Unified RIM

Why it Matters and How to Spot an Imposter

Abstract

If you're in the market for a RIM suite it's important to know what to look for. Some attributes are easy to see, while others are "under the hood" and more difficult to evaluate. This paper outlines key considerations for a RIM suite and explains the business impact of different architectures for the regulatory audience.

As the benefits of unified RIM become increasingly clear, vendors of legacy RIM systems are connecting stand-alone products and calling them unified. To be technically accurate, they are integrated systems.

There is a big difference between a suite that integrates products with separate architectures and a suite that offers multiple products with a single backend. The later can accurately be called a unified RIM suite or a RIM platform.

Some pharmaceutical and biotech companies that thought they were getting RIM unification ended up with much less. Without a singular shared architecture, these suites cannot produce equivalent benefits in visibility, automation, and efficiency.

This whitepaper discusses what to consider if searching for a RIM suite and explains the benefits of a unified RIM platform.

Introduction – The Problems with Integrating Disparate Systems

Industry's growing desire for RIM transformation have led software vendors to represent their offerings as unified, when in fact these suites integrate standalone products with separate architectures. You may ask why you should care what's happening behind the screen. The answer is because architecture matters to your team's agility and to the promised efficiency gains.

What are the harms and inconveniences that regulatory bears when their suites are integrated? Let's start with the user experience.

User Experience

In many product suites, each regulatory capability has a different look and feel. When interfaces differ, the environment becomes more complicated and requires more training. Complexity can prompt users to work outside the system—using file shares, Excel, and email to collaborate. This increases the risk of compliance issues and reduces information quality. Separate user interfaces can also mean duplicate data entry, which wastes time, increases errors, and forces users to check what's current.

System Stability

Products that are connected using "tightly coupled" integrations are brittle. This means that while the integrations appear reliable, they fail when one application is altered in a seemingly minor way. As an example, when updating the publishing tool, it often takes many cycles for the integration with your content management system to stabilize.

Integrations within a suite can also make it more difficult for the vendor to innovate. Developers spend time ensuring that enhancements in one system don't impact those with a different architecture. Updating the connections takes developer time that would otherwise be spent adding functionality.

Limited Visibility

When systems within a suite have their own data models, it limits your reporting capabilities. Gaps between the systems may be hidden from end-users, but they still prevent the reporting engines from connecting the different types of content and activities. Without a unified platform, reporting is either siloed or rudimentary – where you can't drill down or navigate through the process, or it is dependent on a separate reporting tool.

External reporting tools are powerful, but complex. If your end-users cannot build their own reports, they won't have the visibility to work independently or efficiently.

Evolving Regulations

Unified RIM wouldn't be as important if the regulatory landscape was static. It is difficult and disruptive whenever health authorities introduce new requirements. Within your RIM environment, different systems are updated at a different pace. And typically, organizations can only move as fast as their slowest vendor. Vendors with integrated suites must update each affected product, plus all the hidden data mappings.

Modifying your systems to keep up with SPOR, IDMP, ICH E2B (R3), the Falsified Medicines Directive, and others will be challenging. The more systems and data models involved, the more complicated and difficult it will be each time.

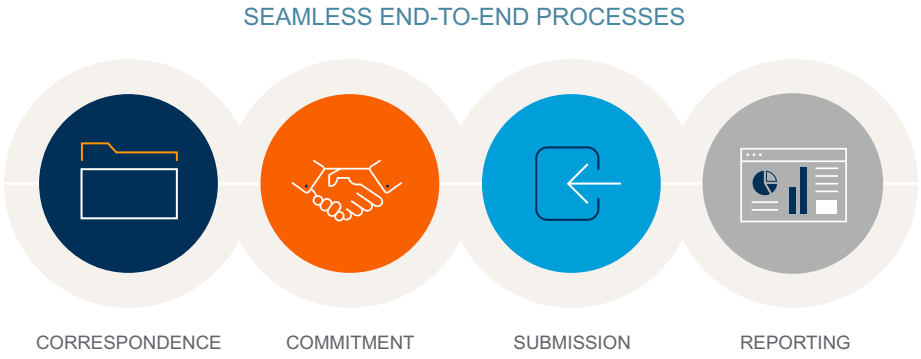
Benefits of Veeva's Unified RIM Platform

Veeva introduced an entirely new approach to enterprise software with its industry cloud for life sciences. Before, most software providers offered horizontal technologies like Documentum and SharePoint that were customized to fit industry solutions. Niche applications, like publishing and registration tracking, were offered by specialty vendors, and integrated with the horizontal platforms. Veeva has taken a new approach by building the necessary technologies to address end-to-end processes, specifically within life sciences. The result—best of breed applications on a single platform—cannot be replicated by traditional system integrations. The efficacy of a unified platform is dependent on a single flexible architecture at the foundation. The primary benefits include:

Content, Data, and Activities

Manage end-to-end processes from planning through execution

Regulatory processes involve multiple types of information: planning and tracking information, product data, submission documents, correspondence, and more. A unified RIM platform provides a frictionless process. By eliminating the information gaps and hand-offs, multiple parties move in harmony from one step to the next.



Single Source of Truth

Complete, accurate, and trusted information

When all parties work with a single shared source for regulatory information, you no longer need to check the consistency and veracity of your information. This significantly reduces bottlenecks when engaging with stakeholders. Affiliates and external parties can access authorized information directly and be confident they are aligned with headquarters.

Single User Interface

Simplifies the user experience

Providing a consistent user experience reduces training and potential errors. Users no longer toggle between multiple interfaces to do their jobs. A consistent interface doesn't mean everyone sees the same thing. When tailoring the interface by region and role, individuals only see what's relevant to them. System settings help ensure that users can access the information they need without being overwhelmed by extraneous information.

Unified Reporting

Forward visibility and backward traceability

In suites that integrate separate architectures, the reporting is siloed by activities. For example, you will see the status of your documents, or the status of your workflows, rather than the progress towards your business goal. To get a holistic view, planning and tracking must occur within the same system as the work that is performed. Then, there is a direct path from performance metrics to the individual documents and activities those metrics are based on.

Unified reporting also makes it easier for individual users to access the information they need. People move faster and more independently because they see what needs to get done and have the information to do it.

COMPLETE TRACEABILITY

CREATING RELATIONSHIPS ENABLES YOU TO TRACE THE IMPACT OF BUSINESS CHANGES

Context-driven Automation

Greater speed and accuracy with less effort

Managing documents, data, and related activities provides Vault RIM with the contextual information it needs to automate most of the manual and repetitive work done today. There are standard forms of automation, such as: autogenerating file names and auto-populating metadata. Then there are more advanced forms, such as auto-populating documents with product registration data, auto-generating a table-of-contents for your submission, and auto-placing documents into your submission structure without duplicating previously filed documents. Automation improves both accuracy and efficiency, freeing your team to work on high value activities.

CASE STUDY

Automating Manual Steps in Submission Development

One clinical-stage biopharmaceutical company used Vault RIM to automate manual steps and improve data quality while developing their recent New Drug Application (NDA). The company had configured Vault to control 100% of document metadata, meaning all metadata was either inherited, auto-generated, or user-selected from a predefined drop-down list.

As a result, there was only a single naming or metadata mistake across over 12,000 documents. And, that single error was caused by a human over-writing the system.

Vault RIM also auto-generated the NDA's 220,000 internal links and bookmarks, based on the company's document templates and styles.

Single Point for Integration

Streamlines cross-functional processes

Business processes that involve multiple functional areas, such as post-approval change controls and safety reporting, are inherently more complex than processes completed within a single functional area. The lack of integration between the functional areas' business systems makes that complexity even worse. Integrations between functional areas makes sense, and yet, they are difficult to develop due to the fragmented environments within each area. For example, if regulatory information is spread across multiple systems, there is inevitably duplication and discrepancies in the data. This makes it difficult to integrate with your CTMS or eTMF because there isn't a single, authoritative source for the regulatory information.

With a single integration point, regulatory can reliably exchange data with clinical, manufacturing, and safety groups, thereby simplifying cross-functional business processes.

Economies of Scope

Rapid innovation that benefits the entire team

Vendors with unified suites benefit from economies of scope, which is an economic term for the savings that result from producing multiple different goods. Each new platform capability can be leveraged by the different applications. For example, a new reporting feature that calculates metrics would apply to managing submission documents, publishing, variations, or commitments. This concept is illustrated by the saying "a rising tide lifts all boats." End-users across regulatory benefit from innovations throughout the RIM platform.

Conclusion

Many regulatory departments are in a period of major transformation. Companies that spent years buying individual systems for each regulatory function are now consolidating those to a single RIM platform. It isn't done in one fell swoop, but they are setting themselves on the path. Smaller pharmas and biotechs that are moving from Excel spreadsheets, are determined to start-off on the right path. Whether you are big or small, as you evaluate your options for regulatory information management, it is important to know the differences between suites that integrate separate architectures and unified suites on a single platform.

Agility, speed, and end-to-end visibility only comes with one architecture: a fully unified RIM platform.

> "Tracking the contextual information helps us see the big picture. Every submission has a purpose—it answers a question, resolves a commitment, or starts a new regulatory objective. [With Vault RIM] we can easily navigate through history and get a clear understanding of what was done and why."
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> — Monica Kennedy, Director of Regulatory Operations, Halozyme

About Veeva Systems
Veeva Systems Inc. is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 650 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. For more information, visit www.veeva.com.

Veeva Systems
Global Headquarters
Pleasanton, California, USA
4280 Hacienda Drive
Pleasanton, California 94588
+1 925 452 6500 | veeva.com/contact-us | veeva.com

How to Spot an Imposter

With some simple questions you can distinguish unified platforms from integrated solutions.

Telltale Signs and What to Ask	Why it Matters
Separate UIs for different capabilities Ask: • May I see how the interface differs for registration tracking, managing submission documents, and publishing? • Where is a "product name" entered (vs. selected) as metadata throughout a business process? E.g. for a product registration, a planned submission, a specific document, when publishing…	Multiple interfaces add complexity, training requirements, and workflow gaps. A single interface provides consistency, visibility, and efficiency. It shouldn't however, mean everyone sees everything. With Vault, you can tailor the displays for different user groups based on their unique needs. Metadata, such as product name or sequence number, should only be entered once and re-used throughout the process. This saves time, improves data quality, and generates the relationships that provide traceability.
Separate reporting Ask: • Can you describe how reporting works within your system? • How does your reporting engine access data from all the different RIM capabilities?	Reporting should provide traceability from a triggering event, such as a new label or manufacturing site, to the final approvals. A unified platform consolidates data from every point in the process and establishes relationships between activities, so you can see what was done, when, and why. Also, every user can view reports and access the information they need. Without unified reporting, teams are limited to narrow views of their operations or they are dependent on others to master complex reporting tools. Separate reporting systems are also another system to integrate and upgrade.
Applications with different upgrade cycles Ask: • Are any of the components upgraded on a separate cycle from the others? • Can you describe the upgrade and release cycle for the different components? • Does the suite have any dependencies on third party technology such as Documentum or SharePoint?	If a vendor can update one RIM application without releasing a new version of the full suite, their RIM suite isn't truly unified. When vendors support applications independently as well as within a suite, it doubles their engineering and test efforts. Innovation will be slower. Also, third party components introduce dependencies that are outside of your vendor's control. The RIM vendor may request certain enhancements, but the parent company of the integrated product likely has other priorities.

Telltale Signs and What to Ask	Why it Matters
Legacy versions of the applications Ask: • Do you support prior versions of your publishing tool or registration tracking? • Do you have a support matrix that describes which version combinations are supported? • Does your software have a multitenant architecture?	Multitenant cloud is a software architecture in which a single instance of software serves multiple customers, all of whom access the software over the Internet. These customers typically receive better performance, easier upgrades, greater security, and faster innovation with multitenant software than they achieve with client-server software maintained in their own facilities. As a result, virtually all modern software is multitenant. You can tell that software isn't multitenant if different versions of the software exist in parallel, e.g. some customers are on version 3.1 and others are on version 2.5 or version 4.0. If RIM vendors are supporting old versions of their software, many of their engineering resources are allocated to maintenance rather than developing new and better functionality.
Separate data models Ask: • Do the applications all share a common data model?or are some data models separate? • How long does it take for the data to synchronize between applications?	A data model is a representation or organizing structure for data that describes real world entities. Software applications use data models to define relevant entities, their properties, and relationships between entities. Different systems will typically have different data models. If there are any data mappings or data synchronizations between applications within a suite, the suite isn't unified. There are multiple challenges involved: • Reporting across products is more difficult or impossible if the data models are different. Data model mappings are difficult to maintain. When one system has a major upgrade, data in the other system may need to be migrated to align with the new version. Data migrations are complicated and expensive, and a major disincentive to upgrade. For end users, that means you'll be stuck on old versions while your competitors using unified, multitenant platforms stay current at all times. Also, when one's data model needs to be updated, say to accommodate a new regulation, making that change is slower and more complicated if there are integrations. Even if the system vendor is making the change, the updates will take longer to get to you.
Acquisition history Ask: • What products have been acquired and are now part of your suite?	When companies buy other companies or software products, they often lose the software engineers who built the products and know how they work. Over time, vendors get stuck with aging software and few if any developers who know how to improve it.