REGULATORY FOCUS

Medicines360 Makes Nonprofit Pharma Possible with Cloud Technology

By Ethan Smith

This article outlines a unique nonprofit pharmaceutical company's path to increased quality and compliance using new cloud-based regulated content management technology. Medicines360 needed a best-in-class solution to efficiently manage and track an increasing number of critical SOPs to help ensure product quality and regulatory compliance as it launched its first commercial drug and prepared for inspections.

In a society where the good guys are often overshadowed by sensationalized negativity, there are still plenty standing tall, including nonprofit Medicines360. The San Francisco-based pharmaceutical company has replaced traditional fiscal objectives with a mission to provide all women with access to quality medicines regardless of their socioeconomic status, insurance coverage or geographic location.

Medicines360 was formed in 2009 by Victoria Hale, PhD who also founded OneWorld Health. Dr. Hale recognized the disparity in the number of unplanned pregnancies and access to highly effective contraception in different parts of the world among different demographics, and set out to balance the scales by making reliable contraceptives more available. The company researches healthcare needs of women to identify gaps and barriers to access and then fills in those medicine gaps by developing new products. Medicines360 also forms strategic partnerships with other life sciences companies to bring its therapies to market

"We are quite unique," said Medicines360 CEO Jessica Grossman, MD. "We are a nonprofit pharmaceutical company, which means we are driven by our mission instead of profit. Our mission is to provide a high-quality, low-cost or affordable product to women in need. How we measure success is by the impact our products have on the lives of the women who need them." Dr. Grossman most recently served as president and CEO of Sense4Baby, Inc., a start-up company that developed an innovative, wireless maternal/fetal heart rate monitoring system for women with high-risk pregnancies.

Medicines360 gained FDA approval of its first product, Liletta®, a hormonal intrauterine device this past February, and formed a groundbreaking partnership with Actavis (now Allergan) to help expand product access to all women. "Regardless of whether a woman is in a certain economic class, whether she lives in the US, whether she has insurance…we want to make sure we expand access and remove any barriers to receiving our products," continued Grossman.

Now, as the company ramps up commercialization of Liletta, Medicines360 is shoring up all of its processes and technologies to efficiently handle increase demand. One of the challenges the company faced was maintaining control over its regulated documents, while simultaneously allowing teams to share and collaborate on content. Many employees work remotely and require access on different devices from home, airports, coffee shops and other locations all over the world. Additionally, as the company expanded, its internal file share and paper-based document management methods created irreconcilable version control challenges, inhibiting team productivity and increasing compliance risk.

This was particularly challenging for Medicines360's quality and regulatory teams to manage Standard Operating Procedures (SOPs). Many FDA warning letters to life sciences companies cite violations from failure to have or to properly follow SOPs—the most fundamental component of current Good Manufacturing Practices (cGMPs). Although FDA has long emphasized the importance of SOP compliance, the agency's increased focus on quality reaffirms the importance of a comprehensive approach to managing SOPs. These are living documents regularly revised to reflect current procedures or improved processes. Without a single document management system easily accessible across the organization, Medicinces360 was challenged to promote approved and up-to-date procedures, reliably track which employees completed required SOP training, and easily reference appropriate procedures in regulatory filings.

In addition, Medicines360 did not have the resources of a for-profit organization to invest in a broad-scope technology system. These client/server, on site systems typically require major customization in order to meet very unique industry needs. In light of these challenges, Medicines360 considered implementing a more extensive file system and researched the document management systems on the market. Medicines360 found a new type of cloud-based solution from Veeva Systems to meet their unique needs.

"I knew we had to move to the cloud to optimize our resources and still be able to deploy a world-class solution," said Kevin Loftus, quality assurance manager at Medicines360. "When we started our search, I wasn't sure we could find a solution that wouldn't require significant customization. Vault's specialized functionality gives us the features we need in an interface that's easy to use. And, validation-ready, Vault QualityDocs has saved us considerable time and energy."

Solution Implementation

Life sciences-specific functionality enabled Medicines360 to quickly get up and running on a quality document management system aligning directly with their business processes and supported regulatory requirements. Unlike on site systems, requiring considerable customization and ongoing IT support, or hosted solutions that shift the physical location of servers, but carry the same high financial burden, this new system is a true multitenant cloud solution with secure anytime/anywhere access and is easy to use, manage and administer. Regular validation-ready application updates are provided so users are always working on the latest, compliant technology without the significant validation effort normally required to upgrade traditional software systems. As important, the solution provides the scalability Medicines360 needs for continued growth—new users can be added in just minutes without the need for major IT support.

Users at home and those working from all over the world picked up this new system immediately—a key benefit for a small, geographically dispersed company now on call for unannounced inspections. The familiar, consumer-like interface makes it easy to use, minimizing the training burden and ongoing support for Medicines360 when bringing on new staff in distant locations. "Vault QualityDocs is intuitive and user-friendly—as easy to use as Amazon," added Loftus.

Medicines360 deployed the system to approximately 50 users across quality, manufacturing and regulatory affairs, and implementation was completed faster than expected

due to built-in life sciences-specific functionality. Medicines360 made just simple configuration changes in terminology to map with the company's existing nomenclature. "As a small company, we thought moving to a new system would be a two-year project, but it was only four weeks. Vault QualityDocs' flexibility and the support of the Veeva project team was impressive," said Loftus.

SOP-Compliant Results

Going paperless has proven to be a positive milestone for Medicines360, according to Loftus. Since implementation, the company has seen significant operational improvements, including increased efficiency, enhanced productivity and speed, and improved compliance preparedness.

Increased Efficiency With Greater Visibility

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

In addition to increased efficiency in the development of SOPs and other quality content, the solution ensures accurate and timely distribution of the latest approved SOPs to all responsible parties with confirmation the SOP has been received and read. Because SOPs are revised with every process change, equipment replacement or regulatory modification, this was critical. The system enables rapid updating and distribution of new SOPs via the cloud. Just as important, the system enables more effective targeting of SOPs to the correct employees, thereby preventing all employees from being overwhelmed by information not applicable to the individual's job tasks.

Improved Productivity With Increased Access

Having access to critical content on any device, anywhere, at any time leads to more productive employees. Users can now complete read and understood tasks for SOPs and review documents on a desktop or mobile device. "We've been more productive in the last six months than the entire year prior," stated Loftus. A user-friendly interface and intuitive viewing options, such as presenting metadata and the document on the same screen, also greatly improves productivity.

Easier Training for Better Adherence

Before implementation, Medicines360 maintained large training binders, which were updated manually every time a training session was completed. Delays in updates and lack of corporate-wide visibility made it difficult to enforce training and track completion. Now, managers can easily and quickly monitor training progress and if needed, rectify a situation. Reminders on re-training also are built in to ensure users are always up to date on SOPs.

The FDA states, "each person engaged in the manufacturing, processing, packing or holding of a drug product shall have education, training, experience or any combination thereof to enable that person to perform the assigned function."*(1)* It is this combination of current written procedures and employee training driving consistent performance for consistent results, and all told, plays a critical role in assuring the quality of a manufactured product and its compliance with applicable FDA regulations. Any system capable of automating SOP compliance tracking is critical to compliance and ultimately, to product quality.

Faster, More Reliable Reporting

Reporting is very simple, allowing users to easily create reports and see which users or departments have outstanding read and understood tasks, enabling companies to proactively address compliance concerns. For example, SOPs need to be reviewed on a regular

basis to ensure they remain accurate, and if there are changes, new tasks are sent out to employees to, once more, confirm they have read and comprehend the new version. Dashboards keep these reports at users' fingertips and make it fast to run reports on dozens of different metrics.

Expedited Inspections Made Easier

As Medicines360 prepares for its first inspection, the company is happy to have an organized and searchable document repository enabling inspection readiness at all times—even for last minute, unexpected knocks on the door. And, since SOPs are reviewed as part of regulatory inspections, it was crucial to maintain audit trails, detailing the activity associated with each new or revised SOP document, i.e., who reviewed it, who approved it and when in order to comply with 21 CFR Part 11. Employees can easily find requested documents or demonstrate compliance with a comprehensive audit trail.

Medicines360 needed a highly efficient solution for managing its SOP documents to meet regulatory compliance and reinforce corporate procedures across the manufacturing function. With limited resources and a sprawling workforce, the nonprofit turned to cloud technology and replaced its manual, paper-based solution. Now properly managed, Medicines360's SOPs provide employees with accurate and easily accessible information, enabling safe and efficient job performance. They also provide the company's management team with a clear view of existing knowledge gaps and potential inefficiencies created by inadequate training. And just as important, Medicines360 is able to mitigate compliance risk.

As Medicines360 looks toward its future, it expects additional commercialization and submission opportunities involving many different stakeholders. Veeva Vault will help Medicines360 organize and control the resulting documentation, manage it all efficiently and compliantly. Already, Medicines360 is planning to expand usage to include all clinical and regulatory content. And, due to the system's flexibility and scalability, Medicines360 will be always poised to add internal and external users as it continues to push forward in its humanitarian efforts and altruistic mission for women everywhere.

References

1. Pickett, J. "Ensuring Effective SOPs in Pharmaceutical Industry." 28 June 2013. *ExpertBriefings.com*. http://www.expertbriefings.com/tips/2474/. Accessed 20 January 2016.

About the Author

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