END-TO-END RIM

Client Challenge
A large pharmaceutical company embarked on an initiative to replace all core regulatory systems, specifically document management, registration planning and tracking, query/commitment management, and change control. A lack of cross-functional processes and scalable systems reduced the firm’s ability to improve submission cycle times, resulting in an inability of the team to effectively keep up with increased submission volume due to geographic expansion of their products.

Red Nucleus Solution
The Red Nucleus team leveraged our process, technology, and domain expertise in the context of our proven methodology to modernize the client’s regulatory capabilities. We established disciplined data accountability and governance and consistent document management processes across all functions responsible for regulatory submissions. We also created a simultaneous submission strategy for submission in the United States, the European Union, and Japan on the same day. The team developed a core submission package and associated processes to reduce multiple builds as result of growth market expansion. We also recommended and helped implement systems that enabled the strategies above.

Value
The Red Nucleus team delivered end-to-end cross-functional processes, enabled by systems that ensured compliance and value.