



Insights to Succeed Throughout the Regulatory Information Management (RIM) Journey

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Introduction

There are many benefits of implementing an end-to-end Regulatory Information Management (RIM) system including the impact on regulatory compliance, speed to market, and revenue. A robust RIM solution can optimize collaboration and streamline processes driving higher quality work, faster. However, to reap these benefits, organizations need to ensure they have a strategy in place as they embark on this journey.

Without the proper plans in place, it's easy to miss key information along the way leading to sub-optimal implementation and lagging user adoption. In order to avoid these pitfalls, it is critical that organizations prepare sufficiently for this change, both from a people and technology perspective.

With that in mind, this white paper will discuss:

- The Challenges Faced by those Involved with the Regulatory Submission Process
- A Solution to the Challenge
- The Importance of a Plan & 4 Critical Steps to Ensure Success



The Challenge

At Astrix, we have the opportunity to work with many clients across the pharmaceutical and life science industry. From our projects and interactions, we often hear common themes associated with challenges faced by leaders relative to regulatory submissions. These are evident regardless of the organization and generate significant strain on the business' resources.

Leaders in these organizations are looking for ways to alleviate the pain caused by these daunting and resource intensive tasks with an objective to determine the best path forward to bring together the disparate and often poorly understood global processes, terminology, and tools.

Ultimately, the regulatory teams are struggling to communicate, collaborate and get submissions out the door on time and with high fidelity. To accomplish these tasks and get the submissions approved by the global health authorities it requires back and forth correspondence that is difficult to track, along with the many health authority questions that cause a scramble for gathering information. Due to this situation, the regulatory team expends extra hours, and in many times days of effort, to collate information to pull together a comprehensive history.

The Solution

The solution to this challenge is to incorporate an end-to-end regulatory information management system along with the right strategy, processes, and technology. This will assist with closing the gaps, improving efficiency, and ensuring the accuracy of the organization's submissions across the global and local regulatory teams.

Whether your organization is already in the process of implementing a new system or you're just starting to explore your options, you'll want to employ the following key steps to ensure success.

The ultimate goal is a seamless, intuitive, "one-stop-shop", where users:

- Are able to Plan, track author, edit, publish, and submit documents all from one tool.
- Can document questions and responses with the health authority within the same system.
- Have everything linked to a single record of truth that allows the organization to easily produce auto trails and source documents.

To some this may seem like a pipedream, however, it is attainable with the appropriate foundation both from an organizational and technical perspective.

The Importance of a Plan

Having a solid plan is extremely important to ensuring a successful implementation. As Benjamin Franklin once said, if you fail to plan, you plan to fail.

In this white paper, we will discuss 4 key steps that will enable a successful plan. Although seemingly intuitive, there are nuances to look out that will ensure critical activities are not overlooked. These four critical steps that should not be missed on your journey are: Defining Your Vision, Identifying Capabilities, Creating the Plan and Managing the Change.



1 Define Your Vision

Guiding Principles & Vision

The first step is defining the company's vision. This is done by bringing the group together and working with the leaders in the organization to develop a vision statement, along with guiding principles. The objective is to collate a succinct set of goals that the organization can retain as the selection and implementation criteria standards for the future state. For example, the organization might want to speed up submission times as a goal so that the quality can be improved or both. Another area might be authoring more efficiently. There may be other aspirations that each organization has to get on a journey towards an end solution.

"As is" State of the Business

While developing the goals, there should also be a baseline of where the organization is today. Many organizations may have the desire to jump ahead and dive into the new, shiny, exciting possibilities of the future state and systems that can help get you there, however, having a solid sense of where you are now before embarking on the best path to improvement is critical.

We've seen many organizations get tripped up because they don't know what they don't know, and with global processes, various tool, spreadsheets, SharePoint emails, any other aspects, it's very easy to miss a critical piece of the puzzle, if you don't step back and develop a solid plan. It starts with defining the scope of the work and following up with business processes. The organization should also review the system landscape, issues, gaps, and areas of opportunity. This helps in bringing to light the areas that are not clearly apparent.

"To be" State of the Business

After the "as is" state has been developed, the organization can learn from that, the vision, and guiding principles to bring those together and define what the future state or "to be" state will look like.

Then depending on how you're going to go about implementation there may be the need of a different level of detail in your future state. Astrix's recommendation is to start by mapping out what you're looking to do from a high-level process flow. From there, the organization can dive in deeper as needed. This can be an iterative process. As you learn more about your organization's needs and the vendor capabilities, and as you get closer to the solution selection, you can iterate back on that future state and add detail as you learn more.



2 Identify Capabilities

Another piece of the puzzle is identifying and prioritizing the capabilities - understanding what is needed to maintain continuity (what you have today) and to bridge the gaps (what is needed in the future). Ask yourself, will these capabilities enable the organization to reach the desired future state? Does the organization have the right technologies, for example analytics recording, or workflow orchestration, in place already?

Identify and documenting these needs will allow the organization to better assess the vendors as you move forward into a solution selection and ultimately drive your implementation later on.

Once you know the capabilities you need to implement, if you haven't already, make sure to take the time to fully assess technology options and evaluate based on the organization's specific requirements. Organizations typically view even foundational capabilities in very different ways, so, look at these technologies based on what your organization needs and how they will fit into your specific situation.

3 Create the Plan

Creating the plan can happen at different points in your process. You might already have a plan, or you're building it as you read this white paper. We at Astrix believe that the plan is a living document and you're going to want to iterate on it as you learn more. Although you might have a good idea of where you're going there's guaranteed to be pitfalls and surprises along the way, so start with a plan but adjust along the way to keep the momentum.

Teams

As part of that strategy and plan you'll need to think about who's needed to support this implementation. Not just from an IT perspective but from your business teams as well who can serve as subject matter experts, champions, and leadership. Thought needs to be given to the size of your team relative to the scope of your work – ensure you have representation from all the key areas that you'd like to improve, including contacts from adjacent groups within your organization who may be impacted.

Roadmap and Workstreams

In enterprise, end-to-end regulatory information management system implementation, there's going to be a lot of work going on in parallel. A roadmap depicting various workstreams will help you align goals and stay in sync.

As you develop the roadmap ask questions like...do your teams have the bandwidth to tackle multiple improvements at once? What is priority work - is authoring more important to your organization than submission planning and tracking? How about publishing, validation, and archiving - are these in scope for your improvements? Are they part of your end-to-end solution, or will you need integration?

The answers to these questions will help you define projects, dependencies, timing, etc. There really is no one right answer as each organization has their own priorities, abilities, and limitations that should be considered when developing the plan of attack.

Once you set the plan in motion, remember – it's a living document. Projects and plan details may need to be reevaluated and adjusted as you follow through on the implementation, so it is important to have a strong project manager or two on your team to help keep everyone aligned and moving forward.

4 Manage the Change

Stakeholder adoption is Imperative to Success

After you've identified your capabilities, planned your roadmap, and have the team together, you will need to ensure users adopt the new system and processes. To manage the changes, Astrix follows a framework that takes into account users' motivation, impacts to their processes, and consistent communication.

As you begin to manage the change, it's imperative to consider all your stakeholders - not just your champions or leadership, but everyone who's impacted by the system change. Various users may be comfortable with the current system and apprehensive about a new way of doing things. You'll need to work with the champions and the subject matter experts to develop communications, training materials, SOPs, etc. to ensure users are ready for and feel comfortable with the change to a new solution.

Additionally, as you create your Adoption plan, account for legacy system migrations that will be needed to support your users and critical milestones (e.g., audits, company holidays, etc.) that may impact your training and Go Live timing.

Taking the time to adequately plan and manage the adoption process will allow users to seamlessly transition. They will have an easier time understanding the new system, finding the information they need, and ultimately will be more likely to adopt (and even champion) the solution.

Key Takeaways

Slow Down to Speed Up

The first key takeaway is “slow down to speed up”. This may sound counterintuitive, however, in order to be successful, take time to assess your current state and to evaluate your potential solutions. All steps, no matter how small, are needed. Give challenges the attention they need to be efficiently mitigated and adjust your plan as needed to account for surprises along the way.

Write it Down

The second takeaway is “write it down”. Document everything - your processes, the roles, responsibilities, the implementation plans, communication plans, legacy systems, the key stakeholders list, etc. That documentation will allow you to look back on critical information and use it to make better, more informed decisions as you work through your implementation plan and manage the change.

Don't Bite Off More Than You Can Chew

Last but certainly not least, “don't bite off more than you can chew”. What we mean by this is that you need to prioritize capabilities, workstreams, configuration needs, user groups etc. Not everything can, or should, be done all at once.

Keep in mind when you're creating an implementation plan. It can be really tempting to fit it all into a short timeframe, however, consider the teams' bandwidth and other obligations. If your teams are over allocated, you will ultimately find yourself running into issues that can cause delays.

Summary

It is critically important, when building out a strategy and plan relative to any new business and/or technology endeavor, to have the right internal staff and external organizations involved to assist in the process. Formulating the appropriate approach along with the proper processes and technology is imperative. Astrix's team of professionals in our Strategic Consulting Service Practice have worked with many of the top life science organizations and leaders to assist them with respect to their business needs in these areas. As a technology-agnostic partner, without a preconceived preference for a specific supplier or product, we work closely with your team to ensure solutions are reviewed and incorporated into your business so that you succeed in realizing your vision and achieving your organizational goals.

About Astrix

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