



Change Management Eases Transition to New Regulatory Affairs Operating Model

The Regulatory Affairs (RA) group for a major pharmaceutical company was operating as a passive participant in the drug product life cycle. Cross-functional teams were interfacing with multiple representatives from RA and often received conflicting information. The company wanted to make the group an active business partner and harmonize information coming from RA through a single point of contact. A new operating model encompassing process, organization, and technology was designed to provide a framework to achieve these goals. The company engaged IPM to manage the change to the new operational model.

KEYS TO SUCCESS

» Integrated Project Plan

Although the implementation team had a schedule for all the planned changes, it was a static snapshot of activities, requiring manual editing for every update, and could not be used to plan, execute, anticipate, or forecast scenarios. IPM created a fully integrated project plan that acknowledged the interdependencies between tasks, as well as communications, team member roles and responsibilities, risks, resources, and the elements of change that would result from the new model.

» Open Communication

IPM provided opportunities for stakeholders of the new operating model to understand the reason for the change and how it would affect them. IPM incorporated question-and-answer sessions at internal training events and routine meetings between regulatory leads and senior management. IPM also created and disseminated surveys throughout the transition to capture feedback and respond accordingly.

» Metrics

IPM created a dashboard tool to track and communicate the organization's adoption of the new operating model, allowing senior management to gauge their success and progress. Metrics included the number of product team meetings held under the new operating model, percent compliance with new monthly reports, and involvement of RA functional areas in the new operating model team meetings.

RESULTS

IPM facilitated the pharmaceutical company's transition from a reactive to a proactive organization by speeding the adoption of the processes, tools, and templates.

in the new operating model, addressing staff concerns with sensitivity, and addressing resistance when it arose.

IPM morphed the initial static implementation schedule into a fully integrated plan, allowing the team to prioritize activities, communicate progress, and manage resources with such efficiency that they were able to reduce team headcount and still meet key milestones.

The operating model was rolled out to the organization on schedule and staff survey results showed a more than 95 percent favorable rating for changes. Informal assessments of key stakeholders showed positive support for the new operational model. ■

IPM was engaged to execute a blend of project management and change management best practices to win the hearts and minds of the RA employees and encourage them to embrace the new operating model.

