



Beyond Compliance: Device Firm Reaps Benefits from Project Leadership

Big new legislative requirements mean big changes at even the most efficiently run companies. But when the company uses project leadership to incorporate those changes into its larger business strategy, the benefits go far beyond compliance.

That's what happened at a global medical device manufacturer that hired Integrated Project Management Company, Inc. (IPM) to help it comply with a new FDA labeling mandate. Besides helping the company successfully beat the compliance deadline by two months, thoughtful planning and communication also led to breaking down barriers between divisions, laying the groundwork for meeting future compliance requirements, and evolving technology that will help the company grow over the next 10 years.

MEETING A GOVERNMENT MANDATE

It all began in 2012, when the U.S. Food and Drug Administration (FDA) announced that all medical devices distributed in the U.S. required a unique device identifier (UDI) code. The objective was to develop a standardized way to identify devices across all information sources and systems, including electronic health records and devices registries. The effort would require relabeling four Class II pumps and 500 different accessories, such as tubing and IV sets, manufactured at three different global plants. Device manufac-

turers also had to submit product information for each device to the FDA's Global Unique Device Identification Database (GUDID), which is accessible by the public. The compliance deadline for Class II products was September 2016.

Realizing the complexity of the project, company management decided it would be best managed by an outside firm with no internal distractions or biases. In January 2013, the company hired IPM—not only to oversee the project at hand, but to provide solutions that would help the company grow in the future.

PLANNING COMES FIRST

IPM began by developing a plan for how to approach the massive changes involved in the UDI transition. Much of the complexity involved the looming compliance deadline that required all products to comply simultaneously. This meant defining and coordinating efforts across six specific work streams: consumable management division, medication management systems, differentiated drug delivery, third-party manufacturer, data collection, and GUDID—as the company's existing SAP system had to be modified to accommodate a global attributes database that could interface with the plants and GUDID. Keeping an eye on future growth, IPM also recognized that the systems had to support global evolution, and needed to be scaled appropriately.

Adding to the challenge was the fact that each of the three manufacturing plants had its unique project solution with its own local equipment suppliers. Following this course would have required corporate—which provided all the information to be printed on the labels—to manage three different delivery approaches.

The company needed a more unified solution that not only met the needs for UDI, but also set the stage for future capability evolution. IPM recognized that a multi-site, team-based approach was required.

CREATING A DEDICATED TEAM

To encourage cooperation and expedite the compliance process, IPM visited all three plants and met with the 35 to 40 people at each location who would be working on the project, including resources from procurement, IT, and administrative functions. This helped build trust and prepare the team for the hard work ahead.

In some cases, employees from different plants had never met before, let alone worked together. By program completion, they were a unified team sharing experience, solutions and lessons learned. This was essential to keeping the project on schedule.

As part of this effort, the plants also needed to replace 20-year-old production line and packaging systems at 21 work stations that were incapable of interfacing with the new SAP systems and databases required to drive the printing. This was the project's biggest capital expense, at more than \$20 million.

As it turned out, one of the plants, which manufactured pharmaceuticals, had already developed a solution based on the practice of manufacturing products individually by serial number and barcodes. By borrowing and enhancing this concept, the two device manufacturing plants could not only meet the needs for UDI packaging and labeling, but could also eventually transition to a serial number-based method in the future as FDA requirements evolve for

product traceability. IPM and the company team decided to use this solution for everything: pharma, pumps, and accessories. This economy of scale also reduced equipment costs, in some cases by as much as 20 percent.

WITH AN EYE TO THE FUTURE

Thinking ahead, IPM helped implement a system that will adapt to future demands with the built-in capability to print labels in real time via on-demand printing. Since the current label definition and vendor sourcing lead time can take over three months, this will be a major benefit for the company as it evolves and streamlines its manufacturing processes.

The medical device manufacturer began printing with the new labels in July 2016, and by July 31 was fully compliant with FDA requirements—two months ahead of deadline and within the scope of the original plan laid out three years earlier. The best practices employed by IPM over that time helped evolve the overall maturity of the sponsor's project management organization. Before the UDI project, very few projects came in on time. By the end of UDI, the techniques for proper project scoping, planning, communication, and execution were being modeled across the organization.

PART OF THE TEAM

Before the conclusion of the project, IPM worked closely with the company's management team on the transition and provided them with a guidebook of detailed information for staying on track with future compliance and evolving FDA and global requirements. After being embedded in the company's team for more than three years, the lead IPM consultant was honored by his coworkers with a commemorative plaque recognizing his dedication to the team.

The project sponsor stated that the real benefit delivered by IPM was the ability to keep the company's best interests front and center. IPM's value was not only meeting the compliance deadline, but looking beyond the immediate requirements and providing a forward-thinking solution. ■