Using GenAI to Draft Local Label Deviations in Pharma

By Adrien Laurent, CEO at IntuitionLabs • 11/24/2025 • 50 min read

generative ai · pharmaceutical labeling · local label deviation · veeva vault rim · ccds · regulatory affairs · life sciences · regulatory compliance

Executive Summary

Local market labeling poses a complex challenge for global pharmaceutical and life sciences companies. Companies maintain a **global reference label** (often the Company Core Data Sheet, CCDS) and must adapt it to meet diverse *local regulatory requirements* and languages in each market. As one industry study notes, even very large companies can lose visibility into these local deviations – local label content often *diverges* from the global base when local health authorities impose additional requirements or translators inadvertently misinterpret global text ([1] www.acolad.com) ([2] www.freyrsolutions.com). This problem has led to costly manual processes: industry case studies recount teams translating thousands of label documents into English, reviewing millions of words, and auditing every piece of artwork to identify discrepancies ([3] www.acolad.com) ([4] www.acolad.com). For example, one Fortune 100 pharmaceutical firm enlisted 400 linguists to retranslate 3,500 label files (13 million words) into English and painstakingly compared them to the master label ([3] www.acolad.com). As local labels mount into dozens of languages and countries, traditional spreadsheet tracking and manual review (as Moderna initially did for its COVID vaccine) quickly proved unsustainable ([5] www.veeva.com).

Veeva Systems offers a modern solution for regulatory information management (RIM) that explicitly tracks *label change concepts* and *deviations*. Its Vault RIM platform supports configuration of **Labeling Concept and Deviation** objects: global label changes propagate to local affiliates, who either accept them or document deviations (differences) requested by local health authorities (regulatory.veevavault.help) (regulatory.veevavault.help). In practice, leading companies (e.g. Moderna) have leveraged Veeva Vault to automate this workflow. Moderna, for instance, replaced spreadsheets with Vault RIM: labeling events are created and linked to Company Core Data Sheet (CCDS) updates, Vault *automatically generates* country-specific activities, and local affiliate deviations become visible and reportable globally ([6] www.veeva.com). This automation prevented "snowballing" spreadsheets of changes, giving the team real-time visibility of hundreds of concurrent label versions across 28 countries ([7] www.veeva.com) ([6] www.veeva.com).

Generative AI (GenAI) and large language models (LLMs) promise further transformation. The pharmaceutical industry is actively exploring GenAI for regulatory tasks, from summarizing guidance to drafting submission documents ([8] www.veeva.com) ([9] www.freyafusion.com). For labeling specifically, GenAI could assist in drafting *local deviations* by automatically generating or adapting label copy for different markets. Potential applications include: automated translation of global label content into local languages with regulatory nuances ([10] www.freyafusion.com); semantically comparing global vs. local label text to flag changes ([11] www.freyafusion.com); and even synthesizing draft label wording to meet local requirements. Emerging case studies and pilot programs indicate substantial benefits: rapid content generation can cut review time (potentially turning days into hours) ([12] www.veeva.com), and AI-driven translation can produce high-confidence results that reduce reliance on manual linguists ([13] www.veeva.com).

However, the promise comes with caveats. Industry experts caution that current LLMs can hallucinate or omit critical precision ([14] www.veeva.com) ([15] pubmed.ncbi.nlm.nih.gov). They lack perfect traceability and may produce non-deterministic outputs, requiring oversight ([16] www.veeva.com) ([17] www.reuters.com). Regulated companies must ensure any AI-created label text meets the strict accuracy, auditability, and privacy standards (GxP, 21 CFR Part 11, etc.). In practice, experts advise using GenAI as an **assistive tool** – to draft suggestions and highlight differences – rather than as an unsupervised author ([14] www.veeva.com) ([18] blog.gramener.com). With appropriate guardrails and human review, GenAI can accelerate local label development. Regulatory agencies themselves (like the FDA) are beginning to adopt AI to streamline reviews ([19] www.reuters.com), indicating institutional acceptance of AI-support, provided compliance and security are ensured.

This report offers a deep analysis of how GenAI can aid **local label deviation** drafting, set against the technical and regulatory context. We examine the baseline labeling process, Veeva RIM's label tracking capabilities, and detailed GenAI use cases. We cite multiple case studies (including Moderna's RIM implementation and a Fortune 100 labeling audit ([5] www.veeva.com) ([3] www.acolad.com)) and current industry perspectives ([16] www.veeva.com) ([20] blog.gramener.com). We present data on labeling volume and complexity ([3] www.acolad.com) ([21] www.freyafusion.com), and scrutinize how LLMs handle regulatory text([22] pubmed.ncbi.nlm.nih.gov) ([23] www.freyafusion.com). Finally, we discuss implications for organizations and regulators, and outline best-practice recommendations. Our conclusion synthesizes whether – and how – GenAI can actually draft local label deviations in a way that is efficient **and** compliant.

Introduction and Background

Global pharmaceutical labeling is bound by a complex tapestry of regulations. **Labeling** includes all the written instructions and information (package inserts, cartons, patient leaflets, etc.) that accompany a drug or device. Each product has an *official label* in every country it is sold. At the global level, companies maintain a reference label (often the Company Core Data Sheet, or CCDS) which compiles the best-known safety, efficacy, and usage data. Local marketing authorization holders (MAHs) then derive each country's label (e.g. EU SmPC, USPI) from the global core. Under ICH guidelines, companies "prepare their own *Company Core Data Sheet* (CCDS) which covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product" ([24] www.freyrsolutions.com). The CCDS serves as the "central document" or master reference of core safety information; local labels are supposed to be aligned with this core document ([24] www.freyrsolutions.com).

However, **local labels frequently deviate** from the company's CCDS. Every regulatory authority has its own required template, phrasing, and mandatory sections. For example, the EU SmPC list navigation items such as "Driving and Operating Machinery," whereas US labels may omit that section ([25] www.freyrsolutions.com). Local content must comply with *both* the CCDS and country-specific rules. In practice, "the final local label might have difference with the proposed label submitted by the MAH. Hence, the local label might deviate from the company position on a product" ([2] www.freyrsolutions.com). Local Health Authorities (HAs) often insist on additions or phrasing changes – for instance, adding country-specific medical data or warnings that the global core did not include ([26] www.acolad.com) ([2] www.freyrsolutions.com). Conversely, translations and decentralized processes can introduce errors: local translators "might misinterpret" CCDS content, and decentralized affiliates may independently modify labels without centralized oversight ([26] www.acolad.com).

Managing these deviations is a major operational challenge. A 2020 case study (Fortune 100 pharma) described a massive effort to identify *all* discrepancies across 95 countries and 47 languages ([27] www.acolad.com) ([4] www.acolad.com). The firm's global regulatory team "lost sight" of local labeling reality; internal audits showed labels with divergent patient instructions ([1] www.acolad.com) ([28] www.acolad.com). They deployed 400 linguists to retranslate 13 million words of local labeling back to English and scrutinized them for compliance ([3] www.acolad.com) ([29] www.acolad.com). The audit found numerous mismatches and classifier flagged issues "classified as significant or critical by the relevant health authorities" ([27] www.acolad.com) ([30] www.acolad.com). Only with this colossal effort were they able to catalogue all deviations.

Traditional approaches rely on manual review, spreadsheets, and translation agencies. In the Moderna vaccine rollout, the regulatory group initially tracked label changes via spreadsheets. Moderna's senior director of global labeling recalled: "Local labels had to be customized, and the number of variations we needed to track snowballed really quickly," especially as the core data sheet (CCDS) was updated monthly ([5] www.veeva.com). In early 2021, managing hundreds of label files manually became "too unwieldy for a spreadsheet" ([5] www.veeva.com). The decentralized process – waves of countries, each with their own regulatory review – meant that without a robust system, local deviations were practically inevitable and hard to track.

Generative AI has emerged as a possible game-changer in this space. Starting in 2023, life sciences leaders began testing large language models (LLMs) in regulatory affairs. GenAI tools can **understand and produce** human language, potentially automating tasks like summarizing guidance documents, translating text, and even drafting new content. Veeva's own regulatory team notes that "the most explored regulatory use case of GenAI is automating draft versions of dossier documents," explicitly including *labels* among document types being considered ([8] www.veeva.com). Meanwhile, forward-looking regulatory agencies (including the FDA) have piloted GenAI internally to handle repetitive reviews and intelligence gathering ([19] www.reuters.com).

In broad terms, GenAI could assist labeling by:

- **Translating and localizing** label text into new languages or regulatory styles ([10] www.freyafusion.com).
- **Summarizing** lengthy regulatory guidances or safety documents to speed strategy.
- **Comparing versions** to highlight where local labels diverge from global templates ([11] www.freyafusion.com).
- **Generating draft content**: e.g. proposing wording for warnings or instructions that satisfy local rules.
- **Answering queries** about labeling history or requirements via conversational interfaces (AI chatbots).

These capabilities map directly onto the core labeling challenge of aligning global and local content. If successful, GenAI could draft local label deviation text far faster than humans, help catch inconsistencies, and reduce translation burdens. Industry experts, however, emphasize caution: LLMs can hallucinate (produce plausible-sounding but incorrect information) or overlook subtle regulatory nuances ([16] www.veeva.com) ([14] www.veeva.com). Hence, the question is whether GenAI can reliably *assist* in drafting and reviewing local label deviations – saving time and cost – without compromising accuracy or compliance.

This report explores that question in depth. We review the current state of label management (particularly via Veeva Vault), examine the nature of local deviations, and survey how GenAI is being used (and could be used) in labeling tasks. We analyze quantitative data where available (e.g. document volumes, pilot results) and incorporate case studies from industry. We also discuss regulatory considerations and future outlook. Each section is based on published sources, including industry white papers, academic studies, regulatory news, and Veeva technical documentation. Claims about benefits or risks of GenAI are supported by citations to real-world experiments and expert analysis. Throughout, we address the central question: **Can Generative AI help you draft local label deviations?**

Pharmaceutical Labeling and Local Deviations

Global vs. Local Labeling

Pharmaceutical labels are legally binding documents. For each medicinal product, the *global core label* or CCDS contains the company's authoritative safety and efficacy profile. For example, the International Council for Harmonisation (ICH) defines the Company Core Data Sheet as covering "material relating to safety, indications, dosing… and other information concerning the product" ([24] www.freyrsolutions.com). In practice, global regulatory teams develop the CCDS in line with the global submissions (e.g. the Common Technical Document, CTD) and health authority-approved labels (e.g. USPI, SmPC). Once the CCDS is approved, it serves as the reference for *all* local labels.

Local labels – which may be called Country-specific Pack Patient Information Leaflets, Package Inserts, or Summary of Product Characteristics (SmPC) depending on region – are derived from that CCDS. The marketing authorization holder (MAH) must submit a local label to each national HA for approval. The local HA may ask for edits, or the affiliate might include additional content required locally ([2] www.freyrsolutions.com). Thus the **affiliated country label** becomes the official label in market.

Crucially, the **local label often deviates from the global CCDS**. Any difference – whether an added paragraph, changed instruction, or omitted section – is considered a *deviation*. Common causes include:

- **Regulatory Template Requirements**: HAs have mandated sections. For example, EU SmPCs always include a "Driving and Operating Machinery" heading, even if the CCDS has nothing specific to say on that point ([25] www.freyrsolutions.com). In contrast, USPI templates do not have that section unless justified. Affiliates may have to insert boilerplate text to satisfy template requirements.
- **Local Safety Findings or Requirements**: Some countries demand additional data (e.g. local population studies, pharmacogenomics info) in the label. For instance, local regulators may add specific frequency tables for pharmacokinetic data, or local child safety warnings not in the global label ([26] www.acolad.com).
- **Language and Interpretation**: Translators might inadvertently alter nuance. One case report notes that "local translators or authors might misinterpret what is stated in the company's prime reference document (CCDS)" ([26] www.acolad.com). Seemingly subtle phrasing changes (e.g. intensity of a warning) can result in meaningful differences.
- **Operational Discrepancies**: In decentralized commercial models, local affiliates sometimes have autonomy to adjust label text for market preferences. This can introduce unsynchronized content across markets.

A summary of the CCDS versus local label relationship is shown below. The CCDS is kept continuously up-to-date with global data, and local labels should either mirror it or justify any differences:

Document	Scope & Role	Control	Approved by
Company Core Data Sheet (CCDS)	Global reference label covering all products, safety, and usage information ([24] www.freyrsolutions.com)	Global RA/Pharmacovigilance team	Company (Health Authorities accept via core submissions)
Local Label (USPI, SmPC, etc.)	Country-specific official label used in local language and format ([2] www.freyrsolutions.com)	Local affiliate / MAH in that country	Local Health Authority (approval required)

Table 1: Global vs. Local Label documents and authorities.

The key phrase from Freyr's industry analysis is instructive: *"the final local label might have difference with the proposed label submitted by the MAH. Hence, the local label might deviate from the company position on a product."* ([2] www.freyrsolutions.com). This deviation is not merely hypothetical – it is the norm. Every major pharma sees routine "local label deviations": when an affiliate implements local HA feedback, additional warnings, or template-required text, the final output diverges. Managing these divergences transparently and efficiently is crucial for compliance.

Challenges in Managing Local Label Deviations

Local deviations pose several challenges:

- **Volume and Complexity**: The sheer number of label variants is huge. A single global product may have labels in dozens of countries and languages. The Acolad case study reported auditing 95 countries and 47 language combinations ([27] www.acolad.com). Moderna, by late 2022, estimated ~ hundreds of label versions at any one time across 28 countries ([7] www.veeva.com). One analysis notes there are over 130,000 drug label documents publicly available for different markets ([21] www.freyafusion.com) – and industry likely has more closed-label docs. Keeping track of which version is active where (and collecting them all) is a burdensome task.

- **Manual Workload and Cost**: Traditional workflows require immense manual effort. The Fortune 100 case described required *3,500 files (13 million words)* to be translated and reviewed ([3] www.acolad.com), plus *21,000 pieces of artwork* to be analyzed ([29] www.acolad.com). Acolad and the customer deployed *200+ assessors* over 18 months ([29] www.acolad.com). Even after that, they needed ongoing interim checks on in-progress labeling. This leads to millions of dollars of cost (the case reported over $1.25M in savings gained by process improvements after the audit ([31] www.acolad.com)). Yet despite these resources, errors can slip through: products might ship with outdated warnings or missing information, risking compliance issues or patient safety.

- **Global Oversight and Compliance Risk**: Regulatory compliance demands that the global RA team stay aware of all local labels. Without good tracking, an unnoticed local deviation could mean failure to meet minimum safety standards globally. For example, if a local HA mandates a contraindication that is ignored, the company could be out-of-compliance internationally. The global team "lost sight of the state of local labeling" in the Acolad example, creating fear that "labels carried different information or instructions to patients" ([32] www.acolad.com). Indeed, local label deviations have landed companies in trouble: fines and product recalls have occurred from mislabeled warnings.

- **Communication Silos**: Often, local affiliates work semi-independently. Communication gaps can occur: the global team updates the CCDS but local affiliates are late in applying changes. At Moderna, "updates to the Company Core Data Sheet (CCDS) were happening monthly, triggering a recurring cascade of local label changes… Multiplying those changes over all local labels became too unwieldy for a spreadsheet" ([5] www.veeva.com). In absence of a unified system, tracking every change request and its local disposition was chaotic.

- **Regulatory Scrutiny**: Inspectors expect a controlled process. As Acolad's customer learned, failure to have clear evidence of compliance can be cited by regulators. Labeling is a high-impact area (affecting patient safety directly), so health authorities demand traceability, documentation, and prompt updates.

Overall, managing local labeling in traditional ways is extremely laborious and prone to errors. The industry consensus is that integrated digital solutions (like Vault RIM, Labeling Suites, etc.) are needed for visibility (regulatory.veevavault.help) ([5] www.veeva.com). Even then, content drafting and compliance review remain human-intensive. This sets the stage for exploring automation – specifically, generative AI – to streamline aspects of local label deviation handling.

Veeva Vault RIM: Label Management and Deviation Tracking

Veeva's Label Concept & Deviation Tracking

Veeva Systems' Vault platform is a cloud-based suite for life sciences content and data management. One application, **Vault RIM (Regulatory Information Management)**, was developed to manage regulatory activities, including labeling. Within Vault RIM, there is functionality specifically for *label change tracking*. According to Veeva documentation, Vault RIM Registrations can be configured with **Labeling Events**, **Labeling Concepts**, and **Labeling Deviations** objects that map global-to-local changes (regulatory.veevavault.help) (regulatory.veevavault.help).

- A **Labeling Event** is an event record (often tied to a clinical or safety update) that impacts labeling. The event captures metadata like Safety Category, Trigger Date, etc. If an event has labeling impact, users can indicate "Labeling Impact = Yes", which reveals fields for linking to the relevant Company Core Data Sheet (CCDS) version(s) (regulatory.veevavault.help).

- **Labeling Concepts** attach to events as proposed changes at the section level. They represent specific text changes or sections of the CCDS that will be updated (e.g. a new contraindication statement) (regulatory.veevavault.help).

- **Activities** are individual assignments for local affiliates to implement a specific Labeling Concept. When an event is assessed, Vault RIM can bulk-create an Activity for each country/product combination impacted. Each Activity asks the local team to implement the concept and report back.
- **Labeling Deviations** are created whenever a local affiliate cannot or does not implement the proposed concept exactly. If, for example, the case requires that a French label omit a new ingredient, or phrase a warning differently, the affiliate records that deviation. Formally, "the Labeling Deviations object… allows for tracking and management of instances where the local market's label differs from what was proposed in the event's Label Concept" (regulatory.veevavault.help).

In effect, Vault RIM automates the **change control** process: when the global label changes, local change requests are generated and deviations are logged. All label content – both the terms of the change and any local disclaimers – are recorded in one system. Administrators can configure fields and workflows so that walking a change through the global-to-local cycle is streamlined (regulatory.veevavault.help) (regulatory.veevavault.help). For example, when a local HA *rejects* or modifies a proposed CCDS update, the affiliate registers the deviation, and Vault surfaces it on the global timeline. The centralized RA team thus "makes the changes and timelines globally and locally visible while the label content is approved, updated, and submitted" (regulatory.veevavault.help).

This approach was remarkably effective for Moderna. By mid-2021 Moderna had "a strong process in place" and worked with Veeva to implement a labeling module. In their new process, any labeling change initiates a Vault RIM event and concept. Vault "automatically generates an activity for every impacted market, eliminating the need to compile local label deviations by hand" ([6] www.veeva.com). The system then tracks each country's completion date and submission status. Previously, Moderna's team had been tracking dozens of label versions manually; by centralizing this in Vault, the regulatory group achieved end-to-end visibility and expedited the vaccine rollout ([5] www.veeva.com) ([7] www.veeva.com). As the Moderna case study quotes, the team "could export the latest status information from Veeva RIM to share with senior managers and inspectors" ([33] www.veeva.com), demonstrating compliance.

Key outcomes of Vault RIM's label management for Moderna included:

- **Time savings**: What took spreadsheets months to compile was done in minutes by the system.
- **Scalability**: As the vaccine moved approval-by-approval, Vault handled waves of new countries without new custom processes.
- **Visibility**: Hundreds of concurrent label changes (for vaccines in 28 countries) were visible in one place ([7] www.veeva.com).

Thus, modern RIM capabilities greatly reduce the logistical burden of *tracking* local deviations. However, even with Vault RIM, the content still has to be *written*. Veeva's solution manages *who needs to change what*, but the *text changes themselves* must still be authored. Enter GenAI as a potential assistant in that task.

Data and Workflows for Label Deviations

To illustrate the scale of work, consider typical data tracked in Vault RIM. In one implementation, thousands of Document and Label Change records are generated each year. Each Label Event might spawn dozens of Activities (one per region or label). Every Activity can have zero or one Deviations if the local affiliate accepts or modifies the change. Over time, the repository of Labeling Deviations becomes a rich dataset of how local labels differ. The Vault platform can store the actual text differences (e.g. with tracked changes) and metadata.

As of Nov. 2025, over 450 companies use Veeva RIM globally ([34] www.prnewswire.com). Among these are many that have integrated labeling in RIM. The Vault Direct Data API (100× faster access) and Vault content management allow partners and customers to query this data for analytics or AI applications ([35]

www.veeva.com). For example, a company could potentially run NLP over all Deviations to identify common reasons for label changes by country, or to flag unusually long review cycles.

This background sets the stage: Vault RIM provides structured data (events, concepts, deviations) linking global labels to local outcomes. In theory, this data could be fed into AI models to learn patterns of deviations or to autocomplete local text. Veeva's own AI Partner Program explicitly offers a **Vault Direct Data API sandbox** for this purpose ([36] www.prnewswire.com) ([37] www.veeva.com). Selected partners (TransPerfect, ZS, etc.) already process Vault data for tasks like translation and labeling workflow optimization. A GenAI tool could thus, for instance, pull the CCDS text and local regulatory templates from Vault, then output a draft local label deviation.

Limitations of Purely Manual Labeling Workflows

Before delving further into AI, it's worth noting the **inefficiencies** that remain even with advanced RIM. Moderna's RIM streamlined the *process*, but content creation still required heavy manual effort: local teams had to craft or approve the actual label text according to the concepts. Similarly, the Acolad story shows that companies often resort to heavy manual QA to ensure compliance ([3] www.acolad.com) ([4] www.acolad.com). These tasks include translating documents, reviewing multilingual text for accuracy, and cross-checking labels against regulations.

In manual workflows, there is often limited reuse of work. For example, two local labels with similar layout changes still require separate translation and review. If a global warning is updated, one must copy-n-paste it into each local template and re-translate, risking inconsistencies. While RIM organizes *which* labels need updates, it doesn't author the content. Thus, productivity gains have primarily come from information management (e.g. replacing spreadsheets with a database) rather than from generative content solutions.

This is the pain point GenAI aims to alleviate. The notion is that an LLM could **draft or update** label text as needed, rather than a human writer writing each one from scratch. If a global warning is modified, for instance, a GenAI could propose how to phrase the new text for each local template. One could feed the model the CCDS change plus a prompt like "Generate the corresponding US label text for [this CCDS change]" and obtain a draft to be reviewed. Similarly, given a set of local HA instructions, an LLM might suggest appropriate modifications to the global label. The rest of this report analyzes such scenarios, balancing potential benefits with practical constraints.

Generative AI in Regulatory Affairs

Modern **Generative AI** (GenAI) – especially Large Language Models (LLMs) like GPT-4 and similar – have opened new possibilities for content creation. In the life sciences sector, multiple studies and pilot programs are exploring GenAI for tasks like document authoring, intelligence summarization, and compliance monitoring ([8] www.veeva.com) ([9] www.freyafusion.com). Here, we review key findings on GenAI's application to regulatory and labeling tasks.

GenAI Capabilities and Pharma Use Cases

GenAI vs. *traditional* NLP: Unlike older rule-based systems, LLMs can produce entirely new text. They combine knowledge from massive corpora with contextual prompt instructions. For example, given a prompt about an experimental result, an LLM might draft a clinical study summary; given a regulatory guidance text, it might produce a bullet-point summary. In pharma labeling, such flexibility is tantalizing: LLMs can read a company's CCDS and attempt to generate the corresponding patient information leaflet in plain language, or vice versa.

Key NLP functions in labeling are already known: one marketing analysis notes that labeling teams can use NLP to "extract and compare critical label elements across versions and jurisdictions," "analyze large repositories of documents to identify trends and inconsistencies," and "automate routine tasks such as label update management, translation, and version validation" ([9] www.freyafusion.com). Generative AI enables these by providing *flexible, scalable, low-cost solutions*: it can do context-aware extraction, semantic comparisons, auto-generation of content, and multilingual support ([38] www.freyafusion.com). In practice, companies have started proof-of-concepts (POCs) for tasks such as:

- **Regulatory Intelligence Summarization**: Automating the scanning of health authority guidances. LLMs can read long documents (e.g. a 200-page FDA guidance) and produce concise summaries ([39] www.veeva.com). Early reports suggest this could "reduce the time regulatory strategists need for impact assessments from days to hours" ([12] www.veeva.com). However, vigilance is required because AI summaries can hallucinate or omit details ([12] www.veeva.com).

- **Translation and Localization**: GenAI-powered translation engines (mixing neural nets with traditional MT) are being tested. Large biopharmas have completed POCs for **AI-driven translation** of submission materials and labels into multiple languages ([13] www.veeva.com). According to Veeva's blog, this has shown promise in "reducing dependence on manual translation providers and accelerating QC cycles" ([13] www.veeva.com). For example, a core English label change could be fed through a specialized model to generate preliminary text in Spanish or Chinese ([10] www.freyafusion.com). GenAI also helps by handling inconsistent phrasing and terminology across languages.

- **Drafting Regulatory Documents**: The output of GenAI can be directly used to draft parts of filings (subject to review). Veeva notes that automating "draft versions of dossier documents" including Module 2 summaries, clinical reports, RMPs, and **labels** is a top GenAI use case ([8] www.veeva.com). In such use cases, GenAI generates human-readable drafts, which experienced writers then refine. The key is that the model must have "sufficient granularity in source document citations and data set traceability" to allow human reviewers to verify every statement ([40] www.veeva.com). Otherwise, you risk spending as much time fixing the draft as you would writing it.

- **Query Response Automation**: Companies are also investigating GenAI chatbots trained on historical HA queries. By retrieving similar past questions, an LLM can suggest answers to regulators' questions (for indeed letters or inspection responses) ([41] www.veeva.com). This approach could "enable near-simultaneous global product launches" by harmonizing answers across markets ([41] www.veeva.com). However, success depends on having a well-curated database of previous queries, which is often a pre-requisite.

- **Knowledge Extraction**: As an example of a research project, GPT-4 was used to **extract structured information from unstructured label text**. In one JAMIA study, GPT-4 was prompted to parse 46,421 free-text drug labels and construct a taxonomy of drug indications ([42] pubmed.ncbi.nlm.nih.gov) ([43] pubmed.ncbi.nlm.nih.gov). The model alone extracted 2,909 distinct indication terms and organized them into hierarchical categories, covering 189 marketed drugs ([43] pubmed.ncbi.nlm.nih.gov). The researchers found GPT-4 excelled at forming concept hierarchies (with agreement to human judgment above 0.7 accuracy ([43] pubmed.ncbi.nlm.nih.gov)). This demonstrates LLMs' power to *understand* label language at scale. (That project also noted that LLMs struggled with subtle concept relationships – pointing out that these tasks remain hard "for human experts" as well ([15] pubmed.ncbi.nlm.nih.gov).)

In all these use cases, GenAI acts as an **assistant**. It can churn through large volumes of text quickly and generate coherent outputs, but it lacks guaranteed molecular-level accuracy or domain-specific memory unless carefully guided. The repetition of concerns is common: GenAI outputs must be checked for errors. Veeva's regulatory AI blog warns of "non-deterministic responses" and "hallucinations" from GenAI, noting that the current wave of experimentation will reveal whether it "matures into an industry-disrupting innovation or remains a mere POC" ([16] www.veeva.com) ([14] www.veeva.com).

Benefits and Challenges of GenAI for Labeling

Potential benefits of applying GenAI to labeling tasks include:

- **Speed and Productivity**: Routine tasks like translation or initial draft writing can be done in seconds by an LLM instead of days by a human. Even with review overhead, overall cycle times can shrink. (Generative summarization alone "could reduce time…from days to hours, even minutes" ([12] www.veeva.com).)
- **Consistency and Coverage**: AI can ensure that all label sections are addressed consistently. For instance, an LLM might automatically populate every required template section appropriately, catching ones a human might forget. It can also continuously monitor and flag changes (as one table below illustrates).
- **Multilingual Scalability**: Modern LLMs support dozens of languages. A single global update might be simultaneously propagated into many local languages by a single multilingual model ([23] www.freyafusion.com) ([10] www.freyafusion.com). This reduces the burden on translation teams.
- **Enhanced Compliance Monitoring**: By continuously scanning text, AI can spot outdated or inconsistent statements. For example, an automated version compare tool could highlight if "strength" or "dose" values changed between versions ([44] www.freyafusion.com). This side-by-side automation can "catch discrepancies instantly, slashing manual review time" ([11] www.freyafusion.com).
- **Data-driven Insights**: Large language models can uncover patterns. Given a repository of past local deviations, AI might learn which countries often reject privacy language, or what phrasing triggers an HA query. These insights can feed into strategic planning.

However, the challenges are significant:

- **Accuracy and Hallucinations**: LLMs sometimes produce plausible but incorrect text (hallucinations). In labeling, such an error could mean adding or omitting a legally critical assertion. As Veeva warns, GenAI can produce "incorrect and misleading results" ([14] www.veeva.com). Citations and references (where an AI claims "according to FDA guideline XYZ") are often non-specific or fabricated. As [15] notes, AI citations "are not granular enough, making it challenging to review accuracy" ([14] www.veeva.com). In a compliance context, that is a red flag. Any AI-drafted label text would need human verification against authoritative sources.
- **Traceability and Audit Requirements**: Regulatory agencies require audit trails. If an AI tool suggests a label change, companies must document how it was generated and reviewed. Current LLMs do not inherently record deterministic paths from source data to output. Veeva's blog emphasizes that traceability must improve before widespread adoption ([14] www.veeva.com).
- **Regulatory Acceptance**: Regulators have begun to grapple with GenAI themselves. The FDA's engagement (Frederick emphasizes data security, user training, and pilot validation) suggests agencies want stringent controls ([45] www.reuters.com). Until there is regulatory guidance, companies may be cautious. For example, use of public chatbots (e.g. ChatGPT) with proprietary label data is generally prohibited under confidentiality standards.
- **Data Privacy and Security**: Label text often contains proprietary or personal data. If using cloud-based LLMs, companies must ensure PHI/PII is protected. The pharma industry has grave concerns about exposing IP to AI vendors. As one industry webinar summarized, "Generative AI technologies like ChatGPT… raise concerns about data privacy" and companies are experimenting with secure, privacy-preserving models ([46] blog.gramener.com). Strict access controls, encryption, and in-house AI solutions may be needed.
- **Need for Human-in-the-Loop**: Best practice is to keep humans engaged. The last section of [52] stresses that while GenAI can streamline processes, "requiring human oversight to ensure accuracy" ([18] blog.gramener.com) is crucial. In other words, GenAI proposals must not be blindly accepted. Regulatory experts will still need to review, correct, and approve label content. The ROI only materializes if AI significantly reduces low-level grunt work and leaves experts to focus on critical thinking.

The following table highlights example labeling tasks and contrasts traditional approaches with potential GenAI-enhanced workflows:

Labeling Task	Traditional Approach	GenAI-Enhanced Approach
Local label translation and adaptation	Human linguists manually translate CCDS changes into local language and idiom (as Acolad did: 400 linguists, 13 million words) ([3] www.acolad.com). QA involves multiple review passes.	AI-driven translation models (fine-tuned on pharma data) convert global text to local language and template. Advanced ML can inject country-specific phrasing. For example, "AI models handle translations and local variations, ensuring that core content is cascaded with language-specific nuances" ([10] www.freyafusion.com).
Drafting new or updated label text	Regulatory writers use templates to manually write local text, guided by the CCDS. Each revision is a full writing/editing cycle (prone to omission).	LLM prompt engineering generates initial label snippets. E.g., prompt with new CCDS warning and country HA notes to produce draft Prescribing Information line items. GenAI serves as first draft "co-author," shaving hours off writing. Early POCs show models drafting dossier texts including "labels" ([8] www.veeva.com).
Tracking local deviations	Regulatory ops compiles spreadsheets or RIM activities to note differences. Human reviews label PDFs side-by-side.	NLP tools automatically compare text strings: highlight where local label diverges from CCDS. For instance, LLMs or diff-checkers can flag missing warnings or changed dosage. AI can produce summary reports of differences. Tools already exist for "extract and compare critical label elements across versions" ([9] www.freyafusion.com).
Monitoring Regulatory changes	RA teams manually review HA guidance repositories and email alerts. Periodic checklists ensure updates.	AI-powered surveillance: an LLM continuously scans new guidelines or even tracks competitor filings, alerting RA of pertinent changes. Automatic summarization of guidance (reducing assessment time from days to hours) ([12] www.veeva.com).
Quality Assurance (QA)	Medical reviewers proofread final labels against CCDS and regulations, catching human errors. Time-consuming.	Automated QA: side-by-side version comparison by AI catches inconsistencies instantly ([11] www.freyafusion.com). Spell-check, compliance checks (e.g. ensuring all required sections present) can be codified.

Table 2: Example Labeling Workflow Tasks – Traditional vs. GenAI-Enhanced.

The table suggests that GenAI is not a monolithic "solution" but a toolbox of capabilities (translation, summarization, content generation, comparison) that together could dramatically streamline local labeling updates. The extent of benefit will vary: straightforward translation tasks might see huge acceleration, whereas drafting complex safety narratives will still need expert refinement.

Use Cases: Generative AI for Local Label Deviations

Having outlined the general GenAI potential, we now focus on *local label deviations* specifically. In this section, we analyze scenarios where GenAI tools could assist in identifying, drafting, and managing local deviations.

Automating Local Language Translation and Adaptation

One of the most direct applications is local-language translation of global label content. When the CCDS is updated in English (or another "first-wave" language), local affiliates must retranslate. Generative AI can accelerate this. Modern LLMs like GPT-4 or specialized translation models can translate medical text at near-human fluency. Veeva's own observations mention POCs where "AI-driven translation" was used to generate submission and label documents for rest-of-world regions ([13] www.veeva.com). These systems typically combine neural machine translation with post-editing by humans. The idea is that AI handles the bulk translation, reducing time and cost, while a reviewer ensures regulatory compliance and nuance.

For local deviations, translation is only half the story – the phrasing must satisfy local template requirements. Advanced AI models can be trained (via prompt engineering or fine-tuning) to respect target-language conventions. A generated text could include country-specific regulatory checklist terms. For example, if an EU label must always have a blank "Driving" section, the AI translator would automatically insert it (possibly with placeholder content). The Freyafusion blog notes that *"Advanced AI models handle translations and local variations, ensuring that a core clinical content change is cascaded accurately across markets, complete with language-specific regulatory nuances"* ([10] www.freyafusion.com). In practice, this could mean an AI translation that not only switches language but formats units, references local approved disease acronyms, and uses terminology that local HAs prefer.

Case Example: A US-based global label updates its overdose warning. Using GenAI, the updated text is instantly translated into 10 European languages. The AI is fed each local SmPC template and instructed to fill only the relevant sections (skipping "driving" if irrelevant, for example). Human reviewers in each region then proofread, drastically cutting their workload. Early adopters report that AI+a single editor can match the speed of an entire translation team exigently ([13] www.veeva.com).

Crafting Country-Specific Draft Language

Beyond translation, local deviations often involve content creation. Suppose a local health authority requires adding a paragraph in the "Warnings" section about a rare local health risk. Currently, a regulatory writer researches local laws and composes text. GenAI can help by drafting initial copy.

Consider this workflow: The global CCDS is updated with new hepatic risk data. The global label now says: "Monitor liver enzymes monthly for first 6 months." In Brazil, the ANVISA requires a supplementary paragraph on tropical disease interactions. A writer could input to an LLM: *"Global label: [text]. Add Brazil-specific warning on hepatitis co-morbidity risk."* The model would output a draft warning tailored to Brazilian Portuguese (or English, to be translated). This draft might include phrasing common in prior ANVISA submissions. The writer then edits the draft. The key is that the AI provides a starting point far faster than blank-slate writing.

LLMs can also help with structural edits. For instance, if the template requires a "Pharmacogenomics" subsection, an AI could synthesize relevant content from the CCDS or literature, filling the template skeleton. Freyafusion's summary of GenAI potential lists "automated document processing and classification" as a utility ([47] www.freyafusion.com). While not tabled, it suggests using AI to populate semi-structured templates.

Identifying and Summarizing Deviations

Another use is for *review*, rather than *writing*. A generative model can highlight where the local label differs from the global label, summarizing deviations. For instance, a smart chatbot could be given the master CCDS text and the local label text, then asked: "What sections changed?" The AI could list bullet points of additions, deletions, and modifications, possibly with confidence scores for each. This is akin to "AI-driven comparison" of label versions.

This approach repurposes the LLM more as an analytical engine than a writer. Some firms are already using NLP to classify label content: for example, extracting all "Indications" or "Contraindications" from documents. A GenAI could do something like: *"Compare the old and new CCDS sections on Indications, and summarize how the local French label's Indications paragraph was modified relative to the updated CCDS."* The answer might say: “The French label added one new indication for pediatric use that was in CPU. The contraindications section truncated the list by removing [X], following EMA guidance.” This could save multilingual reviewers from eyeballing entire sections. As table 2 noted, automated version comparison can “catch discrepancies instantly” ([11] www.freyafusion.com).

Quality Control and Regulatory Compliance Checks

GenAI can also assist in QA. For example, an LLM might be asked to validate the consistency of a generated local label. A reviewer feeds the AI the draft label and the CCDS, asking: *“Does this French label include all warnings from the CCDS? Are any required sections missing?”* The AI would flag any omissions (e.g. if a contraindication was left out). Similarly, it could apply business rules: an AI could check if each required PHI (prescribed information) section is present by comparing it to a template. Veeva’s analysis points out that even non-GenAI automation can “automate document and data quality checks” as a first step ([48] www.veeva.com) – GenAI could enhance this with semantic understanding.

Regulatory Intelligence and Summaries

Generative AI could tie into higher-level regulatory intelligence that affects labels. For example, if a country publishes new labelling guidelines, an LLM could summarize how those changes might affect current labels. Or, if a competitor receives a local approval with a certain label text, an AI could scrape and analyze that label, proposing how to harmonize one’s own label. This is more speculative but aligns with the idea of using GenAI to *compare* cross-jurisdiction data. It could be potentially integrated with systems like Vault RIM’s “Company Core Data Sheet (CCD)” tracking: when CCD changes, the AI automatically suggests what local label sections to revisit.

Empirical Evidence and Pilot Outcomes

At present, much of the above is aspirational or in pilot stages. Public case studies specifically on GenAI drafting labels are scarce. However, Veeva’s blog [15] confirms that *labels are a considered use case*, and partners in the AI program (e.g. translation or regulatory tech firms) are likely exploring these exact scenarios.

From [15]:

> “Large biopharmas are exploring the value of GenAI for … accelerating dossier authoring. The most explored regulatory use case of GenAI is automating draft versions of dossier documents… (d) labels.” ([8] www.veeva.com)

This suggests industry interest is at least at proof-of-concept level. Additionally, the Freyafusion article 30 lists multi-lingual support and side-by-side comparisons as concrete AI functions. These are effectively the building blocks for local label deviation drafting (translation, summarization, QA).

Quantitative data is still emerging. The Acolad story provides pre-AI benchmarks: 13 million words, hundreds of reviewers ([3] www.acolad.com), and significant cost savings after audit. One could argue that if an LLM could replace even half those person-hours, the ROI would be huge. For instance, if automated translation cut 30% of the 400-linguist effort, that’s ~$150K saved (given 500K translation memory savings reported ([31] www.acolad.com)). Early indicators from laboratories outside pharma support similar efficiency gains: machine translation plus human edit is 2–5× faster than human-only workflows in regulated contexts ([13]

www.veeva.com). Extrapolating suggests generative tools could similarly yield multi-hundred-thousand-dollar savings industry-wide.

Risks and Mitigations

Despite potential, risks must be managed:

- **Hallucination Risk**: If an LLM invents facts in a label, that could lead to inaccurate claims. Mitigation: never use AI output without verification. Use lineage tracking; cross-check all AI-written statements with source data (e.g., attach CCDS references).
- **Compliance Risk**: Regulators may question AI involvement. Mitigation: End-of-chain human sign-off is essential. Maintain audit trails (some AI tools now log prompts and outputs; Veeva's Vault could store those as records).
- **Data Privacy**: Company data used in AI prompts must be secured (on-prem models or encrypted channels). Mitigation: use systems built on validated clouds, ensure vendors sign data confidentiality commitments.
- **User Trust**: Early users should be trained that AI is a *drafting aid*, not an oracle. Internal guidelines (like the 5Ws framework in [36]) can help define when/how to use GenAI. In the Grandener webinar, industry leaders emphasize "cautious optimism" and human-in-loop workflows ([18] blog.gramener.com).

Case Studies and Industry Perspectives

We review real-world examples and expert opinions to contextualize GenAI use in labeling.

Moderna's RIM Implementation (Non-AI Automation)

Moderna (biotech) provides a concrete illustration of modern label management without GenAI. Facing an urgent vaccine rollout, Moderna needed to "scale operations to expedite global vaccine rollout" ([49] www.veeva.com). Before 2021, they did manual label tracking. By April 2021, they partnered with Veeva to:

- Launch a *new label management process* in 3 months ([50] www.veeva.com).
- Use Vault RIM to track events, concepts, and deviations (automatically generating country-specific Activities ([6] www.veeva.com)).
- Load initial CCDS versions and begin iterative labeling updates.

Results:

- Automated population of local tasks: "Vault RIM automatically generates an activity for every impacted market" ([6] www.veeva.com).
- Enhanced visibility: They could see "the changes and timelines" globally and locally ([6] www.veeva.com).
- Compliance Ease: The team could export status reports for management and inspectors ([33] www.veeva.com).
- Scale: By late 2022, Moderna's vaccine had hundreds of label versions in 28 countries; the system "strengthened compliance with increased visibility" ([51] www.veeva.com) ([7] www.veeva.com).

While Moderna did not use GenAI for content, their case shows the value of integrated label systems. It benchmarks a successful automation project (3 months rollout, one platform for hundreds of label changes ([52]

www.veeva.com) ([7] www.veeva.com)). It highlights that even large pharma size can rapidly revamp their processes with the right tools. The implication is that adding GenAI into this new infrastructure could yield even greater efficiency.

Generic Manufacturer Labeling (Freyafusion White Paper)

The Freyafusion white paper introduces **Freya Fusion**, an AI-first regulatory information management system. It suggests specific generative AI uses for labeling:

- **Automated classification of label sections** into categories (warnings, dosage, contraindications) ([53] www.freyafusion.com).
- **Continuous compliance monitoring**, scanning label text against HA-specific rules ([54] www.freyafusion.com).
- **Extraction of structured data** from label text, unlocking analytics ([55] www.freyafusion.com).
- **Risk identification** (finding recurring errors in labels) ([56] www.freyafusion.com).
- **Multilingual support** (as discussed) ([10] www.freyafusion.com).
- **Automated side-by-side comparisons** to catch overlooked discrepancies ([11] www.freyafusion.com).

This perspective, albeit from a vendor, aligns with our analysis. The *table below from Freyafusion* (summarized here) matches the mapping of GenAI solutions to challenges:

Regulatory Challenge	GenAI NLP Solution
Diverse standards & frameworks across regions	Jurisdiction-aware text classification and rule-based checks ([57] www.freyafusion.com)
Constantly evolving requirements	Continuous compliance monitoring with real-time deviation alerts ([57] www.freyafusion.com)
Unstructured data and documentation overload	Structured information extraction from diverse sources ([57] www.freyafusion.com)
Multilingual discrepancies (generic companies matching innovator labels)	Advanced translation models to adapt core content with local regulatory nuances ([10] www.freyafusion.com) ([21] www.freyafusion.com)
Need for high accuracy and efficiency	Automated version comparisons to catch errors instantly ([11] www.freyafusion.com)

Table 3: Regulatory Challenges vs. GenAI Solutions (adapted from ([57] www.freyafusion.com) ([10] www.freyafusion.com)).

This "Table 3" is derived from Freyafusion's Table 1 and bulleted text. It underscores that generative NLP is seen as a direct response to the exact pain points of labeling.

Global Regulatory Landscape

Beyond corporate pilots, regulators are themselves engaging with AI. A May 2025 Reuters piece reports the FDA decided to "immediately start deploying AI tools internally" across all centers ([19] www.reuters.com). The FDA's pilot emphasized saving reviewers time and automating repetitive tasks. They are working on *usability, document integration,* and *security* ([45] www.reuters.com). Importantly, FDA is collaborating with providers like OpenAI to explore "AI applications" while maintaining stringent data protections ([58] www.reuters.com). This indicates that regulatory authorities see promise in AI to speed up reviews and compliance tasks, which bodes well for industry adoption – though with caution on data use.

Internationally, frameworks are emerging. For instance, Japan's Ministry of Digital Transformation drafted global AI principles emphasizing explainability and responsibility ([59] apnews.com). The European Commission is also writing rules for AI in regulated sectors (though not specific to pharma yet). Life sciences companies must therefore navigate both the opportunity of AI and the nascent regulation of AI itself. In this report, we assume companies will follow emerging standards for AI validation and governance as they explore these tools.

Expert Opinions and Guidelines

Industry experts emphasize that GenAI in pharma should start as *proof-of-concept and companion* rather than end-to-end automation. A Deloitte perspective notes life sciences organizations should begin with a clear strategy and focus on high-value use cases, gradually scaling ([60] www.veeva.com) (common-sense for any new tech). Veeva's executive commentary claims companies will invest in GenAI but "many organizations have decided to wait for foundational LLM maturity before production use" ([12] www.veeva.com).

A widely cited recommendation is the 2×2 matrix from the Veeva blog: companies should weigh **effort vs. value** for each AI use case ([61] www.veeva.com). For labeling, high value might be in repeated high-volume tasks (like translation) – which requires *moderate* tech effort. In contrast, lavish claims like "fully autonomous label writing" might be high effort with unproven value. The industry appears to be focusing initial GenAI trials on *augmenting processes they already do*, rather than reinventing the wheel from scratch.

The webinar summary from regulatory leaders (Gramener) highlights the adoption path: individuals will first try AI in their own workflows, gradually expanding as confidence builds ([62] blog.gramener.com). At the federal level, experts foresee regulators issuing **voluntary guidelines** to steward this transition ([63] blog.gramener.com). Meanwhile, internal safety measures like privacy-centric design (e.g. anonymized data, minimal external exposure) are top of mind ([46] blog.gramener.com).

In labeling specifically, TransPerfect (a localization services provider and Veeva partner) has promoted AI in translation. They report that hybrid AI/human translation can speed up projects by 50–75% compared to human-only, while maintaining quality. While a marketing claim, it suggests realistic efficiency gains. Organizations like Freya and Gramener emphasize the *requirement* that final review by a qualified professional remains essential.

Implications and Future Directions

Bringing together the above analysis, we address what this all means for stakeholders:

Implications for Companies

For global companies, the question is whether to invest in GenAI for labeling now or wait. The evidence tilts toward *selective early adoption*. Key takeaways:

- **Low-Hanging Fruit**: Begin with augmentation, not automation. For instance, use AI to generate draft translations and then have professional linguists post-edit. This can yield immediate cost and time savings with minimal risk. Similarly, use NLP to flag discrepancies (audit tool), but have humans decide on responses.

- **Data Readiness**: Companies should prepare their labeling data. Vault RIM stores structured label metadata ideally suited for AI (with country, language, and status fields). Getting all labels, approved CCDS versions, and past deviations into a consolidated digital repository is a prerequisite. Data quality (accurate, up-to-date content) is crucial – an LLM can only work with what it's given. Many companies undertake data cleanup for compliance; these efforts benefit later AI use.

- **Partner Ecosystem**: Leverage specialized solutions from Veeva AI partners or software vendors. For example, translation management systems (like TransPerfect's GlobalLink) may incorporate machine translation or AI suggestions for labeling translation. AI startups are emerging claiming to use LLMs for QA or content creation in regulated documents. Given Veeva's partner program, we expect third-party applications that plug into Vault to produce draft label text or QA analysis.

- **Skills and Training**: Introduce GenAI gradually and train regulatory staff. LLMs require skilled prompting; regulatory affairs professionals (non-technical) may need guidance on how to give effective instructions to the AI. Also train reviewers to critically assess AI output. User feedback loops (Humans evaluating the AI's suggestions) will drive improvement.

- **Governance and Oversight**: Develop internal policies for GenAI use. This should cover data privacy (no uploading confidential IP to public sites), validation (comparing LLM outputs against known correct answers), and documentation (recording which model and prompts produced each proposal). Regulatory Affairs and Quality Assurance teams should define approval workflows that integrate GenAI checkpoints while preserving accountability.

- **ROI and Metrics**: Track the impact of AI pilots. Metrics can include time saved per task, reduction in translation volume, number of label cycles shortened, or avoided inspection findings. For instance, if GenAI translation cuts an average of 20% off localization turnaround, that translates to measurable cost savings. Case studies like the Acolad one can inform ROI calculations.

Implications for Regulators

Regulators are aware of AI's burgeoning role. The fact that FDA is piloting GenAI internally and discussing with OpenAI ([64] www.reuters.com) implies they will adopt standards for its use. Possible inductive points:

- **Label Integrity**: Agencies will require that AI-assisted label content be fully validated. They may inspect how companies used AI: e.g., did the GenAI system have a known error rate? Was human oversight documented? One can imagine future audit queries: "Show us how LLM-generated text was verified."

- **Validation and Training Data**: If companies train models on proprietary data, regulators might ask about the training methods and validation sets used (paralleling pharma data/software validation good practices). They will likely insist on preventing leakage of sensitive data into third-party LLMs.

- **Guidance Documents**: Agencies like FDA and EMA may issue (or have issued) guidance on AI in regulatory submissions. While not label-specific, overarching digital health or QMS guidelines may come into play. For example, EMA has a "QMS for software" framework that could extend to labeling software.

- **Global Alignment**: Because local deviations concern local HAs, global regulators may not explicitly dictate AI use. However, agencies could coordinate to broker industry-wide AI certifications or standards (like a validated, medical-grade LLM version). The Organization for Economic Co-operation and Development (OECD) has AI principles that many health agencies follow, stressing AI *explainability* and *accountability*. If GenAI tools remain black boxes, agencies will push for explainable outputs (maybe requiring that LLM rationale be documented, though that's still an open area).

Future Directions

Looking ahead, we can envision:

- **Tighter LLM Integration in RIM**: In a few years, Vault or competitors may embed LLM features directly (similar to email autocorrect). For example, when a user addresses an Activity, Vault might suggest draft text pulled from the CCDS and past deviations. A prompt interface could wire together Vault's structured data with an AI model.

- **Customized Domain Models**: The industry may create proprietary LLMs fine-tuned on biomedical and regulatory text (beyond GPT-4). Indeed, research like [46] is already training AI on drug labels and ontology tasks. A specialized "LabelLLM" could outperform general models in accuracy.
- **Continuous Learning**: Real-world use will feed back into model improvement. If an AI-generated phrase is repeatedly edited to say something else, the system can learn from corrections (reinforcement). Over time, the model's outputs could approach 95–99% initial accuracy, reducing load on reviewers.
- **Expanded Scope**: Once accepted, GenAI could expand from labeling to all regulatory writing (e.g. clinical study reports, safety narratives). Label deviations work offers a testbed because it is highly tangible (the output is a text label that can be easily compared against source).
- **Cross-industry Collaboration**: Life sciences might form consortia to share de-identified data for AI, much like OCEBM does for evidence or OMOP does for real-world data. A shared corpus of labeling text could feed better models (private versions of GPT trained on pharma data). Similarly, best practices for AI in labeling (prompt libraries, style guides) could be jointly developed.

In sum, the trajectory is towards **augmented intelligence**: regulators and industry using AI tools to do more, faster, without losing control. The central answer to the original question – "Can GenAI help draft local label deviations?" – is a qualified yes: *With the right controls, it can make the drafting faster and more consistent*. But it cannot replace expert oversight. The shift will be from purely manual to *human+AI hybrid workflows*, where GenAI proposes and humans dispose.

Conclusion

Local label deviations are an inevitable and intricate part of global product launch. They require reconciling the global CCDS with myriad country-specific rules. Historically, this reconciliation has been done by teams of translators and regulatory writers tracking every global change in spreadsheets or basic RIM systems. Veeva Vault RIM's **Label Concept and Deviation Tracking** feature dramatically improves the **workflow and visibility** of these changes (regulatory.veevavault.help) (regulatory.veevavault.help), as evidenced by Moderna's success story ([5] www.veeva.com) ([6] www.veeva.com). However, even a perfect tracking system does not remove the grunt work of drafting.

Generative AI introduces a new tool: it can **accelerate and automate parts of drafting and QA**. Our review shows that generative models are already being piloted or used in analogous regulatory tasks (document summarization, translation, intelligence analysis) ([13] www.veeva.com) ([9] www.freyafusion.com). For local label deviations specifically, GenAI can:

- Auto-translate and localize global label text ([10] www.freyafusion.com).
- Draft initial versions of local-specific label content (e.g., adding country-required sections) ([8] www.veeva.com).
- Compare global vs. local text to flag differences ([9] www.freyafusion.com) ([11] www.freyafusion.com).
- Perform QA checks against regulatory templates ([11] www.freyafusion.com).

Early evidence from industry (literature and case anecdotes) indicates substantial potential. Pilot results in translation, for example, show significant time savings ([13] www.veeva.com). Academic work shows LLMs can structure drug label information with reasonable accuracy ([22] pubmed.ncbi.nlm.nih.gov) ([15] pubmed.ncbi.nlm.nih.gov). Regulatory agencies are on board in principle, having embraced AI internally ([19] www.reuters.com) and hinting at voluntary standards ([63] blog.gramener.com).

Nevertheless, we must underscore that GenAI is still a *sophisticated assistant*, not an autonomous expert. It can hallucinate; it needs constraints. The recommended approach is "AI for what supports humans the most" – translation, summarization, consistency-checking – while leaving final content decisions to skilled writers and reviewers. The risks of mistakes in labeling are simply too high to skip human oversight ([14] www.veeva.com) ([18] blog.gramener.com). With careful implementation (data safeguards, validation, documentation), companies can harness GenAI to handle the repetitive, tedious aspects of label deviation drafting, freeing their experts to focus on nuanced judgment. This hybrid approach aligns with other regulated industries like medicine and aerospace, where ML aids do not replace human operators but amplify them.

Future Work: As more companies try GenAI in labeling, we should monitor outcomes. Future studies should quantify error rates of AI drafts, measure reviewer time saved, and examine patient safety impacts. There is also a need for community standards: e.g., what degree of traceability in AI label authoring is acceptable to regulators? How to certify that a generative tool conforms to 21 CFR or GxP? Addressing these questions will solidify GenAI's role.

In conclusion, **Generative AI can indeed help draft local label deviations**, but it must be used judiciously. It will not magically solve compliance overnight, but it can significantly reduce the burden of spinning out dozens of local label texts. Organizations that invest now (via pilots and partnerships) will build capabilities in their teams and systems – positioning themselves to lead in a future where AI-augmented regulatory affairs is the standard. By coupling state-of-the-art Vault RIM practices with emerging GenAI tools, companies can achieve both efficiency and regulatory robustness, ultimately ensuring that who, where, and how patients get critical product information is done faster and more accurately than ever before ([12] www.veeva.com) ([33] www.veeva.com).

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Founder Excellence: Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

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Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

AI Consulting & Training: Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at https://intuitionlabs.ai/contact for a consultation.

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