

Leadership in Regulatory Compliance Crises

THE QA PHARM

By THE QA PHARM



It's a most unfortunate ailment of epidemic proportions that the approach taken by many when addressing underlying CGMP compliance issues is effectively based in a checklist mentality — a to-do list. For sure, solving fundamental regulatory compliance problems involves tactical work that is broken down into discrete executable steps. However, I become more convinced every day that the most significant challenges in life — regulatory or otherwise — are more about “being” rather than “doing.”

“Being” requires an examination of personal character and motives. It takes a deep dive into ones willingness and ability to put self-serving interests aside and share a common vision — and for Pete's sake — work together.

Working together is hard work in the best of circumstances, but when faced with transforming an organization from non-compliance complicity to embracing standards and discipline, there is no room for silos and bunkers. What is needed; however, is a central figure — a standard bearer — that rallies the troops and encourages them to great achievements in the face of insurmountable odds.

So when the implication of a consent decree finally sets in, and when you realize more than ever that the all troops need to march in the same direction — what do you do?

1. Be the visible leader.

Face it. Most company management couldn't find packaging line number 3, not to mention know how to converse with a second-shift hourly worker they have never met. But leadership soon recognizes the need to reach out to everyone, and becomes a quick study on how to do it. A leader is personal and accessible in times of trouble. Everyone needs to know and see who is in command of the situation. Lack of visibility builds distrust and people start thinking about their employment options.

2. Accept responsibility.

Blaming the FDA for a tough inspection is not the way to be credible. The workers know better, and chances are, they have been trying to tell you for years about what hasn't been working. Leaders accept full responsibility no matter what. It becomes readily apparent to the rank-and-file whether or not there will be any significant improvement by sizing up management acceptance of responsibility. Without it, there is no reason to expect any lasting change. That's when folks dust off their resume.

3. Rectify the situation.

Fix the problems. Fix it with your regulators, your customers and your employees. Chances are that production has stopped, workers' hours reduced, and inventory is depleted. When it's all over, make it right with everyone. Make them whole. Regain their trust. Your ability to compete and survive depends upon it. Your customer base and eventually your stock price are a vote of confidence. Efforts must be aligned and focused on the real problems, even if the real problem is management. When employees don't see the real issues being addressed, they see the clock ticking and start floating their resume.

4. Solicit help.

Admit when you need help. You may have been rewarded in the past for your lean machine. But if you look around and find that your most experienced technical people took the early retirement program as part of your reduction in workforce program, swallow your pride and hire them back as consultants and contractors to help out. They will be happy for the work, and the going hourly rate will be far more than they were paid when they worked for you. But it will be worth it to them. Consulting groups are often necessary — even mandated by the court — but remember: You run your company. You have to sustain the operation when they leave. In the end, the support must be coordinated to avoid chaos. Don't just turn them loose. When things get chaotic, people start interviewing.

5. Be open, honest and fair to employees.

Don't make false promises. They would rather hear the truth — from you, not the locker room. However, most of the solutions to the real problems lie with the people doing the work. Invite them into the process of fixing the problems. Your credibility will be based on their prior experiences. If you need key people to hang in there

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with you, make it worth their while with retention incentives. If you need them, give them a good reason not to jump at the next good offer.

6. Communicate.

Communicate the problem, the plan and the progress. Make the communication personal. Employees know the difference between when a PR firm has written your sound bites and a message from the heart. Single sites are easier than corporate networks to communicate, but figure it out. It still needs to be direct and personal. Forget about keeping secrets thinking that this regulatory-legal type work is super sensitive. Everything is available on the web or Freedom of Information. Secrets are sometimes so well kept that people doing the work don't know what commitments have been made to the FDA, or what they're supposed to do. That's when you'll look around and find nobody there to communicate to. They've gone to the competitor.

So, while you're occupied with "doing," don't forget the "being."

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