propharma

case study

how to minimize overdue deviations: a multi-site process improvement approach

ProPharma successfully and rapidly supported a global biopharmaceutical client needing a proven and tested approach to reducing a significant deviations backlog.

A global biopharmaceutical client with multiple sites operating under a Warning Letter, needed significant cross-functional support to meet remediation commitments by addressing their overdue backlog of deviations and investigations.

Our client required a strategic and comprehensive view of all the challenges affecting their deviation management system as well as hands-on support for performing root cause investigations and developing effective CAPAs.

ProPharma played an instrumental role in implementing project management methodologies to properly manage the deviation and investigation systems across multiple sites for a global client and provided hands-on support for backlog reduction.

challenge

A global biopharmaceutical company was having difficulty managing a significant backlog of >1000 open deviations and associated investigations across multiple sites.

This backlog put additional pressures on the company to perform investigations that determine true root cause and identify potential red flags and recurring issues.

As a result of an agreement with the FDA, **the company was under a pressured time constraint to reduce the backlog** and put the program into a sustainable management state. The company was also unsure of **how they would meet deadlines given the current resources** available.

To fulfill this commitment, the company needed a team in place who specialized in managing and reducing deviations and investigations backlog in an expedited timeframe.

solution

The client retained the services of ProPharma, and **within a few weeks, we assembled a team of experts, including 20 uniquely qualified professionals.** ProPharma's industry leading recruiting capability efficiently identified the perfect resources and utilized a client-specified onboarding blueprint to rapidly supplement the client's full-time staff with qualified and experienced personnel.

Once the resources were verified by the client, each resource completed a two-tiered training program at the corporate headquarters as well as the manufacturing site location. Once on site, **the new team quickly assimilated and began to make steady progress under the direction of the ProPharma Project Manager**, in collaboration with the client QA management.

ProPharma deployed a specialized, quantitative reporting tool that consistently tracked weekly progress across all project sites. The reporting tool effectively communicated site progress to the client's corporate level. Each report provided top-level dashboards, along with site specific granularity for an in-depth snapshot of progress for the entire project.

For project oversight, the ProPharma Project Manager and senior-level leadership stayed in constant contact with each site as well as the corporate office, to ensure total project success. By using the aforementioned project tracker and thorough oversight by the Project Manager, **each site was able to review overall project success, as well as track site-specific progress, in a timely and consistent manner.**

results

Overdue deviation and investigation numbers were substantially reduced to a level that could be sustained by the client with an exceptional level of quality and efficiency.

The efforts of this support were noted by the FDA upon the next inspection and did not result in any observations.

The successful outcome of this collaboration resulted in very positive feedback from the various client sites as well as their corporate team prompting other divisions to partner with ProPharma for similar compliance-related projects.

With a deep commitment to the higher purpose of improving patient health and safety, **ProPharma efficiently deployed specialized resources across multiple sites in a compressed time frame, significantly reduced the client's backlog of overdue product deviations and delivered a successful outcome** with the FDA requiring no further actions.

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