Implementing a Regulatory Information Management Solution in Small Organizations

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Introduction

Most small pharmaceutical and biotech companies need to strike a balance between their budget and resources for essentially every aspect of their drug development processes, and the selection of a regulatory information management (RIM) solution is no exception. Regardless of budget, essential functionality that should guide the selection of any RIM solution includes the ability to ensure compliance, manage risk, and drive efficiency. Red Nucleus has experience helping organizations of various sizes assess, select, implement, and optimize RIM solutions. We work closely with our clients to understand their business objectives and develop custom programs to meet those objectives. As a result, we have seen the challenges that can face small, midsize, and large organizations. In this paper, we focus on the challenges faced by smaller organizations, which tend to be associated with leaner budgets and resources, and therefore tend to have a relatively restricted set of options available.

Small Company RIM Models

Smaller pharmaceutical and biotech companies tend to function with one of the following models:

1. Operate without a formal RIM solution
2. Invest in a formal RIM solution that is managed and maintained in-house
3. Leverage an outsourced RIM solution that is managed and maintained by an external partner

> **Operating without a formal RIM solution is the least practical and highest risk RIM model.**

In the next few sections, we'll look at some of the advantages and disadvantages for each of these models.

Operate Without a Formal RIM Solution

Operating without a formal RIM solution is the least practical and highest risk model. Whether archiving in a repository such as Box, SharePoint, or Shared Drive, the filing and searching capabilities will be limited relative to a formal RIM solution and will be inadequate to appropriately manage submission documents and data. In addition, there will be questions. For example: *Will it be difficult to find documents when your submissions team has left the project? Will you be able to comply with an auditor's request during an inspection?*

Another disadvantage of operating without a formal RIM solution is that manually managing file structure and controlling naming and metadata standards in these systems can be labor intensive and demanding. While you may have clearly defined naming conventions, quality controlling for consistency could become a difficult barrier. Moreover, in the event of organizational growth, a company is vulnerable to incurring tremendous costs and challenges as they "clean up" their existing system and migrate everything into a formal RIM solution. Furthermore, operating without a formal RIM solution means a lack of structured workflows and a reliance on manual structuring and management of data and information.

Small companies may choose to operate without a formal RIM solution because of cost and/or simplicity, ie, they are not ready to adopt a formal RIM solution because of the added effort in the near term that is involved in the implementation of a more complex solution. But even when they choose not to adopt a formal RIM solution, small companies need to carefully assess the risk/benefit ratio of this model in the future that they forecast for themselves. In the short term, it will likely be the most cost-effective solution; however, continuing without a formal RIM solution may end up being a significantly costlier choice as time goes on, as data cleaning and remediation will be unavoidable and are associated with migration labor and challenges.

Invest in a Formal RIM Solution Managed and Maintained In-House

Operating with a formal RIM solution is the most practical and lowest risk model. But which path should you take? Some small companies decide to manage and maintain the formal RIM solution internally. Once the budget has been approved for implementation and licensing fees, you're all set to invest in a RIM solution! However, it's important at this point to be mindful that no single solution can fit all of an organization's requirements out of the box. Therefore, it is

essential that you perform thorough due diligence to properly choose and configure a RIM solution with in-house management and maintenance that can meet your business needs.

Once a RIM solution is implemented, it is important to consider the ongoing maintenance and support of the solution. For example: *How will you manage the various releases annually? What are the implications for cost and resources? How does the functionality of each release impact the business process? Who will revise the training to ensure it is current with the latest release?* Very often, these are areas that are unaccounted for and/or underestimated.

Leverage an Outsourced RIM Solution Managed and Maintained by an External Partner

A formal RIM solution with outsourced management and maintenance has the advantage of transferring the burden of initial configuration, ongoing maintenance, release management, and help desk support. The cost effectiveness of a formal RIM solution with outsourced management and maintenance is driven by reducing the drain on your internal resources.

Red Nucleus RIM Solution for Small Companies

Red Nucleus has partnered with Veeva to build a model that makes RIM Vault more accessible to smaller organizations. Red Nucleus's Partner Vault allows us to take care of everything for your company, so you won't have to worry about time and resource drains associated with

- Initial configuration
- Training
- New releases
- System maintenance
- Security and permissions

Having implemented and optimized multiple RIM Vault solutions, we have defined best practices and have configured the Partner Vault accordingly. At first, moving from an informal RIM to a Partner Vault model can feel overwhelming, but establishing a formal RIM up front can facilitate efficiencies in the long term. Red Nucleus provides a step-by-step structured approach to facilitate the transition.

Red Nucleus has a proprietary and unique methodology for ensuring an efficient and successful RIM implementation that is based on industry best practices. Our methodology and approach ensure that the appropriate building blocks are laid down prior to construction. The business processes and requirements are defined and well-developed before the system is configured, and organizational change management (including training and post implementation support) is considered for an overall successful program.

Final Thoughts

The selection of your RIM solution should be approached with great care and attention to where your company is today and where you expect it to be in the future. Red Nucleus suggests including the following steps in your decision-making strategy:

- Business process to drive the foundation for configuration and training

- Data standards along with well-defined attributes and metadata values to ensure consistency

- Security and user permissions to drive access controls

- Training program to ensure all stakeholders are aware of "how" to leverage the system to enable their business processes

- Standard operating procedures to drive the compliance needs of the organization in system use

- Governance to ensure that the system is maintained to meet cross-functional and global needs

- Organization change management to ensure that your business partners welcome and positively adopt the solution

About Red Nucleus

Red Nucleus R&D is a specialized provider of cross-functional research and development services and solutions. With deep industry expertise, our subject matter experts work hand-in-hand with our life sciences clients to strategically resolve global R&D challenges and mitigate compliance risk. Our global submissions, system implementation, information management, labeling, and business transformation solutions improve efficiency, streamline operations, and enhance productivity.

At Red Nucleus R&D, we pride ourselves on a collaborative approach that instills and reinforces industry best practices in every project delivered. Our core values are centered on our clients, contributing strategic value and ensuring success on every engagement. Our dynamic team of R&D management consultants specialize in cross-functional R&D delivery stemming from activities led by regulatory affairs.

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