KYTHERA®
biopharmaceuticals

Success Story

Kythera Chooses Veeva Vault to Manage Regulated Content Enterprise-wide and Shaves TMF Reconciliation Time by 40%

The Customer

Kythera is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel prescription products for the aesthetic medicine market. The company's objective is to develop prescription products using an approach that relies on the scientific rigor of biotechnology to address unmet needs in a rapidly growing market. Kythera's initial focus is on facial aesthetics – the market's largest segment. The company's drug for the reduction of sub-mental fat is currently in late-stage clinical development.

The Challenge

Kythera needed a system to improve clinical document management and facilitate business processes for the development of its newest product candidate. The company had 26 studies already on file along with four active clinical studies, resulting in thousands of documents to share, manage, and store. Kythera had been using a patchwork of different document repositories and systems for each functional area, including a file share system for TMF documents and a SharePoint-based system that was difficult to access and use for internal collaborators and external partners. Multiple versions of documents changed hands with no reliable document accountability. The resulting errors slowed study processes and added risk. Exchanging documents by couriers internationally only added to the inefficiency.

Kythera's legacy system was also extremely difficult to manage and update. Without the luxury of a large internal IT team, Kythera required a turnkey system that integrated clinical, regulatory, and medical affairs document management and didn't require dozens of staff to implement and maintain. Kythera's Senior Manager of Document Management, Renee Fate, who was already familiar with cloud technology, knew that a multitenant cloud-based solution would be easy to update and be managed remotely by the vendor.

> "We are shaving at least 40% off the time needed to reconcile TMF documents at the conclusion of a trial with our Vault eTMF cloud system. Now, we have full visibility and can track the status of the TMF in real time for the entire duration of the study."
>
> *Renee Fate - Senior Manager, Document Management*
> *Kythera Biopharmaceuticals*

The Search

Preparing for rapid growth and facing increased volumes of content, Kythera wasted no time and turned to industry leader in cloud technologies, Veeva Systems. After a brief trial, Kythera selected cloud-based Veeva Vault, an end-to-end regulated content management platform built for the global life sciences industry, supporting business-specific applications and connecting work streams across clinical, regulatory, and medical affairs.

"We looked for an enterprise-wide solution that could effectively serve diverse masters across the business – regulatory, CMC, clinical, sales and marketing, HR, finance, and legal – with different requirements for user knowledge, compliance, and security," said Jeff Webster, Kythera's chief operating officer. "Vault was the right solution for us, given its intuitive interface, functionality across Mac and PC platforms, mobile access, full complement of 21 CFR Part 11 compliant capabilities, and the security and backup features necessary for our most important asset: our content."

Fate added, "As a growing company without an IT team, we needed a cloud environment. With Veeva, we have no servers to manage, updates are pushed out automatically without any disruption to our teams, and our mobile workforce can access the system from anywhere in the globe, using any device."

The Solution

Veeva's Vault suite of cloud-based applications now connects Kythera's teams from clinical to commercial. Initially, Kythera rolled out Veeva Vault eTMF to manage all of its trial documents and support global collaboration between sponsors, CROs, sites, and investigators with its integrated Investigator Portal. Kythera is also leveraging Veeva Vault QualityDocs to establish a single source of truth for all quality documents, and Veeva Vault MedComms to simplify the global coordination of medical communications.

According to Fate, "Over the years, I have always received the same feedback from users: 'we want more visibility, with information available in real time.' Veeva Vault delivered on all fronts and was validation-ready, which makes my life much easier. Feedback has been very positive."

Kythera has established Vault eTMF as its central hub for exchanging documents with CROs, investigator sites, and other clinical partners. Each exchange is tracked by Vault and available via real-time reports that provide visibility into trial status and TMF completeness. The resulting data also provides actionable insights that allow Kythera to proactively improve study processes.

Today, Kythera has more than 100 Vault eTMF users and plans to expand further with each new study site. The new solution brings Kythera a wide range of advantages, including:

Improved Workflow

Vault delivers total electronic access to documents that were previously transmitted as email attachments or as paper copies via courier. For Kythera, this has improved workflows throughout the trial process. For example, protocols authored by the medical writer are now uploaded directly into Vault, automatically notifying the requisite six or seven reviewers. The reviewers can make comments simultaneously in real time, and then the editor can consolidate, obtain final approvals, and publish to Vault, helping Kythera move more quickly and reduce cost.

Electronic Signature Capture

Kythera can now capture electronic signatures and is building new SOPs to take full advantage of this time-saving convenience. "Historically, we collected many more signatures than the government requires, adding a lot of inefficiency to the process because everything gets stalled while we wait on those signatures," notes Fate. Electronic signatures will prevent needless delays in creating submission ready documents.

Timely eTMF Reports

Vault eTMF allows Kythera to run a full range of standard and ad hoc reports effortlessly, giving the company a view into trial progress and enabling better management of the study. Kythera uses Vault's expiry report to proactively alert team members before documents expire. Manually tracking expiration dates, due dates, and receipt confirmations takes an enormous amount of time. Everyone on the Kythera team is happy to have Vault automate that work. A site document report shows the study documents on file for each site, and a site initiation report shows the status of documents by milestone.

"When everyone has visibility into the reports, it removes a lot of questions at team meetings. We can spend less time meeting and more time working," Fate said. "The best part of Vault's reporting is that I can pull my own reports. I don't need to ask IT or get special training. I can easily run custom reports to answer questions as they come up. If you haven't had that before, you might not realize how wonderful it is."

For Kythera, the biggest change has been transitioning from a predominantly paper-driven TMF system to electronic. The company has taken the time and attention needed to ensure a successful changeover – analyzing and homogenizing its taxonomy, creating helpful classification 'cheat sheets' for users, developing new SOPs, and integrating new electronic processes into daily workflows. Vault eTMF's close alignment with the industry-approved Drug Information Association (DIA) TMF Reference model and consumer-like interface have also helped the conversion to a paperless system go smoothly.

"Vault is easy to use for a fairly painless transition that might have otherwise overwhelmed us," added Fate.

The Results – Paperless Trials Get Crucial Drugs to Market Faster

Vault eTMF, Kythera's first step towards paperless trials, is helping the company speed study start-up, enhance visibility into trial operations, ensure documents are organized in a common structure for easier search and retrieval, and collaborate more efficiently. Now, Kythera can securely exchange documents with all authorized study participants, including auditors, to support inspection and remain audit-ready at all times.

Efficient Processes

According to Kythera, the greatest benefit of Veeva Vault is the speed and efficiency gains that accompany going paperless. Paperless processes have directly resulted in numerous efficiencies such as faster site start-ups with real-time review of all documentation and expedited approvals. Because everyone can access the system at any time, processes keep moving regardless of the participating individuals' physical locations. Moreover, the easy access and powerful search capabilities of a cloud-based electronic system offer a vast improvement over Kythera's prior experience with paper documents. Often, teams endured a 48-hour-or-longer wait for a box to arrive from off-site storage, only to find that it didn't contain the desired document. Today, the correct documents are retrieved in seconds in Vault eTMF.

Reduced Errors

Versioning documents through Vault ensures every member of the team is accessing the most recent copy, reducing errors and making certain that work is not duplicated. All users' interactions with the content are automatically tracked by the system, so everyone has visibility into changes and updates. Vault also helps Kythera protect its information. "Our people tended to keep everything in email, which was risky," noted Webster. "When someone left the company, any information or document maintained by that employee was basically gone. No one goes through an old archive to find a file. Now, company information stays accessible."

Expedited Inspections

With Vault eTMF, documents are filed, QC'd, and approved throughout the course of the trial, saving time at study close, according to Fate. "It's much harder to look for information at the end as opposed to making changes along the way. Now, we can identify missing documents as they occur rather than finding 'surprises' at the end that force us to back-track and waste time," Fate continued. "Document reconciliation can take months of work. To do this in real time would save 40% of my time at study close." Plus, auditors get immediate, remote access to the appropriate documents within an intuitive system that requires minimal training.

With the increased focus on TMF quality from the Medicines and Healthcare products Regulatory Agency (MHRA), the benefits from going paperless for audits and inspections carry additional weight. The MHRA recently found 35% of commercial sponsor inspections required extra days to accommodate incomplete or inaccessible TMFs. As such, the MHRA has updated their definition of critical GCP inspection findings to include a provision for TMFs that are not readily available or accessible, or are sufficiently incomplete that inspectors cannot successfully carry out their duties. As such, 33 percent of respondents to a recent Fierce Markets survey expect to provide auditors with remote access to an eTMF by early 2015, and an additional twelve percent with no clear timetable indicated they would provide remote access "as soon as they have the technology."

Changing Mindsets

For Kythera, converting to an electronic system meant reimagining prior business processes and eliminating its mental reliance on paper in order to fully leverage the new solution's capabilities. "We have had to adjust the way we think – from a paper mindset to electronic. As an organization, Kythera cannot adopt an advanced system like Vault while maintaining old paper processes. To fully leverage Vault's capabilities, we had to make changes from the ground up like revising many of our SOPs in parallel with deployment," said Fate.

Today, only 43 percent of source documents are created electronically (on average across trial parties including sponsor, CROs, sites, IRBs/IECs), according to the Fierce Markets survey. As Kythera has discovered, the industry needs to adopt a paperless operating model in which the eTMF is used by all clinical parties to execute trial management activities from planning, through conduct, to completion. Only then can sponsors maximize their eTMF systems, fully optimizing process efficiency and maintaining inspection-readiness at all times."

"The biggest issue when it comes to transitioning to a new system – and letting go of paper – is the fear of losing control. But, when employees and partners see the increase in efficiency that comes from a more streamlined, repeatable process, they are more likely to embrace the system and accept a new digital business environment," concluded Fate. "Veeva Vault has made this transition much easier than expected because users are enjoying many benefits that improve their daily work, increase performance, and enhance productivity."