Bristol Myers Squibb™

Customer Success Story

Regulatory Transformation at Bristol Myers Squibb

When Bristol Myers Squibb kicked off a major corporate initiative around speeding medicines to patients, speed became a greater priority than ever before. At the same time, BMS pivoted its R&D focus to oncology—an area that is advancing faster than virtually all others.

The regulatory team made the case that modernizing their systems and processes was critical for BMS to reach its corporate objectives. Management approved an initiative to transform their regulatory business operations with a global, authoritative source for regulatory information.

The RIM Transformation Plan

The initiative kicked off with a 60-person team spanning multiple geographies and functional areas. They mapped out goals and requirements for people, processes, and technology:

Harmonizing processes	Consolidate 21 fragmented processes to 12 simplified ones.
Empowering people	Define new roles and responsibilities for entering and managing data, as well as governing the new processes.
Modernizing technology	Consolidate four enterprise RIM systems and thousands of Excel spreadsheets into one global platform.

The new, standardized processes would shift where work gets done. Rather than individuals working independently with local processes, they would contribute to a shared authoritative source for all regulatory information. Danielle Beaulieu, head of global regulatory business capabilities at BMS described how they came to name the RIM platform, “This is an enterprise-wide program and people are excited about it, so we didn’t want to go the standard route and create some acronym. We call the new platform Verity for ‘The Truth.’ That’s what it is for us.”

The plan was organized into three discrete phases:

PHASE 1	PHASE 2	PHASE 3
Enable a global view of worldwide submission plans and submission content plans. Involve teams across labeling, safety, medical writing, and CMC.	Expand to all process for commercialized products: registration tracking; managing correspondence and commitments; and submission planning and tracking for CMC change control, labeling, safety aggregate reports, and risk management plans.	Extend use of the system to planning and tracking clinical trial and investigational new drug applications. Add dossier storage and management of health authority queries.

Streamlining Global Processes for Planning Submissions and Defining Dossier Content

For Phase 1, BMS rolled out two new processes for submission planning and tracking, with the goal of greater visibility for headquarters and a lower burden for local offices. There are shared responsibilities for entering and managing data. Headquarters manages global events such as global submission plans for initial marketing applications, new formulations, and new indications. Global events result in local submissions that are planned and managed by affiliates within Vault RIM. Affiliates also enter information they generate, such as when sending a submission or receiving an approval.

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 Vault RIM minimizes data entry errors and delays. Affiliates will have personalized views that only display relevant information. And, once submission planning covers all types of submission, most local tracking spreadsheets can be retired.

Headquarters can now oversee global events and monitor the status of local submissions from planning through approval.

Submission Content Planning

The second process within Phase 1 is planning and tracking submission content. Component-level visibility allows BMS to project future resource requirements during submission development. Beaulieu explained, “When managing a large submission, it is difficult to identify component delays early enough to make a course correction. Tracking 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 the capabilities and processes to do this within Vault RIM.”

BMS can also look at performance across multiple submissions. While delays in submission content are often inevitable, it is difficult to pinpoint their cause. Regulatory dashboards show where bottlenecks occur, enabling BMS to make informed changes to the overall process.

Change Management at BMS

BMS had an extensive change management program to go along with the implementation. Part of that program included designing a new business role called the Client Engagement Liaison, to be physically located in the regions. The liaisons proactively engage with end users to answer business process questions and any “How do I...” type questions. They have helped write FAQs, conduct training, and answer support requests. “The client engagement liaisons were key to the project’s success,” said Beaulieu.

The Bottom Line: Better Visibility and More Efficient Processes

RIM transformation gives companies the opportunity to become more efficient and create better collaboration across the business. For BMS, the teams’ commitment during Phase 1 paid off with an immediate win—better visibility for fellow team members and other functional areas.

Beaulieu described the additional benefits she anticipates with Phase 2, “When we connect the dots by linking submissions, correspondence, commitments, and application metadata, we will see the complete story and a full view of regulatory activities. When coupled with a global process, the operational gains will be significant.”