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Opinion: FDA Isn't A Monolith. Engage The Agency Better By Answering These 5 Questions

by Steve Silverman

In this op/ed, former US FDA device compliance chief Steve Silverman argues that savvy manufacturers understand the organizational and operational differences between agency centers and offices. Here, he offers five questions firms should answer before engaging the agency.

Imagine this: You run a medical device company and the US Food and Drug Administration inspects your facility. The inspection is nothing major – just a compliance check. Your company is in San Diego, so an FDA Office of Regulatory Affairs (ORA) investigator, based nearby, conducts the inspection.

The investigator cites your firm for failing to assess and report device adverse events. And you respond: "Yeah, we don't report, but our device is unique and standard reporting requirements shouldn't apply. In fact, we need you to adopt a new adverse event reporting framework. And it should extend nationwide."

This scenario is absurd for many reasons – asking an ORA investigator to rewrite national compliance policy being chief among them. Still, what I've described is not too far off for medtech companies that treat the FDA as a monolith. This view is wrong and it can lead to bad regulatory results.

Yes, the FDA is one agency. But it's comprised of distinct entities with distinct strengths, priorities and cultures. To suggest, for example, that device makers should engage the FDA's device center and the ORA in the same way because they report to the same commissioner is naive; such views misunderstand the FDA's organization and operation. Savvy companies account for these organizational and operational differences in shaping their engagement

strategies. Uninformed companies don't.

The good news is that the FDA's organizational and operational practices are knowable, and device companies can leverage them to inform regulatory strategies. Manufacturers should begin by answering these five key questions:

1: Which FDA Component Are You Dealing With?

This question requires a device company to identify the specific FDA component that it's engaging or wants to engage. This includes the responsibilities and authority that the component has (and doesn't have). For example, ORA staff members routinely judge whether device makers meet quality manufacturing requirements. These are facility-specific assessments in geographically bounded areas. ORA staff typically will not consider whether standard regulatory requirements should apply to novel devices. Such policy discussions are the purview of the FDA's Center for Devices and Radiological Health (CDRH), which leads regulatory strategy for medical devices. Likewise, a device maker challenging inspection results should direct its arguments to the ORA office that conducted the inspection, which has primary responsibility for inspecting device facilities and determining inspection results.

2: What Is The FDA Component's Culture?

Multiple components comprise the FDA, and these components have distinct "personality" traits. Effective engagement requires knowing and factoring these traits into engagement strategy.

For example, the CDRH supports device innovation and stakeholder collaboration. These traits are visible in programs like the center's *Case for Quality* initiative, the *Digital Health Center of Excellence*, and the *National Evaluation System for health Technology* (which promotes real-world evidence).

When industry proposes new ways to meet regulatory requirements, or to change those requirements, the right partner is the CDRH. Bringing these proposals to the ORA wouldn't succeed. Even the ORA's leadership group, which has national reach, doesn't typically retool regulatory requirements; this group focuses instead on how best to enforce these requirements. So, engaging ORA staff about whether an inspection showed quality system compliance is fruitful. Even discussing how best to meet regulatory requirements is productive. But asking that staff to carve out compliance exceptions for new device types will fall flat.

3: Is The Discussion Topic Novel?

Knowing the discussion topic is as important as knowing which FDA components must join the discussion. Topics that the FDA regularly addresses, which don't raise novel concerns or seek new accommodations, don't demand special preparation.

Device facility inspections are a good example. ORA staff regularly talks with facility operators to explain inspection findings and evaluate remediation. Device makers shouldn't walk into these discussions unprepared, but such discussions don't require the extra preparation needed to raise novel topics, new regulatory models, or national compliance changes. In such cases, extra preparation is a must. Industry participants must explain why their operations require new or revised FDA practices, and they must explain why the accommodations serve device safety, efficacy and quality better than established practices.

As important, industry participants must make their points to the right FDA audience. With apologies for the *Star Trek* reference, an ORA field office isn't the right place to propose "boldly going where no man has gone before." Bring such novel topics to the device center.

4: Who Are You Engaging?

Some device makers routinely include FDA senior staff in regulatory discussions, believing that these leaders streamline talks. That instinct can be wrong. Engaging agency leaders is important and helpful, sometimes, but that is a context-specific decision. For novel topics, regulatory revisions, or changes to national policy, senior staff involvement is essential. But for standard FDA activities, engaging staff directly responsible for these activities is better.

Here's an example: A device firm receives a CDRH letter claiming that it violated facility-registration requirements. The firm confirms its proper registration and considers who at the CDRH to contact about this possible administrative error. Certainly, the firm could contact the center's senior leaders, asking them to direct junior staff to make the needed corrections. But this interposes unnecessary management layers and risks miscommunication among these layers. The better strategy is to talk with the CDRH staff directly responsible for facility registration. That staff best knows whether administrative errors occurred and, if so, how to fix them.

No doubt, firms face more complex scenarios when engaging the FDA. But even then, the principles remain: smart firms define the issues for discussion, identify who at the agency manages those issues, and engage those individuals.

5: What Is Your Goal?

Before approaching the FDA, device makers must decide what they want to accomplish. The answer informs which agency components, and who from those components, are at the table. This point builds on the prior ones and requires little further discussion.

Simply put, if the goal is to address a standard activity, then engaging FDA staff with direct responsibility for that activity makes sense. Often, this is not senior staff. Leadership engagement should focus on novel topics, changing established practice, and broad-reaching initiatives.

A Note About Other FDA Components

In detailing the questions above (and their answers), this article focuses on two FDA components: ORA and CDRH. This makes sense because most device firms spend most of their time dealing with these components. But the questions (and their answers) apply equally to other agency components. Device firms dealing with the FDA Commissioner's Office or the Office of Chief Counsel, for example, also should consider the topics for discussion, the results that they seek, and who can best provide those results.