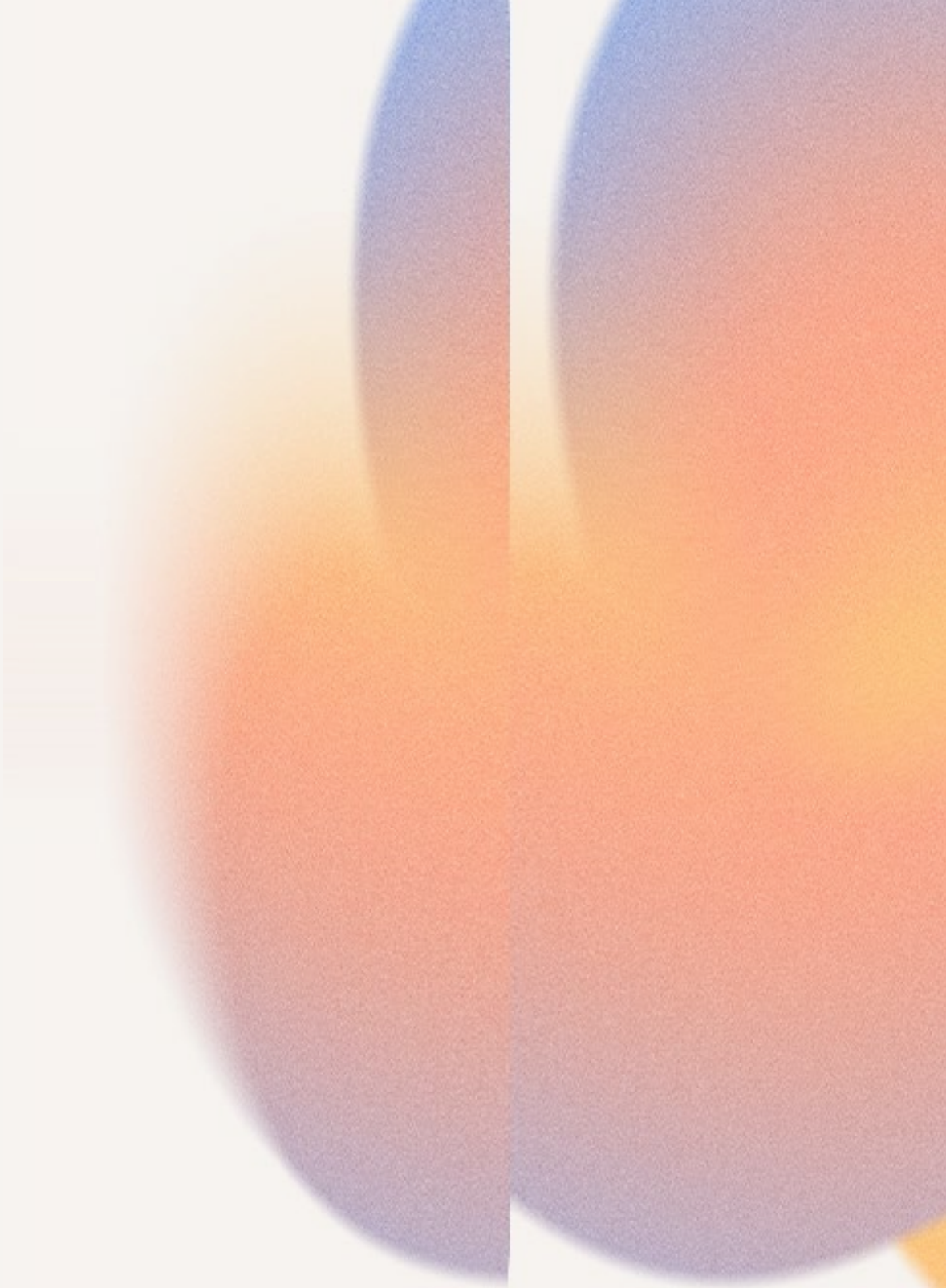
- Indexing AI-extracted structured information from unstructured text
- Enabling searches that retrieve concepts and categories, not just specific terms
- Combining extracted content with existing structured data from regulatory filings to improve insight discovery

### **Interactive query interface**

Scientific Explorer can offer a chat-like interface where authorized users can explore search results more interactively while always linking back to the original regulatory documents for validation and verification.

## **Pharmaceuticals and Medical Devices Agency (Japan) and Central Drugs Standard Control Organisation (India)**

While the specific tool names are less published publicly, many regulators, such as Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and India's Central Drugs Standard Control Organisation (CDSCO), are exploring or piloting AI-enabled dossier validation and submission support systems, often integrated with their e-governance portals.



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