CDRH's "Digital Transformation Initiative" Moves Forward

By: Randolph Fillmore

November 4, 2021

Categories: *AAMI News, Medical Device Manufacturers*

FDA says its premarket review program is strengthened by new digital platforms

If there are any "up sides" to the COVID-19 pandemic, the challenges it posed has served to encourage many to strengthen their digital systems. One such effort by the Food and drug Administration (FDA) and its Center for Devices and Radiological Health (CDRH) has been to launch its Digital Transformation Initiative, a part of FDA's Technology Modernization Plan. According to the FDA, the initiative offers more online platforms to support virtual work, especially regarding its medical device premarket submissions review program.

On October 14, CDRH issued an update on aspects of its Digital Transformation Initiative.

"We are committed to protecting the public health by ensuring patients have more timely access to safe, effective, and high-quality medical devices," said CDRH Director Jeff Shuren, MD, JD. "This includes our responsibility to review premarket submissions for certain new medical devices and modifications to devices currently on the market. As part of this ongoing work, the FDA continues to take steps to strengthen the premarket review program and make it more efficient, consistent, and predictable."

Digital Transformation Initiative

According to the FDA, there are currently more than thirty data systems used by CDRH for premarket review. All of them are "outdated, complex, fragmented" and time-consuming to use. Upgrading or maintaining these systems was not an option because of costs, so the FDA invested in an "integrated knowledge management system" with secure, cloud-based data storage. FDA believe the initiative will improve data delivery, both internally and externally.

Customer Collaboration Portal

When a firm submits a traditional 510(k) to CDRH for review, the company's Official Correspondent can monitor its progress online in a simple, concise format called the Customer Collaboration Portal (**https://www.fda.gov/medical-devices/industry-medical-devices/tracking-your-premarket-submissions-progress-progress-tracker**). FDA launched a pilot portal earlier this year, but the portal is now fully functional for tracking the progress of a 510(k) (**https://www.aami.org/news/article/fda-launches-progress-tracking-program-for-510(k)-premarket-applications**).

Submission Memo and Review Template (SMART)

CDRH's SMART program, designed to make administration of premarket review more efficient and consistent, can be used by reviewers to evaluate information across disciplines, such as biocompatibility, sterilization, and cybersecurity, said William Maisel, MD, MPH, director of CDRH's Office of Product Evaluation and Quality (OPEQ).

"SMART incorporates regulatory requirements and guidance expectation and provides links to important resources, like FDA-recognized standards, as well as other support tools," explained Maisel. "We believe the efficiencies of SMART have the potential to strengthen review of other submission types across the total product life cycle."

Electronic Submission Template and Resource (eSTAR)

As an interactive aid for 510(k) e-submissions, eSTAR, says FDA, helps to ensure that submitters provide "quality, comprehensive data" for FDA premarket review. It is an interactive PDF with standardized formats. Its content was summarized in an FDA September 2021 draft guidance (**https://www.fda.gov/regulatory-information/search-fda-**

guidance-documents/electronic-submission-template-medical-device-510k-submissions). Public comment on eSTAR remains open until November 28, 2021. Now, eSTAR can be used on a "voluntary basis" to make a 510(k) submission. Mandatory use will come when the draft guidance is finalized.

Decision Management Portal

As a new, internal platform that aims to help CDRH reviewers work more efficiently, the Decision Management Portal provides a single location where CDRH staff can see all their work and work assigned to their team in a consolidated interface.

What's next?

According to Shuren and Maisel, future advances in technology will improve postmarketing capabilities and improve device safety monitoring, and the FDA will help speed those innovations.

"The Digital Transformation Initiative, and the dedication of our talented CDRH staff, are key parts of the effort that continues to drive forward critical program enhancements," concluded Shuren and Maisel in their October 14 statement.