



Ensuring FSMA Compliance at a Major Food Company

Even the biggest, most efficiently run companies can be overwhelmed by the need to quickly comply with sweeping new federal regulations. And when a company runs lean, it can lack the resources to devote to time sensitive, complex, and intensive projects that require major operational changes.

The FDA's Food Safety Modernization Act (FSMA) is a new regulation that affects every aspect of a food manufacturer's business, including the entire supply chain—a new requirement in the food and beverage industry. A large company producing 16 of the top 50 brands of ready-to-eat cereal was required to follow the FSMA rule mandating Preventive Controls for Human Food by Sept. 19, 2016.

This meant the company needed to develop 45 separate food safety plans (FSPs) to cover all of its facilities and production lines and have them internally approved on or before the Sept. 19 deadline.

Although management had spent months educating themselves on FSMA, they recognized that the project's magnitude would strain their resources. By June, they had created an FSP template and established some milestones, but the project lacked a point person to drive it through execution. Additionally, the company is a

lean operation with less capacity to manage a project of this size, complexity, and tight timeline. QA managers at its plants were fully consumed managing daily operations and unavailable to take on this type of responsibility.

Recognizing it needed help, the company turned to Integrated Project Management Company, Inc. (IPM) to create a strategic roadmap for closing FSMA compliance gaps; develop an integrated program schedule with realistic timeframes identifying major interdependencies, responsibilities, and constraints; and help execute this plan.

Because time was tight, IPM and company management decided that execution would run parallel with the planning phase to hit the FSMA deadline.

As the project unfolded, several issues came to light. The team's focus on developing detailed FSPs was slowing down their development. IPM addressed these concerns by pinpointing the need to reallocate resources to targeted plants that were getting bogged down in the process. This was accomplished by stepping up meeting frequency to address questions of how to interpret specific elements of the FSMA regulation and expediting the internal approval process.

By July, IPM had helped accelerate the project by using weekly stakeholder meetings to review and resolve issues while closely monitoring progress and adjusting resource assignments as necessary.

By Sept. 14, the company had submitted 37 FSPs for internal approval, with the remainder submitted by Sept. 17. After hitting the deadline, IPM began to transition the FSMA-related tasks to an internal company supervisor, who became responsible for ensuring that remaining action items were closed out appropriately.

However, FSMA compliance didn't end with the project's completion. FSPs are living documents that must be updated as plant production and other variables change, requiring ongoing involvement to ensure that

each FSP remains evergreen and robust. The control and communication plans developed by IPM and the appointment of a primary point person will help the company complete these and other FSMA-related tasks, including standard operating procedure (SOP) changes, employee computer-based training, FSMA training, FSMA compliance as it relates to the R&D process, and oversight of future FSMA regulations.

The need to adapt to change extends beyond FSMA. In today's fast-paced business world, change—whether by government mandate or market conditions—is inevitable. Lean organizations must be prepared to act quickly to identify these changes and properly identify and allocate resources to address them. ■

THE IMPORTANCE OF FOLLOWING PROCESSES

Since the mandate for FSMA compliance had been in the works for some time, most company stakeholders knew what needed to be done; the issue revolved around how to reach the regulation's goal. One of IPM's first priorities was to develop a comprehensive project plan to start moving more quickly and collaboratively toward compliance. This included developing:

- » *Workstream and program schedules, updated weekly to include risks or concerns, with timeframes identifying major interdependencies, resource responsibilities, constraints, and paths between different workstreams for each plant*
- » *Action item lists, providing assurance that nothing would slip through the cracks*

- » *Team structure charts defining individual roles, responsibilities, and decision-authority levels*
- » *Communication plans, outlining stakeholder management plans and individual one-on-one meetings*
- » *Scope management plan for the sponsor to keep FSP execution on track*
- » *Risk management plan with mitigation strategies.*

Most organizations have the subject matter knowledge and expertise to address FSMA and other regulatory and quality mandates and/or initiatives. Often what is missing is the plan and orchestration that efficiently integrates and applies these talents to assure rapid and efficient execution and sustainability.