Essential Design Principles to Develop CLIA Waived Devices

Invetech

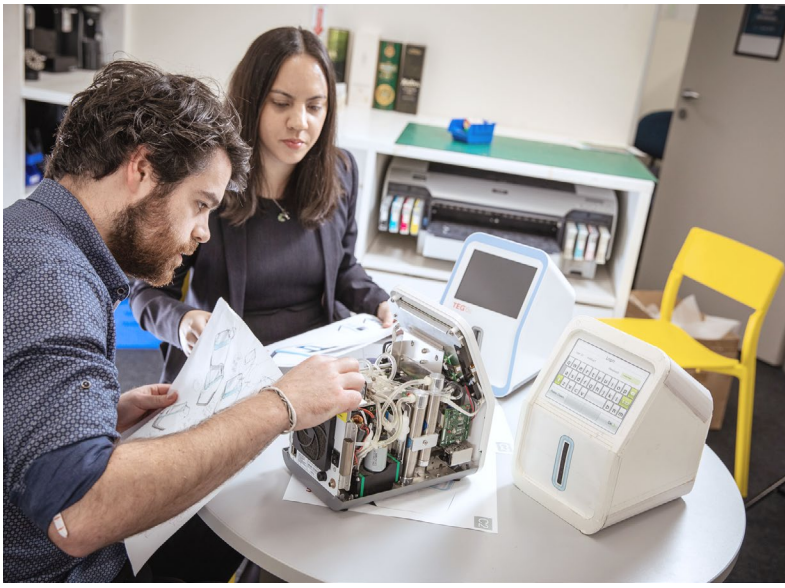
Make it simple. Reduce risk of harm. Reduce the potential for error. These are guiding principles when designing point of care (POC) diagnostic devices for CLIA Waiver.

Complex diagnostic tests that were previously performed by laboratory technicians or technologists are now being run by medical assistants, emergency medical technicians or patients themselves. This is possible because parts of the testing process that were previously performed by highly trained laboratory technicians have been automated. In a point of care setting, the tasks remaining for less-skilled clinical staff must be designed to be intuitive and in such a way that contamination, errors or other risks are reduced significantly.

Making a complex test easy for end users is an interesting challenge and diagnostic device manufacturers must embrace good design principles to get it done. That means visiting user sites to understand aspects of the workflow and environment. Even more crucial is the effort to understand the needs of the people who will be handling the instrument through formative evaluations that test the device with real users.

As part of the CLIA Waiver process, the FDA will want evidence the design and development process includes evaluating the product with the representative users. Evidence of that process must be documented to allow for FDA review.

As part of the CLIA Waiver process, the FDA will want evidence the design and development process includes evaluating the product with the representative users.



Pursuing a CLIA Waiver

To earn a CLIA Waiver, point of care diagnostic devices must be easy to use. They must be so intuitive that users cannot easily make mistakes that might harm themselves or patients or produce inaccurate results.

The FDA sets high standards for safety and simplicity in CLIA Waived devices, and a strong human factors engineering (HFE) and design approach can help device companies achieve that.

In particular, diagnostic device manufacturers should consider the following as they develop their device:

- Whether interpreting results requires independent judgment by end users
- QC and calibration requirements
- What training users will need to ensure error avoidance and reduction of risk of harm
- How might the test procedure be designed for simplicity

Visiting the site(s) where a device will be used is good practice for product design in general and will usually reveal user goals, needs and pain points.

Understand and research the user experience early on

Meeting the high bar for CLIA Waiver requires a thorough understanding of the user experience.

Early in the design process, a contextual inquiry by a trained practitioner should be conducted. This user experience research should include observations of the following:

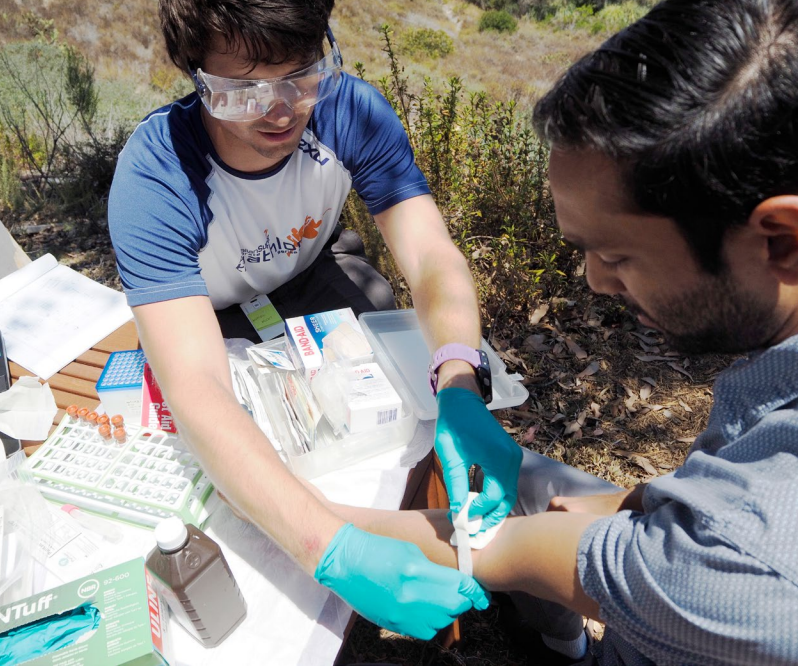
- Intended representative users of the device such as nurses or medical assistants in the case of a physician's office
- The use environment itself such as a busy Emergency Department with noise and many distractions
- Use scenarios which may include running a test, printing a result or cleaning the device

Visiting the site(s) where a device will be used is good practice for product design in general and will usually reveal user goals, needs and pain points. By starting this process early in the product development process, you can mitigate risks in early stages rather than late in the process when correcting a usability problem or risk of error is a more expensive fix.

During site visits, the design team closely observes the way users work. In particular, the team will watch for subtle clues that might flag challenges with current systems they use, such as embedded workarounds. For example, users might rig a cardboard shield to prevent barcode errors in a batched workflow, revealing that misreads could generate serious errors. It is important to identify these problems early and fully understand the true root causes.

Through this observational process, designers can identify hazards and begin developing strategies to mitigate risk, such as automating a specific task rather than adding more instructions.

For diagnostic startups, which generally do not have an in-house, multidisciplinary design team to guide them through this process, choosing the right consultant is critical. Partnering with a company that has both design expertise as well as HFE for medical devices makes for a more efficient process by minimizing dilution of design intent as you progress through development.



Use prototypes to evaluate and iterate

Moving from concept to prototype allows the design and HFE teams to evaluate the critical tasks such as sample transfer or interpreting digital interface instructions. Identifying usability problems and risks early will allow the team to mitigate the risks with a better design.

You can begin with low-fidelity models, using foam core, 3D-printed parts and consumables. These will keep costs down while providing a way to identify any use-related risks.

This iterative process with end users must be conducted in an un-biased manner. The evidence collected should be documented for the Usability Engineering File.

Using prototypes and collecting evidence of use will support the process of pursuing CLIA Waiver.

Using prototypes and collecting evidence of use will support the process of pursuing CLIA Waiver. The FDA will want evidence the product has been thoroughly tested with all targeted representative end users.

Advantages of field research

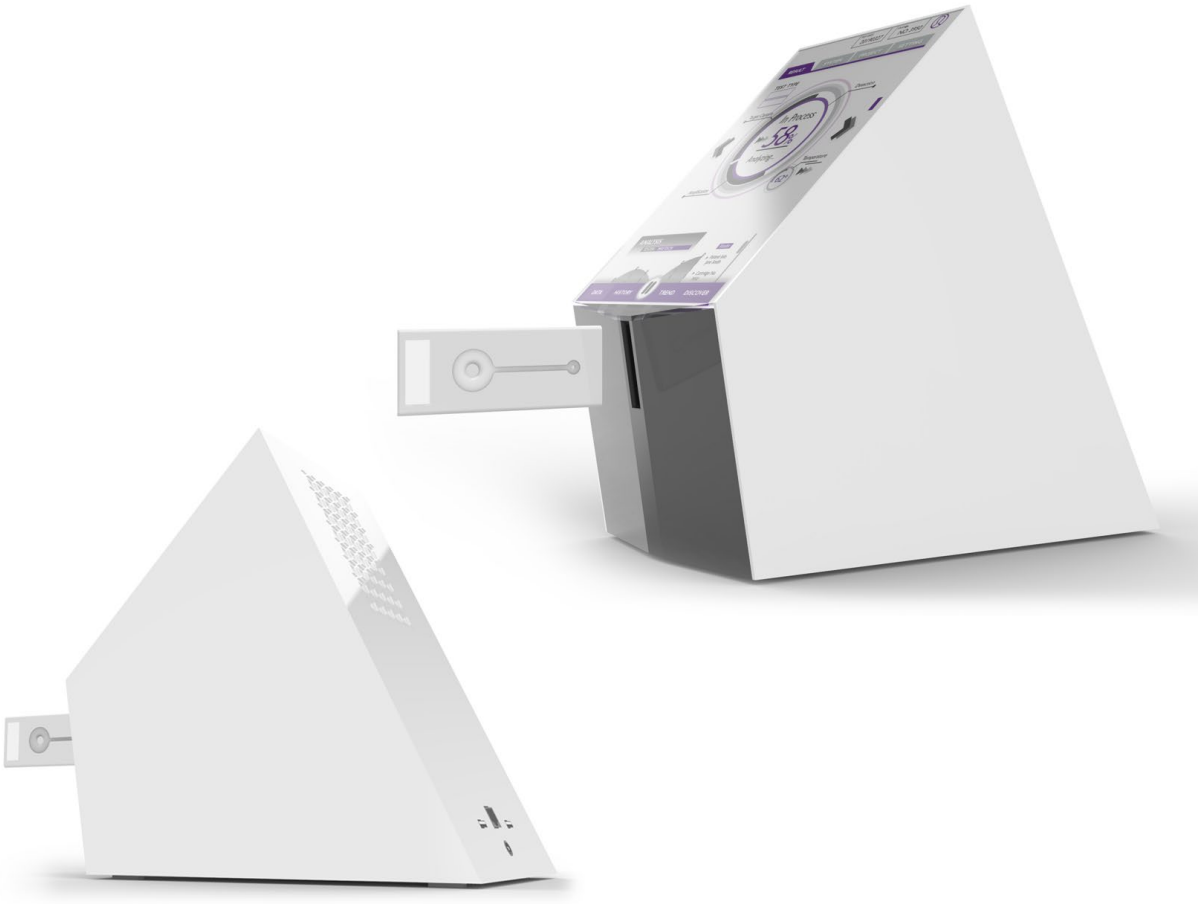
Lessons learned from field research will not only lead to the creation of a safer, more user-friendly device, they also provide invaluable insights to help differentiate your product in the marketplace.

Field research is essential to understanding how end-users work, and leads to the creation of a safer, more user-friendly device.

Recently, Invetech tested a client's initial design in several environments, including emergency departments and Ob/Gyn offices, learning the challenges device users would encounter in these settings. The sample transfer process proved to be the most challenging. The team worked rapidly to mitigate issues early in the development process. Each iterative design was evaluated using low-fidelity prototypes initially and then progressed to more advanced protypes as the design developed.

The insights from intensive user research also helped develop a clear value proposition for the device. We found that the physician offices clearly valued easy to use devices that helped the medical assistants stay focused on patient care rather than complex diagnostics. This became an important differentiator in the marketplace for the product.

In addition, this work was carefully documented, creating a body of evidence that could be submitted to the FDA to show the device had been designed with good principles of HFE for medical devices.



Closing thoughts

Before designing a POC diagnostic device, whether it will be CLIA Waived or not, it's critically important to understand the users, use scenarios and environment where the instrument will be used. Iterative design and formative studies with representative users can identify risks of harm, giving design teams the insights they need to design for simplicity and reduced risk of error or harm.

But beyond the regulatory aspect, human-centered design is simply good business. Identifying potential issues early will eliminate expensive redesigns down the road. In addition, usability is an important differentiator for any product, potentially giving it greater reach in the marketplace.

Invetech

Invetech specializes in the design, development and manufacturing of clinical diagnostic instruments and point of care devices. With hundreds of successful collaborations over the past 30 years, we bring innovative thinking, processes and people to empower your path to progress.

GLOBAL OFFICES

Melbourne
495 Blackburn Road
Mt Waverley (Melbourne), VIC 3149
Australia
+61 3 9192 6000

San Diego
9980 Huennekens St, Suite 140
San Diego, CA 92121
USA
+1 858 768 3232

Boston
159 Swanson Road
Boxborough, MA 01719
USA

For more information, or to discuss your project, visit **invetechgroup.com** or email us at **connect@invetechgroup.com**.