Connecting Silos THROUGH SYSTEM INTEGRATION

Monica Kennedy, Director of Regulatory Operations at Halozyme, discusses how technology can be leveraged to address inefficiencies in organizations.

PV: What do think has led to operational silos and created inefficiencies?

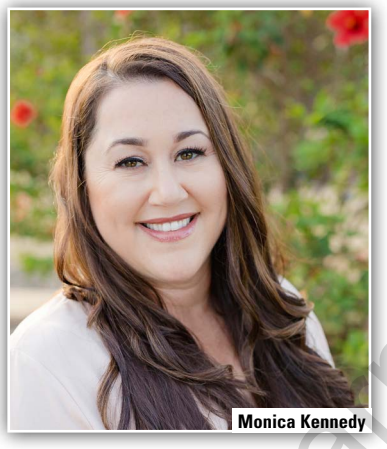
KENNEDY: Technology is one factor, but it alone is not responsible for operational silos; it's the lack of process-enabling shared technology across functions that contributed to silos. We operate in an industry where it is essential to leverage technology for information sharing, automation, compliance, and decision-making. Far too often, a single functional area determines that it needs a system to support a process and selects the system that best suits the department's needs. When this happens across many functions and over time the result is disparate systems. Such systems are incapable of supporting cross-functional processes or creating scale within an organization. The ability to leverage information within, and between systems, is not as strong or as efficient as it could be if the information resided within a common platform. To gain efficiency of a common platform approach, companies need to be able to leverage the expected look and feel of the system, which eases the training efforts across platform segments.

PV: Why is it important for systems to talk to one another?

KENNEDY: It boils down to efficiency and cross-functionality. For example, let's look at regulatory operations and content management. Regulatory operations is responsible for publishing regulatory submissions for delivery to health authorities. The vast majority of the information contained within submissions is cross-functional in origin — quality, clinical, safety, nonclinical. If each of these contributing functions had its own content management system, regulatory operation's access to the information would likely be an issue. Even with access, content would need to be exported from the functional systems and imported into the regulatory content management system resulting in duplicates, versioning issues, and inefficiency. If research and development content was in a common platform and integrated with the publishing software, submission content could be planned, authored, reviewed, approved, and archived without leaving the system.

PV: How can technology improve efficiencies?

KENNEDY: I recommend cross-functional collaboration to develop scalable processes and a strong



Monica Kennedy

partnership with IT to facilitate the selection of the best technology to enable those processes. At Halozyme, IT partners with the business functions and seeks to truly understand the business processes and needs. Our IT team has a big picture sense of where the organization needs to go in terms of technology and encourages a common platform approach where it makes sense to meet business goals.

PV: Can you share some lessons from Halozyme's IT efforts?

KENNEDY: The most recent system implementation that I contributed to was the Veeva Vault RIM, a cloud-based regulatory information management (RIM) system. This is a powerful system geared toward planning and tracking submissions to health authorities, correspondence to and from health authorities, questions and commitments, as well as the submissions that resolve them. Before the implementation, regulatory operations tracked submissions and correspondence and regulatory affairs tracked questions and commitments. They were not tracked centrally and, because of this, relationships between items could not be made. I recognized early on that we needed to do better, and we created the business case for a RIM system. The result of this effort is that all of our regulatory information is now in a centralized system. Regulatory affairs owns the information and regulatory operations acts as the custodian. Changing our process through the use of an advanced RIM solution has enabled us to preserve the regulatory history of our products and partnerships in a more robust manner.

I learned several valuable things from this project. First, whether you are implementing a new system or migrating additional information into an existing system, there needs to be a clear understanding of the scope of the project by all parties involved before executing the project. For example, determine if you are configuring an empty system that will be implemented and fed upon go-live or if you want to go live with migrated data in the system. We did the latter. This was a lot of work, but certainly worth it as we went live with a usable system and began recognizing a return on investment with newly realized efficiencies in the areas of capturing and reporting metrics.

Because timelines can be aggressive and the day job has to continue, I also learned the importance of identifying what pre-work — clean-up, collection of metadata, classification — can be done off the critical path. When we started the RIM project, our submission and correspondence tracking had previously been completed using Excel spreadsheets. They were product specific and consisted of eight fields. With the RIM system, we are now tracking 17 objects with multiple fields on each object.

A phased approach is completely acceptable, too. With this project, we had some information that wasn't ready to be brought into the system. It wasn't complete and the time it would take to collect the additional metadata and accurately create relationships would have delayed the rest of the project. We made a deliberate decision to leave it out and include it in a future phase.

Finally, having complete and accurate information is essential. Just owning a system to house regulatory information doesn't solve that problem alone. If you have incomplete or inaccurate information, a system is only going to highlight that.

PV: What other factors should be considered as part of a technology implementation?

KENNEDY: I'll reiterate the importance of a strong partnership between IT and the business functions. Also, test and retest configuration with real-use cases within a sandbox environment before locking down the specifications. This process will enable you to catch and resolve issues before the configuration is locked. Third, have a solid understanding of the roles and responsibilities, this is critical to any project team. And, finally, after it's all said and done, take the time to reflect on what went well and areas for improvement for the next project. There will always be a next time. PV

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