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## Transitioning From Legacy Systems to Modern Regulatory Information Management (RIM) Platforms

Author Name: **Sharath Reddy Venna**

Role: Senior Manager Regulatory Operations/Informatics

Affiliation: Leadiant Biosciences, USA

Email: vennasharath@gmail.com

**Abstract-** *The Regulatory Information Management Platforms are the subject of the research. The research has analysed the different benefits and challenges that are associated with companies transitioning from legacy systems to modern regulatory information platforms (RIM). The literature review has established the value of RIM in handling regulations efficiently under the current context. It also reveals how RIM is being impactful in creating better collaborations among the stakeholders. The handling of compliances and understanding the legal aspects across different geographies become easier. The system faces the challenges of acute data privacy and the complexities of migrating data. The use of secure network systems, data cleansing, and employee training have been suggested for developing a flawless system.*

**Index Terms:** *Legacy systems, RIM, challenges of RIM, benefits of online, regulations, operational efficiency, compliance ease*

### I. INTRODUCTION

#### A. Background of the study

There are disruptive changes and transformations in the way regulatory affairs are being conducted globally. The regulatory landscape is evolving at a rapid pace compared to before. The organisations are hence moving from legacy systems towards fully integrated regulatory systems. The delivery of timely, reliable and high-quality regulatory system is possible with the evolutions. The modern regulatory information management platforms are enabling companies to synergise the processes across the geographies. The regulatory data management is paving the way for interoperability and the vital prospects to be realised across the business [1]. There are faster operations possible across the regulatory platforms with the embracing of information management platforms.

#### B. Overview

The RIM platforms are enabling companies to attain the competitive edge needed across the business. The procedural change can support the increased harmonisation in terms of documentation and enhanced capabilities with respect to future variation [1]. The platforms are facilitating better governance of systems and businesses [2]. Over the last few years, the regulators have placed increasingly granular disclosure requirements [3]. With the use of

information management platforms, they become easier to manage and deploy. The RIM is effective in increasing regulatory intelligence in real time. The quality of interactions with the authorities and automation of complex processes is derived from the implementation of RIM.

### *C. Aims and Objectives*

The objectives of the current research are as follows:

- 1) To analyse how the companies are evolving from legacy systems to modern regulatory information management platforms.
- 2) To examine the critical advantages derived from the implementation of RIM platforms across the company's governance.
- 3) To identify the challenges and issues that can arise with the integration of RIM platforms across the system including data migration issues and insufficient training.
- 4) To recommend the suggested techniques for overcoming the issues faced on implementing RIM.

### *D. Problem Statement*

Despite the crucial functional advantages gained by implementing RIM, there are a slew of pitfalls the company can encounter. The ongoing change from an industrial model to an informational one creates problems for the existing regulatory system [4]. Many companies are struggling to attain the needed balance with the extensive data migration needed and the dynamic training of employees. The study will hence focus on how the systems are evolving and the emerging challenges that will need to be tackled. Organisations can gain strategic benefits by switching to regulatory information platforms.

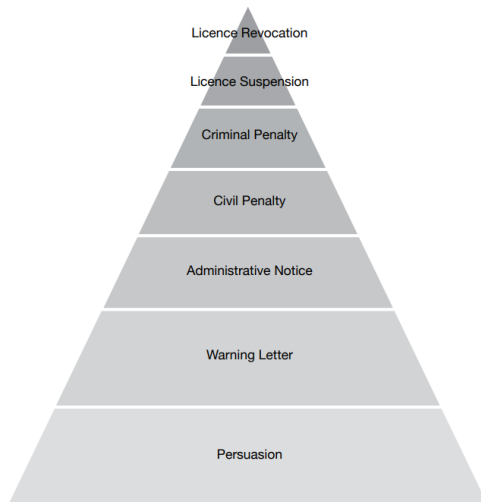
### *E. Scope and Significance*

The study examines how companies are transitioning from regular legacy systems to information regulatory platforms. The research is being done on how critical advantages are being derived with the use of information regulatory platforms. The challenges and issues faced that need to be tackled through appropriate measures are being suggested through the study. The validity of the study is in its close examination of the regulatory changes that can provide the needed edge to organisations. The organisations can function better on receiving knowledge of the benefits and complexities of the application.

## II. LITERATURE REVIEW

### *A. Transitioning towards Regulatory Information Management Platforms*

The global financial crisis has paved the way for a deregulatory approach to financial processes. The data-driven financial services are creating the need for an evolved regulatory system across the global environment. The development of specific and new regulatory frameworks is allowing companies to regulate actions [5]. Managing product information and keeping up with submissions is time-consuming and repetitive. The RIM technology is radically reducing the time and costs associated with gaining the necessary compliance. The companies are increasingly transitioning towards RIM on account of the efficiency and compliance achieved. The RIM is ensuring that enforcement is possible not just by the state. The surrogate regulators are included as well [6].



**Figure 1: The Enforcement Pyramid**

(Source: [6])

The Enforcement Pyramid reveals the different steps involved across the regulatory framework. The efficient flow of information across all the parties involved is attained with the information system. The companies burdened by legacy systems are attaining easier workflows with the inception of RIM. The regulatory tasks at certain points are being executed with minimised intervention.

There are increasing debates around the efficient handling of regulatory data capable of yielding results. There has been the emergence of harmful or illegal content that has resurfaced as a major international regulatory issue [12]. Thus, there is a significant departure from legacy systems to more efficient regulatory information management. The transnational regulatory schemes can be complex to navigate across. There can be self-regulatory codes as well as broader initiatives bringing together different actors. Multistakeholder governance is better managed with the inception of Regulatory Information System. All the participant can access the information needed.

### *B. The RIM applications benefit to organisations*

The RIM is greatly benefitting the organisations leveraging critical information. The product and registration tracking are available over diverse geographies. The intelligent automation of labelling is possible with the integration of RIM. The Metacyc is a vital RIM tool being used across pharmaceutical organisations [7]. The regulatory data for enzymes and the detailed information available ensure smooth operations compared to legacy systems. The phenomena of digitalisation and data-driven decisions are disrupting contemporary business models [8].

The RIM is tendering critical advantages to several industries. The inspection and tracking of the flow of drugs to prevent counterfeit drugs is one of the critical aspects of healthcare [10]. The use of RIM ensures further tests, tracking and consultation with key investors within the reduced time. There have been increasing complexities encountered across the operations of the food supply chain. The food supply chain comprises of actors still making use of individual quality standards to comply with the international regulations. To enhance the traceability of food items, companies need to exchange critical quality assurance information with each other in a detailed manner [11]. The RIM is aiding in such activities with quick access to information and assuring the overall quality of goods. However, with the increase in the dynamics of the

digital market, there is an urgent requirement for sustainable and regulatory approaches across the organisation.

### *C. Challenges of RIM applications across organisations*

The regulators of RIM are presented with new challenges regarding their execution. The first challenge lies in deciding who should be regulating the platforms [8]. The second issue lies in how the platforms should be regulated. There are inherent questions associated with data protection, the legal quotient of non-personal data and inherent dispute resolutions [8]. The co-regulation is one of the adequate options in the current format. The regulation of digital platforms regarding data privacy and ethics continues to present critical challenges to lawmakers around the world. The use of algorithms in platform governance for policing, finance and health care can often lead to biases and discrimination [9]. Organisations may struggle to attain the needed balance and reach critical regulatory decisions.

The regulatory information system is subject to various challenges that need to be overcome. The RIM can also face challenges in noting critical information and automating workflows accordingly. There are the issues of fragmented data, keeping track of critical evolving regulations across the regions and the management of complex submission processes. The internal ecosystem of RIM can be hard to manage provided the increasing attacks on systems. The deep expertise in privacy issues associated with personal data needs to be continuously updated [13]. The traditional regulation is being replaced by information systems owing to their greater capacities for traceability and managing crucial information [14]. However, there are underlying risks that need to be managed with the implementation of RIM. The management of multiple market actors and potentially harmful content are among the critical challenges that can engulf RIM [15].

## III. METHODOLOGY

### *A. Research Design*

The study has made use of an explanatory research design to attain the desired findings of the study. The evolution of legacy systems to RIM platforms requires the establishment of cause-effect between the important variables in the study. The explanatory research strives to explain the phenomenon establishing how the transition towards Regulatory Information Management Platforms are fraught with numerous challenges, advantages and complexities. The study will review how the operations are being effective in terms of correspondence and commitments required across the regulatory platforms. The submission planning, registration and automation of labelling benefitted via the use of regulatory platforms is being comprehended. Thus, explanatory research is essential for delving into the vital features and inherent infrastructure of RIM posing challenges and advantages to the organisations. There will be case studies and industry reports used to understand the problem and address it with factual evidence.

### *B. Data Collection*

The research is making use of secondary data collection for reaching the objectives. The research is gathering both quantitative and qualitative data to reach the results. The qualitative data is being collected from professional whitepapers, journal articles and expert opinions so as to gather in-depth insights. The expert knowledge on the areas of legacy systems transitioning to RIM is being assimilated to evaluate the outcomes. The informational management systems being benefitted with the access to cross-domain interactions is being derived through the secondary data [16]. The quantitative data is consisting of the different reports, statistics, graphs and analyses lending real-time information on the subject. The

assimilation of both types of data ensures a more detailed analysis of the complexities of data privacy and advantages of multiple stakeholder management possible with application of RIM in business processes.

### C. Case studies and examples

#### Case Study I: Johnson & Johnson

Global Healthcare Company Johnson & Johnson started its digital transformation process when it transitioned from having Regulatory Information Platforms for its global product registration and global regulatory submissions [17]. In 2019, the company transitioned to Veeva Vault RIM, boosting visibility for the company's worldwide regulatory processes, team collaboration, and cutting considerably on compliance risk [17]. Utilizing for the system significantly improved traceability of documents and reduced cycle times for approvals, especially in hectic markets such as the EU or Asia.

#### Case Study II: GlaxoSmithKline (GSK)

In 2017, GSK modernized its regulatory operations in one big bang, that is, implementing a large scale cloud based Regulatory Information Management (RIM) system [18]. This was aimed at harmonizing the global regulatory processes and making visibility across the product lifecycle. Central RIM was implemented by GSK to support submission tracking, registration management, and health authority correspondence [18]. This shift enabled the company to lower the launch delays of the products, become more audit ready, and improve the agility among the company's regulators affairs teams globally. In addition it allowed for more rapid adaptations to ever changing regulations in the EU, North America and Asia Pacific regions.

### D. Evaluation Metrics

The compliance and business risks are huge for companies such as Amazon and Samsung. The acceptance rates of the RIM have been used to understand its contribution. The reductions in the degrees of risks and the predicted usage of the technology have been taken into account [18]. The compliance system ensures that different laws, regulations and practises in diverse countries are handled efficiently without any disruptions. Thus, the lack of disruptions in operations has been monitored. The reductions in the issues faced owing to RIM have been used as metrics to determine the viability of the system.

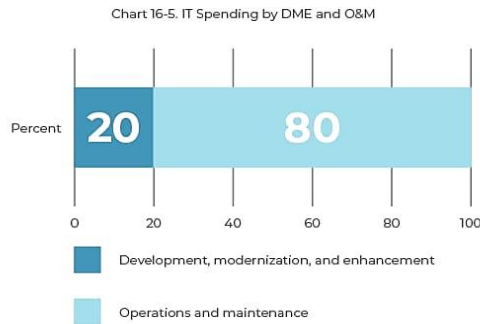
## IV. RESULTS

### A. Data Presentation



**Figure 2: Regulatory Information Management System Market Size**  
(Source: [19])

The global Regulatory Information Management (RIM) system market has a strong upward trend from 2020 to 2031 according to the above graphs. It is estimated that the size of the market will increase from around USD 1.6 billion in 2020 to USD 4.7 billion by 2031, more than triple that within the next 10 years [19]. Market share of the Asia Pacific region stands out most with leaders surpassing Europe and North America. Although growth in Europe is steady, Europe is consistent, while for North America, growth is steady, yet at a slower pace. The contribution of LAMEA (Latin America, Middle East and Africa) is the least but gradually gaining strength by 2031 [19].



The percent of the governmentwide IT funding going toward DME and O&M (2018)

**Figure 3: Legacy System Modernization**  
(Source: [20])

This graph shows the allocation of IT spending for the government wide development, modernization and enhancement (DME) or operations and maintenance (O&M) for the calendar year 2018 [20]. In 2019, O&M was responsible for striking 80% of the budget, while DME received only 20% [20]. The heavy reliance on outmoded infrastructure represented in this distribution can accommodate little innovation or transition to a more up to date regulatory system such as RIM. It is a representation of systemic barriers that, historically, have intended to impede digital transformation and modernization in large institutions of all kinds.

*B. Findings*

Under the current context, there is an explosion of legal complexities. The international transactions and financial operations on digital platforms further create difficulties in operations. Seamless operations are only possible with the help of Regulatory Information Management Systems Platforms [21]. The findings suggests that it is an emerging need for regulatory information systems, as demand is rapidly growing in emerging markets. Higher Asia Pacific indicates attempts to improve regulatory compliance in rapidly industrialized countries [19]. These trends indicate that RIM systems are increasingly becoming an indispensable tool in controlling the complex regulatory bubbles across different lands due to the adoption of digital transformation and cross border operations. The revenue impacts, faster time to market and increasing efficiency are some of the immediate outcomes. However, challenges of data privacy, system integration and data migration from legacy systems to RIM require impactful solutions.

*C. Case study outcomes*

Case Study	Strategy	Impacts of the RIM Systems Used	Key Results

Johnson & Johnson	Implementation of Veeva Vault RIM to standardize global regulatory submissions and improve visibility	Improved cross-regional collaboration, reduced compliance risks [17]	Faster approval cycles, enhanced traceability, and reduced submission errors
GlaxoSmithKline (GSK)	Deployment of centralized RIM to harmonize processes and manage global regulatory data	Streamlined tracking of product registrations and improved audit readiness [18]	Timely market launches, reduced delays, and better adaptation to regulatory changes

**Table 1: Comparing case studies of Johnson & Johnson and GlaxoSmithKline (GSK)**  
(Source: self-created)

The table compares how Johnson & Johnson and GlaxoSmithKline (GSK) have been able to create critical changes in their operations. The use of RIM benefitting the operational processes have been depicted.

#### *D. Comparative Analysis*

Aspects of the literature review	Focus of the study	Findings	Gaps in study
[4]	The regulatory state	In the era of information	Lack of discussion regarding the

	via the lens of the evolving political economy	capitalism the regulation is of prime importance [4]	core RIM applications
[5]	Examination of regulatory elements	The transcription factors needed in regulation	Lack of analysis on the use of RIM
[8]	The regulation of digital platforms	The self-regulation replacing the hierarchical regulation [8]	Less discussions on the challenges [8]
[10]	The process efficiencies achieved through the regulation of data	Creation of business opportunities possible via regulations	The lack of proper analysis on the opportunities of regulations
[12]	The regulation of user generated content	The need for RIM considering the currently evolving landscape [12]	Reduced discussion on technical aspects of RIM

[14]	Discussing challenges of RIM	Need for co-regulatory framework in order to attain critical results [14]	Reduced discussion of the challenges of RIM [14]
[15]	Failure of enterprise risk management (ERM) in outsourcing and offshoring	This shows how lack of context adaptation and systemic oversights in ERM framework (Regulatory information systems), fail when applied in volatile transnational business environment [15].	Lacks detailed investigation of how modern RIM can prevent outsourcing/offshoring failures through the data driven compliance and risk anticipation mechanisms.

**Table 2: Comparative Analysis**

(Source: self-created)

The analysis of literature depicts the migration from legacy systems to the more powerful RIM lending access to information online. The complexities presented by the data privacy and migration continue to remain an area of concern.

## V. DISCUSSION

### A. Interpreting the results

The use of RIM is poised to increase tangibly owing to the sheer advantages offered by it. The centralised data repository is crucial in creating an integrated system. There is enhanced collaborations and automation of workflows possible with the application of RIM. A more efficient handling of compliance leading to reduced business risks is possible through it. There are however intricate challenges of the data privacy and data migration. There is also a need to stay updated with the change in regulations that can be present new complexities to the companies using them. The lack of effective communication across teams can thwart their implementation. In addition, according to global market trends, adoption of RIM globally is clearly going to grow with a tremendous pace in the Asia Pacific region which is expected to overpass all other regions by 2031 [19]. This shows the necessity of digital regulatory systems in the development of new compliance needs on a global scale.

### *B. Practical Impacts*

The application of RIM can be beneficial for all organisations irrespective of their industries of operations. The companies can handle the compliances and understand the legal impacts of their operations spread globally. The migration from legacy systems to RIM can lead to faster operations and efficient processes. The vital operations of a company including merger and acquisition can be benefitted with the use of RIM [20]. The tracking of product registrations and identification of product counterfeiting is rendered easier with the integration of RIM. The regulatory compliance is easier with the help of RIM applications used across the company.

### *C. Challenges and Limitations*

Despite the numerous advantages, the RIM continues to experience complexities and challenges across the operations. There can be attacks on the confidential data stored across the company's repositories. The governance of data is necessary to prevent such catastrophes. The data migration can be cumbersome from the legacy systems to the modern RIM. The data standardisation and lack of communication across teams can present complexities as well. Hence, these are critical areas of limitations that can prevent the RIM from providing companies with advantages. The fragmented and regulatory data across multiple systems can be hard to manage. The regulatory changes across diverse geographical regions can be hard to update and maintain considering the current situation of evolving dynamics.

### *D. Recommendations*

The organisations need to be more systematic in terms of implementing RIM. There can be ineffective data management in regulatory context creating intricacies [1]. The organisations should train their employees and develop effective systems capable of yielding results. The data migration and data cleansing should be done to eliminate possibilities of errors. The focus should be on the training of employees enabling them to handle any types of errors later on. They should be efficient in dealing with the system and understanding how to derive results. There are strong security standards needed for upholding data privacy.

## VII. CONCLUSION AND FUTURE WORK

The study has focused on the legacy systems evolving to more impactful RIM frameworks for companies. The benefits, challenges and solutions for better system implementation has been stated. The RIM is tendering significant advantages upon the company in terms of operational efficiency and compliances. However, the challenges of data privacy and keeping the system updated can be cumbersome. The study signifies the importance of RIM in current business environment.

The future work should focus on the steps needed for implementing RIM so as to yield favourable results. The focus should be on developing the processes and outlining the steps for tackling the various challenges. The features of RIM that can contribute to an efficient regulatory landscape should be studied. The knowledge will help companies to switch towards the efficient systems and frameworks yielding positive results.

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