

Web-based tracking system goes worldwide to speed critical decision-making process

A global medical company needed to capture information and make decisions on a worldwide basis about product performance issues that could impact patient safety. *But the manual process was slow and inefficient.*

Background:

Mallinckrodt Inc. is a leading global manufacturer and marketer of specialty medical products and pharmaceuticals. As with all medical products, events may occur during the manufacture or use of Mallinckrodt's product that may impact patient safety.



When such events occur, information must be gathered and shared among various departments as rapidly as possible. After analysis, a field action plan is developed and

approved that outlines the company's response. The plan typically includes a formal response to the FDA or other worldwide regulatory agencies, and may indicate that a product recall is required. Considerable effort is expended to assure that the company's response is not only timely and accurate, but also medically and legally appropriate.

Situation:

Development and approval of a field action plan requires expert input from many different business groups, including Legal, Medical, Manufacturing, Quality, Regulatory and others. With groups located all over the world, information was being communicated by fax, phone and e-mail, often with several different people trying to consolidate details. When a final draft was circulated by mail for sign-off, even the slightest change required the process to be repeated.

Mallinckrodt's situation became more complex as new businesses and product lines were acquired and the company expanded into new geographies.

Response time diminished and more and more administrative effort was required to coordinate the review process.

Solution:

Mallinckrodt partnered with Cornerstone Solutions Group to develop a *web-based, issue-tracking and decision-management system* that significantly reduced the time and effort required to capture information, gain consensus and approve field action plans.

The application runs on a secure Mallinckrodt intranet web server and is available to authorized personnel worldwide. A system profile controls each user's ability to make changes. For example, a Quality officer may have complete administrative capabilities, while a Public Relations manager may have only viewing privileges.

When a new issue is created, an e-mail is automatically sent to the appropriate employees, alerting them that their input is required. Employees access the system through their web browsers and work at their convenience across time zones. Information about the event is captured on standardized forms and stored in a SQL Server database. As details of the situation are confirmed, key reviewers input their expert opinion regarding how to understand and respond to the event.

A threaded history log records their comments, helping all reviewers to track the discussion and arrive at the best possible consensus decision.

When each reviewer is satisfied with the details of the plan, he or she approves the document independently.

If needed, a conference call among all reviewers facilitates final changes in real-time. Once approved, the owner of an issue "locks" the field action plan, thereby formalizing the decision. This ensures integrity of the plan as it is disseminated through the company and reports are distributed to regulatory agencies.

Depending on the nature of the issue and the response required, up to four different consensus decision-making steps may be needed. The unique information and reports that are required for each step are built into the system, allowing Mallinckrodt to provide a repeatedly consistent response to regulatory agencies.

Testing and Validation:

Cornerstone wrote and implemented an extensive test plan to validate the performance of the software. The test methodology was designed to comply with Mallinckrodt Quality Assurance standards and FDA Good Manufacturing Practices (GMP). The testing validated not only that the system meets all design requirements, but that overall business processes are supported and end users' needs are met.

Benefits:

The new system provides several key benefits for Mallinckrodt:

Faster Decisions:

The system allows Mallinckrodt to capture and share information among departments much more quickly. Because paperwork is eliminated and users have instant access to current information, issue resolution is speeded up dramatically. Consensus review is often completed during a single teleconference, rather than in an extended series of separate phone calls or meetings.

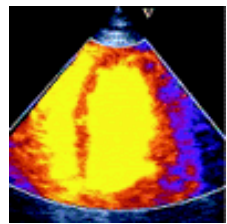
Better Decisions:

When reviewers have access to the same data, it is much easier to share opinions and gain consensus. The real-time collaboration of different experts results in superior analysis that greatly enhances the quality of the plan.

Improved Quality and Documentation:

Previously, variations among different reports would cause internal confusion or unwarranted concern from regulatory agencies. Because the new system consolidates all information in one database, the data in all reports is represented uniformly.

The system also provides an important tracking function. Once a consensus decision has been reached, the threaded history discussion is deleted and only the final approved answers are recorded. These answers cannot be changed retrospectively, only amended or modified in new versions of the plan. Should a legal or regulatory audit be required, a clear record of all formal decisions can be easily generated.



Increased Throughput:

Because administrative logistics are taken care of by the system, Quality Assurance employees have more time to focus on analysis and decision-making. As a result, more field action issues can be handled at any one time.

Reduced Administrative Workload:

Information is easily entered into the system by whoever first receives it or has access to it. Less time is spent re-keying data gathered from other departments or third parties. Resending lost or misplaced e-mails and faxes has been eliminated.

*With Cornerstone Solutions Group,
Mallinckrodt has found a partner to help
keep quality on track.*

