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What Does 'Digital' Mean For FDA's Device Center?

by Steve Silverman

Yes – the US FDA will adjust poor-fitting practices to accommodate digital devices. But the agency is not going to set aside product review, postmarket quality, and other basic requirements, former FDA device center compliance chief Steve Silverman argues in this opinion piece.

A quick caveat: There are kids with TikTok accounts who are more digitally savvy than me, so I'm not here as a sherpa for all things digital. But I've been paying attention to digital developments related to the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH), and I have some thoughts.

First, there's no denying "digital fever." You can't swing a dead mouse (pun intended) without hitting a digital product. This enthusiasm extends to medical devices and the CDRH shares it. A look at the FDA's new Digital Health Center of Excellence (DHCOE) shows this. And there's the CDRH *Digital Health Innovation Action Plan*, which envisions "timely [patient] access to high-quality, safe and effective digital health products."

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But what does the CDRH mean when it talks about digital devices? Does this mean devices that are only digital? Does "digital" include traditional devices with digital capability? The answer to both questions is yes. The *FDA acknowledges* that digital technologies "include technologies intended for use as a medical product, [and] in a medical product."

As important, will the CDRH do anything meaningfully different for digital devices? Yes and no. Certainly, the center must adjust its product-development mandates for digital devices. Take product design, for example. Digital development often follows an "agile" model, with iterative changes and revisions to meet evolving needs. By contrast, traditional quality system requirements use a more fixed, stage-gated approach. The CDRH must adapt this approach to device development (for example, by rethinking design control requirements). And the *CDRH knows this*, conceding that the FDA's "traditional [regulatory] approach … is not well suited for the faster, iterative design, development, and type of validation used for [digital technologies]."

But there are more basic principles – relating to premarket review, and approval and clearance – that the CDRH will not change. It's 2021 and we have a Democrat-controlled Congress. There's little appetite for a digital "fast lane" that exempts devices from FDA review. (Remember when a group of senators freaked because the center considered evaluating device makers instead of devices? That's what I'm talking about.)

So what does this mean for device companies? There will be regulatory flexibility. This will focus on areas within CDRH control that do not undercut or revise basic agency practice. For example, in evaluating product design, the CDRH will continue to endorse technology-specific methods such as "agile."

But don't look for basic changes in how the CDRH does business. Digital device makers will still need to meet essential requirements for product development, approval and manufacturing. Device clearance and approval, and quality imperatives like design and supplier controls, are not going away.

Savvy stakeholders will know where to push and what to leave alone. And these stakeholders will work with the CDRH. The collaborative environment is ripe. Digital is evolving and CDRH views are evolving with it. Meanwhile, the center does not own digital wisdom. Industry, academics, health care providers and others offer key views, and the CDRH solicits this input through mechanisms like the DHCOE.

But most important, public health is the lodestar of this work. No doubt, the CDRH knows this: protecting and promoting public health is central to its mission. This public health drive must underpin any discussion about how to accommodate and promote digital devices. This frame will support robust exchanges that allow the best thinkers – inside and outside the CDRH – to develop the best solutions.