

Baxter and Exact Sciences: Lessons Learned from RIM Transformation

As new regulations like EU MDR and IVDR increase the burden of maintaining compliance and keeping products on the market, medtech companies are being put to the test. However, a recent study of device and diagnostics regulatory affairs professionals found that only 13% of respondents have a digital, global RIM system in place to manage regulatory affairs.¹

But some leading medtech manufacturers, including Baxter and Exact Sciences, have embraced these regulatory challenges as an opportunity to rethink their processes and technology. Rather than continuing with manual information-sharing methods, these companies opted to unify operations across regulatory affairs and business units using digital technologies.

Hasan Sohail, director of regulatory operations at Baxter, joined Exact Sciences colleagues Kelly Barbeau, regulatory affairs manager, and Jaya Vaishnav, senior IT project manager, to share how their companies have transformed regulatory information management to drive efficiency and ensure compliance. Here are the highlights.

Drivers for change

Barbeau explained that in the last few years, Exact Sciences has grown rapidly from a single-site, single-product company to a global enterprise with multiple acquisitions under its belt. The regulatory affairs team experienced post-acquisition growing pains trying to manage multiple, disparate systems. Even just sharing documents was very difficult. “For example, we had teams in California that couldn’t access certain files because they were stored in a specific server at our headquarters in Wisconsin,” said Barbeau.

While Exact Sciences already adopted digital technologies in other areas, the company was still struggling to wrangle its regulatory data. So they set out to find a solution that would harmonize data, automate manual workflows, and help ensure compliance.

Baxter was in a similar situation with multiple systems used for submissions and registrations. In addition, Sohail explained, nothing was standardized globally and data sat in multiple locations. Four years ago, Baxter started its digital transformation journey and now uses Veeva Vault RIM as its single source of truth.

¹ Veeva MedTech Regulatory Benchmark Report

“For example, in legacy systems and processes it used to take two days to update a simple registration record, with Vault RIM – the end user can directly go in the system and update the record much quickly” said Sohail. Baxter has also cut down the time it takes to track health authority approvals by moving from multiple trackers/ systems for different regions to a single system where a user can update the record instantly.

Before you start a RIM implementation

It’s imperative to get leadership on board early to help communicate value and drive user adoption. Baxter leaders hosted events like coffee chats and town halls to keep RIM users engaged and aligned as they ramped up on the new cloud system.

Exact Sciences also identified clear goals before starting a RIM implementation. “It’s important to understand organizational priorities before embarking on a system change. At Exact Sciences, one of our long-term goals is to shift away from manual processes toward digital technologies. We already had similar initiatives across other business units, so our Vault RIM implementation fit well with our priorities,” said Vaishnav.

Preparing for RIM implementation

All three leaders agree that ensuring total buy-in from the leadership team is the first step. It’s important for the core team to know that key decision-makers across the organization support the project as a priority.

The next step Exact Sciences took was working with business units across the organization to create a robust communication plan to prepare stakeholders for change.

Baxter set up a steering committee of regulatory affairs employees that met regularly with different business units and led training. “We set up small group sessions with stakeholders. We wanted to prepare them for what to expect from the system from day one,” said Sohail.



Lessons learned

Data migration and identifying what to migrate can be a challenge. Baxter took a very specific approach to ensure clean data before migration. Sohail recommends getting all stakeholders together a few months before go-live to review their data and decide what really needs to be migrated to the new system. Data migration can be tedious, but having clean, accurate data is crucial to the project's success.

Training is another key area where the panelists had lessons to share. Exact Sciences blocked three to four hours several times a week for configuration sessions. However, they didn't account for the time commitment people had to put in outside of those sessions to get comfortable using the system. "For future software implementations, I think we'd try to truly understand the project's full scope during the planning and SOW process so that our core team members aren't overwhelmed with the amount of work," said Vaishnav.

The final lesson is to focus on solving the core pain points first and foremost. Make sure you solve those problems before moving to additional process improvements and adjustments. Barbeau explained, "Vault RIM has so many different capabilities. But, it's important not to get distracted during the implementation stage and to prioritize the specific problems your organization is trying to address." Additional improvements and optimizations should come after the core capabilities are in place.