



# CASE STUDY

## Focused Effort Enables Market Re-Entry of Medical Device After FDA Withdrawal

### PROJECT BACKGROUND

After several patients died following treatment by a widely used medical device, its global manufacturer and the FDA entered into a consent decree, halting worldwide sales of the product until problems were fixed. In addition to correcting defects in the device, the company also had to remediate the product's design history file (DHF), which had fallen out of FDA compliance. The DHF not only failed to reflect changes made to the product during the years it had been on the market, but both FDA regulations and the company's own internal requirements had changed in the interim.

Generating more than \$150M in revenues annually prior to the withdrawal, the product played an important role in the company's portfolio.

To lead the remediation effort, the company engaged Integrated Project Management Company, Inc. (IPM), which accepted direct accountability for the success of this critical project.

### IPM'S SOLUTION

IPM first assembled the company's regulatory experts to review the existing DHF. After a thorough analysis, the group determined that it was impractical to fix just the document. Instead, the company had to recreate the DHF from scratch—an enormous undertaking.

IPM immediately prepared a project plan to guide the effort, which, to succeed, would require the dedication of a highly focused cross-functional team. IPM conducted a stage gate review with company leadership to secure their buy-in and formal approval.

After the go-ahead, the project team moved to a remote area of the corporate campus to reduce day-to-day distractions and start building team unity, which was strained by functional silos and internal politics. The IPM project leader used objective facilitation to engender trust and collaboration among team members, without which they would be unable to meet the aggressive project timeline.

During creation of the DHF, IPM helped the team solve problems and make fact-based decisions quickly and efficiently, ensuring that the project stayed on track.

To keep everyone in the loop at all times, IPM produced weekly project dashboards and conducted daily status meetings, frequent project reviews, and leadership presentations.

Along with providing technical expertise for structuring the DHF documentation, IPM helped the company to develop its FDA review and response strategy, and prepared documentation for FDA communications.

### PROJECT RESULTS

The team completed the DHF in three months (which was ahead of the FDA-mandated schedule), using half of the resources the company had originally projected.

The FDA deemed the new DHF in full regulatory compliance. The company resumed sales of its device.

