PHARMICA CONSULTING

Get Better Pharmacovigilance

The Challenge

Typically, pharma companies store their pharmacovigilance documents just about anywhere, dubbing the process as part of their "Pharmacovigilance System Master File" or PSMF. There was no centralized, authoritative source to go to if a regulator requested a PV document. This is still is the case with many companies due to the overwhelming nature of organizing the mess - let alone finding a simple, practical solution that does not cost millions of dollars. At the end of day, if users dislike a PSMF system they won't use it, and companies will continue to carry unnecessary regulatory risk.

How Pharmica Helped

Pharmica consultants identified the problems and risks associated with disorganized documents and implemented a simple, practical solution. A SharePoint solution was tailored in accordance with the EMEA guidance document to create a centralized place for storing PV documents. Workflows were created that prompted users to review a team member's sections based on a monthly process, ensuring ongoing compliance. The workflows guaranteed the client was always audit ready. In addition, a report was created to easily show updated versus out-of-date documents in any given month.

Lasting Results & Relationships

With this simple but powerful solution, the client now has a streamlined process free of administrative burden. For new stakeholders, compliance tasks are black and white. Ambiguity has been eliminated for all. No more long searches to find documents or asking team members where documents are stored - and no more using email as a document repository.

Compliance and Quality are two integral components to any pharmacovigilance organization. It is assumed that high administrative burden corresponds with increased compliance of a PSMF solution. Pharmica knows pharmacovigilance. Let us work with you to to implement practical, easy to use solutions that will let you sleep without the worry of a health authority inspection.

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