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Medical device risk management

These days the use of many medical devices requires them to connect or interact with other devices or IT systems. That's why the U.S. Food and Drug Administration wants device manufacturers to make safe connectivity a central part of their design process. Manufacturers need to provide a "reasonable assurance of safety and effectiveness" for their interoperable devices, according to the agency.

FDA recently released its final guidance on medical device interoperability. Developed using feedback from industry, device designers and the public, the guidance is meant to give manufacturers specific considerations to keep in mind with developing their technologies, and recommendations for information to include in pre-market submissions.

Ensuring proper connectivity of medical devices is a means to protect patient safety. "Errors and inadequate interoperability, such as differences in units of measure (e.g., pounds vs. kilograms) can occur in devices connected to a data exchange system," said Bakul Patel, associate director for digital health at FDA' Center for Devices and Radiological Health. Thus, appropriate functional, performance, and interface requirements for devices with such interactions are essential, he added.

The FDA guidance focuses on three areas that manufacturers should keep focused on to ensure "smart, safe, and secure" interoperability of medical devices and IT systems.

1. Manufacturers should design systems with interoperability top-of-mind as a core objective.

"In designing a medical device's electronic interface, manufacturers should consider the level of interoperability needed to achieve the purpose of the interface, as well as the information necessary to describe the interface," according to the document. "The labelling should be in sufficient detail to allow anticipated users to connect and use the medical device and interface as it is intended."

2. They should conduct "verification, validation and risk management activities" as appropriate.

"Manufacturers' risk management strategies should address the risks associated with the anticipated users of the device, reasonably foreseeable misuse of the device, and reasonably foreseeable combinations of events that could result in a hazardous situation," according to the guidelines. "However, FDA recognises that a manufacturer cannot be responsible for all possible uses outside of the purpose of the interface."

3. They should be sure to specify, with clear labelling, the devices' relevant functional, performance and interface characteristics in a user-available manner such as labelling.

"One way to reduce risk and facilitate safe and effective medical device interoperability is to include in labelling the functional and performance requirements of the electronic interfaces that may be used to connect medical devices with other electronic equipment," according to FDA. "The manufacturer should determine the appropriate way to provide the information based upon the anticipated users and the risk analysis."

Without communicating devices' capabilities, clinical users could use them inappropriately, especially in conjunction with IT systems, in ways that could cause device malfunction – leading to potentially serious adverse events, the agency said.

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