

What Does Operating in a State of Control Mean?

THE QA PHARM

By THE QA PHARM



Once upon a time, I asked this question of a senior management group at an off-site “strategy” meeting. You know — one of those meetings where a working breakfast was followed by a day of golf, and I was the one doing the working.

The question was particularly germane to the purpose of my invitation, because these executives did not want to follow the path of other major industry giants into ruin by taking their eye off the proverbial cGMP compliance ball.

After a bit of awkward silence, someone offered a stab at the answer: Zero defects. Another rebuked his colleague: That’s so passé. It should be “Right first time.” The next 10 minutes was Battle of the Buzzwords, and I was the game show host. Conversation erupted in a murmur across the room.

I responded by saying that perfection was a worthy goal, but statistically impossible. I am highly suspicious of perfection, and firms that punish less than perfection drive bad behavior. In fact, when things are too perfect — I suspect fraud.

That quieted the room.

To operate in a state of control does not mean perfection. It does mean, however, the capability of a firm to detect and self-correct trends before it becomes a problem. And whenever a problem does emerge, the firm is capable of taking action to understand the reasons behind the problem, and making decisions that favorably

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affect the trend or prevent recurrence of the problem.

To make this more relevant, I drew an analogy with the Sales and Marketing Department.

Their markets are broken down into regions and further into territories. Each territory manager has sales targets that they track and report up to the regional director. The regions report to countries. Eventually, all the performance metrics reach the company boardroom. Unfavorable trends and problems are investigated, decisions made and actions taken. An eye is kept on the metrics to see if their decisions and actions were effective.

There is nothing here about perfection.

In this analogy, the market represents the quality management system, and the regions and territories are its various parts organized by discipline. The territory managers, regional directors and boardroom are the system owners and responsible management that exercise governance. Sales performance metrics are quality system performance metrics.

It was one of those beautiful “aha” moments.

I was intentionally being provocative with my question because I wanted this group, which was responsible for a multi-billion dollar business, to seriously consider how they were exercising stewardship of their portfolio — for patient and investor.

What they expected to hear were Strategies for Avoiding a 483, but what I gave them was a refresher in Management 101.

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