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Shuren Gives Peek Behind Curtain With 3 Lessons FDA's Device Center Learned During Pandemic

by Shawn M. Schmitt

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Jeff Shuren says the US Food and Drug Administration's device center has been tallying up lessons learned from the coronavirus pandemic.

"COVID-19 has presented challenges for the world, our country and the FDA," the director of the Center for Devices and Radiological Health (CDRH) said on 15 September at RAPS Convergence 2020, hosted by the Regulatory Affairs Professionals Society.

"The greatest tragedy of the pandemic would be if we did not learn from it, and not just how we can be better prepared for the next outbreak, but how we can take the lessons learned to better serve patients at all times," Shuren said.

He said the CDRH has learned three lessons:

1. The importance of flexibility. "During the pandemic, CDRH leveraged its emergency use authorization [EUA] authorities to maximize timely product availability, with some assurances of safety and effectiveness when the medical device is authorized. Since the beginning of February, CDRH has authorized over 500 medical devices, almost … more devices authorized than in all prior outbreaks combined. And we're authorizing, on average, one test every single day.

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"We also rapidly adapted our policies to meet evolving circumstances on the ground as COVID-19 spread and new information became available. As in health care, from the early days of the outbreak, where health care professionals were trying to figure out how COVID-19 was affecting patients, and how best to treat them based on limited and evolving information – but not having the luxury of time to wait for answers – so too did FDA have to adapt and adjust on the fly as best we could with what we knew at the time. So far CDRH has issued 23 guidances and seven emergency use authorization templates that have recommendations for how to validate different types of tests, as well as issued several updates to some of those guidances and templates.

"The level of regulatory flexibility has been unprecedented and could serve as a model in the future. However, a challenge we face is that the regulatory paradigm established for medical devices is over 40 years old and is not well suited for many modern-day technologies. So as we look to the future, we should consider how to make this level of regulatory flexibility … routine practice."

2. The value of engagement. "CDRH took its collaborative approach with developers that we apply to our *Breakthrough Devices Program*, and essentially put it on steroids. We established a pre-emergency use authorization process through which developers can interact with center experts in real time, through emails and phone calls, and provide data for review on a rolling basis.

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"The more recent great limiting step has simply been not having enough people to handle the volume of work and sustain that level of engagement. For example, the number of premarket submissions we received during this time, as compared to last year, has been no different. But on top of it, we have so far received over 4,500 pre-EUAs and EUAs. Now, if you consider each

submission as equivalent, our workload more than doubled during this time, as compared to last year. And yet the number of people that we had did not increase.

"Now, we've adapted as best we could by applying new approaches and moving people around to shore up where we needed more support. In the beginning of the pandemic, we were routinely authorizing new tests within two or three days – often within one day of receiving the EUA submission. And now it can take several days to several weeks, depending on the priority of the submission, given that there are over 1,200 EUAs still in the queue. And yet it's still a very remarkable achievement.

"We also engaged with developers through weekly and biweekly *webinars*. Posting on our website and continually updating our frequently asked questions, and establishing a *24-hour hotline* [and] multiple email boxes to receive and rapidly respond to questions. To date we have received over 300,000 telephone and email queries. The level of engagement we have provided to developers has been instrumental in accelerating the development, validation and authorization of medical devices during the pandemic.

"In the future, finding ways to provide this level of engagement, what could be most beneficial and can have a significantly positive impact on health technology innovation in the US, should be something to explore."

3. The value of the CDRH's Total Product Life Cycle (TPLC) approach. "Luckily we had already *reorganized within CDRH to restructure our premarket, postmarket, and compliance and quality activities from siloed offices to integrated teams*. As a result, we've been able to problem-solve more rapidly and better work with the developer and health care provider communities during the pandemic.

"In the future, we'll look for ways to better and more broadly apply this TPLC approach. And in that spirit, we look forward to engaging [stakeholders] to better understand and apply the lessons learned from COVID-19 so our post-pandemic future is a brighter one than the world of today."