Integrating usability engineering into your medical device design process

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The Landscape is Changing...

In 2016, the FDA finalized their guidance on how human factors and usability engineering should be applied in the design process for medical devices. While this may be new to some, practitioners of user-centered design have known for years that these practices not only improve product safety, they also result in a better product. For those who find themselves in unfamiliar territory, we revisit why usability engineering is so important and how the fundamental elements of usability engineering can be integrated into the design process.

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Understand users, use environment, use scenarios

Formative usability evaluations

Use Error Analysis

Incorporate use risk controls into requirements and design

Validate use safety and effectiveness

Use Related Risk Acceptable?

YES

Ready for regulatory submittal and product release

NO
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Why should you integrate usability into the design process?

Make it safe and save money. Effectively integrating usability into your design process will save you time and money on re-design or worse outcomes like safety issues and product recalls. Catching usability issues early allows you to optimize your user interface to avoid use “surprises” in usability validation, or even in the field after product release. Design iterations made late in development can be significantly more costly than addressing issues early in product development. Not to mention costs of injuries or recalls.

It’s required. If saving money isn’t enough motivation, the FDA and the international community expect manufacturers to incorporate a usability engineering process and have included usability/human factors reviews in their approval processes. For more information, see FDA’s guidance, Applying human factors and usability engineering to medical devices, and IEC 62366-1, Application of usability engineering to medical devices.

Make a product users love. People develop emotional associations with things that they use and medical devices are no exception. A product that is difficult, non-intuitive, or otherwise “quirky” to use is not going to get traction in the marketplace when compared to something that is elegant and simple. Healthcare practitioners don’t have the time for overly complex devices and savvy patients increasingly have a voice in making their healthcare decisions.
How Can You Integrate Usability?

The key word is “integrate”. This means thinking about usability during the design process, and iterating based on real user feedback early and often. It also means thinking about what use errors could happen early and designing in ways to avoid them. Here’s how:

**Step One: Know your users and your environment.** Have you thought about who your users are and where they’ll use the device? Consider what characteristics such as knowledge, training, and physical capabilities or limitations are truly unique as it relates to use of the device and make a list. This is important because each distinct user group will be tested separately down the line in usability validation (typically at least 15 users per group). More broadly, this exercise enables the developer to design with empathy for the user, a key principle of user-centered design.

**Step Two: Know how your users interact with the device.** You don’t need a prototype to start talking with users. Use their input to develop a task analysis to understand each user action and how the device could respond. This provides a framework for understanding the different use scenarios for your device. Storyboarding and process mapping are useful tools to gain insights into how people interact with the product under each scenario.

**Step Three: Think about what could go wrong.** Analyze possible use errors for each of the device operating functions identified in the task analysis, considering risks associated with human behavior, abilities, and limitations. Brainstorm possible hazardous use scenarios that could come from the error and estimate risk. Then, identify controls that can mitigate the risk. This analysis should be integrated with the overall risk management activity for the device.

**Step Four: Add requirements to control use errors.** Add controls identified in the use error analysis to the device requirements specification. This ensures that the design includes appropriate features for usability and provides traceability to show control implementation. Ideally these controls should be implemented through improvements in the design of the device (i.e., not through training or administrative controls). At the end of the day, the design of the device itself should invite users to use it properly and avoid hazardous situations.
Step Five: Evaluate usability early and often... and iterate. Collect feedback from users whenever you have the opportunity. For example: even before you have a prototype, consider conducting user interviews to understand how they interact with similar or predicate products. Once prototypes or storyboards are available, conduct formative usability studies to identify possible use errors and opportunities for improvement, and further refine expected use scenarios. At a minimum, you should complete a formative study that closely mimics the planned summative usability validation as a “dry run” before the design is finalized. Use the results of each study to iterate on the task analysis, risk assessment, requirements, and design. Iterate then validate, not the other way around.

Step Six: Prove it. Planning and execution of usability validation is supported by groundwork laid by Steps One-Five. You’ve identified user groups, implemented controls, and defined use scenarios and possible hazardous use scenarios. Now test according to these to demonstrate safe and effective use of the device in usability validation. If you’ve already iterated on usability, there shouldn’t be any surprises and you’ll be on your way to regulatory approval and marketing of the device.

Takeaway: Process is Key

Whether you follow the steps above or your own interpretation, the most important thing is to have a process. These steps follow a usability engineering process that is aligned with IEC 62366-1 and FDA guidance for applying usability engineering to optimize medical device design. Evaluate usability early and often, and iterate to develop the best possible design and avoid surprises down the line.
About the Author

Katie McHugh is a senior systems engineer and usability expert with 13 years of experience designing a wide variety of medical device systems. Her experience includes low cost single use devices as well as capital equipment. Katie is also a usability engineering expert and has led formative and summative evaluations of medical devices.

Katie provides oversight and direction to project teams on successful integration of system and user requirements, risk management, and usability engineering.

Katie most recently executed a usability engineering program for a disposable bleeding control device, which included defining usability specifications/use scenarios, developing usability validation plans, and planning and coordinating execution of formative and summative usability evaluations in healthcare environments.

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