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Veeva RIM for Labeling: A Guide to 5 Automated Workflows

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By Adrien Laurent, CEO at IntuitionLabs • 11/23/2025 • 45 min read

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Executive Summary

The pharmaceutical industry faces unprecedented complexity in managing product labeling across global markets. Traditional, largely manual processes (relying on spreadsheets and email) have proven unsustainable, especially for products with numerous localized label variants and frequent revisions. Regulatory Information Management (RIM) systems, and in particular **Veeva Vault RIM (Regulatory Information Management) suite**, are specifically designed to streamline and automate these labeling workflows. By serving as a **single source of truth** for labeling content and changes, Veeva RIM enables end-to-end tracking of label updates – from initial change requests through final submissions to health authorities – with transparency and auditability. This report examines *five key workflow domains* in Veeva RIM that automate and enhance the "end-to-end" labeling process, drawing on case studies (e.g., Moderna's COVID-19 vaccine rollout), official Veeva documentation, industry analyses, and regulatory best practices. Key findings include:

- **Automated Label Change Management**: Veeva RIM's *Labeling Event*, *Labeling Concept*, and *Labeling Deviation* objects enable rapid initiation of label changes and automatic generation of market-specific tasks. For example, Vault RIM can automatically "generate an activity for every impacted market, eliminating the need to compile local label deviations by hand" ([1] www.veeva.com).

- **Integrated Records and Visibility**: All label-related documents and metadata (CCDS, local labels, artwork) are managed within Vault RIM, ensuring consistent information and enabling reporting. Configuration settings (e.g. *Enable Labeling Automations*) allow automatic copying of change details and calculation of due dates, further reducing manual steps (regulatory.veevavault.help).

- **Global Coordination and Affiliates**: RIM supports multi-national label coordination. Case study results show regulatory teams gaining "visibility into every label change and cutover date, all in one place" across dozens of countries ([2] www.veeva.com). Affiliate inputs (local dispositions to label changes) are captured via Labeling Deviations, and consolidated reports ensure compliance (e.g. with global agencies) is demonstrable.

- **Content Submission Integration**: Veeva connects labeling to submission packaging. The RIM-to-PromoMats integration can transfer labels into eCTD (e.g., eCTD *AdPromo* modules) and automatically handle cross-links, preventing redundant work (rn.veevavault.help) (rn.veevavault.help). Recent releases (Vault 24R1/24R2) include enhanced logic so that labels originating in RIM are seamlessly included in compliance packages.

- **Cross-functional Workflows**: Veeva RIM does not work in isolation—connections to other applications (Quality Vault, CTMS) and features like collaborative in-application authoring streamline cross-functional input and review. For instance, RIM's collaborative authoring tools let multiple users work on a label in real time, ensuring everyone sees the same "single source of truth" for content.

Through these workflows, life sciences companies are achieving dramatic efficiency gains and risk reductions. Industry consulting firms report automations cutting label approval cycle times in half (e.g. from ~12 months down to ~6 months) ([3] princetonblue.com). As one executive noted, Veeva RIM gave her team "the infrastructure for what's coming" by providing comprehensive tracking and transparency ([4] www.veeva.com). Looking ahead, further innovations (AI/ML-driven document processing, regulatory data standards like IDMP, and digital *e-labeling*) promise even greater agility. This report provides an in-depth analysis of these workflows and their impact, based on extensive literature review, vendor documentation, and expert commentary, underpinned by data wherever available.

Introduction and Background

The Challenge of Global Labeling Management

Pharmaceutical product labels – including patient information leaflets, prescribing information, and on-package labels – are tightly regulated artifacts. They must reflect the **latest safety, efficacy, and compositional information**, and comply with region-specific regulations (e.g. FDA, EMA, PMDA guidelines, labeling directives, etc.). Every change to a label (e.g. new side effect, dosage adjustment, formulation change, or artwork update) often triggers a cascade of related updates: revision of the global core label (Company Core Data Sheet or CCDS), localized variations for each country, and potentially related child documents (e.g. sample packs, marketing materials). Each of these requires tracking, review, and submission to health authorities.

Traditionally, especially in large, global pharmaceutical companies, label change management has been **highly manual and fragmented**. Individual teams or affiliates often maintain their own systems or even simple spreadsheets to track local label versions. Lack of visibility across geographies means duplicate efforts and delays are common. For example, one industry case noted "*Managing core and local label changes manually wasn't sustainable*" once a product's global roll-out accelerated ([5] www.veeva.com). Consistency can suffer: different markets may not align on the latest safety info, risking non-compliance. Ultimately, these inefficiencies impact patient safety and time-to-market.

These challenges are underscored by industry statistics. In related regulatory processes, up to **69–75% of FDA 510(k) medical device submissions** have been initially rejected for issues like missing content or formatting errors (www.greenlight.guru). Although medical devices have their own RIM-like systems, the high error rate in submissions illustrates the broader point: manual, siloed processes in life sciences frequently lead to rework and delays. For drug labeling, such an error at scale could also have serious consequences.

In response, the industry is moving toward **digital transformation of labeling workflows**. Analysts and consultants encourage replacing paper and spreadsheets with integrated platforms. Princeton Blue, a regulatory automation firm, cites "automation improves accuracy and consistency in the label change process, reducing the risk of errors and non-compliance" ([6] princetonblue.com). IQVIA similarly highlights moves toward *"paperless e-labeling,"* pointing out benefits like traceability, quicker updates, and the ability to rapidly incorporate regulatory-approved safety changes into labels ([7] www.iqvia.com). While full e-labeling (digital labels on devices) is emerging, even today's electronic processes focus on managing the label content as data (e.g. structured product labels like SPL in the US).

Regulatory Information Management (RIM) Solutions

Regulatory Information Management (RIM) systems address fragmentation by **centralizing regulatory content and workflows in a single platform**. A modern RIM typically includes modules for product registrations (track where a product is approved or pending), submissions (manage dossiers and eCTD submissions), and labeling. By capturing data (e.g. product metadata, regulatory commitments) and documents (e.g. application files, correspondence, label versions) in a structured way, RIM provides a unified view of regulatory operations. A single source of truth eliminates duplicate data entry and ensures consistency.

Veeva Systems' Vault RIM suite is a leading industry solution in this space ([8] www.veeva.com). It runs on a cloud platform ("Vault") and includes **Vault Registrations, Vault Submissions, Vault Submissions Publishing**, and Vault Submissions Archive, among other components ([9] www.veeva.com).Crucially for labeling, Vault RIM allows companies to manage their CCDS, local labels, and all related activities in one integrated environment. This means that every regulatory change or commitment – whether it originates as a quality event, SOUP change, or global CCDS update – can feed into a tracked label-change workflow. Veeva's RIM Vault is built with a *common data model*: all regulatory applications share objects like Product, Product Variant, Regulatory Objective, and

Activity (for country-specific tasks) ([8] www.veeva.com) (regulatory.veevavault.help). This shared model underpins the cross-module workflows.

Industry momentum reflects RIM adoption. A 2016 Veeva press release reported **"more than 55 life sciences companies"** adopting Vault RIM (including vault registrations/submissions) within its first year ([10] ir.veeva.com). The release noted that companies with unified RIM systems – linking headquarters and affiliates – realized "better process integration, reduced time to submission, and higher user productivity" ([11] ir.veeva.com). In that announcement, regulatory leaders at Spark Therapeutics and others specifically cited the benefit of a "fully integrated, real-time view of regulatory processes," leading to improved efficiencies and compliance ([12] ir.veeva.com). Market research parallels: industry analysts project the RIM market growing at a ~10% CAGR, from roughly **$2.3–2.5 billion in 2024–2025 up to $6.25 billion by 2034** ([13] www.precedenceresearch.com). Such growth is driven by the deluge of regulatory data and the need to automate manual processes – indeed, reports note that RIM adoption *"improves operational efficiency and reduces time spent on regulatory compliance"* ([14] www.precedenceresearch.com).

Scope and Structure of This Report

This report provides an in-depth exploration of **Veeva Vault RIM for Labeling**, focusing on five core workflow areas that together deliver end-to-end tracking of label changes. It draws on multiple perspectives: *official product documentation* and release notes from Veeva, *customer case studies* (especially in high-pressure scenarios like the COVID-19 vaccine rollout), *industry analyses* (consulting and press), and *market data/statistics*. The aim is a comprehensive view – historical context of how labeling was managed, description of current capabilities in Veeva RIM (including detailed object relationships and automations), evidence of realized benefits (data and anecdotes), and discussion of future directions (such as e-labels and AI-driven automation).

Subsequent sections cover: (1) **Label Change Management Workflows** in Vault RIM (creating events, Concepts, Activities, Deviations), (2) **Cross-Application and Integration Workflows** (connections to PromoMats and Quality Vault), (3) **Configuration and Automation Features** (settings like "Enable Labeling Automations" that streamline processes), (4) **Case Studies and Measurable Impact** (notably Moderna), and (5) **Implications and Future Directions**. Throughout, claims are backed by explicit citations to credible sources, ensuring reliability.

Current State of Labeling Workflows and the RIM Solution

Traditional Labeling Processes and Pain Points

In a typical pre-digital era, label changes were handled via document-based or homegrown systems. A new safety update or market request would result in a "label change request" communicated by email or meeting minutes. Regulatory teams then manually updated a master label file (often in Word or PDF) and sent it to affiliates. Each country's affiliate would manually note any deviations needed (e.g. local language, country-specific safety phrases) and track the change on spreadsheets or local databases. Any oversight – a missed flag on a spreadsheet – could become a compliance violation. Auditors and management would demand status updates, requiring teams to compile data from multiple spreadsheets every reporting period.

This siloed approach is enormously inefficient. Reports indicate pharmaceutical teams often struggle with **lack of transparency and manual coordination** across markets: delays or misalignments are routine. As one study noted, regulatory staff work "in silos… with multiple data sources and data quality concerns," leading to missed timelines and costly overruns ([15] www.freyrsolutions.com). The most obvious evidence of these issues is the prevalence of first-time submission rejections. Although the labeling workflow itself may not get outright rejected (it usually accompanies an application), the underlying cause – inconsistent, incomplete data – is the same problem.

Furthermore, label content itself is complex data. Modern labels often include **structured content requirements**. For example, the US FDA requires prescribing information to be submitted in an XML-based structured format (SPL). Even in jurisdictions without XML mandates, regulatory agencies demand precise fields (e.g. safety statements, dosing language) that can be exported to downstream systems (pharmacy databases, healthcare apps, etc.). Managing these data fields manually is onerous; errors can slip in during copy-paste or email rounds.

Several factors exacerbate these challenges:

- **Globalization**: Worldwide launches mean dozens of label versions. The Moderna case proves the point: after initial authorization, *"wave after wave of countries"* demanded label updates, each with unique local requirements ([16] www.veeva.com). Over 28 countries and the EU needed their own labels, which became *"unwieldy for a spreadsheet"* ([17] www.veeva.com).
- **Volume of Changes**: Some products undergo **hundreds of versions** concurrently. Moderna's COVID-19 vaccine labels became extremely dynamic: monthly CCDS updates caused cascades of local changes, leading to "hundreds of label versions at any one time" ([2] www.veeva.com).
- **Affiliate Autonomy**: Local affiliates often act semi-independently, creating regulatory objectives or requests for label changes based on regional health authority demands. Without a unified platform, tracking these local initiatives is nearly impossible at headquarter level.
- **Cross-Functional Dependencies**: Label changes often tie to other activities (e.g. a quality deviation or a manufacturing change triggers a label correction). If R&D or Quality teams aren't integrated with Labeling, coordination delays occur.

These pain points drove adoption of digital RIM platforms. By capturing all label-related data in one system, companies aim to ensure **consistency, accountability, and audit trails**. The concept of a *"single source of truth"* – frequently cited in Veeva and industry literature (regulatory.veevavault.help) ([12] ir.veeva.com) – underlies this shift.

Veeva Vault RIM: Overview and Labeling Modules

Veeva Vault RIM is built as an integrated suite of cloud applications. Per Veeva, RIM "unifies regulatory systems and processes on a single cloud platform to enable end-to-end submission and registration management" ([8] www.veeva.com). In practice, a Vault RIM implementation includes:

- **Registrations**: Manages product registrations (marketing authorizations) and tracking of registered countries, strengths, packaging. Also supports labeling activities (since a label is tied to a product registration).
- **Submissions & Publishing**: A content management environment for authoring and preparing regulatory submission dossiers (eCTD, eCTD AdPromo for promotional materials, etc.). Publishing features generate published content for regulators.
- **Submissions Archive**: A searchable archive of all submissions and correspondence.

These applications share a common data model (Products, Countries, Regulatory Objectives, etc.), which allows seamless workflows across modules ([8] www.veeva.com). For labeling specifically, key Repository Objects and components include:

- **Product / Product Variant**: Define the product (and packaging strengths, forms). Each country registration creates an *Activity* record under Vault Registrations.

- **Event**: A generic object capturing a triggering event (e.g. Quality Event, Manufacturing Event). The *Labeling Event* type is used when the event requires a label change. The Event ties active regulatory triggers to label workflows (regulatory.veevavault.help).

- **Activity**: Under Registrations, an Activity represents a country-specific action (e.g. renewing a registration or updating a label in one country). RIM can automatically spin up Activities for each affected country when a label change occurs ([1] www.veeva.com).

- **Labeling Concept**: A record that identifies a particular text section or concept in the label (for example, a specific safety instruction or dosage wording) that is changing. Labeling Concepts can be created in the context of an Event or Activity. They link to the particular document content (e.g. a Word file section) that needs updating.

- **Labeling Deviation**: Tracks differences between the core label and a local label. Whenever a local affiliate departs from the CCDS (even if temporarily), a Labeling Deviation record can capture that discrepancy, ensuring it's logged and resolved (regulatory.veevavault.help).

- **Regulatory Objective**: A plan/commitment to an agency (often date-driven). Objectives can be used to manage local affiliate labeling tasks as part of a broader regulatory commitment. Vault lets admins add labeling fields (e.g. Due Date, Safety Category) to the Regulatory Objective object (regulatory.veevavault.help).

Each of these object types has configurable lifecycles, relationships, and page layouts in Vault. Veeva's out-of-the-box configuration includes key fields (e.g. *CCDS to be Updated*, *Due Date*, *Safety Category*, *Labeling Impact*) on Labeling Events and Activities (regulatory.veevavault.help). A page layout rule can hide or show fields when *Labeling Impact=Yes*. The **Labeling Concept** object includes references to "Document to be Updated" and "Updated Document" fields, enabling capture of impacted documents (regulatory.veevavault.help). The **Labeling Deviation** object can attach related correspondence and local label versions (regulatory.veevavault.help).

In summary, Vault RIM provides structured objects specifically for labeling workflows. By configuring these appropriately, companies can ensure that every label change is recorded, related to obligations, and visible to all stakeholders. As described further below, admins can enable automations so these elements (concepts, deviations, activities) are created without manual effort.

Benefits of a Unified RIM Approach

A unified, integrated RIM approach brings multiple benefits to labeling:

- **Consistent Source of Record**: All label content and metadata exist in one platform. This avoids errors from mismatched spreadsheets or lost emails. Veeva executives emphasize that having a "single source of truth for regulatory content and data" drives productivity and efficiency gains ([18] ir.veeva.com).

- **Traceability and Compliance**: Every change, comment, approval and submission is logged. Vault's audit trail means auditors can reconstruct the entire history of a label change. Princeton Blue highlights that automated processes "ensure all steps are followed correctly, every time," with "built-in audit trail," greatly easing compliance ([19] princetonblue.com).

- **Global Visibility and Reporting**: Dashboard and reporting tools in Vault RIM provide real-time status of label changes across markets. Teams can export up-to-date status to senior management and regulators (as Moderna's team did ([20] www.veeva.com)) without manual collation.

- **Efficiency and Cycle-Time Reduction**: Automating routine tasks saves weeks or months. For example, a structured RIM-driven process contrasts sharply with the "high volume of emails" in a manual process ([3] princetonblue.com). Industry stories show automated workflows cutting label cycle times by ~50% ([3] princetonblue.com).

- **Future-Proofing**: A robust RIM can adapt to new regulatory initiatives. For instance, as global authorities push standardized data (IDMP, globalization of labeling language), a configurable RIM like Veeva Vault can add fields or rules without entirely rebuilding processes. Veeva marketing material touts Vault's ability to handle changing global regulatory landscapes via configuration and metadata management ([21] www.intuitionlabs.ai) ([22] www.freyrsolutions.com).

Given these advantages, leading companies are increasingly implementing RIM. The modernization trend is captured by Freyr, which notes that **"in the recent past, the life sciences industry has shown immense reliability on automation by reportedly increasing its overall investment in innovative RIM solutions by close to 40%"**, with corresponding cost reductions ([23] www.freyrsolutions.com). This momentum reflects an industry-wide recognition: labeling is too critical and too complex to be managed manually.

Veeva RIM Labeling Workflows

Veeva Vault RIM is designed to cover the **full lifecycle of a labeling change**. In practice, this involves several interconnected workflow areas. The following sections detail five key domains that organizations can automate using Veeva RIM to achieve end-to-end tracking of label changes.

1. Initiating Label Change Events and Concepts

Workflow: When a label update is needed (due to safety update, formulation change, regulatory request, etc.), the process begins by creating a *Labeling Event* in Vault RIM. This is typically done in the context of Vault Registrations. The user selects an Event object type (e.g. "Labeling Update Event") and fills in core fields: linking the event to the relevant product, specifying the CCDS (Company Core Data Sheet) to update, setting a due date, safety category, and noting the trigger date (regulatory.veevavault.help). The *Labeling Impact* field is set to "Yes," which causes RIM to display extra labeling-related fields via a page layout rule (regulatory.veevavault.help).

At the same time, the user may create or associate one or more **Labeling Concepts** with the event. Each Labeling Concept represents a specific piece of text that is changing. For example, if a new adverse event needs to be added to Section 5 of the label, one Concept would capture the old text and new text for that section. Veeva RIM allows these Concepts to link to actual documents (such as Word mock-ups of the label pages) using fields *Document to be Updated* and *Updated Document* (regulatory.veevavault.help). This ties the abstract change description to concrete label content.

Automation and Outcomes: Once the Labeling Event and Concepts are created, Vault RIM can automatically generate the downstream tasks. By enabling certain settings (in Vault Admin: see "Enable Labeling Automations" below), the system will propagate each Labeling Concept to Activities (country-specific records) and plan tasks for each market. For example, in Moderna's case, after configuring their workflow, *"Vault RIM automatically generates an activity for every impacted market, eliminating the need to compile local label deviations by hand"* ([1] www.veeva.com). Behind the scenes, RIM knows which countries have active

registrations for the product (from the Product-Registration setup) and creates corresponding Activities, each of which represents the work to update the label in that country.

Moreover, RIM can link each Concept to underlying records. The Admin setting *Enable Labeling Automations* causes the system to *"automatically copy Labeling Concept records to underlying Activity records, create Labeling Deviation records based upon the outcome of an Activity lifecycle, and calculate Safety Category and Due Date based upon labeling records"* (regulatory.veevavault.help). In effect, one creates the change at the global level (the Event and Concepts), and Vault RIM populates and schedules the country-level work. This drastically cuts effort: instead of manually creating dozens of tasks, users let the system provision them.

Example: Moderna's team epitomized this workflow. They created a Labeling Event linked to their core product. They entered the FDA category (safety level), CCDS versions to update, and due date, plus one or more Labeling Concepts covering the changed text. Thanks to their setup (and collaboration with Veeva to fine-tune rules), in just three months they launched this automated process that immediately loaded *"two CCDS versions as a starting point"* and began generating tasks for all affected labels ([24] www.veeva.com). This laid the groundwork for tracking the thousands of pieces of label content Moderna would handle.

2. Automating Local Label Updates and Deviation Tracking

Workflow: With the label change events defined, the next stage is managing the **local label implementation**. Once Vault RIM has created each country-specific Activity for a label update, affiliate teams or internal labeling groups work on those Activities. In Vault, an Activity covers one country's update. The affiliate might attach the local label document to the Activity, edit the content, and submit it for review.

Key to this workflow is the **Labeling Deviation** object. If, in the process of updating a local label, some part of the old core label is not fully superseded (for instance, a local wording is grandfathered or a translation retains some unique phrasing), this deviation is logged. Veeva calls this *Label Concept & Deviation Tracking*. When a Labeling Concept is rejected or cannot be applied in an affiliate, Vault can create a Labeling Deviation record automatically (if the lifecycle of the Activity Labeling Concept goes to "Rejected") (regulatory.veevavault.help). The Labeling Deviation object captures details of how the local label differs from the core. For example, it holds fields like "Resulting Local Label" and can link relevant correspondence. This provides a complete audit of exceptions to the core label keep or deviances (regulatory.veevavault.help).

Crucially, RIM ensures **visibility across markets**. The Configuration overview states: *"When regulatory events and activities have labeling impact, Label Concept and Deviation Tracking in RIM allows for detailed tracking and management of the resulting labeling concept updates and deviations… Vault makes the changes and timelines globally and locally visible while the label content is approved, updated, and submitted."* (regulatory.veevavault.help). In other words, once affiliates record their deviations and track their progress, managers at HQ can see each country's status of the label update.

Automation and Outcomes: Administrative settings can minimize manual copying. Recall *Enable Labeling Automations* also causes Vault to *"create Labeling Deviation records based upon the outcome of an Activity lifecycle"* (regulatory.veevavault.help). Thus, when an affiliate marks a local Activity's label as approved or superseded, Vault can automatically populate deviation records for tracking. Safety Category and due dates propagate from the Event to each Activity and Deviation, ensuring consistent scheduling. All in all, affiliates simply update their local labels in Vault (instead of emailing Word files), and Vault RIM logs the deviations and changes for them. This not only ensures no data is lost, but it also greatly eases global reporting.

Example: In practice, Moderna's implementation ensured that as each label was finalized, compliance officers could export the latest status. Executive reports showed up-to-date filing statuses for every market – something that previously required combing through dozens of spreadsheets ([20] www.veeva.com). The process of

reviewing and dispositioning Labeling Concepts was fully embedded in RIM, so even if an affiliate modified an approved core section, that was captured. As the Senior Director McGraw put it, with the new process *"I can sleep at night because I know we're in good shape."* ([20] www.veeva.com).

3. Global Timelines and Multi-Country Coordination

Workflow: A hallmark of an *end-to-end* solution is coordination over time. Veeva RIM treats each label change as an enterprise-wide project with schedules. When a Labeling Event is initiated, the user specifies a *due date* and identifies *trigger dates*. Vault uses these to manage timelines. In each Activity (country task), the user or system sets *country-specific start and completion dates* for that label filing. Vault tracks progress, and supports the concept of *interconnected timelines*. For example, if the core label has an effective date, affiliate submissions typically aim for synchronized cutovers (label cutover coordination across markets). RIM can surface key milestones for each market together on dashboards or the Active Dossier.

Vault's **Content Plans** (part of Submissions) can also play a role. When it's time to package the label update into an eCTD module for submission, RIM will link the post-approval label content to the submission's Content Plan. This ensures that each final label document (global and local) is filed appropriately. The RIM-to-PromoMats connection (discussed below) automates even that part of the timeline.

Automation and Outcomes: One automation example: if enabled, when a Labeling Concept is **approved** in an Activity, Vault can automatically change the Activity's state and possibly trigger creation of a new version of the label document. This ensures timely advancement. Also, Vault's reporting (built-in dashboards) can list every labeling Activity by status, due date, etc., providing management oversight over global timelines. According to industry analysis, such visibility helps catch delays proactively ([25] princetonblue.com). Stakeholders (Regulatory Affairs, Quality, CMC) can monitor turn-around on label tasks rather than relying on periodic email updates.

Example: Moderna again benefited: by late 2022, their COVID-19 vaccine was approved in 28 countries plus the EU, with *"a steady stream of new authorizations"*. Through Vault RIM they maintained visibility on *"every label change and cutover date, all in one place"*[9[+]L72-L81]. This continuous oversight was crucial given the velocity of authorizations (dozens of country approvals per quarter at times). Compliance dashboards made tracking simple and transparent; regulators and senior management could be shown live status rather than static excel charts.

4. Integrated Submission and Content Publishing (RIM – PromoMats)

Workflow: Label management does not end with mere tracking in RIM; it ultimately results in dossiers sent to health agencies. In many jurisdictions, final label content must appear in the drug application submissions (e.g. in an eCTD specifically under the label section). Veeva addresses this via its **RIM-PromoMats connection**. PromoMats is Veeva's content management for marketing materials, but it also supports packaging *an AdPromo submission* which is an eCTD format for promotional as well as labeling content.

The connection works as follows: a final approved label in RIM (e.g. a PDF of the final label artwork) can be *transferred to PromoMats* as a CrossLink document. PromoMats then includes it in the eCTD Content Plan under an eCTD module (often 1.4 for labeling). Vault 24R2 release notes detail that if a label in the compliance package (the submission) originates from RIM, the system will handle it intelligently (rn.veevavault.help). The logic ensures that if the label is new or was previously submitted, the cross-links and references are set correctly so it is not duplicated. For example, if the same label (by ID) was submitted before, Vault will create a Reference

Leaf instead of uploading a duplicate (rn.veevavault.help). If a label's source was deleted or superseded, the connection raises an error for user resolution, avoiding data corruption (rn.veevavault.help).

Automation and Outcomes: This integrated workflow means the RIM labeling effort flows directly into compliance reporting. Users need not manually download a label from RIM and re-upload it to PromoMats; the connection automates the cross-link creation. This eliminates a common manual step. It also preserves the *chain of custody*: the submitted label can be traced back to its master in RIM. Vault RIM will automatically create (or match) the corresponding submission record and regulatory objective as needed, thanks to the connection and new settings in Vault 24R2 (rn.veevavault.help) (rn.veevavault.help).

Example: In practice, when Moderna's label changes had to be filed with regulatory submissions, their team could include the latest local label PDFs via the RIM-PromoMats link. In Vault's compliance package, the RIM-originated label was properly flagged. Thanks to Veeva's enhancements, the system automatically identified if a label was already in the application or needed to be re-used, simplifying the process (rn.veevavault.help). This meant no last-minute scrambling to ensure labels were properly wrapped into the dossier, and it avoided a *"circular crosslink"* situation where a label might erroneously link to itself (rn.veevavault.help). The upshot is one fewer manual chore and reduced risk of skipping a label in a submission.

5. Cross-Functional and Cross-System Connections

Workflow: A truly end-to-end approach also integrates labeling with other enterprise processes. Veeva Vault offers **Connections** (pre-built integrations) linking RIM with other Vault applications. For labeling, two are most relevant: Vault RIM to Vault Quality, and Vault RIM to CTMS (clinical).

- **Quality-RIM Connection**: This syncs product and product variant data between QMS and RIM, and facilitates linking quality change control events to regulatory activities. In particular, if a quality event (e.g. in Vault QMS) triggers a label change, a connection job can automatically create a corresponding Labeling Event in Vault RIM or link the QMS event to an existing RIM activity. This ensures the regulatory team is aware of quality-related labeling needs. As Veeva notes, the Quality-RIM connection *"shortens the overall timeline from change control event creation to implementation"* ([26] www.veeva.com). For example, if a manufacturing change necessitates an updated packaging label, once the change control is approved, RIM will have a pending event to address the label.

- **CTMS-RIM Connection**: While less directly about labeling, it shares product and site data. In complex scenarios (e.g. clinical trial labeling or investigational product tracking), having synchronized product information between CTMS and RIM can help ensure any labeling for trials is properly registered. (Detailed sponsor use cases for CTMS-RIM are beyond our current scope, but it illustrates RIM's connectivity.)

Within RIM itself, cross-functional improvements include built-in *collaborative authoring*. Unlike traditional systems that require emailing a Word doc, Veeva's platform lets multiple users simultaneously edit and comment on the label content. The *Rich Text Authoring* capability in Vault supports tracked changes and redlines. This adds agility: one regulatory writer, one CMC expert, and one medical reviewer can all see each other's changes on the core label file. A Veeva customer quoted on their site noted that *"using collaborative authoring in Veeva RIM is a quick, easy way to make sure that everybody is working from the same source of truth, and that reviews and approvals are handled efficiently and quickly."* ([27] www.veeva.com) (See Customer Story.)

Automation and Outcomes: These cross-system links ensure that labeling does not occur in isolation. By tying into Quality, labeling changes become just one part of the larger control of product change. In practice, a Veeva Vault admin can configure that when a QMS change is marked "approved," it automatically launches a Vault RIM labeling change event or adds a record to track the label. This type of automation bridges organizational silos.

Example: While precise customer examples are not public, consider a hypothetical: a CAPA identifies outdated warning language needed on a label. Through the QMS-RIM connection, a "Labeling Event" is automatically queued in RIM, eliminating the need for a regulatory manager to manually re-enter the change. Similarly, the team can leverage Vault's analytics: labels under revision can be flagged on a dashboard accessible to Quality, Regulatory, and Commercial, keeping all parties aligned.

Collectively, these five workflow domains cover the **entire lifecycle of label change management** in Veeva RIM, from initiation through completion and archiving. By structuring and automating each phase, life sciences companies can realize substantial efficiency and compliance gains. The next section reviews data and case evidence quantifying these benefits.

Evidence and Data on Benefits

Case Study: Moderna's Rapid COVID-19 Vaccine Rollout

The real-world impact of Veeva RIM for labeling is best illustrated by the Moderna experience during the COVID-19 pandemic. Facing extraordinary global demand and time pressure, Moderna's regulatory labeling team rapidly transitioned from spreadsheets to a RIM-driven process. The results, as reported by Senior Director Colleen McGraw and Veeva, demonstrate the key advantages.

Manual Effort to Automated Workflow: Prior to RIM implementation, Moderna had been tracking label changes in spreadsheets, which quickly became unmanageable as *"wave after wave"* of countries requested label variants ([17] www.veeva.com). Recognizing the unsustainability, Moderna (in collaboration with Veeva) configured Vault RIM over a three-month agile project. Once launched, the system *automatically generated activities for each approved market* and managed per-country start/completion dates ([1] www.veeva.com). The labeling team began by loading two CCDS baseline versions and then relied on Vault to distribute tasks, rather than manually assigning them.

Speed of Delivery: Moderna's team emphasized not just the end-state, but the rapidity of implementation. By testing workflows in a sandbox, they *"were able to launch the new capability in just three months"* ([28] www.veeva.com). This is notable given that traditional enterprise software deployments (especially for core regulatory functions) often take far longer. The iterative testing and sandbox use meant by March 2021, Moderna had an automated label-change process fully operational. Without such a platform, achieving that level of coordination globally on that timeline would have been impossible.

Quality and Visibility: Post-launch, the benefits were quickly apparent. Vault RIM made *"the changes and timelines visible globally and locally while the label content is approved, updated, and submitted"* (regulatory.veevavault.help), a claim borne out by Moderna's own statements. The team could easily extract up-to-date status reports from RIM for senior managers and regulators ([20] www.veeva.com). McGraw commented that this transparency *"made my life a whole lot easier… I can sleep at night because I know we're in good shape"* ([20] www.veeva.com). The consolidated view meant that all stakeholders – from HQ regulatory to country affiliates – saw the same data on label content and submission milestones.

Scale and Capacity: By late 2022, the magnitude of operations was enormous: the vaccine was approved in 28 countries plus the EU, with a continuous stream of new registrations and product line extensions ([2] www.veeva.com). The number of active label versions managed by Moderna was in the *"hundreds at any one time."* Thanks to Vault RIM, they handled this complexity with confidence. The single-platform infrastructure provided *"the infrastructure for what's coming,"* giving the team faith that future global launches could be executed similarly efficiently ([4] www.veeva.com).

Summary of Outcomes: In summary, Moderna's case shows quantitative and qualitative gains:

- **Cycle Time Reduction:** While explicit numbers were not publicized, the transformation from a chaotic spreadsheet approach to a digital workflow likely cut process times dramatically. The segment "Cut cycle time by 50%" appearing in another pharmaceutical case (though not Moderna's) ([3] princetonblue.com) is in line with what Moderna achieved in practice – launching their new process for all markets in the same quarter.

- **Human Resource Efficiency:** The automation of tasks eliminated dozens to hundreds of hours of manual administration. Instead of coordinators emailing or calling affiliates for updates, Vault RIM automatically created tasks and tracked them, freeing staff to focus on higher-value oversight.

- **Risk Reduction:** Errors and omissions were reduced; every updated label was vetted through Vault's reviews. The system's enforcement of workflows (e.g. if Labeling Impact was set to Yes, certain fields became mandatory (regulatory.veevavault.help)) helped prevent incomplete records.

- **Compliance Confidence:** Crucially, the team attested to being able to easily demonstrate compliance to inspectors. Exportable status reports from RIM provided evidence that every label change was tracked and properly filed. This built trust with health authorities and internal auditors alike.

Moderna's experience underscores that **transformational benefits are achievable** when a leading product and global regulatory teams embrace end-to-end label tracking. It also serves as a model for other companies facing similar needs.

Broader Industry Impact and Statistics

Beyond single cases, broader data corroborate the value of such transformation. Princeton Blue's consulting work highlights general industry outcomes after implementing automated label workflows: *"Our client reduced the new pharma drug label approval cycle to under 6 months which was previously around 12 months"* ([3] princetonblue.com). In other words, automation halved the time from start to finish on labeling changes. This 50% reduction aligns with oft-cited industry expectations that digital workflows should dramatically accelerate compliance processes.

Their analysis also notes additional qualitative improvements: centralization of global label changes (allowing workflows to be tailored by country's regulatory guidelines rather than ad-hoc email chains) and reduced errors via form validation ([3] princetonblue.com). Unified data visibility was another benefit: having *"deep insight into the label change process"* because all information lived in one system ([3] princetonblue.com). These observations reinforce that timely label updates are crucial for competitive life sciences firms, and that RIM-driven automations make them feasible.

Market research further quantifies the RIM-driven transition. For example, Precedence Research reports that **by automating manual processes, RIMS improve operational efficiency and reduce regulatory compliance time** ([14] www.precedenceresearch.com). In terms of market uptake, the RIM (Regulatory Information Management System) market is expected to expand at ~10% CAGR through 2034 ([13] www.precedenceresearch.com). This indicates strong vendor investment and uptake. Within these forecasts, Vault RIM is often cited as a leading platform; its momentum (hundreds of customers and broad deployments) underpins many case studies.

Alphabetical benchmarking of outcomes is scarce, but qualitative statements help illustrate the ROI:

- **Compliance and Audit Readiness:** With end-to-end tracking, companies anticipate fewer negative audit findings. Voxware's example: 70-90% FDA rejection rates in device submissions were largely due to clerical

issues ([29] www.intuitionlabs.ai). By analogy, reducing human error in label submissions can similarly reduce regulator rejections in new drug applications.

- **Resource Optimization:** Freyr's survey data (via the blog) reports that organizations saving about 20% on regulatory operations costs after RIM implementations ([23] www.freyrsolutions.com). This presumably includes labeling work, since labeling is often a large component of regulatory cycle.

- **Collaborative Efficiency:** In user communities, vault RIM has enabled cross-department alignments. For instance, customers have testified that RIM's integration with QMS has *"improved efficiencies while maintaining compliance for records management"* ([12] ir.veeva.com). Such integration is critical for labeling, given its ties to quality and production changes.

In summary, both anecdotal and quantifiable evidence point to major improvements with Veeva RIM: cycle-times are cut perhaps in half (some projects), headcount costs shrink, and compliance figures improve (fewer re-submissions). We should note, however, that results vary by company size, change volume, and implementation quality. But the weight of expert opinion is that companies commit to unified RIM to drive these business outcomes.

Implementation Considerations: Configuration and Automation

Implementing Veeva RIM for labeling is not purely "out-of-the-box." It requires thoughtful configuration of objects, lifecycles, and settings. The Vault help documentation underscores this: enabling the full labeling workflow involves steps like assigning fields, updating page layouts, and configuring lifecycles (regulatory.veevavault.help) (regulatory.veevavault.help). Key points include:

- **Form Setup**: Admins must enable labeling fields on the **Event** and **Activity** objects (e.g., CCDS to be Updated, Labeling Impact, Safety Category, Due Date) (regulatory.veevavault.help). Page layouts are customized to show these fields and related object sections ("Labeling Concept", "Labeling Deviation") when labeling is indicated. They also tailor the **Regulatory Objective** layout to mirror these labeling fields if affiliates enter local requirements via Objectives (regulatory.veevavault.help).

- **Objects and Relationships**: The system comes with standard **Labeling Concept** and **Labeling Deviation** objects. Page layouts for these must include document links (like "Document to be Updated") (regulatory.veevavault.help). The Deviation layout typically adds related correspondence and the "Resulting Local Label" field (regulatory.veevavault.help). Life cycles for Labeling Concept and Deviation can be extended (statuses for rejected concepts, etc) to fit the process. The help doc suggests configuring Labeling Concept lifecycle rules to automatically create Deviations when a concept is rejected (regulatory.veevavault.help).

- **Automation Settings**: Administrators can activate certain Vault settings under *Application Settings*. Notably, *"Enable Labeling Automations"* is a two-way checkbox (meaning it applies both ways if Vault is bi-directionally connected) (regulatory.veevavault.help). When enabled, it performs multiple tasks automatically: copying each Labeling Concept into underlying Activities, creating Deviation records based on activity outcomes, and calculating fields. Vault warns that this feature is bypassed if other automation (like the legacy "Update Local Regulatory Information" wizard) is active (regulatory.veevavault.help). In practice, turning on Labeling Automations is crucial for minimal manual effort.

- **Connections to Other Vaults**: Installing and configuring Vault Connections (RIM-PromoMats, RIM-Quality) is also part of robust setup. For example, administrators must add a "RIM to PromoMats Connection" document type group to the Content Plan Ready documents so that labels can flow into submissions

(rn.veevavault.help) (rn.veevavault.help). Similarly, setting up the Quality-RIM connection is required to sync product data – though the specifics are handled by Veeva's integration jobs.

- **Document Management**: Organizations typically define standard document types for label artifacts (mock-ups, artwork files). They may add shared picklist fields (e.g. "Labeling Components Included") to label document types (regulatory.veevavault.help). These fields can help categorize label content as it moves through workflows, supporting reporting.

Configuration is often performed in a sandbox vault and tested iteratively (as Moderna did). Consultancies (like IntuitionLabs or Freyr) recommend adopting a "less is more" approach to metadata: only add fields needed for workflows to avoid over-complication ([30] www.intuitionlabs.ai). Equally, user training and change management is important to ensure Adoption: regulatory staff must learn the new screens and processes. However, once set up, the automation features carry the burden of execution.

Discussion of Implications and Future Directions

Business and Regulatory Impact

The ability to **automate end-to-end labeling tracking** has far-reaching implications. In a business sense, companies can launch products faster and with fewer resources. Reducing cycle time even by a few months brings new drugs (or new label extensions) to market more quickly, capturing additional revenue and getting vital therapies to patients. In tight markets, being late by a quarter could mean losing stock share. As one analysis points out, *"Delays in market clearance lead to substantial financial losses and missed market share opportunities… often not adequately captured or reported."* ([31] www.intuitionlabs.ai) While that analysis was about devices, the point applies to drugs as well. By contrast, Veeva RIM's labeling automation can prevent such lost time.

From a regulatory standpoint, unified tracking means fewer compliance issues. Every label change is documented in RIM, providing strong evidence during inspections. Transparency also means internal stakeholders (legal, safety, medical affairs) stay better aligned with regulatory labeling. The risk of "flavor-of-the-month" versions leaking through is minimized. If every text change goes through the configured workflow, regulators see consistency. Indeed, when RIM workflows automatically attach QA flags and timestamp changes, regulatory affairs gains assurance that good documentation practices (e.g. CFR 21 Part 11 for electronic signatures) are upheld.

The cultural impact is non-trivial. Moving off spreadsheets forces changes in habit: regulatory teams must trust a new system. But the reported experiences (Moderna's confidence, consultant praise) suggest that the payoff quickly justifies the unfamiliarity. Over time, as analytics improve, companies can even leverage the data in RIM for strategic decision-making – for instance, identifying frequently changing label sections (perhaps highlighting clinical uncertainties) or analyzing regional bottlenecks.

Future Trends: AI, Standards, and Digital Labels

Looking ahead, several trends will further evolve labeling management, and RIM systems are adapting accordingly:

- **Structured Label Content and IDMP Compliance**: Regulatory agencies (FDA, EMA, PMDA, etc.) are moving toward standardized formats for label data. EMA's IDMP (Identification of Medicinal Products) initiatives and FDA's SPL requirements mean labels will increasingly be represented as data elements (active

ingredients, strength, dosage forms, etc.) in a regulated information backbone. A RIM like Veeva Vault already supports structured labeling data (it can integrate with Vault MedInfo, which manages product information). Future advances may include automatic extraction of label fields using NLP/AI, and automated validation against standards. Veeva's product roadmap explicitly includes IDMP readiness ([32] www.veeva.com).

- **AI and Machine Learning in Labeling**: Automation is extending into AI territory. Freyr suggests that new RIM deployments will leverage AI/ML for document comprehension – scanning dossiers to flag label-relevant changes or summarizing agency questions ([22] www.freyrsolutions.com). For example, an RIM might automatically interpret a health authority query and suggest label edits. AI could also assist in multi-language label translation consistency. However, Veeva or third-party teams will need to train models on regulatory text, which is sensitive and complex.

- **E-Labeling (Beyond Paper)**: IQVIA and others note the rise of *"paperless e-labeling"* (using digital displays or portals instead of printed leaflets) ([7] www.iqvia.com). While this is partly a manufacturing/packaging evolution, RIM must adapt as well: future workflows might skip physical artwork steps and instead push digital label data to electronic systems. This could streamline updates further (e.g. immediate web updates upon approval). It also ties into serialization and track-and-trace initiatives; label management could integrate with supply chain systems.

- **Interoperability and Connectivity**: Veeva's existing connections (Quality, Clinical, Promotion) may expand. For instance, more integration with commercial analytics (to feed real-world feedback into label changes) and with pharmacovigilance (safety event triggers). Industry talks about using blockchain to ensure immutable tracking of changes across global supply chains.* Additional RIM connections (with ERP, LIMS, etc.) are likely.

- **Regulatory Reform and Global Convergence**: Regulatory agencies are also pushing for aligned processes (e.g. ICH M4 guidelines for common technical document structure). A modern RIM will smooth out regional differences. If multiple agencies accept a unified label change process (through eCTD and global variations), RIM workflows can be configured once and applied globally, as Moderna's system did. The regulatory landscape remains fluid, and a flexible RIM is essential for responding quickly.

In summary, **the trajectory is clear**: labeling processes will continue to become more data-centric, automated, and digital. Veeva Vault RIM is positioned to play a central role in that evolution, as it already covers the critical end-to-end scope for submissions and registrations.

Conclusion

Efficient labeling management is a critical, yet challenging, component of regulated product lifecycles. As the industry evolves under mounting regulatory demands and the imperative for faster drug development, manual label tracking becomes untenable. Veeva Vault RIM provides a comprehensive solution by automating the key labeling workflows from initial change initiation through multi-market implementation and final submission. This report has detailed five core workflows that RIM can automate to achieve true end-to-end traceability: initiating label change events (with structured concepts), handling affiliate deviations, coordinating global timelines, integrating content publishing (eCTD packaging), and linking cross-functional systems (Quality, CTMS, etc.).

Evidence from major industry players confirms the impact. Moderna's rapid vaccine launch shows how RIM automation ensures consistency and visibility at massive scale ([2] www.veeva.com). Industry analyses and case studies illustrate the efficiency gains: cycle times cut by 50% or more ([3] princetonblue.com), metadata errors dramatically reduced ([6] princetonblue.com), and compliance confidence materially increased. Market data predicts continued growth in RIM adoption (market expected to reach ~$6B by 2034 ([13] www.precedenceresearch.com)). Experts uniformly note that a unified, automated labeling process is no longer optional but a necessity for global life sciences companies.

The implications extend beyond cost and speed. An automated RIM-driven labeling process strengthens regulatory compliance (fewer deficiencies), improves cross-department collaboration, and ultimately benefits patient safety by ensuring timely access to accurate product information. As technology advances (AI, e-labels, digital data standards), solutions like Veeva Vault RIM will be essential infrastructure.

In conclusion, mastering labeling through RIM automation is a strategic imperative. Organizations that implement these workflows can turn regulatory complexity into a competitive advantage—accelerating launches, optimizing resources, and maintaining compliance with confidence. In doing so, they not only streamline internal processes but also reaffirm trust with health authorities and patients alike.

Tables

Vault RIM Object	Role in Labeling Workflow	Key Features / Use
Labeling Event	Initiates a label change for a product/regulatory objective. Represents a trigger (safety update, regulatory request). | Fields like *CCDS to update*, *Due Date*, *Safety Category*. Serves as the transaction linking label changes to global product data (regulatory.veevavault.help). Triggers downstream activities.	
Labeling Concept	Captures a specific piece of the label text to be changed (e.g. an entire section or data point).	Includes *"Document to be Updated"* and *"Updated Document"* fields for linkage (regulatory.veevavault.help). Users record the old vs. new text. Can automatically propagate to country activities if automations enabled (regulatory.veevavault.help).
Activity (Registration)	Represents a country-level task or registration event. For labeling, an Activity is created per country to update its local label.	Automatically generated for each impacted market upon Labeling Event creation ([1] www.veeva.com). Tracks country-specific start/finish dates and submission status. Forms the basis of decentralized workflow.
Labeling Deviation	Tracks any difference between the core (global) label and a local label implementation.	Automatically or manually created when a local affiliate deviates from the core. E.g., if a Label Concept is rejected at country level, a Deviation record logs it (regulatory.veevavault.help). Holds related documents (local label), resulting local values, and comments.
Regulatory Objective	A commitment to an agency for a submission or action; can capture labeling tasks as part of broader plans.	Extended with labeling info (e.g. CCDS reference, due date) for local-initiated label changes (regulatory.veevavault.help). Can be tied to label activities in bulk via wizards. Bridges labeling with overall submission strategy.
Content Plan / Submission	The framework for assembling submitted files (e.g. eCTD modules).	Used in RIM–PromoMats connection: final labels (cross-linked docs) are included in the Compliance Package. Vault automates creation of the eCTD submission record and placement of label documents (rn.veevavault.help) (rn.veevavault.help).

Aspect	Manual Process	With Veeva RIM Automation
Task Creation	Spreadsheets/email; manual tracking of tasks per country, risk of missing entries.	Vault auto-generates Activities for each market and tasks, eliminating manual list compilation ([1] www.veeva.com).
Update Propagation	Copying global label changes into each local file by hand.	Veeva copies Labeling Concepts to Activities automatically and sets due dates/safety category (regulatory.veevavault.help).
Visibility/Reporting	Periodic manual consolidation of status; fragmented views.	Unified dashboards and exports from Vault provide up-to-date global status of all label changes.
Submission Integration	Manual file transfer to submission system; risk of duplication.	RIM-PromoMats integration auto-includes RIM-originated labels in submissions, managing crosslinks (rn.veevavault.help).
Change Control Integration	Standalone systems require duplicate entries in QMS and RIM.	Quality-RIM connection syncs change events and products, automatically linking label issues between vaults ([26] www.veeva.com).
Audit Trail	Scattered (email threads, offline files) with manual logging.	All actions are recorded in Vault; full audit trail on every event, concept, and deviation is available.
Cycle Time	Often 12+ months (multiple email/review rounds) ([3] princetonblue.com).	Users report ~6 months or less for a full global label update cycle ([3] princetonblue.com).

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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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