

## Grifols

Industry: Life Sciences | Process Focus: Change Control Management

Grifols is the world leader in plasma industry with more than 250 dedicated plasma donor centers across the United States, Europe, and Asia and facilities in more than 100 countries around the world. Grifols has more than 75 years of improving people's health producing essential plasma-derived medicines for patients and providing hospitals and healthcare professionals with the tools, information, and services they need to help them deliver expert medical care.

### Situation.

Grifols handles more than 700 Change Control Requests (CRs) for the Plasma Division every year, driven by a variety of needs and initiatives. The CRs are handled by administrators that must manually verify each request for its completeness and validity. The administrator then assigns the CRs to additional reviewers across several functions to perform impact analyses before being able to close the request.

This review and approval process requires a lot of time consuming back-and-forth work amongst administrators and reviewers. This includes sharing of comments, documents, and other relevant data, executed in siloed systems including email and spreadsheets.

### Solution.

Grifols sought to establish a streamlined system to initiate, review, validate, track, and close all of their CRs. They needed a solution that could orchestrate end-to-end change control management, with appropriate forms to capture CR details, task assignments, review and approval cycles, document uploads, and impact assessments.

#### Additional system requirements included:

- All involved personnel having simultaneous visibility into the process and all comments/analyses
- Approvals being electronically compliant with 21 CFR Part 11
- Dashboards and reports providing tracking and visibility into all change requests
- Simplifying approval cycles and automated notifications to make it easier for individuals to perform their tasks in a timely manner
- Providing personalized and filtered queues of pending tasks and status to the team involved
- Providing a full audit trail of each CR and associated changes to be maintained in the system

### Implementation.

Grifols chose Appian's low-code platform to help innovate their change control management process. Appian helped bring Grifols' system from idea to deployment in 18 weeks. With the new solution, Grifols is now able to efficiently and effectively manage the constant influx of CRs with enhanced capabilities:

- Electronic submission of change requests (CRs) with automatic assignment of CR Number upon submission
- Automated suggestion of task assignees as well as default due dates calculated automatically
- Automated Email notifications for changes made to the CR, task assignment and completion, and reminders for overdue tasks
- Enhanced compliance and better handling of complex GxP logic, with automation and compliant Electronic Signatures on submission, authorization, and approval
- Real-time process visibility into the status of CRs for relevant participants across all departments with audit trail
- A single, unified view of each CR with a repository for all related documents needed for review and approval

### Results.

- 83% reduction of data entry and CR filing time
- Reduced from ~180 minutes per CR to ~30 minutes per CR
- 62.5% reduction on tracking and follow up
- Equivalent to 2,010h of labor savings per year
- Time spent on tracking and follow up reduced from 8 hours/week to 3 hours/week
- Stayed on budget, even with extended testing time
- 75% faster development time
- This process has gone from paper-based to paperless



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