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Opinion: The Case For Quality – AND Compliance

by Steve Silverman

The medtech industry should promote regulatory compliance as a good goal, former US FDA device center compliance chief Steve Silverman argues in this opinion piece.

To quote the geniuses from the comedy troupe Monty Python, "Now for something completely different": The medtech industry should promote regulatory compliance as a good goal.

That's different than the *Case for Quality (CfQ) Collaborative Community*, which seeks more, including high-quality device design and manufacturing practices.

First, some context: I support the US Food and Drug Administration's Center for Devices and Radiological Health and the CfQ. In fact, during my time as CDRH compliance director, I helped launch the CfQ – and I want it to succeed.

But I wonder, do we really need the CfQ? That is, can industry *and* the FDA *and* patients survive, and even thrive, if regulatory compliance is the benchmark and the norm?

The answer (I think) is sometimes. No doubt, quality is key. The CDRH should endorse it and device makers should continue to seek it. But sometimes compliance may be enough. As FDA inspections show, many device makers struggle just to be compliant. Helping them understand and meet regulatory requirements would produce good results. Better compliance would almost certainly mean fewer defective devices and fewer recalls. Widespread compliance also would free the FDA to spot and resolve defects quickly, before they harm patients. Extra resources also could be directed to other critical activities, like proactive communication of good device manufacturing practices. Notably, these results flow from compliance, not device quality.

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> *"Many device makers don't appreciate the difference between compliance and quality."*

Here's another argument for compliance: Many device makers don't appreciate the difference between compliance and quality. When asked if they seek quality, device makers almost uniformly say yes. But when asked to define "quality," these same manufacturers often give responses that basically mean really, really good compliance. That's not surprising. Especially for small and mid-size manufacturers, quality is not on the radar. When these companies think beyond getting devices to market, they want to know what the compliance requirements are and how best to meet them. Quality doesn't factor into the mix, whether because these manufacturers lack the resources to achieve quality, or because there's no commercial need to seek it.

Plus, sometimes compliance is more "marketable" than quality. That's because business leaders focus on data. Before buying into a project (like the CfQ), these leaders want to know what they're paying for and what they get. Defining the cost and value of quality is amorphous, a challenge that the CfQ recognizes. The CfQ describes device quality as a key endpoint. That goal is valuable, but it's hard to translate into precise numbers. The costs of noncompliance, by contrast, are apparent: Device makers can see how competitors are penalized and what it costs when they aren't compliant.

Here's another challenge: the CfQ is imperfectly aligned with FDA and international practice. That is, the CfQ (and its commitment to quality) is a CDRH project. But other parts of FDA seek *compliance* with manufacturing requirements. This is evident in device inspections. Most of these inspections focus exclusively on compliance, not quality. The proportion jumps to 100% when accounting for programs like the Medical Device Single Audit Program, which considers compliance exclusively.

> *"Is quality a bridge too far and should we be talking only about compliance? No."*

And let's not forget ISO 13485:2016. The CDRH is committed to aligning its device manufacturing requirements with this international quality system standard by way of *the*

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center's proposed Quality Management System Regulation. That soon-to-be transition is the 600-pound gorilla that will occupy the device center and the rest of the FDA for years to come. Nowhere does ISO 13485 talk about, or even acknowledge, quality as a point beyond compliance. Rather, it turns on regulatory requirements and the ways to meet them. As the CDRH aligns its device oversight with ISO 13485, how much bandwidth will there be for quality as a separate measure?

So, while the CfQ is critical, it faces obstacles. Managing these obstacles requires time and effort – limited resources made rarer by CDRH pandemic activities and work on user-fee negotiations, digital device regulation, and other projects. This means a long haul to promote quality as a device endpoint. Meanwhile, there's value in praising compliance. If nothing else, it's a key accomplishment on the road toward quality.

Now What?

Where does this leave us? Is quality a bridge too far and should we be talking only about compliance? No. First, quality should absolutely be the North Star for medtech. The CfQ repeatedly (and rightly) treats compliance as table stakes. Implicit in that view is the idea that there's more to win. Betting on quality produces better results for the FDA, device makers and patients.

The CfQ Voluntary Improvement Program shows this, for example, by joining FDA, industry, and experts to find manufacturing practices that consistently produce high-quality devices.

As important, the CfQ drives innovation. The push for quality includes finding compliance requirements that do not work. Sometimes these requirements are in place because they have historically existed, even if they don't improve quality. The CfQ then considers how these requirements can be modified (or retired) to best serve device design and performance. *The CfQ corrective and preventive action (CAPA) improvement initiative* is a good example. This initiative replaces standard, confusing CAPA measures with a risk-based framework and a pilot process to implement it.

So yes, compliance is critical and it deserves its due. But compliance is a stop on a longer journey toward device quality. That journey produces better regulations that promote better devices that better serve patients.

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