ARTICLE

The Critical Path to Profitability and Patient Care

Q&A with Pat Shafer on Regulatory Information Management (RIM)

What is the Regulatory Information Management (RIM) Reference Model?

It's important to realize, and some within a pharmaceutical or a device company don't give enough credit for this, that regulatory is on the critical path to revenue, on the critical path to getting lifesaving medications to patients. If you don't do regulatory well, you end up with delays getting your products to the patients or having your products withdrawn from the market.

Regulatory Information Management has been a challenge for the industry. As a company's portfolio grows and its products are registered in more countries, complexity increases geometrically. Companies also face complexities trying to make sure the right "flavor" product is released to the right country and managed in an efficient manner.

Vendors have developed technology platforms that allow companies to manage all their regulatory documentation, data, timelines, etc. The problem is that they've been operating for years, if not decades, with data that's been captured in Excel spreadsheets, in Word documents and, in some cases, on paper. Managing all the data, the documents, the correspondence has become a real challenge. Moving all that legacy information to a modern RIM system presents its own challenge.

Up to this point, there has been no implemented standard for regulatory data or data structures. The purpose of the RIM Reference Model is to create an industry-wide, common structure. It is not a standard, but a data model; it is a nomenclature and taxonomy that facilitates organization and cleaning of data and more rapid configuration of the RIM solution. Without that, companies struggle, wasting a lot of time and resources. In short, the Reference Model represents an opportunity to get your data house in order before trying to implement a solution.

Specifically, what types of companies benefit from the RIM Reference Model?

Our expectation is that all companies that have products registered with health authorities will be able to benefit from the RIM Reference Model. We anticipate that the greatest beneficiaries will be companies that may have only one product in one market but are expanding to other markets or bringing new products onto the market. This is an opportunity to get it right the first time and create a system that allows the ability to build effectively from the ground up.

Mature companies that are expanding the scope of their RIM system, or are acquiring new companies, can also benefit from the Reference Model as they work to align data.

Based on your depth of experience in the pharmaceutical, biotech and medical device industry, what are some of the key insights that drove you to develop the Reference Model?

The data is always a problem. A company may anticipate a 12-month implementation cycle, but if they haven't started cleaning up their data and defining their organization's taxonomy a year or two ahead of time, that implementation is typically delayed. In my experience, it takes at least a year for a global organization to get their information aligned and cleaned before they can hope to migrate it into a new RIM system.

What tangible value does the RIM Reference Model bring organizations?

Regulatory Information Management is all about managing regulatory submissions, helping companies develop and submit those in a timely manner, and then managing registrations post-approval. The Reference Model should allow faster, more effective implementation. Getting RIM right drives: (1) compliance, (2) speed to market, and (3) cost savings in terms of the cost of poor quality.

For example, let's consider the concept of right product/right country. Recalls related to releasing the wrong product into a market can cost tens of millions of dollars or more. Yet the issue of recalls pales in comparison to approval delays or having to withdraw products because you haven't maintained registration due to ineffective Regulatory Information Management.

What are three actionable RIM strategies an organization considering implementation must consider?

Of course, data. You must clean up your data; begin sooner rather than later. With more mature and larger pharmaceutical companies, this is frequently a large issue because the data has been neglected for years, if not decades. Companies need to make sure that their data house is in order before they can migrate. If bad data is migrated, much of the value of a RIM solution may be lost. So that's number one, the data.

The second is to include all stakeholders early. Many functions touch regulatory processes, whether it's research and development teams, clinical teams, manufacturing, supply chain, distributors, trade compliance. Change management is essential, especially if you're dealing with an organization that hasn't traditionally had good cross-functional communication. Presenting and communicating the value proposition for effective regulatory information management to all stakeholders is key. Working cross-functionally across your internal and external ecosystem is critical to success.

And then the final piece is governance. Organizations must develop an effective operating model to manage or enforce documentation and metadata. It requires a culture of accountability and compliance. Technology is one piece of it, but how you manage use of technology has significant impact. Getting all that right — data, identifying your stakeholders and defining an effective operating model — is critical to success.

The RIM Reference Model team has some notable people in the industry. I'm curious how everyone came together and what learnings arose from the collaboration?

Many people are participating in the development of the RIM Model. We have a brilliant core team, including V. Balasubramanian, Vanessa Brewer-Yizar, Kathie Clark, Bernie Coney, Joel Finkle, Vahé Ghahraman, Sheila Mahoney-Jewels, Don Palmer, Keith Parent, Cary Smithson and myself.

We've been meeting almost weekly to design and build this reference model over the past couple of years. But this core team is part of a larger industry group. We've been pressure-testing the model with people from within the industry, including Steve Gens, who has run a comprehensive RIM survey and report over the last several years. The RIM vendors who build the technology systems have reviewed and contributed to the model as well.

What's been most interesting is that there is no one way to define the reference model. That is why working as a team and accommodating multiple perspectives is critically important. We've gone back and forth with varying terminology. We've changed the order of the hierarchy a few times, and we continue to fine-tune and optimize the model. As we improve it, the reference model gains more and more acceptance within the industry. Our expectation is that the model can lead to some level of standardization that will benefit all companies greatly.

We think the model will help companies undergoing mergers and acquisitions to more readily integrate registration data. Market authorization holders should benefit from the model as they work with their distributors and affiliates to manage registrations and submissions.

We hope to come up with something that's pragmatic, if not perfect. Because the regulations are evolving and because the data requirements are growing, the RIM Reference Model will be ever evolving.

Are there cutting-edge developments like artificial intelligence that are starting to pop up related to RIM?

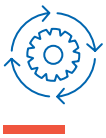
Many regulations, especially in smaller markets, aren't published or available. Many regulations, even when published, are vague and allow room for interpretation. It's important to

understand health authority expectations as well as the written regulations. As a result, the industry has begun to use machine learning and intelligent automation to understand those expectations based upon a wealth of past experience.

Companies are also using machine learning to mine submission and registration metadata to forecast how quickly regulators will respond to applications and what questions they might ask. Being able to anticipate how quickly the authorities will approve a variation or approve a new application directly impacts the timing of your marketing campaigns, manufacturing and even your inventory control.

Machine learning and artificial intelligence are just gaining traction. These tools will become more commonplace and will be very powerful in the future. But right now, the real win in the short term is simply getting your data right.

5 Key Takeaways



1. **Get your data right.** Start cleaning your data now. Start last year if you want to implement next year.

2. **Define your processes.** RIM systems have the potential to automate workflow and drive performance, but it's important to define those processes before starting to configure the solution.

3. **Engage all stakeholders up front.** Regulatory Information Management impacts the entire ecosystem, both within and outside the company. Getting the configuration right the first time requires engagement of all stakeholders from the start.

4. **Culture is king, and effective communications are a prerequisite.** If you have a culture of noncompliance within your company, you'll need to take steps to address that. RIM can't be effective if people aren't following policies and processes.

5. **Your operating model is critical.** Define a structure that works, whether it's a centralized, command-and-control approach or features distributed accountability and responsibility. Maintaining accurate information is critical to compliance, critical to keeping products flowing to patients, and critical to keeping revenues coming into the company.

PAT SHAFER
Managing Director
+1.646.379.8307
Pat.Shafer@fticonsulting.com