



CASE STUDY

Improved Safety and Quality Issue Handling Reduces Medical Device Liability Risks

PROJECT BACKGROUND

A leading global medical device company engaged Integrated Project Management Company, Inc. (IPM) to ensure one of its business units was not only compliant, but also proactive and productive in following the company's Corrective Action and Preventive Action (CAPA) process. The unit had a history of not always handling the CAPA issues on a timely or efficient basis, presenting undo safety and liability risks. The General Manager of the business unit faced an overwhelming challenge to meet the requirements of the parent company's global CAPA standards due to a lack of organizational competency and resources. The General Manager believed that IPM was uniquely qualified to tackle this project based on IPM's familiarity with the company's culture, processes, procedures, and its proven track record of enabling it to reach its goals faster and more reliably on other critical projects.

IPM'S SOLUTION

In order for the business unit to become compliant with creating, managing, and closing CAPAs per the new global standard operating

procedure (SOP), a cross-functional team was pulled together and a number of ambitious goals were identified:

- Harmonize the business unit with the new global SOP for creating, managing, and closing CAPA issues
- Clearly define roles, responsibilities and accountabilities for handling CAPA issues
- Leverage key stakeholders' experience and expertise to achieve tighter control on the ever changing quality standards
- Identify the most efficient way to maintain control of product quality within the organization's mandated quality systems
- Enhance cross-functional communications
- Train key technical, business, and quality personnel to not only provide technical input and to solve problems, but to be more proactive with product quality IPM provided the tools and discipline needed to identify, prioritize, manage, resolve, and follow-up on every CAPA issue.

By working with key stakeholders, IPM facilitated the development of CAPA

metrics for time to completion and quality of content. At the same time, IPM developed a CAPA project plan and schedule to manage resources, create and assign tasks to appropriate staff, set expectations, and track activities to established due dates. Since there were so many interdependencies, the project plan was linked with critical business projects to create a single business portfolio approach. Customized templates were designed to instantly escalate issues that may otherwise be overlooked, and a dashboard report developed to provide stakeholders and management with actionable information. Finally, training was implemented for the business unit team members on the new processes required to harmonize with the corporate CAPA quality system.

PROJECT RESULTS

This project resulted in reduced turnaround time, and the consistent and accurate handling of all CAPA issues. Because the business unit achieved 100% compliance with the corporate CAPA standard, its safety and quality risk exposure was dramatically diminished. These results were achieved through significant

improvements in communication and collaboration between the various functional areas and business units within the organization, which enabled the solving of business critical issues before they manifested into larger issues. The overarching portfolio plan enabled appropriate resourcing, prioritization, and budgeting for all critical business programs.



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