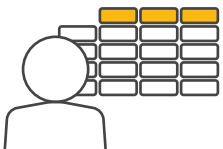


The Four Pillars of Inspection Readiness and Success

A mid-sized biotechnology company passed an FDA inspection with only two days' notice. Here's how they created a culture of quality and inspection readiness on the foundation of Veeva Vault eTMF and ultimately ensured a successful inspection.

1. Engage Employees with Accountability Framework



The company uses foundational tools and frameworks to guide their work, including ALCOA+ and a TMF index. They augmented this with an accountability matrix for document owners.

They created this matrix in collaboration with the functional groups affected and used it to outline roles and associated expectations. Now, document owners know they must ensure the quality of their documents before uploading them.

This exercise helped the company integrate the eTMF in their business processes (rather than use it as a static repository), empower subject matter experts, and increase efficiency in maintaining inspection readiness. It also informed their eTMF structure and content form ahead of their inspection. The clinical trial manager said it improved quality throughout the trial lifecycle, too.

“We aim to thrive versus survive during an inspection,” she said. “We have confidence that if we begin with quality people and quality in the way we do our job, we’ll reach the goal of maintaining a healthy eTMF.”



KEY TAKEAWAY

Develop an accountability matrix and give document owners shared responsibility for ensuring document and overall eTMF health.

2. Use Reports and Dashboards to Assess eTMF Health



The company also developed customized reports and dashboards to track metrics, identify trends, and assess risks. Within their Vault eTMF, they configured:

- Dashboards to report on metrics, like expected document list (EDL) counts, with color-coded flags for quick view and assessment
- Automated reports sent to selected recipients to display CRO upload and quality check (QC) reject counts month-by-month
- Filters to explore document data in greater detail, such as by study region, which improved oversight as they split operational activities with a CRO

They refined the dashboards to examine critical documents as defined by ICH guidelines and their risk tolerance rather than track every eTMF document. They also created a dashboard to report on timeliness, with a KPI that each critical document was uploaded and approved in 60 days with a stretch goal of 30 days.

These metrics enabled them to take snapshots of eTMF health throughout the study lifecycle and remediate issues as they arose, rather than risk a critical finding in the inspection.



KEY TAKEAWAY

Use configurable reports and dashboards to monitor eTMF health and translate insights into action.

3. Train on an Ongoing Basis



The company used those same metrics to identify areas where they needed to take corrective action in training, too. They pinpointed areas where document owners needed to be retrained, guides and instructions that need to be updated and incorporated those learnings in onboarding training moving forward.

For example, with ongoing snapshots of documents that did not meet quality standards, they could identify repeat quality issues, such as missing metadata. Through this ongoing training for both internal and external staff, they socialized the importance of eTMF health.

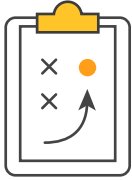
“As more teams were onboarded and trained, we saw a marked improvement in eTMF health,” the trial manager said. “This has provided efficiencies in the finalization of the documents.”



KEY TAKEAWAY

Incorporate insights to improve onboarding, ongoing training, and instruction materials.

4. Use Insights to Storyboard and Prepare for Inspection



The company used the Vault eTMF reports and dashboards to create a list of the most challenging questions (MCQ) and prepare a storyboard ahead of the inspection, too. With the visual aids, the team aligned on the trial story and trends — and they felt prepared because they had prioritized inspection readiness from the outset.

The trial manager added: “We want to invest time and effort in training and developing Veeva champions. We want to invest in products that provide us with visibility into goals and performance, which promotes a planning culture and results in high-quality data.”



KEY TAKEAWAY

Use Vault eTMF to assess trends, inform your teams, and prepare for inspections.

A Successful Inspection



During the inspection, which lasted four days, the inspector first requested to review the TMF index and key standard operating procedure (SOP) documents. The inspector also conducted more than a dozen interviews and involved eight functional groups in the inspection.

Although the inspection encompassed other systems, too, the inspector reviewed the eTMF three separate times because of its importance to the regulatory process. The company passed the inspection without incident or complication.

In all, the company found that the key to a smooth inspection was ensuring that their business processes and foundational tools, including their Vault eTMF, worked in lockstep. They can apply these same learnings whether they work in their eTMF, share an eTMF with a CRO, or oversee an eTMF.

“Quality is the foundation,” the trial manager said. “Follow your SOPs and update as needed. The eTMF isn’t just important — it’s critical. But your eTMF health and inspection readiness are only as healthy as your cross-functional accountability.”