Veeva

EBOOK

The Path to Unified RIM: Key Attributes Driving Regulatory Excellence

Biopharmas are heavily investing in regulatory transformation initiatives — nearly $3.8 billion over the last five years, according to the 2024 Gens & Associates Report, **"World Class RIM: Extending the Power of RIM."** Organizations achieving regulatory operational excellence have high process maturity, strong data governance practices, high data quality, and business metrics that drive continuous improvement. Adopting a unified RIM platform strengthens data and process governance, improves efficiency and information connectivity, and increases end-to-end submission speed.

However, many potential business benefits remain unrealized. As RIM investments mature, biopharmas will continue to identify key success metrics and performance improvement initiatives to measure and drive unified RIM value across the enterprise.

This eBook explores the benefits of a data-centric approach with a unified RIM platform, current regulatory challenges and industry trends, and key investment areas for leading organizations.

> **"If you do it right, a RIM system is an indispensable and strategic asset."**
>
> **Matt Neal**
> Executive Director, Global Regulatory Operations Strategy & Innovation, Multinational Biotech

The growing need for unified RIM

As biopharmas launch new products, enter new treatment areas, and expand into new markets, regulatory functions are elevated from a compliance necessity to a strategic partner and competitive differentiator. With evolving global health authority (HA) guidelines, regulatory teams have the opportunity to lead the transition from a document-centric to a data-centric organization.

Companies that reduce duplicate manual efforts and harmonize data move faster and achieve higher-quality outcomes. Unified RIM replaces siloed systems, processes, and data with a single solution for a streamlined, data-centric approach. This enhances regulatory efficiency, strengthens cross-functional collaboration, and minimizes errors and rework — eliminating the need for complex integrations.

Unified RIM also enables **continuous publishing**, speeding time to market with parallel publishing processes, moving many activities upstream, and readily supporting new requirements like eCTD 4.0 and IDMP.

With high-quality data and process governance as well as the right organizational culture, a unified RIM platform accelerates cross-functional work and collaboration with external partners. Unifying regulatory systems lays the foundation for seamless data connections across critical business areas, improving interoperability and data quality — one key factor in achieving efficiency gains promised by **AI proof of concepts**.

Building a foundation for unified RIM

The journey to adopting a data-centric approach and increasing operational efficiency with a unified RIM platform will be different for every company.

Large biopharmas must take a methodical approach to break down global silos, simplify complex legacy systems, and streamline ways of working. Emerging biotechs, on the other hand, can take a unified approach from the start but will need to move quickly with fewer resources to implement and adopt the new solution successfully.

No matter where a company is on the path to unified RIM, there are several foundational principles that companies should consider.

Data quality and governance

Ensuring that high-quality data is seamlessly maintained and accessible across the business in real time is core to a unified RIM approach. However, siloed systems and disparate data sets compound other challenges, including:

- Unclear data ownership
- Complex integrations across systems
- Lack of standardization
- Manual and error-prone processes
- Different or evolving health authority requirements
- High volume of external partners

To counteract this, end users must clearly understand organizational data governance and accountability to ensure consistent data quality. When all teams work from a shared understanding of regulatory operations, it paves the way for collaboration, automation, and other innovations.

According to the Gens Report, study top performers have an overall 63% high data quality confidence rating, compared to just 38% for everyone else. Top performers are also significantly more likely to have dedicated data quality roles, a formal regulatory data governance structure, adhere to corporate data governance structure, and leaders who advocate for data quality.

DATA QUALITY CONFIDENCE

63%
for high performers

38%
for everyone else

Process excellence and governance

If data is the lifeblood of R&D organizations, process excellence could be considered the musculoskeletal system. Accurate, high-quality data has the greatest impact when it is used effectively across optimized, efficient processes with speed. Companies may consider various approaches, including dedicated teams to oversee processes or **establishing Centers of Excellence (CoE)** within the organization.

There are six key performance contributors that industry leaders exhibit with greater proportion in comparison to their peers, according to the Gens Report, including:

- Adopting a metrics-driven continuous improvement program
- Reducing complexity and redundancy in global processes and systems
- Adopting formal data governance programs (which increases data quality)
- Integrating business processes
- Simplifying local affiliate interactions
- Exchanging information effectively with other functions

Culture and transparency

Lastly, unified RIM requires a strong company culture to drive widespread adoption and success. For many organizations, this may represent a significant change from a traditional "functional excellence" approach. It often requires end-users to understand and buy into how data, processes, and workstreams can impact other teams, both upstream and downstream.

A clear vision, consistent communication, and change management are critical to establishing a strong culture. Companies should consider both "push" and "pull" methods for building culture. For example, establishing feedback loops like end-user surveys and providing education on how the overall mission — delivering products to patients with speed — ties to regulatory goals and outcomes.

Industry leaders also exhibit strength in key cultural attributes compared to their peers, according to the Gens Report where study top performers were compared to everyone else, including:

- Implementing and executing changes: 68% vs. 17%
- Displaying and/or having a high degree of trust between teams: 68% vs. 34%
- Consistently applying a "right first time" quality mindset: 64% vs. 22%
- Effective cross-functional collaboration: 64% vs. 41%
- Regulatory information is transparent to all stakeholders: 55% vs. 22%

Leadership's investments in data quality and governance, process excellence, and a strong culture lay the best foundation for driving unified RIM value.

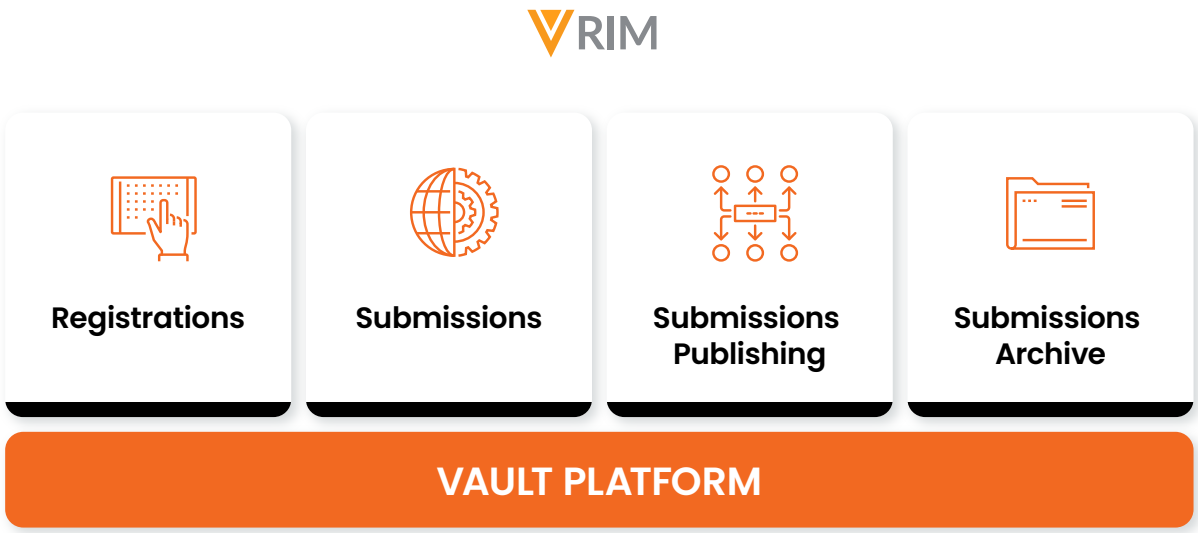
The value of a unified RIM platform

Nearly 70% of companies are expected to have an end-to-end RIM system strategy in place in the near future, according to the Gens Report. Companies' recent global RIM program investments have reduced levels of operational complexity and increased data quality. A third of companies in the Gens Report see more transformative benefits — such as reducing submission approval times with health authorities — with more companies expected to see improvements in the next two years. By leveraging centralized RIM data while monitoring global requirements, regulatory operations become a strategic advantage and competitive differentiator for navigating industry change.

Each company's journey to unified RIM will be different: some are starting anew, others are filling gaps in systems or processes, and still others may be undergoing a significant regulatory transformation. While the path may be different, the goal will be the same: a single, unified RIM platform and authoritative source of enterprise-wide regulatory data and documents that will reduce rework, improve visibility, and streamline compliance globally.

An end-to-end solution should unify registration tracking, health authority interactions, submissions document management, submission publishing, and regulatory submission archiving. **Veeva's RIM platform** streamlines these regulatory processes, enabling faster responses to product changes, compliance concerns, and health authority requests. Veeva RIM also enhances data quality and simplifies data management, ownership, and accountability with a common data architecture.

VEEVA RIM: A SINGLE SOURCE FOR REGULATORY CONTENT AND DATA



Moving from traditional to continuous publishing

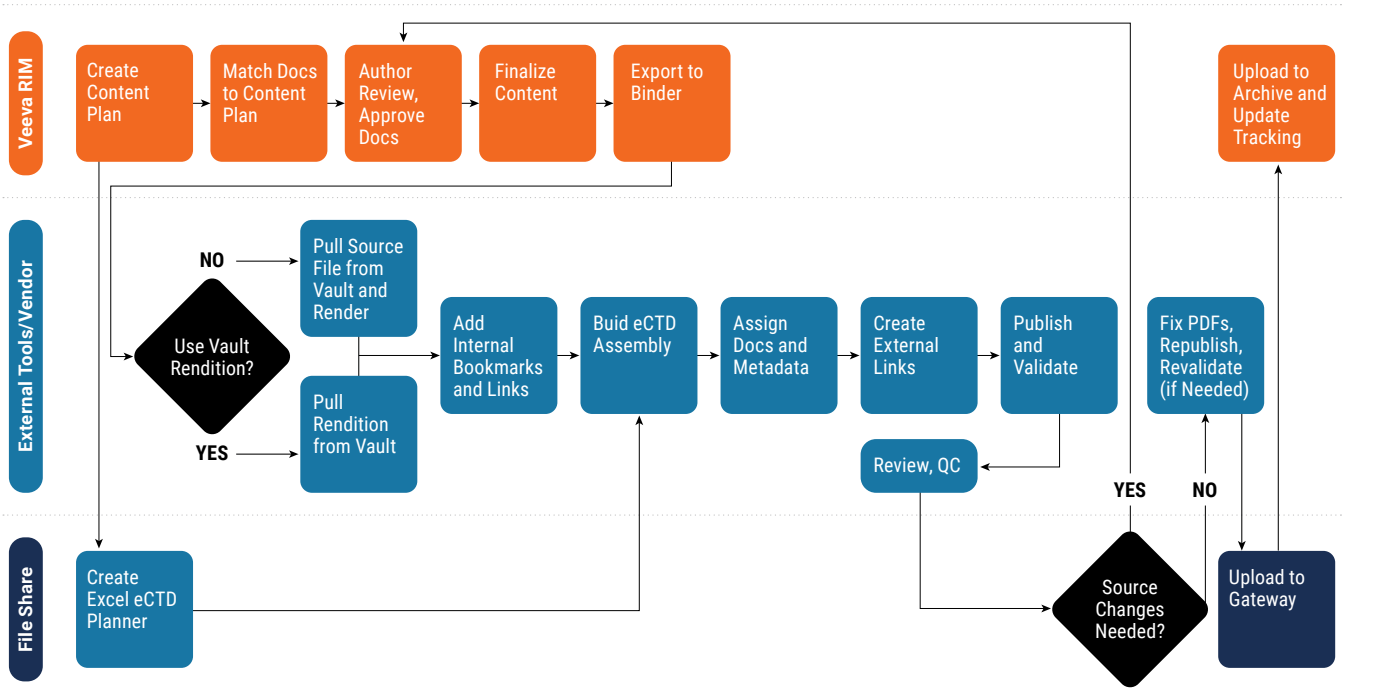
A key advantage of a unified RIM platform is **continuous publishing**, enabling the parallel completion of traditional downstream publishing and validation tasks alongside upstream submission planning and authoring. This streamlined approach accelerates end-to-end publishing processes and improves document and messaging quality.

Traditional publishing models require publishing teams to wait for content approval before starting publishing tasks for a given document. Publishers often review and validate submission output only when the entire submission or a given module is completed. This final submission quality check often happens just days before the final submission is due. Catching content revisions or validation errors at this late stage can put the submission timeline at risk.

Traditional publishing often includes unnecessary complexity and redundancy, such as:

- Planning the outline and tracking progress in a separate tool from where documents are authored and the published output is generated.
- Creating multiple versions of the same file to accommodate different steps in the process or moving the files between different tools.
- Manually creating hyperlinks only after the cross-reference is made and the document is approved.

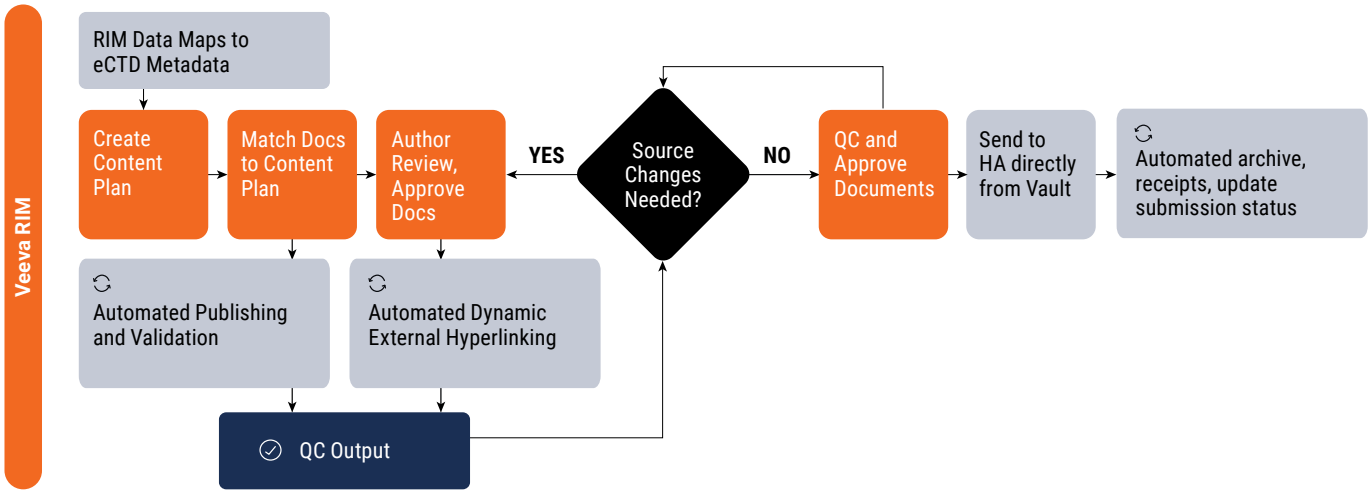
TRADITIONAL PUBLISHING



With continuous publishing, teams can publish in parallel with planning and authoring. Users can also conduct content review and approval in the context of the eCTD output without waiting until the final step. This leads to high-quality content with fewer review cycles because:

- Content approvers can access the HA-centric view earlier, making it easier to follow links and check the consistency of messaging across documents before they are approved.
- Regulatory teams can address errors before the document is approved, saving rework and eliminating issue accumulation at the end of the submission process.
- Teams can leverage data and document connectivity within a single platform to automate many "first pass" steps, allowing them to focus more time on collaboration, unified messaging, and quality control.

CONTINUOUS PUBLISHING



How unified RIM improves regulatory functions

A unified RIM platform improves data and document management across all regulatory workstreams while enhancing collaboration, visibility, and efficiency. Here are some examples:

Managing registrations

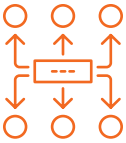
Sponsors can plan, track, and report on global product registrations along with health authority correspondence and commitments. **Veeva Registrations** provides tools that help teams quickly assess the impact of manufacturing or labeling changes to make **data-driven decisions** throughout the product lifecycle.

> **“Veeva Registrations provides additional granular detail into our submissions. This visibility saves time and sets us up for global change management.”**
>
> **Wim DHaeze**, Senior Director, Regulatory Operations, Sarepta

Managing submissions

Submissions teams can plan, author, review, and approve regulatory documents. **Veeva Submissions** lets teams manage the entire submission lifecycle from planning to publishing with greater **access, visibility, and control** over their documents and data.

> **“We're able to capture data through the authoring process and bring it into the publishing process and into registrations, and then be able to use that data in regulatory strategy and planning.”**
>
> **Scott Cleve**, VP Regulatory Operations, Daiichi Sankyo



Publishing submissions

During the submission process, with **continuous publishing**, publishers can review and revise each authored document as soon as it is completed. **Veeva Submissions Publishing** allows users to complete publishing tasks — including cross-document hyperlinking and validation — earlier in the process when issues are easier to fix, reducing multiple rounds of revisions to publish a submission.

> **In the past, content authors didn't have to worry about [submission] lifecycle states. Now they reflect on those issues, and [authors] do some of the prework for publishing instead of merely telling the publishing team what text to replace or what changes to make."**
>
> **Tina Fuson**, Former Senior Manager of Regulatory Affairs, Eli Lilly

Archiving submissions

Create a global, secure repository of submission published output. **Veeva Submissions Archive** functions as the authoritative source of applications submitted to health authorities. Regulatory teams can store eCTD and non-eCTD electronic submissions (NeeS) and link **health authority correspondence to related submissions** for a complete view of regulatory communications. Affiliates can download submissions or submission components for reuse in local markets and upload submissions already sent to various health authorities.

The future promise of unified RIM

A unified RIM platform sets the foundation for future innovation and operational excellence across the business. As a company's unified RIM strategy matures, it will naturally move from adding core functionality and capabilities to continuous operational improvement and value realization initiatives.

Strategic initiatives the highest percentage of companies are working on, according to the Gens Report:

- **83%:** Improving data quality
- **70%:** System and process simplification
- **63%:** KPI metrics program

The right unified RIM platform should evolve with changing regulatory requirements, business needs, and technology advancements like AI. When moving to a unified RIM platform, consider these key questions:

Does your organization have the right foundation for a data-centric approach? Disconnected systems and disparate data models can block future innovation. Getting data right the first time is also one of the most important building blocks for unified RIM. Veeva's RIM applications share a common data model, allowing regulatory business functions to operate independently while ensuring a single trusted source of regulatory data.

Does the platform seamlessly connect to other parts of the organization? A unified RIM platform maximizes value when connected across the enterprise to improve data and document quality as well as make it easier for teams to work together. **Veeva Connections** seamlessly transfer data and documents between Vaults. For example, the Veeva RIM to Veeva Clinical Operations Connection enables users to automatically share product, study, and site information, and the Veeva Quality to Veeva RIM Connection shortens the overall timeline from change control event creation to implementation.

Does the platform support continuous improvement? In the past, on-premise solutions could take up to five years to update and re-validate. Cloud-based solutions like Veeva RIM help companies be agile, responding swiftly to industry changes with **three automated releases per year** and **self-service online publishing training**. A change-as-usual mindset combined with fast and easy updates by a few dedicated systems and business administrators allows biopharmas to keep up with new capabilities and regulations.

Learn how Eli Lilly is shortening timelines and improving quality with a unified RIM approach and visit us at the next R&D Summit.

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Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,100 customers, ranging from the world's largest biopharma companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves.

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