pharma TECH OUTLOOK

MARCH - 2017 WWW.PHARMATECHOUTLOOK.COM

Top 10 eClinical Trial Management Solution Providers-2017

Back when the pharma industry was rather skeptical in regards with adopting new technologies, the trial management arena involved time consuming tasks such as maintaining spreadsheets, documents, and often sisyphean communications. Clinical Trial Management Software (CTMS) and associated services came out as an eye opener for pharma companies. They streamlined the approach across clinical development programs which have in turn enabled centralization, standardization, efficiency, and cost saving in terms of drug development. CTMS' have since evolved from being mere transaction facilitators to decision support entities within the eClinical realm.

While Scalability, customizability and ease of deployment are among addressable challenges of CTMS'; the market is witnessing mergers, acquisitions and multinational operations. As such, client expectations appear to push the boundaries as far as the capabilities of CTMS are concerned. Intersections with data management and capture, processing, and analytics have blurred the lines between CTMS and other eClinical verticals. This has given rise to an ecosystem of competitive product offerings, vendor innovations and our motive to identify established as well as emerging players in the space for our readers.

For this edition of PharmaTech Outlook, our distinguished panel comprising of CEOs, CIOs, analysts and our Editorial Board has reviewed companies with a proven record of expertise in assisting the pharmaceutical and life sciences sector. In our selection we looked at companies' ability to identify client requirements, develop strategic approach and provide support and customization through their offerings. We present to you Pharma Tech Outlook's Top 10 eClinical Trial Management Solution Providers 2017.

Company:
LMK Clinical Research Consulting, LCC

Description:
LMK Clinical Research Consulting is a group of experts working together to provide high quality TMF (Trial Master File) consulting and services

Key Person:
Sholeh Ehdaivand
President & CEO

Website:
lmkclinicalresearch.com

LMK Clinical Research Consulting
Sustainable Processes for Clinical Trial Quality

From being stored in cardboard boxes, to sophisticated online databases, the Trial Master File (TMF) has always been an essential component in every clinical trial, despite the evolution. Based on the singular belief that TMF is the foundation of every clinical trial, Sholeh Ehdaivand has dedicated 15 years of her career to mastering clinical trials, TMF subject matter and management, ultimately founding LMK Clinical Research Consulting in 2013. "We are a group of professionals who have come together on the belief that the TMF is the most important deliverable of a clinical trial and everything that we do stems from that certainty," says Sholeh, Principal Consultant, CEO and President of LMK Clinical Research Consulting. "If a clinical trial is a 'daisy', the TMF is the eye and everything stems from the eye of the daisy."

LMK's goal is to provide clients with not only high quality TMF services, but to also educate them about the importance of the TMF within a clinical trial. Sholeh's emphasis is on providing their clients with quality people and a sustainable process—the twin factors for a solid TMF foundation. "The process doesn't necessarily revolve around the technology," says Sholeh. Being technologically agnostic, LMK focuses on the process and the people, who have perfect understanding of clinical trials and quality to help their clients plan, collect and maintain their clinical trial documents.

"It is important for us to educate our clients about the TMF from the process standpoint and not the technology standpoint," delineates Sholeh. LMK's TMF University—a collection of module-based TMF learning courses, educates clients about everything from regulations to TMF quality. "Our goal is to help our clients understand why the TMF is important and how it should be managed."

Aside from clients, employee education is paramount at LMK. Being involved with various client types, from large pharmaceutical companies to small biotech firms, LMK employees need to understand the challenges faced by their clients and, use an appropriate approach when dealing with their TMF needs in order to assure a high-quality service. LMK's consultants are equipped with the required know-how to provide adequate support and ensure that all documents are inspection-ready.

> If a clinical trial is a 'daisy', the TMF is the eye and everything stems from the eye of the daisy

Ultimately, the objective of LMK is to provide their customer's with an accurate TMF for success during a regulatory inspection. According to Sholeh, one of the challenges they [clients] face is in ensuring TMF documents are collected and filed within a given deadline. Consequently, Sholeh mentions the appropriate solution, "We created a process for collecting the documents which ensures the documents from the various functions are collected and filed in a timely manner. We also review the TMF for completeness. If there are missing documents, we remediate immediately."

Finally, what benefits the client in the end is a complete TMF, with all documents filed appropriately and diligently according to the milestone and event which occurred during the trial.

LMK stands unique in clinical research consulting through its combination of TMF expertise and extensive knowledge of the clinical drug development process. Sholeh concluded, "by improving the quality of the TMF during trials, we believe that the world will be introduced to medications and medical devices in a timely manner that could potentially save many lives."


Sholeh Ehdaivand