Foresight
Business Consulting™, Inc.
856 Fair Way ■ Libertyville, IL 60048
224-520-0506 ■ steve@foresight-consultinginc.com
www.foresight-consultinginc.com

Strategic Marketing Advisors for the Healthcare Industry

Addressing the FDA's Device Usability Focus

Device usability is a significant FDA focus. Following a string of issues where medical device use resulted in user errors causing patient harm, the Agency implemented draft guidance for integrating device usability into the design process in June, 2011. These guidelines are intended to establish a systematic approach that will reduce use related errors and medical device–caused injuries. The FDA also recognized ISO/IEC 62366, and AAMI/ANSI HE 75; both documents that identify principles for application of usability engineering into medical devices.

What is different?

Although the FDA has required medical device manufacturers to conduct medical device risk analyses for some time, these new guidelines require manufacturers to integrate human factors testing into the risk analysis. It is no longer acceptable to rely on the opinions of the clinical affairs group, conduct focus groups, or implement post-launch questionnaires to document usability. The Agency specifically identifies one approach manufacturers should use to ensure that use related hazards are avoided, the Human Factors Validation Test (HFVT). The HFVT is conducted with actual device users, using production-equivalent devices in a user environment.

The challenges

Two challenges face medical device manufacturers. First, although design groups are already adept at design verification and validation, they are not trained in the techniques required for human factors validation testing. The HFVT most closely resembles the structured personal interview technique utilized in market research. Gaining the most out of the personal interview technique requires skills such as: question design, discussion moderating; listening, unbiased observation; and body language/non-verbal cue interpretation. The FDA requires that moderators selected for the HFVT have no product design responsibility.

Second, the Agency does not specify any particular methodology for conducting the HFVT, which generates confusion for manufacturers. Is a structured interview approach required, or can the discussion be free-form? Should the company implement a "cognitive walk through" approach or a "think aloud" protocol?

Integrating the HFVT into the development process

The HFVT is structured around the use related hazards identified by the design team. Planning should be initiated early enough so the moderator understands the device functions and their risks for incorporation into the HFVT.

In conjunction with the design team and the regulatory group, the moderator develops a usability validation plan, which outlines sample size, user types, the device processes subject to user error, the pass/fail criteria for each process and the use environment under which testing will occur. The moderator uses this plan to develop a testing protocol that records the user ability to perform the tasks without error, including the data collection instruments.

During the HFVT, the moderator instructs the user to operate the device and records the user's performance as pass, fail or pass with difficulty. The moderator also records instances where the user delays taking action. This is followed up later in the test protocol. Besides testing the device operation sequentially, the HFVT should also be designed to test how the user manages multiple devices or integrates operation of the new device with other medical devices already found in the user environment.

Including a subjective evaluation of the user experience is important. This free-form data collection method provides the moderator with the opportunity to dissect the users thought process and provide richer feedback for the design team, particularly for steps the operator found difficult or failed. By using open-ended questioning, the subjective evaluation technique reliably identifies unanticipated user errors. Typically after discussing difficulties, the moderator will probe the user for work-arounds to make the device operation less hazardous.

Mitigating the risk of schedule delays

While the approach laid out above follows the FDA guidelines, it creates significant schedule slippage risk. If a company identifies a significant user error during the HFVT, the design team must stop the development program while it designs a method to address the risk and implement a design change or new training procedure that will mitigate the user risk. Once new designs are implemented verification and validation must be reinitiated, and the resources employed for the first V & V tests are wasted.

In order to avoid this troublesome scenario, human factors testing should be conducted earlier in the design process, using device prototypes, sketches or screen mockups. Testing performed at these earlier junctures of the design phase is called formative testing. Formative testing can identify sources of user error quickly so that mediation can occur before the design team moves too far down the development path.

Formative tests are conducted in much the same manner as the HFVT, in that a moderator observes the user perform device operations and a subjective evaluation is performed as well. Since formative tests are not required by the FDA, documentation requirements are less rigorous. This makes the formative test easier to implement and significantly more flexible. A portion of the questions could even focus on marketing issues.

Author's note

I hope these thoughts have been helpful. Having successfully conducted HFVT testing for Foresight's medical device clients, we've learned a lot about what works and what doesn't work in this field. If you're thinking about the new FDA usability guidelines and their implications for your business, and want to kick this topic around, give me a call.