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Opinion: Getting Work Done in the 'New Normal' CDRH

by Steve Silverman

In this op/ed, consultant and former FDA official Steve Silverman reveals how medical device firms can best interact with the US Food and Drug Administration's Center for Devices and Radiological Health as the COVID-19 pandemic recedes.

No question, the Center for Devices and Radiological Health at the US Food and Drug Administration is massively busy – just look at the pandemic wind-down. Hundreds of devices with emergency use authorizations now must undergo standard premarket review – think *lots* of PMAs and 510(k)s. That means new priorities and resource demands for CDRH. It also means additional stakeholder communication and device submissions, all of which must be reviewed and managed.

Adding to this, CDRH has a raft of process improvements agreed to in MDUFA V – the latest round of device user-fee negotiations. Plus, CDRH issued many, many COVID guidance documents. Most of these will be retired, but some will remain. This means even more work to close out some guidances while preserving others.

Against this backdrop, it's tempting to say, "there's no more room at the inn." These key activities will consume CDRH resources, straining regular product review and leaving room for nothing else.

But that view is shortsighted. As I've written, FDA (including CDRH) is not monolithic. CDRH is comprised of discrete units with their own focus and objectives. These units aren't stuck in agar, waiting for center-level initiatives before getting their own work done. While these units support CDRH programs, they're also spending time (and resources) on their own work and finding better ways to get that work done. Savvy stakeholders know this and engage these CDRH units on "local" topics.

Digital devices are a good example. These devices use computer platforms, software, and other technologies to diagnose and treat health conditions and disease. Digital technology is ubiquitous and crosscutting. Many CDRH groups grapple with how this technology impacts review requirements, evidentiary submissions, and post-market oversight, and such crosscutting questions will generate crosscutting responses.

But these questions won't stop CDRH components from managing the devices that they regulate. CDRH's coronary-device reviewers, for example, won't give digital questions a "pass" simply because orthopedic devices raise similar questions. These and other CDRH reviewers will answer questions – even digital ones – germane to the products before them.

And this model is exactly what stakeholders sought during MDUFA V negotiations. COVID upended CDRH practices, processes, and timelines. The pandemic required CDRH to shift staff and resources to manage urgent public-health needs. Now, with some normalcy on the horizon, MDUFA stakeholders urged CDRH to go "back to basics," meaning standard, predictable timelines and interactions. "Normal" doesn't mean a carbon copy of pre-COVID life; it means the *new* normal, combining pandemic lessons learned with better technology and practices.

TAPping Agency Resources

But what about CDRH's Total Product Life Cycle Advisory Program (TAP)? Isn't TAP the MDUFA V 600-pound gorilla? Won't TAP pull resources away from standard device oversight? Maybe.

There's no question that TAP, which was designed to improve device innovation and market access, is a CDRH priority. CDRH leaders pushed hard for TAP even when facing stakeholder doubts. But TAP is being deployed as a pilot program focused first on cardiovascular devices and then expanding slowly. There's little doubt that TAP projects will rise to the top of the pile for CDRH staff, but the number of those projects will be relatively small. So, TAP won't keep CDRH reviewers away from work closer to home.

This is what stakeholders, including device makers, want. TAP can play out with resources left for standard product review. This means that there's room to discuss issues affecting specific devices and device types, even when those issues don't match CDRH top priorities.

No doubt, stakeholders must account for the larger environment. CDRH priorities exist, they're clear mandates, and they may impinge standard device oversight. But these are questions of degree, not threats to program availability. CDRH staff and stakeholders will collaborate on product-focused initiatives, and these initiatives will coexist with, and sometimes further, CDRH

priorities. This means multiple paths for CDRH engagement, including paths focused on getting core work done.

Steve Silverman is the president of The Silverman Group, a consultancy that serves medical product companies on regulatory, strategy, and policy issues. Steve's professional experience includes extensive time in senior FDA roles. At the FDA, Steve directed the CDRH Office of Compliance, where he led device-quality initiatives, engaged Congress and the press, and guided the office's reorganization.