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Regulatory Affairs

Regulatory Information Management (RIM)

Growing Regulatory's Strategic Value
The Value of a Holistic RIM Capability

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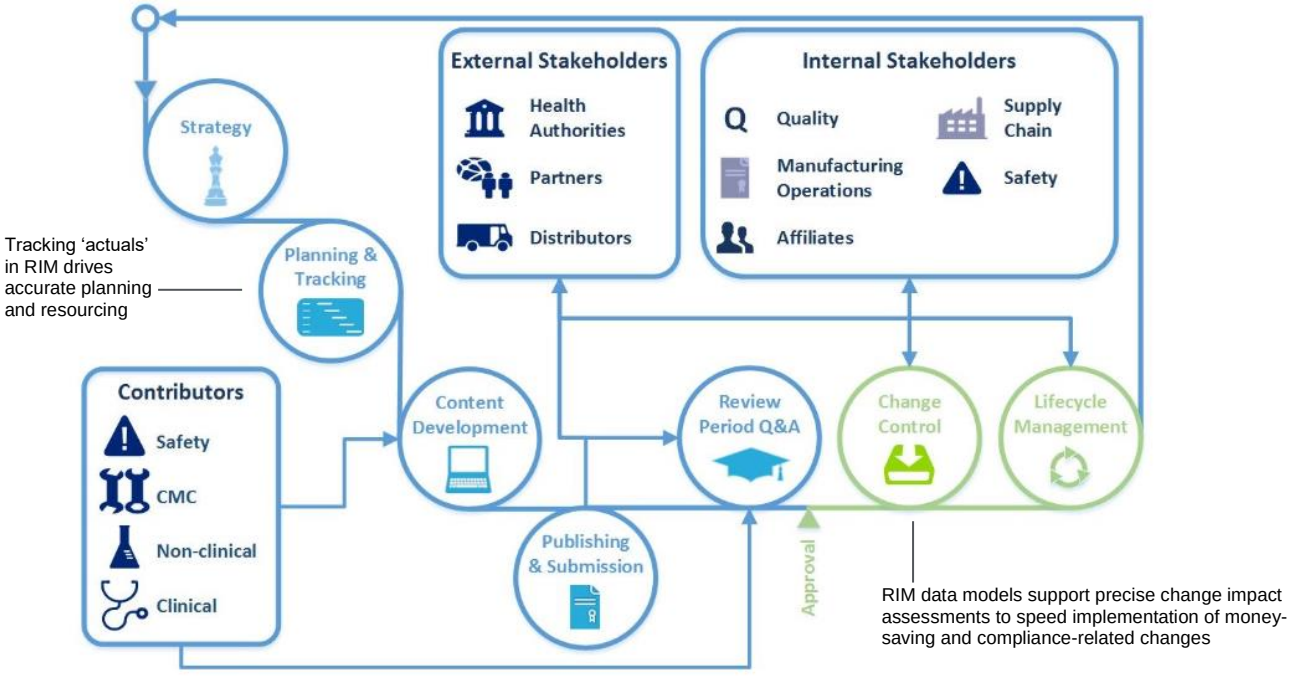
Contents

The Regulatory ecosystem

1.1 Regulatory Affairs' Critical Role

Regulatory functional groups (commonly Regulatory Affairs, Regulatory Operations, Labeling, and Lifecycle Management, among others) are on the critical path to new product launch, and are directly involved in enabling continued access to marketed drug products. RA teams can be instrumental in speeding time to market through innovative registration strategies as well as effective submissions development processes. Regulatory also plays a key role in maintaining patient access to products and optimizing profitability through effective lifecycle management. The business case for leading-class regulatory capabilities should therefore be focused on maximizing revenue and minimizing compliance and quality costs, rather than simply focusing on process efficiency.

Regulatory reporting requirements and business financial imperatives are driving regulatory from a largely document-based paradigm to a data-based paradigm. Managing structured and unstructured content as well as a wealth of metadata demands a new level of precision in executing Regulatory's responsibilities.



1.2 The Evolving Landscape

Challenges Facing Industry
Industry must address multiple challenges that, in aggregate, make it very difficult to achieve full Regulatory process continuity as well as a comprehensive view of Regulatory information:

- **Cross-functional responsibilities**—Regulatory processes touch multiple functional areas: Commercial, R&D, Quality, Manufacturing, and Supply Chain and Distribution.
- **Geographic diversity**—Each market represents potentially varying requirements and approval processes, making it difficult to establish common processes and submission documentation.
- **Partnerships**—Regulatory roles and responsibilities may be spread across multiple companies throughout a product's lifecycle. Contracted relationships with suppliers (e.g., CROs and MCOs) and development partners (e.g., via in-licensing) add layers of governance.
- **Health Authority scrutiny**—Regulators from different markets are working together to identify instances of non-compliance as well as misalignment of information in submissions and other communications with regulators. There is a trend towards increasing risk-based inspections with a promise of greater scrutiny and sanctions for non-complying organizations.
- **Technical and data complexity**—Regulatory reporting requirements and business financial imperatives are driving regulatory from a largely document-based paradigm to a data-based paradigm. Managing structured and unstructured content as well as a wealth of metadata demands a new level of precision in executing Regulatory's responsibilities.

These factors can cause delays in filings and approvals, introduce waste and rework and increase risk of non-compliance. The potential consequences are significant increases in costs as well as a possible significant reduction in a product's revenue potential.

RIM value model

Value reflects the balance between *costs* and *benefits*. Investment in an effective RIM solution involves not only the RIM technology, but process, organizational change and data management elements as well. However, these investments, if made appropriately, will likely return substantial benefits in terms of cost avoidance and improved regulatory and financial performance.

2.1 Potential Benefits of Doing RIM Right

Companies have had challenges defining the business case for investing in a RIM solution, in part because they have had trouble defining scope. Taken in pieces, any single RIM capability will likely have a proportionally smaller impact. Taken in the broader context, enabling the full set of regulatory capabilities across the product lifecycle in a unified approach can deliver returns greater than the sum of the benefits from smaller, isolated initiatives. Potential benefits from a unified approach to RIM include:

- **Faster time to approval**—A unified RIM solution connects planning to execution, allowing improved, real-time process monitoring. Teams can quickly spot constraints and take corrective action. Also, adoption of a common platform can help drive consistency and reduce wasted efforts such as reviewing or editing the wrong version of a document or needing to validate data brought in from another system. Improved quality typically translates to fewer health authority questions and commitments during the review process, increasing the likelihood of an on-track approval.
- **Optimize profitability and access to drug products**—Integrating regulatory intelligence and knowledge management with critical processes allows companies to bring new products to more markets more efficiently. During lifecycle maintenance, this same intelligence speeds the change control and variation management process, allowing companies to manage change efficiently and reducing the risk of change-related recalls. One Top 20 pharma company estimated wasting 75,000 hours per year on manual data entry and rework due to inefficient change control and variation management processes. At a conservative hourly rate, that's $7.5 million per year across the regulatory and quality teams.
- **More efficient use of data, authoring and submissions**—Process visibility, data quality, and simply knowing where to find

Efficiency: Doing more with fewer resources—Companies have reported that 30% to 50% of a regulatory team member's time can be spent looking for information, with the higher levels of time wasted in the affiliates, lower levels in HQ.

Cost of Poor Quality: Reducing recalls and rework related to regulatory activities—One large, multi-sector company measured the cost of label-related recalls (specifically sending the product with the wrong label into markets) at $130 Million to $150 Million per year. Another calculated the financial impact of a warning letter at $200 Million.

Reduced IT costs: One company currently has over 100 systems supporting new molecular entity and lifecycle submissions. They are planning retirement of half those systems as new capabilities are moved to the RIM platform, saving license fees, hosting, training and support costs.

Sources for above: Internal surveys conducted by MedTech and pharma companies

information and documents can greatly increase resource productivity. The unified platform also paves the way for more efficient content reuse, such as Structured Content Management (SCM), which allows automated propagation of content across documents within the global dossier (as well as across dossier templates). This allows a "write or enter once, review once, use many times" paradigm.

- **Better planning and tracking**—Faster time to quality, universal access to the plan. Plan stays current and accurate. Data is reliable, don't need to verify before using numbers, etc.
- **Improved Health Authority (HA) interactions**—More effective control of the submission, enabled by a unified platform, can lead to a leaner, higher quality submission. This translates to a more efficient review process for authorities, and builds credibility. In this era of risk-based oversight, credibility translates to speed and potentially a reduced regulatory burden.
- **Operational oversight and metrics**—A unified RIM solution allows companies to proactively monitor end-to-end regulatory processes, collecting detailed accurate data about process performance. The resulting performance metrics can inform corrective actions and drive process improvements.
- **Compliant product release**—Integrated change control and variation management processes and connection to ERP systems can greatly reduce the likelihood of releasing updated products into a market before HA approval of the variation. Recalls associated with label-related changes alone cost the industry hundreds of millions of dollars per year.
- **Talent retention**—Many companies report that employee turnover on regulatory teams is linked to the stress of the filing, and increases greatly if team members consider processes to be inefficient or wasteful. Being able to perform one's job efficiently and the perception of being part of a high-performing organization contributes to employee satisfaction and retention.
- **IDMP Compliance**—As new European requirements are implemented and other regions consider adopting similar requirements, companies will need to submit increasing volumes of structured product information across regions. A unified RIM capability is critical to sourcing and linking data and submissions, supporting the broader supply chain with accurate and accessible global product data.

2.2 Cost Avoidance

In addition to the benefits of managing regulatory information effectively, there are also substantial cost avoidance opportunities. These potentially addressable costs are often those categorized as *Costs of Poor Quality* (CoPQ), and are commonly associated with wasteful processes and practices. They are typically expressed in terms of *Internal Costs* and *External Costs*:

Internal costs—These costs impact profitability but are "contained" within the company. Examples include wasted effort such as reviewers making updates to content that they should not be touching, rework such as editing the wrong version of a document, and loss of productivity.

Reducing the time spent looking for information, whether looking for regulatory intelligence, a specific submission document, or information about a commitment, can have a profound impact on productivity and speed. Having information exist in multiple places compounds the problem by increasing the likelihood of inaccurate data, which impacts downstream costs.

External costs—External costs reflect quality issues that impact the company after the product has left the factory: recall costs, delays getting drugs to distributors or to patients, stock-outs, and extended approval times (due often to poor data quality or misunderstood authorities' expectations.)

External costs go beyond those immediate impacts to revenue. External costs affect outside stakeholders and can have immediate impact on market capitalization. There can also be long-term, cascading impacts such as loss of customer loyalty or loss of credibility with authorities, which can result in increased surveillance. And, of course, there is the potential for fines related to specific findings related to improper release of product due to lack of visibility to regulatory status.

Direct Technology costs—Although companies find greatest value in growing revenues and avoiding quality and compliance costs, there are also savings directly related to the cost of technology. One company is planning to replace up to 100 systems and tools supporting regulatory affairs when considering affiliates.

Cost category
Internal failure costs
Remediation
Rework
Scrap/Spoilage
Nonconformances (NCR, CAPA, SCAR)
External failure costs
Post market surveillance (Complaints)
Field Corrective Actions (FCA)
Holds
Recalls
External inspections/Audits
Agency observations/WL
Liability
FDA/MOH communications

Sample CoPQ Dashboard (Courtesy MDIC)

The table below captures potential savings from greater efficiency when consolidating RIM systems globally and across RIM functions[1].

Note that these estimates solely reflect the gains from a unified RIM technology. The benefits stand to be far greater if considering the process improvements enabled by unified RIM and the much greater external savings that would likely result from product quality gains.

Table 1: Internal Efficiency Gains with Adoption of Veeva Value RIM Suite[1]

		Large Company*	Mid-sized Company**
Process	**Cost Reduction Assumptions**	**Annual Savings**	**Annual Savings**
Creating regional documents	Reduced time spent searching for documents and identifying the correct version; assumes potential benefit applies to 2.5% of all submission documents	$2,163,000	$867,300
Submissions content planning	Creation and management of LARGE submission type/regional templates to make planning and tracking more efficient	$1,050,000	$525,000
	Creation and management of MODERATE submission type/regional templates to make planning and tracking more efficient	$10,500	$4,200
	Creation and management of SMALL submission type/regional templates to make planning and tracking more efficient	$5,250,000	$2,100,000
Submissions content assembly	System driven submission development and content filing automation across plans (auto filing of content across plans)	$1,648,000	$660,800
Respond to commitments and queries	Reduce response times for commitments and queries through improved visibility	$1,821,600	$729,000
Submission traceability	Unified master data across all the RIM applications allows users to easily leverage existing regulatory/submission content and data to assist with future work	$1,442,000	$578,200
Tracking registrations	Global visibility into registrations eliminates needs for calls and emails to local sites; assumes 200 global registrations per product	$3,375,000	$1,350,000
Operational reporting	Partial automation of operational status reporting	$480,000	$192,000
Data cleaning and harmonization	Leveraging data already maintained in Vault Registrations reduces data collection and change tracking effort is reduced by managing the process in one system	$1,380,000	$552,000

*Assumes company with 50 marketed products that files 2 large, 20 moderate, and 10,000 small submissions/yr.

** Assumes company with 20 products that files 1 large, 8 moderate, and 4,000 small submissions/yr.

[1] Source: Veeva Systems

2.3 Investing in RIM

Of course, achieving significant returns on implementation of effective RIM requires an initial investment. The costs associated with technology solutions can be significant, especially if companies are maintaining several point solutions. *Total Cost of Ownership* (TCO) of the technology solution(s) typically includes software licenses and support costs to the technology vendor. Other costs of technology include requirements definition, configuration services, integration services, validation, testing and training. Some solutions may require significant investment in infrastructure, especially if implementing multiple, on-premise point solutions. Identity and access management, back-up and recovery solutions, and technical support should also be figured into calculations. Many companies under-invest in organizational design and change management. Often, aligning stakeholders on a common process and technology involves addressing multiple value propositions and effectively communicating the rationale and benefits associated with the intended changes.

Companies often look at 5-year cost of ownership, which should include 5 years' worth of ongoing maintenance and support, as well as, on average, one upgrade for one of the set of existing on-premise solutions. Other costs of implementation and ongoing operation are related to process and governance, and are presented in the next section.

Sample TCO Calculations			
		5 Year	Periodic
Software			
	Licenses		
	Maintenance		
	Support		
	Upgrades		
Infrastructure			
	Hardware		
	Set-up		
	Support		
	Network		
	Other services		
	Allocations (power, etc.)		
	Back-up / DR		
Design			
	Requirements		
Implementation			
	Configuration		
	Loading		
	Data Migration		
	Testing / Validation		
	Training		
	Change Management		
Launch			
	Training		
	User support		
Total costs (running and periodic)			
Total 5-year cost			

Achieving results

Historically, RIM implementations have been limited, with few if any companies implementing the full suite of capabilities. Additionally, there were no end-to-end solutions. RIM solutions grew from a "specialty" capability focus—registration management, planning and tracking, and/or content management. The non-specialty areas were relatively weak, and companies preferred to implement best-in-class point solutions. The resulting quality and consistency challenges are a matter of record.

Unified Platforms

RIM vendors have recognized the pain points associated with disparate systems, exacerbated by IDMP requirements, and are moving to unified platforms. These platforms, which include what were up to now four or five separate technologies, accommodate structured and unstructured content (regulatory documents). Integrated planning, tracking and commitment management allow managers to assign responsibility and measure progress at the data or document level. Publishing activities are performed as background processes throughout submission development. Archiving is automated, and users can link to the appropriate content within the same solution environment. The upside will be automated transfer of data and documentation from one process to another, one team to another. Integrated, end-to-end process reporting will be simplified.

Implementing RIM technology alone will not deliver transformational results. Companies must also address organizational, data and process dimensions to fully realize the potential of a comprehensive RIM solution.

3.1 Organizational Improvements

Implementing RIM on a global basis brings opportunities for rethinking roles and responsibilities at the local and regional levels. From assuming strong governance to assuring data quality, a global RIM implementation can provide visibility across a company's regulatory ecosystem. Also, leading companies are leveraging local affiliates and distributors to update regulatory requirements and other regulatory experience. The result is a high-functioning network that enjoys the benefits of centralization and economies of scale while maintaining sensitivity to local market requirements.

An end-to-end RIM solution will often interface with other functional teams, especially to processes such as change control. Leading companies are enabling cross-functional visibility through a variety of solutions.

Finally, new opportunities mean new roles and responsibilities and likely changes to competency models and training related to RIM. Centers of Excellence allow for concentration and optimization of competencies specific to the workgroup. Note that a "Center" does not need to imply co-location. CoE's simply support the adoption of common processes and a common toolset. The result is consistency, an ability to identify and replicate leading practices, and an opportunity to accelerate continuous improvement activities.

3.2 Data Improvements

Implementing a broad RIM platform will likely eliminate many data hand-offs and contribute to improved overall data quality and visibility. However, RIM technology alone will not solve data quality issues.

Companies should first pursue improvement in Data Governance and Data Management integrity capabilities. As different groups may each "own" their own systems, data will need to be aligned as the product progresses through its value chain and lifecycle. Hand-offs must be seamless. For this reason, and holistic approach to mastering data including common dictionaries and taxonomy is key, especially as IDMP requirements come into effect. One key concept is identification of the authoritative source for each data element. A comprehensive Master Data Management (MDM) solution should keep track of historical values as well as track changes to data values as different processes impact those values.

3.3 Process Improvements

Unified RIM systems enable more efficient regulatory processes. These processes must work together seamlessly. When they do not, teams often find work-arounds or other opportunities to bypass the process. Quality suffers and inefficiencies are amplified. As mentioned previously, leading companies are aggressively pursuing process optimization, which can take many forms:

- **Rethinking the critical path to launch**—e.g., pursuing aggressive front-loading of submission writing by aligning on key messages early in the clinical design phase (writing to the protocol end points)
- **Information flow optimization**—mapping systems and the dossier to identify information reuse opportunities and dependencies

(data/document reuse). Enter data once reuse many times across systems and documents.

- **Review cycle consolidation**—limiting the number of review cycles and limiting the scope of authority to make comments to specific sections of the dossier
- **Process monitoring**—defining cycle-time and quality metrics to promote speed and consistency and to enable both corrective action and continuous improvement.

Once processes have been redefined (collaboratively, with broad stakeholder input), the RIM solution can be configured to support or enforce process compliance.

3.4 Emerging Complimentary Technologies

Companies are exploring a range of technologies to interface with core RIM capabilities, including automation and artificial intelligence. A few of the technologies that can complement the end-to-end RIM solution include:

- **Robotic Process Automation (RPA)**—RPA is the application of robotic "users" to perform repetitive or rules-based tasks within the computing environment, essentially very efficient "cut and paste" activities. While not as effective as a full integration or unified platform, RPA can provide a stop-gap interface between systems. This can make sense as a short-term investment since the pay-back periods are extremely short, or as a longer term solution when investment in integration is further off or unlikely altogether.
- **Structured Content Management (SCM)**—Also known as Structured Content Authoring, SCM provides for propagation of content within a document or across multiple documents. The idea is to write once and reuse as many times as needed. The capability also supports more efficient reviewing by having reviewers focus on the primary content, knowing that the downstream content will be automatically updated to reflect the upstream changes. In some cases, business rules are applied to make sure updates are appropriately propagated.
- **Natural Language Processing (NLP)**—NLP is a "cognitive" technology, one where the software learns by reading and is able to distinguish concepts and "understand" the document and text. NLP can be used as a classification tool to read and classify legacy documentation for archiving, or as a parsing tool to extract structured data from unstructured content. Companies are also

exploring NLP to map their dossiers and integrate with SCM capabilities.

- **Natural Language Generation (NLG)**—NLG is in a sense the compliment to NLP: companies can use these tools to generate content automatically from structured data. Early applications have been developing narratives from patient data for Case Report Forms (CRF's) and narratives for Adverse Event Reports. While companies look to automatically write content from data, they are concurrently working to minimize the amount of content needed for a submission, hoping to achieve the holy grail of NLG generated submission.

Next steps

4.1 Understanding Current State

It is important to objectively evaluate your current capability maturity and pinpoint areas that are deficient. The resolution may be process, technology, organization or data-related, or some combination. To start assessing where to improve, determine if your processes need to be harmonized, whether your employees are proficient in needed competencies, and if your data is in order.

4.2 Organizational Change Management

Implementing an effective solution, however attractive to leadership and to users, involves significant change. It has been said that "culture trumps strategy"; as such, changing attitudes and behaviors is no simple effort. *Organizational Change Management* (OCM) should be integrated in all design, piloting, and implementation efforts. Investing in communications, training and ongoing support will help ensure successful adoption and sustainment of the changes associated with implementing RIM.

4.3 Defining Your Roadmap

Your roadmap to realizing the value from RIM must reflect understanding of current state, interdependencies, and the target business priorities and expected benefits. Companies should plan, and budget for, non-technology activities such as process and data as part of your RIM program. Prioritize those capabilities that will provide the greatest return on your investment and implement iteratively, capability by capability, even if pursuing a unified platform solution. It usually makes sense to pick a high-value yet achievable capability area rather than trying to do a big bang. Most importantly, communicate sufficiently to identify and align stakeholders as many will be impacted—all for the better.

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