Compliance Issues? FIRST, DON'T PANIC.

A hurricane is coming. You heard about it on the radio. Everyone in the family jumps to it. You rush to the grocery store and pile as many cans of Chef Boyardee as will fit in your cart. Your spouse nails boards across the windows. The kids run around the house collecting candles. But when the storm hits, you realize you have plenty of ravioli but no drinking water, windows that are protected but a neglected leak in the roof, and candles but no matches.

It would have been far better to stop. Take stock. Make a well-coordinated plan based on the requirements and realities of your situation. Then take action.

The same goes for addressing a regulatory compliance issue. Whether a 483, a warning letter, a recall, or a consent decree, it's all hands on deck, to be sure. But a rigorous process-driven approach helps secure the outcome you want, and ultimately provides the fastest path to get you there.

Rule No. 1: Take a deep breath.

When a regulatory compliance issue is identified, especially a serious one, everyone leaps into action. But speed without structure can make things worse than they are already. Although the clock is ticking, to prevent missteps and redos, it's important to spend the time to thoroughly examine the issues raised by the regulator and build a rock-solid plan to address them — before the "go, go, go."

Rule No. 2: Dedicate a full-time project manager.

A dedicated, experienced project manager is a must for pharmaceutical regulatory compliance programs, when it's absolutely essential to hit the mark.

He or she knows how to guide the development of an airtight project plan based on objective analyses; to make sure the web of activities remains coordinated; and to facilitate rapid problem-solving when the team hits the inevitable speed bump or two.

Rule No. 3: Fully understand your regulatory requirements.

It's not unusual for a company faced with a compliance issue to seek a swift remedy and misunderstand the true depth and root cause of the problem. The result? The fix doesn't fully address the agency's requirements. Then you've really got a problem. For a successful outcome, make sure you thoroughly understand the regulator's expectations. Then build into the project plan regular oversight by your regulatory group as the project progresses, to ensure that every activity ties back to agency requirements.

Rule No. 4: Prioritize and pressure test.

Complex issues require complex remedies. But trying to do too much can be as detrimental as doing too little, resulting in confusion, errors and missed deadlines. When building your project plan, identify each activity required to get the job done. After squeezing out slack time and bottlenecks, can you meet your regulatory deadline? If the answer is "no," can you identify any "nice to haves" that you can drop from your to-do list? If still "no," you know it's time to add or reallocate resources, or appeal to the agency for more time. Then retest your plan.

Rule No. 5: Be vigilant but flexible.

Stick to the project plan but maintain flexibility. If the schedule starts to slip, find out why. Problem with one of the personnel? Major holdup in one area freezing the entire project? Investigate, fix it, then adjust your project plan to match the new reality.

Rule No. 6: Make sure it doesn't happen again.

Once it's all over, debrief. How did you get into this mess in the first place? Problems can stem from a failure to keep up with rapidly changing regulations or from the mindset that "we've always done it this way." It's common nature after a major, stressful push to want to quickly get back to work. But taking the time to evaluate what went wrong is well worthwhile. You'll raise the quality of your operations and strengthen your organization overall.

To illustrate some of these principles in action, read the case study of:

How a global biopharmaceutical company faced doom and emerged unscathed

It wasn't a good day. Management had received a warning letter citing nearly 90 observations at one of their manufacturing plants, ranging from contamination problems due to faulty aseptic procedures to inadequate document storage. The plant told the corporate office not to worry; they had it covered. They'd been operating for decades. It would turn out fine. But the facility's track record on delivering had not been stellar. Management assigned a seasoned project manager to assess the facility's plan and progress.

The pressure was on. The corporate quality

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manager had invited the FDA to visit the plant in a couple of months. After issuing the warning letter, the agency could show up again anytime. Management decided to take some control over the timing by inviting them back proactively.

Making a list

Upon arrival, the first step taken by the project manager was to create a list of projects; not just of those related to the warning letter, but of all projects facility-wide, to get a handle on the full scope of activity at the plant. For the first month and a half, the project manager met with every single person who was leading a project. "Project" was defined as anything with a definite start, definite end, and that required resources. The resulting list — nearly 40 — was far bigger than expected. Though he'd sensed it, the facility manager was taken aback at how much was underway at his plant, which, until all documented in one place, had not been apparent.

Prioritizing

With the list in hand, it was now possible to prioritize projects based on how critical they were to address the warning letter. The project manager worked closely with the corporate QA group, comparing the list of observations against the plant's current project list. Line by line, which projects were compliance-driven? Where were the gaps? What current projects could be cancelled or postponed in order to reallocate staff and budget to compliance projects? In the end, about a quarter of the less-than-critical projects were put on hold, such as the relocation of a lab support facility and balanced scorecard implementation. The compliance projects to address the warning letter were then themselves prioritized.

When the FDA came for their follow-up site visit, management now had a list of projects demonstrating exactly how they would address every one of the agency's concerns.

Recipe for disaster

During his initial interviews with team, the project manager quickly realized they were all rushing toward a cliff. The bulk of the compliance work was planned to take place during the facility's usual summer shutdown. The plant would cease operations to replace several systems and make other major fixes, so the timing was ideal. But the scope of each project was enormous, comprised of huge lists developed in concert with the corporate regulatory and quality groups. The project manager asked the facility team if they'd be able to get all activities done in the time allotted. The answer: an unequivocal "no." But the corporate message had been "get it done." No excuses. So the team committed to doing it, and they'd give it their best shot.

Evidence-based solution

To skirt catastrophe, the project manager worked with the facility team to develop three scenarios:

- **Scenario No. 1:** The "schedule" scenario assumed the facility must complete as much as its compliance work within the designated summer shutdown period as possible. Given the current project scope, what activities would the team have to remove to provide 100 percent confidence they could meet the schedule? Result: They would have to eliminate so many activities and thus would accomplish so little that they'd meet none of the regulatory objectives. The FDA could shut them down.
- **Scenario No. 2:** The "full scope" scenario was at the other end of the spectrum. If the team were to perform every single activity on the project list, how long would it take? Result: As expected, it would take many months more than the FDA would accept and than the business could maintain supply continuity.
- **Scenario No. 3:** The "balanced" scenario was prioritized based on the regulatory viewpoint. What were the absolute "must haves" that would satisfy FDA's requirements and prevent a plant shutdown? What could they wait to do later? The team assembled that list, and projects were prioritized into tiers. Next: How long would it take to perform these projects? Calculations showed that the shutdown would start slightly later and last slightly longer than the original summer shutdown timetable, but the facility could build up adequate inventory in advance, and they'd meet the FDA's timetable.

Building the three scenarios took almost a full month: gathering data, developing detailed schedules and identifying resource requirements. It was time well spent. All scenarios were presented to corporate management, with the third "balanced" scenario as the team's recommendation. The official corporate response: "It's a no brainer."

Tightly integrated, fully orchestrated

To stay within the "balanced" scenario schedule, every activity had to be carefully coordinated. The original plan had included four projects. They were integrated into a single program, led by one program leader and four sub-project team leads. The overarching plan had to be extremely detailed in terms of timing, handoffs, and sequential and parallel activities. Otherwise, at some point, 20 people would suddenly converge into a five-by-five-foot space to work.

During execution, the program leader and project managers stayed close to their teams to ensure they had what they needed to meet the schedule every day, problem-solving as necessary to keep the projects on track. Due to frequent communications, facility and corporate management remained fully in sync throughout.

Outcome

The facility met its targets, the warning letter was lifted, and a shutdown was avoided. The organization as a whole improved its ability to plan and execute complex projects. And the corporate culture evolved to keep more ahead of the curve on regulatory compliance.

Tackling difficult compliance issues is not easy. But a process-driven approach provides an objective framework for regulatory success. No missed deadlines. No failed requirements. Plenty of matches. PV

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