Medicines360 Takes Control of Regulated Content with Vault QualityDocs

Navigating life sciences' compliance waters is challenging enough, and is even more complicated for geographically dispersed companies. Medicines360, a nonprofit company, wanted to improve control over its regulated documents, and allow easy sharing of information for efficient collaboration among employees in remote locations. Just in time for the launch of its first product, the company solved its content management challenge with innovative cloud technology from Veeva Systems.

About Medicines360

Medicines360 is an innovative, global nonprofit, women's health pharmaceutical company with a mission of expanding access to quality medicines, regardless of socioeconomics, insurance coverage, or geographic location. The U.S. Food and Drug Administration (FDA) recently approved Medicines360's Liletta™ (levonorgestrel), a hormonal intrauterine device (IUD). Leveraging a cloud-based, advanced content management technology to efficiently handle the demands of launching a new product, Medicines360 is now ramping up commercialization of its new product.

Challenges Supporting Remote Teams

Medicines360 relies heavily on geographically dispersed teams and partners. With only email, file share, and a paperbased system, it was challenging to control and securely share regulated content. It was also not feasible for remote employees or contractors to come into the office when they needed to refer to a standard operating procedure (SOP) or other regulated document.

Medicines360 was also moving beyond research and development to launch and commercialize its first product. Existing processes for developing, reviewing, approving, and tracking training of controlled documents was complex and inefficient. Without a single document management system that was easily accessible from anywhere, the company did not have a consistent or efficient way to distribute controlled content and track SOP training to ensure compliance.

> *I've implemented many innovative systems to replace cumbersome manual processes or poorly designed systems. Veeva Vault QualityDocs is hands-down the best, and dramatically improves the document control processes at Medicines360.*
>
> ***– Kevin Loftus,** QA Manager, Medicines360*

"As a pharmaceutical company with employees around the globe, we needed to access, review, approve, and securely distribute SOPs and other controlled documents from anywhere," explained Kevin Loftus, quality assurance manager at Medicines360.

Ultimately, these challenges and regulatory requirements for electronic records and electronic signatures (ERES) provided the catalyst for Medicines360 to look for an electronic document management system.

Searching for a Compliance Ready Solution

Medicines360 evaluated a number of solutions, and only Veeva Vault QualityDocs met all the requirements: intuitive user interface, robust audit trail, compliant electronic signatures, and validation support. Based on past experiences with legacy systems, the team also knew they wanted a cloud-based document management application. On premise systems require considerable IT support and infrastructure, and hosted solutions only shift the physical location of servers, carrying the same high financial burden.

As an organization with mobile users and partners around the globe, Medicines360 needed a solution that did not require extensive user training or IT maintenance. "A complicated interface would have taken several months to configure, validate, and train all the users. We simply didn't have the time or the people to support that," said Loftus.

Vault QualityDocs is intuitive and accessible from any major web browser, allowing users to easily learn and access the application from anywhere – minimizing training and ongoing support. With Vault QualityDocs' true multitenant cloud and validation-ready software updates, Medicines360 is always on the latest release. The ability to seamlessly view PDF documents also removed the infrastructure complexity and connection challenges experienced with other applications. Free from system maintenance, Medicines360 is focusing resources on research and development, and commercialization of the new product.

"I knew we had to move to the cloud to optimize our resources and still deploy a world-class solution," noted Loftus. "When we started our search, I wasn't sure we could find a solution

that would not require significant customization. Vault's specialized functionality gives us the features we need in an interface that's easy to use for end users and administrators. Validation-ready, Vault QualityDocs saves us considerable time and resources."

Vault's cross-browser, cross-platform functionality also allows Medicines360 to easily collaborate with different functional areas and share best practices in real time. Vault's complete suite of fully interoperable content management applications gives the company compliant, efficient document processes across marketing, clinical, quality, and regulatory teams as it transitions from R&D-only to also supporting commercial operations.

Short Implementation Time

Medicines360 implemented Vault QualityDocs dramatically faster than expected – largely due to native life sciencesspecific functionality including preconfigured quality workflows and document taxonomy. Veeva's understanding of the regulated environment is also reflected in the validation documentation that is available with each release, and electronic signatures and audit trails that meet 21 CFR Part 11 requirements - making compliance easier for organizations.

The team made only a few, simple terminology changes to map Vault QualityDocs' document types names and fields with Medicines360's nomenclature. "As a small company, we thought moving to a new system would be a year-long project," remarked Loftus. "Instead it was only four weeks to get the system up and running with our configuration - including workflows. It took only another four weeks to have 80% of our quality management documents fully migrated and managed exclusively in Vault QualityDocs. The flexibility of the application and the support of the Veeva project team is absolutely extraordinary in my experience."

Many users were also able to pick up the system with very little formal training – a key benefit for a small, virtual company that is now on call for unannounced inspections. "Vault is intuitive and user-friendly – as easy to use as Amazon," added Loftus.

Making Compliance Easier and Increasing Operational Efficiency

Going paperless has proven to be a positive milestone for Medicines360, according to Loftus. Since implementing Vault QualityDocs, the company has seen significant operational improvement, including:

Increased Efficiency

Gone are the days of shuffling folders from reviewer to reviewer. Managing document and workflows electronically with Vault QualityDocs keeps documents visible, no matter where the content is in its lifecycle, and maintains strict version control, regardless of who has access or makes changes. Authorized users can quickly search across all documents to find what they need and easily share content, greatly improving collaboration and task execution.

Improved Productivity

Having access to critical content on any device, anywhere, and at any time leads to more productive employees. Users can now complete 'Read & Understood' tasks for SOPs and review documents on a desktop or mobile device thanks to Vault. "In terms of managing our document lifecycle – taking documents from draft, through review, revision, approval, issuance, and training, we have been more productive in the last six months than the entire year before that," stated Loftus. A user-friendly interface and intuitive viewing options, such as presenting metadata and the document on the same screen, also greatly improve productivity.

Easier Training

Before Vault QualityDocs, Medicines360 maintained large training binders, which were updated manually when a training session was completed, making it difficult to enforce and track training. Now, managers can easily monitor training progress and rectify any problems quickly. Reminders on re-training are also built-in to ensure users are always up to date on SOPs.

Faster Reporting

With Vault QualityDocs' extensive reporting capabilities users can easily gain visibility into compliance status, such as which users or departments have outstanding 'Read & Understood' tasks. The Vault dashboards keep reports at users' fingertips and make it easy to run reports on dozens of different metrics.

Expedited Inspections

Vault's organized and searchable document repository, electronic signatures, and detailed audit trails facilitate inspection-readiness at all times. Users can easily find requested documents or demonstrate compliance with 21 CFR Part 11 compliant e-signatures and audit trails.

Expanding to Clinical and Regulatory Content

As Medicines360 looks toward the future, the team expects additional commercialization and submission opportunities involving many different stakeholders. Veeva Vault will help Medicines360 manage and control the resulting documentation efficiently and compliantly. Already, the company is planning to expand Vault usage to include all clinical and regulatory content. With the flexibility and scalability of Vault, Medicines360 is always poised for growth.

About Veeva Systems

Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 1,100 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves. For more information, visit veeva.com.