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Regulatory Information Management (RIM): Getting Ahead Of Change

By John Lawrie, director of product strategy, Veeva

Let's paint a painful, yet all too familiar, scenario: After the launch of your organization's product, new safety data necessitates a safety profile change that sets off a chain reaction affecting product composition, artwork, packaging, and labeling. And, given the globalization of product marketing, the links of this chain extend to all registrations for that product around the world. These grueling product updates are often complex, difficult to manage, and lead to extensive manual churn across the organization and its partners. Not only are change processes terribly inefficient, but they also introduce a high likelihood of error.

So what causes such inefficiencies? The primary culprit is disconnected systems and data. According to a 2014 Regulatory Information Management (RIM) report from Gens & Associates, a majority of life sciences organizations have a fragmented technology landscape with disparate tools and systems for identical-and-related tasks. Recognizing the inherent problems using siloed systems, Gens & Associates 2015 study reports that a growing number of life sciences companies are starting to employ global models. Even so, more than half of companies still don't have worldwide RIM capabilities, which are defined as at least 75 percent of affiliates using headquarters' system for anything except registrations.

With increased globalization and looming regulatory changes, the technology and data disconnect is bound to worsen. Some organizations have tried to rectify this problem by creating custom data integrations, but they are often not scalable to support the increasing volume of data today. As an industry, there needs to be better

mechanisms to unify regulatory systems and their data in order to achieve compliance, while reducing process churn and associated high costs.

RIM technology may offer hope. Traditionally, RIM has consisted of a disparate mix of systems that manage regulatory events (such as manufacturing change controls), product registrations, labeling, submissions, health authority correspondence and commitments, and content management. In this model, product changes instigate a reactionary assembly line of manual data and document checking, emails and meetings, content authoring, and planning responses in the form of submissions.

Uncovering The Pain Points

When looking deeper into this daisy chain of inefficiency, some specific issues become apparent:

- ***Disconnected systems and data:*** In this age of information sharing, the life sciences industry is woefully behind the times when it comes to integrated RIM systems. In most cases, quality/manufacturing applications do not share change control or product information with a registration system. In turn, data is not shared with a submission planning system, which does not share information with a content management system used for authoring the response. In addition, there may be lost connection points to other regulatory-impacting areas, such as labeling and health authority information.
- ***Local affiliate differences***: There are often regional differences in terms of how data is tracked, particularly registration and labeling data. In many cases, headquarters is "flying blind" when assessing impacts to local registrations.
- ***Content disconnected from data***: Without knowing which submission files are tied to the change being made, the first step in assessing change is often a laborious review of content. The content then has to be updated piece by piece.
- ***Barriers to information access***: Often, the reason that local affiliates have their own systems for managing registrations and submissions is because they simply cannot connect to the central system because of security barriers (VPNs or tokens), poor system performance, or noncompliance of their infrastructure (software downloads or unsupported browser versions).

Alleviating Change's Sting

The pain associated with product updates has been felt for years, but in today's digitally connected world, relief is finally within reach. RIM technology that's interoperable across key areas can help automate and streamline the entire process to save time and reduce error.

Start by looking at the IDMP (Identification of Medicinal Products) regulatory changes as an opportunity for overall business improvement rather than as just another compliance challenge. Its underlying intent to standardize product information will not only improve product safety but also regulatory efficiency.

The next step to both meet IDMP requirements and enable more efficient operations is to centralize product and regulatory data. Establish a data model and supporting system that allows data to be shared seamlessly across manufacturing, registration, labeling, and submission domains. A single, master product repository based on IDMP would allow the technical and regulatory teams to confidently maintain product information, while simultaneously achieving compliance and cost reduction.

While consolidating data, it is also important to consolidate systems to reduce the likelihood of data quality issues and redundancy. RIM systems have evolved to manage the data involved across the full lifecycle of regulatory events, including change controls. Essentially, this allows companies to connect registration data with response planning and content — associating data directly with action. By bringing together registration data and submission documents, technical and regulatory groups gain widespread visibility into where and how a change impacts the documentation required for their registrations.

Finally, life sciences companies must remove barriers to external access in order to harmonize data and processes for affiliates around the world. Convergence of affiliates and headquarters onto the same system with a shared platform improves efficiency globally so companies can finally get ahead of the inevitable changes. Since most of these barriers tend to be technological, look for a solution that makes it easy to connect individuals without placing software requirements or performance barriers on external users seeking access.

Any change to producing or selling a drug product creates an enormous ripple effect. A tidal wave of work barrels across many different constituents in a global life sciences company. The change can be driven by business decisions (e.g. to change manufacturing sites), but it's often the compliance-driven changes that create the most urgency and that touch the greatest number of areas across an enterprise. By rethinking the typical data processes and technologies in use today and moving towards a more consolidated model, companies can finally get ahead of change, calming the wave to prevent an overwhelming situation while increasing efficiency and reducing costs in the process.

About the Author

John Lawrie is director of product strategy for the Veeva Vault RIM suite of applications. Prior to joining Veeva, Lawrie led the consulting group at Octagon Research Solutions (now Accenture) which specialized in assisting clients with the planning and development of CDISC-based data and regulatory submission capabilities in order to achieve regulatory compliance while maximizing operating efficiencies. Lawrie has also worked for Computer Sciences Corporation where he led business analysis, process design, organizational change and project management activities. John graduated with honors from Bucknell University with a B.S. degree in Mechanical Engineering.