Case Study
R&D

COMPLIANCE WITH TIME-SENSITIVE SUBMISSIONS

Client Challenge
The client, a large global pharmaceutical company, was anticipating an audit by the FDA for several of its time-sensitive submissions. This client did not have visibility in the end-to-end process, was unable to track or report on the status of these submissions, and was at risk of receiving a warning letter for noncompliance. The client required an assessment and optimization of the processes and supporting procedural documentation to ensure compliance with regulated submission timelines and a mechanism for tracking and reporting against those timelines. Some of the identified processes were cross-functional in nature and spanned multiple systems. Aligning functions and streamlining the fragmented systems were key measures for successful delivery.

Red Nucleus Solution
The Red Nucleus team partnered with the client to develop and execute a plan that delivered the needed solution. Their initial assessment identified what worked well, areas of risks/gaps, and activities that required optimization. They established requirements for future success with cross-functional alignment on the identified needs.

The team developed optimized processes to address gaps, risks, and areas of process improvement need. They also developed a process and mechanism to track and report compliance of the time-sensitive submissions quarterly to all relevant senior management stakeholders. Finally, they developed a training, communication, and implementation plan for roll-out. The program included e-learning materials for efficient and streamlined implementation.

Value
Within 6 months of implementing the optimized processes, the client’s compliance rate significantly improved. For example, they were happy to report that the 1572/CV submission process was IMPROVED FROM A BASELINE OF 30% TO 96%.

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