MAINTENANCE OF R&D GxP QUALITY AND CLINICAL VAULTS

Client Challenge
The Client, a large global pharmaceutical company, was in need of support to maintain the newly implemented quality and clinical Vaults as validated systems with carefully managed change controls. The client needed a resource that could understand the needs of both the business in their daily operations as well as the technical capabilities of the systems. The information system owner (ISO) needed day-to-day support to ensure the systems could continuously be optimized per business expectations and remain in a validated state.

Red Nucleus Solution
The Client engaged a Red Nucleus project manager (PM) who served as an informatics business liaison, managing the ongoing change requests coming from the business, mitigating system risks/issues and supporting continuous enhancements. The PM reviewed the various change requests and categorized the type of change to determine if a formal change control was necessary. The PM then developed and executed a plan to deploy the change to all end users. This included completion of all change control documentation, validation testing, and oversight of its technical implementation. The PM served as a liaison with the business, IT, and the system vendor (in this instance, Veeva) to ensure successful implementation of all change controls.

Value
The Client has an ongoing approach for managing change controls for both the Quality and Clinical Vaults. Change controls are assessed, prioritized, and implemented more efficiently. The operational workload for the ISO is reduced by outsourcing the management of change controls to a trusted and dedicated partner, enabling the ISO to focus on more strategic activities. The Client can now rely on a Red Nucleus resource who serves as an extension of the Client team and understands the organization, the business needs, and technical sides of the systems and their use.

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