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Path from EDMS to The Cloud

By Kristin Brooks, Contract Pharma | February 18, 2016

Ronald Hernando of MacroGenics discusses his journey to the cloud at DIA's RSIDM Forum in Bethesda, MD, February 8-10.

In recent years, the life sciences industry has begun to view regulatory functions more holistically, as an end-to-end process. Document management, publishing, and technical regulatory requirements are all subsets of regulatory information management (RIM) at its broadest definition. Recognizing this convergence, the Drug Information Association *(*DIA) consolidated three events this year into a single forum where leaders met to discuss emerging operational standards, best practices, and the processes for submission, creation, and maximum use of regulatory information generated along the drug development continuum.

One of the highlights from DIA's Regulatory Submissions, Information, and Documentation Management forum was MacroGenics' presentation outlining the company's path from an aging on-premise electronic document management system (EDMS) to the cloud. "After 18 months struggling to implement an on-premise EDM system we gave up," said Ron Hernando, MacroGenics' director of Regulatory Operations. "We did an about-face, switched to a cloud-based solution, and were live in less than seven weeks. If we knew how fast it would be, we would've moved to the cloud a lot sooner!"

MacroGenics, based in Rockville, MD, with more than 260 employees, is a clinical-stage biopharmaceutical company focused on discovering and developing monoclonal antibody-based therapeutics for the treatment of cancer, autoimmune disorders, and infectious diseases. The company has eight clinical stage programs in its growing pipeline, requiring a modern document management system to keep pace with mounting submissions and to improve overall efficiency. MacroGenics is not alone. According to research from Gens & Associates, business cases for RIM are evolving from basic "primarily compliance" to also generating more strategic benefits of efficiency and productivity. In fact, more than half of the companies in the 2015 Gens survey view RIM not only a necessary part of the business infrastructure but as a strategic business asset.

Contract Pharma: *In your DIA RSIDM 2016 presentation, you talk about the tremendous challenges you experienced implementing an on-premise EDMS solution. What were the biggest challenges you faced?*

Ron Hernando: We spent a total of 18 months working to replace our initial on-premise system with another on-premise alternative. We had initially planned for the upgrade to be completed in 12 months, but the validation effort required with the on-premise solution proved to be a challenge as

we had limited internal resources and submission timelines took priority over our validation efforts. As a result, our EDMS upgrade timelines were repeatedly pushed out, and our budget continued to increase as well. Even worse, we were stuck using our original system throughout the implementation process as the new system was being validated. After a year on the project, our budgetary, timeline, and validation challenges persisted. Furthermore, performance problems and usability issues remained a daily issue with our current EDMS.

Around the 16th month on this project, we welcomed a new vice president of IT to MacroGenics, and he suggested halting the project and moving to Veeva Systems' cloud-based solution. I was already familiar with the provider, so we did a rapid evaluation and then quickly shifted gears to implement Veeva Vault Submissions, part of the Veeva Vault RIM suite. Remarkably, we were live on a global cloud solution with all our documents migrated in less than seven weeks and on a flexible system that's always improving.

CP: *How did the new cloud solution compare with the on-premise system?*

RH: There's really no comparison – the two systems are like night and day. With Veeva Vault Submissions, configuration was easy and didn't require any programming skills. As an industry-specific solution, Vault already had much of the functionality and workflows we needed. Even so, it was easily customized for our needs, allowing users to have their own filters and views. Another advantage of the cloud, of course, is the lack of infrastructure required, which dramatically reduces the total cost of ownership and frees the regulatory team from relying on IT for support. Third, the cloud allows secure access to Vault Submissions across the enterprise, from anywhere, from any device, at any time. We are even evaluating access for external business partners to efficiently collaborate on editing, reviewing, and approving documents. Everyone likes that they don't need a VPN to access the system and people enjoy working with a single authoritative source – everything is captured in the system for a full audit trail to support compliance and provide management with greater visibility.

Also, Vault Submissions' performance has been great. It used to take minutes to open larger files and it now takes seconds. Our San Francisco office often complained of lag time, but after we switched to Veeva, that's no longer an issue. Their performance is exactly the same as if they were in our Rockville, MD headquarters. With minimal training, at least 75% of our company now uses Veeva Vault. Our frequent, "super" users appreciate the system's ease of use and flexibility. They even want to start using it for documents outside of the original project scope.

CP: *What process changes have you made or do you plan to make, to fully leverage the cloud solution for RIM?*

RH: We were able to make strategic process changes up front by leveraging the new functionality that we gained from Veeva Vault Submissions. One example that I refer to in my DIA presentation is reporting from the at-a-glance dashboards that provide information in real time. Through built-in dashboards, we are able to obtain real-time metrics, such as the number of submissions submitted to the FDA on any given month, quarter, or year. We now can see trends, and report this to senior management within seconds. In addition, we used to track our submissions and correspondences manually via spreadsheets. Now, we just upload all our correspondences and submissions into Vault and can instantly generate reports.

We really wanted something more robust and that supports our global strategic initiatives regarding

RIM. Now, everything is automatically tracked in the system so we can run reports on various combinations of metrics, leading to rich insights that will help MacroGenics improve processes, spot missing documents, and speed submissions.

CP: *Looking ahead, what is your vision for RIM at MacroGenics?*

RH: With a flexible platform like Veeva Vault, I expect to bring more areas of our organization into the system for a holistic approach to content management globally; we'll add more detailed reporting and strategic process improvements over time. Immediately, however, I want to begin the submission authoring process directly inside of Vault Submissions to improve accuracy, gain reliable metrics from document creation through approval, and increase control – this will potentially include providing secure access to our external partners. Ultimately, I hope to provide all of our regulatory counterparts with the ability to edit and sign-off on documents inside Veeva Vault Submissions without having to email any documents. Before that can happen, we will need to update our SOPs, test security, and train our partners, but that's the goal.

CP: *Any advice for your peers considering a content management or RIM technology change?*

RH: The biggest hurdle to cloud is getting your stakeholders, especially IT and QA, to be familiar and comfortable with basic cloud terminology and functionality. Once that basic groundwork is laid, then you can start to evaluate cloud vendors, do vendor audits, and make sure you're comfortable with how they handle your data, approach security, implement disaster recovery, etc. You will want to pay close attention to user authentication and access, as that is often handled differently with cloud vendors. Often times, you'll find that cloud offers better security, availability, and flexibility than your on-premise infrastructure, and your fears were just a result of lack of information. Once you figure out how it works, you'll realize it's not the big unknown monster that you were imagining. You're still fully in control of your data, even if it isn't in your building.

Finally, with the cloud, you don't need hardware, software, or the IT staff to manage it all. The ownership is transferred to the business owner, making it more efficient to manage and implement. You are always using the latest version so your system won't be out of date just months after implementation, thereby protecting your investment and ensuring that users are benefitting from the latest technology innovations. Veeva provides regular updates and each one enhances the user experience. Documentation and training are provided and everything is pre-validated – we just do user acceptance testing, which is pretty fast. We've only had the system up and running for a few months, but are already reaping the rewards of real-time reporting, informative dashboards, and access flexibility.

Ronald Hernando's tips for switching from on-premise to cloud:

- Know your metadata and workflows ahead of time to save time during configuration
- Secure agreement with IT and QA on the scope of validation needed to address regular updates
- Engage users for feedback on a quarterly basis to identify process improvements
- Migrate all documents, but leave the audit trails in your old EDMS to save time
- Use the out-of-the box features as much as possible

For more than 15 years, Ronald Hernando has been working in Regulatory Affairs, Quality Assurance, and most recently as MacroGenic's Director of Regulatory Operations. Prior to MacroGenics, Hernando worked in regulatory affairs at Datafarm and Vical. Hernando specializes in

electronic regulatory submissions and publishing, implementation and validation of EDMS and electronic publishing software, international regulatory submissions (eCTD, IND/BLA/NDAs, MAAs), QA audits, gap analysis, RFPs, project management, document control, training, development and implementation of Work Instruction Documents and SOPs. He can be reached at hernandor@macrogenics.com - See more at: http://www.contractpharma.com/contents/view_online-exclusives/2016-02-18/path-from-edms-to-the-cloud/#sthash.CmnjLzbQ.dpuf