REGULATORY FOCUS

Re-Designing Regulatory Capabilities

By Randolph Fillmore

Faced with growing regulatory burdens, Bristol Myers Squibb (BMS) and Halozyme each committed time and resources to connect regulatory functions from end-to-end with the goal of improving efficiency and transparency. This article describes how two very different companies made their business case, streamlined processes and managed change. The article also provides elements of what the two companies learned along the way.

Introduction

Life sciences companies are driving initiatives to make regulatory processes more efficient and effective. "Over the next two years, more companies will build or modernize their Regulatory Information Management (RIM) foundation and information flows," noted Steve Gens, managing partner at Gens and Associates, in a recent commentary. "Regulatory is starting to look at connecting to other functions and improving the information flow across functions."

Preparing for the Identification of Medicinal Products (IDMP) standard compelled companies to take an enterprise view of product data, according to Gens. Now, they are looking at the cross-functional processes that generate and consume that data, such as adverse events, supply release, and product change control.

That was the case for Bristol Myers Squibb (BMS). Enterprise access to regulatory data was a key driver behind its decision to launch a major change initiative. The regulatory team had fragmented processes and outdated systems that could not support an open flow of information or the complexity of working globally.

Halozyme was in a different situation. The growing oncology biotech had manual processes that did not scale and needed greater control over their information as it added more strategic partnerships. In response, Halozyme's regulatory team decided to redesign their processes and replace their Excel spreadsheets with a full RIM platform.

BMS – a 23,000-person global organization – and Halozyme, with about 250 employees, both committed time and resources to improve regulatory operations. This article describes how two very different companies made their business case, streamlined processes and managed change as well as what they learned along the way.

Starting Point: Defining the Need for Change

Business Case for BMS

BMS wanted to simplify its global processes. However, it relied on outdated technology built on three different platforms. Nearly two decades old, its primary system did not support the company's need for greater speed and information sharing. Likewise, business processes established when the system went live needed updating. BMS' commitment tracking system was separate from its RIM system, complicating commitment tracking and duplicating data entry. Old technology and processes allowed for little cross-functional access to regulatory data. Since regulatory shares information with clinical, safety, global supply, manufacturing and project management, these limitations meant information was assembled and shared manually, creating information gaps and delays. Finally, each market stored correspondence and dossiers locally, which made visibility difficult across the organization.

Modernizing BMS' RIM systems was an enabler and a prerequisite to process re-engineering. Business and IT collaborated to build a business case around the need to share data across the organization, replace aging systems and standardizing processes – all leading to quantitative and qualitative gains for the organization. The company's decision to modernize regulatory processes and systems also aligned with an increased focus on speeding medicines to patients.

Business Case for Halozyme

While BMS looked to harmonize processes and provide easy access to regulatory data, Halozyme's growth and need for scalability prompted its RIM initiative. Halozyme had relied on tracking spreadsheets to manage regulatory information, but as the company started to grow, this method did not scale. Visibility into the status of a supplement or a list of outstanding commitments was hampered, for instance, so it took hours to gather information and report on key metrics.

Part of the problem was regulatory operations tracked submissions and correspondence, while regulatory affairs tracked health authority questions and commitments, each in their own spreadsheets. Regulatory operations maintained 35 Excel workbooks across all products and partnerships and the amount of information tracked was limited to eight critical fields. Since tracking was conducted chronologically, it was difficult to see the status of regulatory events or business objectives. Manually rummaging for answers to questions would not scale with the growing number of alliance partnerships.

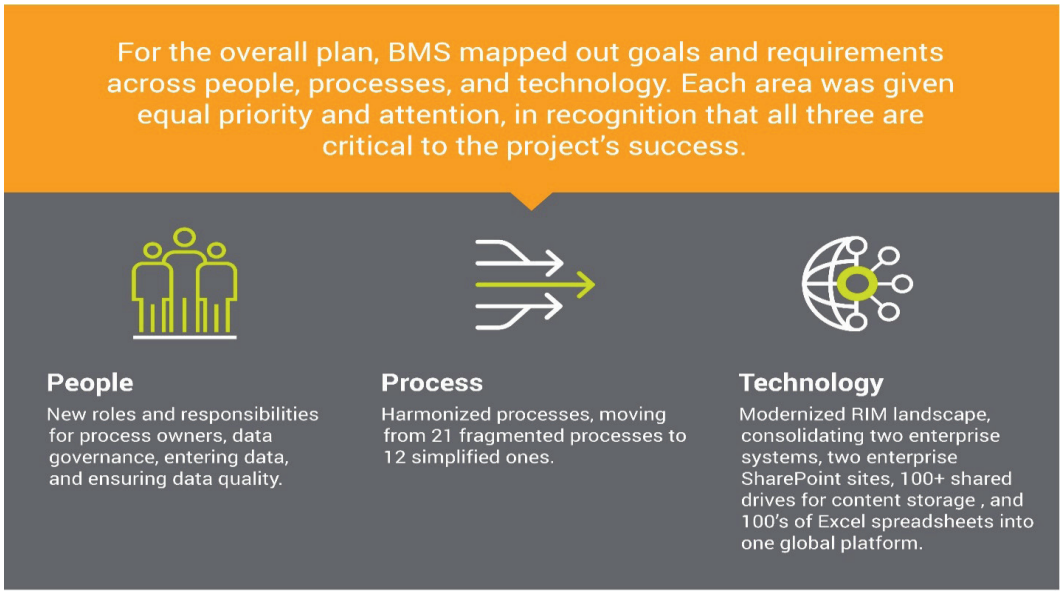
"We wanted a way to reuse answers across partners to ensure the team was responding accurately and efficiently. If we centralized tracking, we could standardize our methodology and build relationships between submissions, correspondence, questions, and commitments," said Monica Kennedy, director of regulatory operations at Halozyme.

Charting the Journey: the Transformation Plan

Planning at BMS

In 2014, a 60-person team covering worldwide geographies and multiple functional areas gathered to kick off the initiative at BMS. The team identified 21 processes and mapped a plan to reduce those to 12. When deciding where to start, they identified planning for submissions and defining submission content was a major pain point for teams in labeling, safety, medical writing, Chemistry, Manufacturing, and Controls (CMC) and of course, regulatory. Fixing submission planning would yield significant benefits for multiple areas of the company. However, this also meant that re-engineering the process would take longer.

Figure 1. Three Dimensions of Change Given Equal Priority



Harmonization initiatives require broad participation and buy-in from regional affiliates. Ultimately, BMS expected that representing their needs would lead to strong adoption and ensure the regions remained aligned as the company rolled out new phases.

Planning at Halozyme

Like BMS, Halozyme's first step was to coordinate with stakeholders and determine how they all accessed, used and reused information. Based on these interviews, Halozyme settled on a plan of action:

1. centralize all types of regulatory information into a single RIM platform
2. establish an efficient and consistent method of capturing information
3. create traceability between regulatory plans, activities, data, and documents
4. clarify roles and responsibilities and assemble a governance board

Halozyme chose to start with health authority interactions and submission planning because these processes are wholly owned by regulatory. The team could move quickly and show results fast, before addressing submission development.

One lesson learned from the planning process was around data migration. Halozyme initially planned to go live with an empty RIM system, but realized they needed to retire the legacy trackers to maximize efficiency and pre-load all existing information into the new system. This small change in plans had a big impact on implementation timelines since Halozyme would be managing more information than before. Significant data gathering was needed from regulatory affairs, CMC and regulatory partnerships. The teams worked together to collect data and knit together the relationships between applications, correspondence, questions, commitments and submissions. While this complicated the implementation, it paid off with greater user acceptance.

Reaching the Destination: Roll-Out and Results

BMS Remodels Processes

In early 2017, BMS introduced a new RIM platform and streamlined global processes for planning major submissions and developing submission content plans.

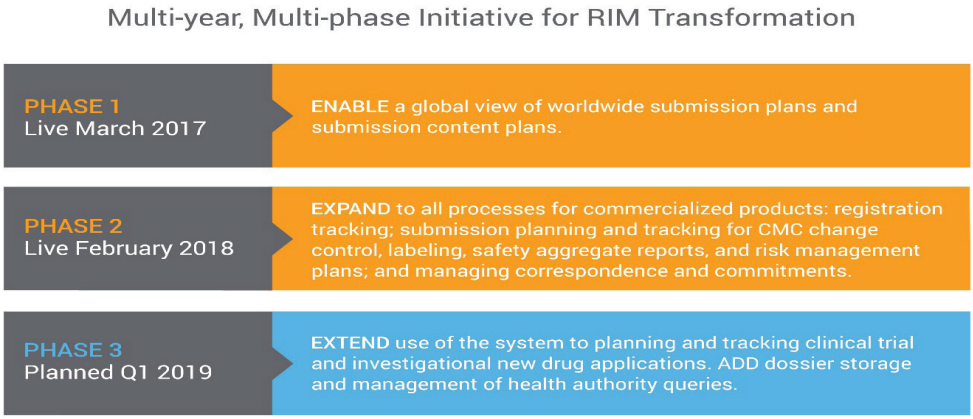
The new processes include shared responsibilities for entering and managing data to reduce the burden at the local office. Affiliates enter information they generate; for example, if an affiliate sends a submission or receives an approval, he or she enters that data. BMS' Global RIM Services team enters supporting information and manages global

events such as CMC change controls and Company Core Data Sheet (Labeling) distribution. These global events result in local submissions that are planned and managed by affiliates within the shared system.

During the planning process, affiliates may input draft planned submission dates while global teams manage the governance-approved dates. Giving affiliates responsibility for working directly within the platform minimizes data entry errors and delays. Affiliates will get personalized views that only display relevant information. And, once submission planning has been expanded to all submissions, most local tracking spreadsheets can be retired.

The Global RIM Services team can now monitor the progress of local affiliates assessing global events, and the status of local submissions from planning through approval, allowing headquarters to oversee the local implementation of global events.

Figure 2. BMS' Multi-Phase Initiative for RIM Transformation



As part of Phase 2, BMS is addressing their inefficient processes for managing health authority correspondence. Because content has been organized on shared drives with individualized, country-specific naming conventions and virtually no metadata, searching for documents is challenging. Moving to a metadata-driven RIM system will significantly increase efficiency, providing in seconds what used to take minutes or hours to find.

"When we connect the dots by linking the submission, correspondence, commitment and application metadata, we see the complete story and get a full view of regulatory activities and data. When coupled with a global process common to all affiliates, the operational gains will be significant," said Danielle Beaulieu, director of global regulatory business capabilities at BMS.

For a description of BMS' submission planning process, see the supporting infographic *Global Submission Planning at BMS.*

Halozyme Remodels Processes

In contrast to BMS, Halozyme's first major step was to standardize and expand information tracking. The company now tracks 10 times more information than before, with data management spanning 17 business entities, including products, applications, registrations, submissions, correspondence and commitments. Each entity is defined by multiple fields with individual tracking records created for each application, submission or commitment.

When capturing information, the context is important. Kennedy explained, "Every submission has a purpose. It answers a question, resolves a commitment or starts a new regulatory objective. Tracking the contextual information helps us see the big picture."

To create those relationships, each data entry form reflects a thought process: Does this submission modify drug production details? Should we create or modify a registration? "With these improved data entry processes, we can easily navigate through history and get a clear understanding of what was done and why," said Kennedy.

Regulatory information is collected and entered in the system throughout the process, not all at once. If a submission addresses a health authority question or commitment, that relationship is auto-generated and only net-new information is added. This part of the process is key for Halozyme's regulatory department to translate raw data into business insights.

"I've got information at my fingertips," added Kennedy. "I can easily answer questions like 'What are all the health authority questions regarding a specific submission?' That would have taken 45 minutes to compile and now I have instant access."

In addition to monthly reporting, Halozyme has a real-time view of activities organized by regulatory objective – a complete history of the objective and its supporting materials. Regulatory objectives can be defined for new formulations, indications or applications. Collecting this data would have taken two or more hours before and now takes less than one minute. Halozyme is also creating personalized dashboards that aggregate information from different reports for individual stakeholders and senior management.

Navigating the Route: Preparing to Change

Change Management at BMS

Given the company's size and global breadth, BMS took care to involve affiliates throughout the process. First, BMS created a 'train the trainer' program where 25 representatives were responsible for training individuals in their regions. The time commitment was significant; each member travelled to the US and received a full week of training on the new processes and platform. Additionally, trainers customized materials for their individual audiences and invested as much as 18 hours each training others.

BMS also created a new role to help team members adjust to the processes. BMS staffed a client engagement liaison in each of the four major regions. The liaisons spend half to all their time helping others, answering questions and soliciting feedback. They have helped write FAQs, conduct training and answer support requests. "The client engagement liaisons have proven to be key to the project's success," said Beaulieu.

Change Management at Halozyme

New processes introduced changes across Halozyme's entire regulatory team. Halozyme developed a comprehensive training program, including screenshots and relevant examples for each of the different roles. Data within the system was pristine so the company also created a data entry consistency manual to help maintain the quality of inputs going forward.

Halozyme also formally welcomed feedback throughout the roll-out. Its governing Change Advisory Board evaluated comments and requests to ensure the initiative stayed focused and any changes would be lasting.

Table A. RIM Provider Landscape

Accenture
Acuta
Amplexor
Appian
ArisGlobal
CSC
Cunesoft
Ennov
Extedo
Lorenz
PAREXEL
Veeva

Conclusion: Results and Moving Forward

Launching a RIM initiative is a significant undertaking for any organization as regulatory impacts nearly every area of a life sciences business. For BMS and Halozyme, their journeys resulted in better visibility and more efficient, harmonized RIM processes.

The regulatory team at BMS is gaining visibility into submission status with component-level planning and tracking. Regulatory will soon be able to show where delays and bottlenecks occur, giving the team insight into performance throughout submission development so BMS can course-correct during submission development. Beaulieu explained, "When managing a large submission, you often cannot identify component delays early enough to allow for course correction. Real-time dashboards that track the delivery of critical path components in the context of the dossier should surface risks to the delivery schedule early enough for us to react. We are now deploying a RIM system and processes to provide that visibility."

Looking at performance across multiple submissions, BMS can make informed improvements to the overall process.

Halozyme's regulatory team now has the information it needs to quickly assess a situation and make smart decisions. The process of collecting accurate and complete information required more work upfront, but it was important. The rapidly growing company now has reliable information and compliant operations with greater efficiency.

Today, Kennedy has three favorite go-to reports: outstanding health authority questions and commitments by product, submissions for adverse events by study and submissions and correspondence by regulatory objective. They provide end-to-end traceability, enabling the team to see what has happened and decide what to do next.

RIM transformation gives companies the opportunity to become more efficient and collaborate across functions and regions. BMS and Halozyme took different paths, yet both improved speed and agility through better information management.

About the Author

Randolph Fillmore is a technical writer for Florida Science Communications, Inc.

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