FDA Reveals Key Findings for Pre-Cert Pilot Program for Software as a Medical Device

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The U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) has released an Executive Report exploring key findings from its Pre-Cert Pilot Program for software as a medical device (SaMD)

The Pre-Cert program is a voluntary pathway intended to streamline the premarket review of SaMD products by certifying the companies that develop them. According to the FDA, such a program was needed because the agency's traditional hardware-based approach to regulation was too slow for the rapid pace of software development.

The pilot program explored innovative approaches to regulatory oversight of medical device software developed by organizations with a robust culture of quality and organizational excellence and committed to monitoring real-world performance of their products once they reach the U.S. market.

According to the report, *The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings*, SaMD is increasingly common in the healthcare sector. However, SaMD are developed differently than traditional hardware-based medical devices. These devices need to be able to take on postmarket updates quickly, both to enhance their efficacy as well as make modifications in the event of malfunctions and adverse events. As a result, the FDA and CDRH sought to explore more versatile validation process than seen with traditional devices.

FDA issued a number of documents to describe its vision and approach for exploring whether it could provide reasonable assurance of safety and effectiveness when compared with the traditional regulatory paradigm. According to the report, the goal of the Pre-Cert Pilot was based on an assessment of a manufacturer's culture of quality and organizational excellence, their ability to develop safe and effective devices, and to continuously monitor key indicators of product performance.

As part of the pilot, FDA investigated it feasibility within FDA's current laws and regulations. FDA tested the PreCert Program by conducting retrospective tests of SaMD regulatory submissions previously reviewed, and prospectively conducting tests of SaMD regulatory submissions with volunteers using the *De Novo* premarket authorization pathway as described in the Regulatory Framework document. It compared the premarket review and regulatory decision with "mock" packages created using the Pre-Cert Program approach.

In the retrospective review, FDA found that an Excellence Appraisal summary for use in lieu of certain other premarket software documentation traditionally included in premarket submissions should either be a concise statement of precertification without the expectation of further premarket review of the Excellence Appraisal information, or a detailed report of the Excellence Appraisal process and results to be reviewed in-depth in the context of the device subject to review. High-level summaries between these two extremes were the least viable approach.

FDA then developed and refined the Excellence Appraisal approach with pilot participants based on the feedback from retrospective testing. However, in continuing pilot, Excellence Appraisals and conducting premarket reviews during prospective testing, FDA did not find the *De Novo* submission-based approach as outlined in the Test Plan to be the optimal test method for the pilot. The pilot investigated processes for obtaining insight into 14 Key Performance Indicators (KPIs)15 at an organizational level, and whether this information could be used to help streamline premarket reviews. The Excellence Appraisal activities explored:

- Leadership and Organizational Support
- Transparency
- People
- Infrastructure and Work
- Environment
- Risk Management: A Patient Safety Focus
- Configuration Management and Change Control
- Measurement, Analysis, and Continuous Improvement of Processes and Products
- Managing Outsourced Processes, Activities, and Products
- Requirements Management
- Design and Development
- Verification and Validation
- Deployment and Maintenance

FDA also found that software development environments differed in specific clinical and technological considerations associated with the devices under development. However, the pilot appraisals reinforced that the appraisal methods needed to accommodate different approaches to medical device software development to balance flexibility with standardization.

Based on the lessons learned from the pilot, FDA said that if appraisals become a routinely used method and tool, the collection of standardized, structured data during an appraisal and ongoing monitoring by FDA or by an FDA-accredited third

party could facilitate a consistent and efficient view of an organization's culture of quality and organizational excellence and promote product quality outcomes and outcomes related to device safety and effectiveness.

FDA noted the need for new statutory authority for SaMDs. "The faster cycles of innovation and the speed of change for medical device software would benefit from a new regulatory approach," concluded the report.