Pharmaceutical MANUFACTURING

Veeva Vault eTMF

In the face of increasing clinical trial cost and complexity and changing regulatory guidelines, life sciences companies are turning to cloud-based Veeva Vault eTMF to improve clinical trial master file (TMF) timeliness, completeness, and inspection readiness. In just over a year, five of the world's top 20 pharmaceutical companies have standardized on Veeva Vault eTMF, joining more than 50 Vault eTMF customers – from emerging biotechs to CROs and large pharmas – gaining better access, visibility, and control over clinical trial content and processes.

Regulatory authorities worldwide are placing higher levels of scrutiny on the TMF. The United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) updated its definition of a critical good clinical practice (GCP) finding to include trial master files that are incomplete and inaccessible. There is also a growing recognition of the role TMF management can have in speeding time to market. These changes have prompted an increased focus on actively managing the clinical trial master file throughout the trial process.

Lacking deep, industry-specific capabilities for TMF collaboration, collection, and management, many eTMFs today are simple file shares that serve as document storage. To increase efficiency while strengthening inspection readiness, companies are moving toward process-driven eTMF applications—and seeing major benefits. Those using advanced eTMF technologies report greater audit readiness, visibility, compliance, and cost savings from their eTMF than those using local or cloud file systems.[i]

"A major transformation in TMF management is underway," said Jennifer Goldsmith, vice president of Veeva Vault. "The industry is rapidly moving away from TMFs as simple, static archives. Companies are utilizing TMFs more strategically to improve trial management and long-term trial design and planning, allowing them to bring products to market more quickly and efficiently."

By proactively guiding processes, quality, and visibility at every stage, Vault eTMF is helping companies streamline the clinical development process from start to finish. "Cloud-based solutions for eTMF are becoming the standard for the industry, and Veeva Vault eTMF is leading the charge," said Jamie O'Keefe, vice president of Paragon Solutions' R&D consulting practice. "Before Veeva and cloud, a typical eTMF implementation could take 12 to 18 months and would provide limited capabilities. With Veeva Vault eTMF, implementations take a fraction of the time and organizations are supported by an eTMF application that manages process, enables global collaboration, and ensures inspection readiness."

Veeva Vault eTMF is part of Veeva Vault, a cloud-based content management platform and suite of life sciences-specific applications. Vault eTMF enables real-time collaboration between external partners, internal teams across clinical and regulatory, and study sites globally to deliver a single source of the truth for content. It eliminates the risk and ineffectiveness of manual processes, improving efficiency, visibility, and control. Additionally, Vault eTMF's comprehensive reporting and

configurable dashboards provide actionable insights to drive ongoing clinical trial improvement and ensure inspection readiness at all times, in compliance with global health authorities.

Category: Contract Services

Product Type: IT

Manufacturer: Veeva Systems

Website: www.veeva.com