Don't let these 2 quality nightmares keep you up at night

It's poor quality, not high quality, that is expensive. Staying ahead means staying awake and making the right quality investments.

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Executive Summary

Former CDRH Office of Compliance Director Steve Silverman advises device manufacturers to address two common "quality nightmares": competitors passing them by as they address quality issues and regulatory enforcement actions that can cause them to fall behind other firms. "Good quality doesn't just save device-makers from less-than-baseline compliance; in fact, good quality usually saves money due to fewer compliance deviations," Silverman writes along with his McKinsey & Co. colleagues David Keeling, Enno de Boer and Ted Fuhr in this "Gray Sheet" Medtech Talk column.

There has been a big shift over the past five years in how the FDA and device manufacturers think and talk about postmarket engagement. Before 2010, we saw the agency explaining—and device-makers trying to meet—baseline compliance requirements. Those requirements remain, but the discussion has since turned to product quality.

We see this shift in strategies led by the FDA, for example, with its Case for Quality initiative that brings the agency and manufacturers together to identify and promote design, production and distribution practices that drive device quality.

For their part, device-makers have also picked up the quality mantle. The Medical Device Innovation Consortium, a public-private partnership between the FDA, industry members and other stakeholders, hosts forums to engage participants on quality-related topics. In parallel, the device industry trade association AdvaMed has developed a Library of Successful Quality Practices, which offers a roadmap to improve companies' quality performance through proven design and production approaches.

Given this changing backdrop, there's little doubt that if asked whether quality matters, senior industry executives would answer with a resounding "yes!"—but that's the wrong question to ask. The real question is whether executives are identifying and deploying class-leading quality practices.

Too often, the answer is "no." We see firms that remain overly focused on meeting basic compliance requirements to avoid costs stemming from FDA noncompliance decisions. Yet while executives worry about whether their firms are compliant, they're not considering two nightmare scenarios that should keep them up at night.

Quality Nightmare No. 1: While you're busy assuring compliance, your quality-capable competitors pass you by.

The common wisdom is that compliance is expensive and that quality is really expensive. This means pulling resources from product development, marketing and other profit centers to support quality, while the FDA holds firms accountable for compliance.

Our experience with quality-capable firms belies this view. Strong quality performance doesn't require more investment. To the contrary, high-quality performance can reduce the cost of poor quality and increase efficiency. Top performers see fewer nonconformances and production holds, meaning fewer investigations, and corrective and preventive actions. In turn, reduced deviations minimize quality costs, allowing firms to focus on product development and meeting customer needs.

These benefits aren't speculative. Among manufacturers of disposable devices we saw a thirtyfold difference in nonconformances between average and class-leading performers. This translates to a cost of poor quality that's five times greater for those average performers. In fact, we estimate that moving to top-quartile performance would increase average performers' profits by 3% to 4% of revenue. This translates to a roughly 14 percent growth in earnings before interest, tax and amortization for an average company.

Put simply, it's poor quality, not high quality, that is expensive. Leaving aside the costs of FDA enforcement, where revenue losses can exceed 20%, even ordinary quality problems can be expensive. We've seen revenue losses of 5% or more when firms have operations staff work to address quality deviations, and when products are lost because of recalls, rework and rejection. Firms that are good at quality can invest those revenue savings in product development, promotion and other activities to help grow market share.

And there's more. Because firms that get quality right have fewer production errors, they also see greater customer satisfaction—a competitive advantage. Clearly, customers include health care providers and patients, but smart firms also think of regulators as customers.

A great example of this is the critical-to-quality pilot run under the FDA's Case for Quality initiative. The pilot allowed the FDA to work with manufacturers and other stakeholders to identify the operations, design considerations, and controls that support quality outcomes. The FDA then linked these factors to its inspectional approach and shared this approach with participating firms.[1]

[1] Related: "Next Step For FDA's 'Case For Quality'? 8 New Guidance Docs" — *"The Gray Sheet,"* Nov. 3, 2015.

Feedback was overwhelmingly positive: Firms described greater transparency heading into inspections and more opportunities during inspections to focus on quality-drivers instead of technical compliance. This focus allowed firms to pull a wider array of participants into quality-related discussions, which helped staff across their organizations to understand why quality matters.

FDA enforcement follows findings of noncompliance, not poor quality. Yet manufacturers that remain compliance-focused are spending money simply to hold their ground. They're not reducing their quality costs and re-investing the savings into product development and expanded market share. They're not building good will with customers–whether they are doctors, patients or regulators. So even when these firms are market leaders, their executives have reason to be up at night: That sound is their competitors using quality to outpace them.

Quality Nightmare No. 2: Regulatory enforcement pulls you behind your competitors.

Basic compliance isn't good enough because it cedes competitive ground. But there's another critical problem: Manufacturers that focus on compliance in place of quality might fall down on both fronts. First, these firms ignore practices that drive product quality. For example:

A device benchmarking analysis showed that sites with low-quality products tied critical control points to defined critical quality attributes 61% less often than top-tier firms.

The same analysis showed that low-quality sites were 33 percent less likely to assess suppliers in relation to their ability to meet critical quality attributes.

More to the point, bad quality translates into bad compliance. When manufacturers fail to meet even basic compliance requirements—design controls, complaint investigations, CAPA and other quality system elements—the end result is often FDA enforcement. As examples over the past decade show, outcomes range from disrupting to game-ending:

- In response to a corporate warning letter, one device manufacturer spent more than four years and $300 million remediating 15 manufacturing sites.
- Another manufacturer paid more than $200 million in disgorgement and penalties, and lost $1 billion in sales while conducting consent decree remediation.
- A third manufacturer saw a 10% to 15% loss in segment revenue and a 2% to 4% drop in total revenue related to the recall of its infusion pump. The manufacturer was subsequently acquired by a competitor.
- Even without these dire results, remediation can still more than double a manufacturer's per-unit product cost. These costs stem not only from the expense of consultants and retooling procedures, but also from slowdowns while changes are underway. The outcome is made worse when manufacturers can't meet customer demand and they lose market share to their competitors.

Share prices that take years to rebound show the impact of these scenarios. In the worst cases, the comeback doesn't occur—the manufacturer is so financially compromised that it leaves the market or is absorbed by a competitor.

Want to sleep better at night? Become excellent at quality!

Good quality doesn't just save device-makers from less-than-baseline compliance. In fact, good quality usually saves money due to fewer compliance deviations.

Recognizing this, why don't more companies spend more time identifying and deploying high-quality design, production and distribution practices?

The answer is, in part, that some companies have a very limited understanding of what quality means. While firms can use regulatory provisions, guidance documents, FDA warning letters and other resources to create a clear picture of compliance, the elements of strong quality operations seem comparatively less clear.

But we know what quality looks like: it runs the spectrum from ad hoc firefighting on one end, to the use of quality as a competitive advantage on the other. For the low-end firefighters, we see decisions that aren't transparent, reactive management and inconsistent practices. Top-level firms link quality and production, embed quality in continuously improving processes and treat quality as a non-negotiable part of their company's reputation.

Of course, it's not enough to know what good quality looks like. Firms have to know how to get there. Best performers use quality drivers that include:

- **Product and process controls** that highlight quality and product simplicity. For example, a device benchmarking analysis showed that companies with fewer devices of poor quality more often tied critical control points to critical quality attributes.
- **Strong operating structures** that focus on employee retention and cross-functional quality goals. The same benchmarking analysis showed a steady reduction in the rate of low-quality products as the share of employees with quality targets grew. Sites with higher quality likewise saw less employee turnover.
- **Capable investigation and CAPA procedures**. Among implant manufacturers, there was as much as an 80 percent recurrence rate for investigations closed early and more than a 30 percent recurrence rate for investigations that lingered.
- **Strong supplier controls**. Seventy-five percent of sites with the lowest share of poor-quality products assessed suppliers based on their capabilities related to critical quality attributes. Of the sites with the most low-quality products, only half made this assessment.
- **A firm-wide culture of quality**. This is the greatest difference between high- and low-performing firms. In the pharmaceutical sector, embedding culture in sites can reduce rework by 40% to

50%. The device arena shows similar impact: among disposable device-makers, the best performers reported 17 percent of non-quality FTEs engaged in quality operations, compared to only 3.1 percent at the worst performers.

Three-part value proposition

An enterprise-wide quality culture has an immediate, tactical impact on the quality of a firm's devices. But more broadly, it is the first of a three-part value proposition that firms seeking best-in-class quality must treat as core beliefs.

The second part is recognizing that compliance is essential, but that quality is the measure of success and the driver of continuous improvement. The third is the urgency of this work. Firms that launch their quality journey after compliance problems crop up spend time, money and credibility regaining compliance, which means any move beyond that marker to high-quality performance often doesn't happen.

But with an investment in quality as a goal beyond compliance, with an investment today—not later—and with an investment in a cross-functional quality culture—not a siloed quality role—the risks of being derailed by compliance failures fade.

More important, these investments provide a marketplace advantage that allows firms to pull ahead of their less quality-adept competitors. With those benefits, concerns about quality need not keep company leaders up at night.■

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