PHARMICA CONSULTING

Get Better Pharmacovigilance

The Challenge

A mid-sized Japanese BioPharma had experienced critical findings during an inspection due to the lack of compliance oversight in the organization. They were not generating metrics on a regular basis to understand if they were being compliant in case processing. While the company had reports summarizing cases, identifying the root cause of compliance issues proved far more perplexing making it difficult to draft an effective CAPA, much less proactively identify trends to prevent future issues affecting patient safety.

How Pharmica Helped

Pharmica met with the client to map out and improve their PV processes. Their tools weren't aligned to their processes, causing them to miss important quality and compliance trends. Based on the technology assessment, Pharmica developed a PV data visualization tool tailored to their processes and their CAPA management goals.

Lasting Results & Relationships

With the Pharmica solution implemented, the client could identify and implement 6 CAPAs that led to an increase in overall ICSR submission compliance from 70-90% in just 2 months, saving millions of dollars. A secondary issue was also identified, which enabled them to improve their overall compliance from 90-98% and meet the company's ICSR Submission compliance requirement. Furthermore, Pharmica's solution cut the resource effort to QC a case by 71% and enabled ongoing real-time insight into the quality of the performance of internal resources and vendors.

Compliance and Quality are two integral components of almost all PV activities that can lead to a large CAPA backlog if not managed effectively. It is easy to miss the forest for the trees of case processing, but it is imperative for all BioPharma companies to stay on top of the big picture. Pharmica knows Pharmacovigilance. Let us work with you to unlock the value of your data and show results that will let you sleep the night before a health authority inspection.

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