Automated Change Control System in Just a Few Weeks

Industry: Pharmaceutical

A leading Global Pharmaceutical Company implemented changes to internal operations through a series of paper forms and emails. Per GxP practices and to help ensure quality standards, any change required a multi-stage review focused on its impact, implementation details, and effectiveness.

The company's change control process woefully lacked scalability. No matter how big or small, a single Change Request (CR) required every impacted business group to approve multiple implementation stages via asynchronous emails. Multiple managers directed the process by meeting with direct reports, tying up precious time for many employees. With dozens of business groups potentially involved, CRs generated tangled spiderwebs of email chains,

signatures, and document versions. Trouble with accountability and responsibility arose as each group was subject to different priorities and tried to coordinate entire networks of people.

Physical documents served as artifacts for the change process, causing problems with accessibility and traceability. CR Admins were forced to search for and collect needed documents - often "reinventing the wheel." A single document locked in an absent employee's desk could bring CRs to complete standstills. To make things worse, CR admins struggled to identify these bottlenecks due to a lack of reporting mechanisms. Performing audits on changes, as regulations require, necessitated weeks of dredging up archived emails and documents, as

Challenge Continued

well as any team members who implemented the changes. Finally, there was little-to-no feedback loop to measure a change's effectiveness once complete. This system ultimately proved chaotic, leading to information getting lost and change initiatives getting stuck.

Solution

Macedon started by leveraging the existing CR process and automating its five stages (Impact Assessment, Implementation Prep, Implementation, Closure, and Effectiveness Check) into a Stage and Gate system with centralized comments and documents. We converted CRs into Appian records, creating dashboards to consolidate all relevant process details and presenting CR-related actions to the user. We replaced the email chains that were used to assign and track approvals with automated task assignments, enforcing accountability and ensuring that staff involved with the CR know what's expected of them without them having to wait for a manager's direction.

We represented functional areas with Appian Groups, allowing for granular granting of approval permissions. We implemented News Feed notifications, providing a single location for impacted individuals to watch each step of a CR's progress. The new system allows each team member an opportunity to capture comments relevant to their part of the approval process. It provides document upload capabilities, enabling users to capture a complete record of each change in an easily accessible, central place. The system offers advanced audit-related reporting (a GxP requirement), allowing CR admins to track every adjustment directly from CR Records. Other reports include process metrics, giving insights into potential process bottlenecks and allowing for further streamlining.

Results

The new Change Control system gives CR Administrators the power to efficiently and effectively drive necessary change through all corners of the organization. Regarding scalability, CR Administrators have processed upwards of 700 new change requests per year, distributing tasks to over 250 unique users. The new solution reduced the regular auditing process from weeks to hours. Four years after initial deployment, the system continues to perform as the organization's single source of truth for CR information.

Impact Assessment — Stage → Gate → **Implementation Prep** — Stage → Gate → **Implementation** — Stage → Gate → **Closure** — Stage → Gate → **Effectiveness Check** — Stage → Gate

About Macedon Technologies

Macedon has improved business processes and developed automation software since 2009. We offer first-class intelligent automation to evolve the way businesses work and achieve better outcomes. We help organizations connect technology to their core business model while aligning it with the marketplace and their culture.

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