# Design Viewpoint

## The Human Factor

**Steve Maylish, Chief Commercial Officer** • *Fusion Biotec*
**Dave Hines, Chief Artistic Officer** • *Fusion Biotec*

Humans come in all shapes and sizes, ages, and abilities. Sometimes they aren't logical. Engineers come with logical, rational minds, but sometimes don't consider emotional behavior. Factoring humans into device design is not always a predictable process, but as of a year ago, human factors and design controls are joined at the hip.

For industrial designers, human factors have long been part of the design process, but in the past many companies considered it an unnecessary expense. As of last April, the U.S. Food and Drug Administration (FDA) requires use-related risks to be identified, mitigated, and validated as part of a formal risk analysis process for premarket submissions.

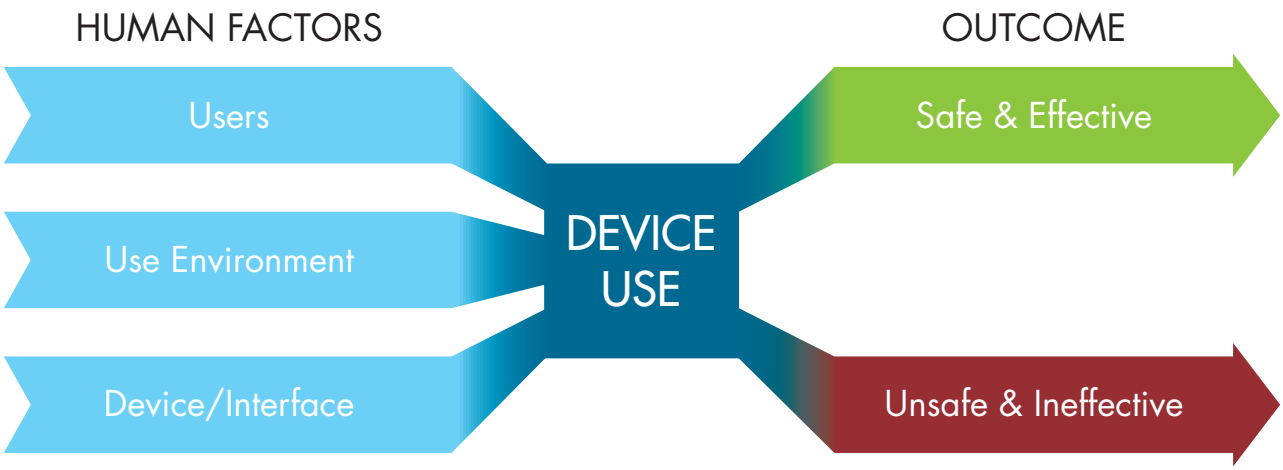
Human factors, as defined by the Association for the Advancement of Medical Instrumentation (AAMI), are "…the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations…." The International Organization for Standardization (ISO) defines usability as "characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction." Therefore, human factors are applied to improve usability.

Historically, FDA risk analysis emphasized physical, mechanical, thermal, electrical, chemical, radiation, and biological hazards. These were based on actual device or component failures. As failure trends were analyzed, however, it became apparent that just as many issues resulted from the usability of a device. These can be as varied as not comprehending the instructions-for-use manual because of poor wording, a screen font too small for the elderly to read, wrong buttons being pushed because their spacing is too close, or a confusing message on the display. Consider the consequences of a badly worded direction read by a non-native English speaker.

For devices where "the results of risk analysis indicate that use errors could cause serious harm to the patient or the device user," the FDA requires human factors and usability as part of the design control process. Now, use-related risks must be identified and mitigated using the risk analysis process, and designers must conduct human factors/usability validation testing on those mitigations involving significant use-related risks. This reads like a serial process, but any industrial designer will inform that it's iterative. Representative users in simulated-use testing should tryout a device and uncover any unanticipated hazards over the entire design cycle.

Industrial design should start early in the development process so there's time to iterate. Often, industrial design/human factors starts before the design inputs are complete, during a feasibility phase. This early discovery process initially defines the problem the potential device is solving. This process can include contextual inquiry, research analysis, concept exploration, communicating results, and iterating the design.

The main theme an industrial designer brings to the table is "the human comes first." One of the most difficult areas in the design process is the human interface, whether a wearable device or a display screen. Industrial designers are taught, and most often have, a natural instinct and empathy toward the user. Early in design school, the design student is introduced to critical thinking and the design process or "design methodology."




Human factors considerations for industrial designers.

The first step to any design process is to define who the user is, the environment of the user, and how they will use the product. Why is there a need for the product in the first place? Is there any history of the product to be designed? Are there similar products in the current market?

Defining these issues reveals current problems to avoid and advantages or beneficial ideas to apply. Some tools industrial designers employ to better understand the user are: real-time observation of the user in his or her environment, workflow mapping, quick execution or rapid visualization sketches (to create good ideas and flush out bad ones), and mock up studies (to give an idea in 3D form of the impact of size, shape, and volume). The mock up will also start to define arrangement or hierarchy of buttons, handles, switches, doors, display angle, display location or size, etc.

It's important to understand the designer has a tried and true methodology. Every tool the designer uses is meant to facilitate decisions quickly and painlessly, which ultimately impacts the success of the product. As an example, it's much easier to throw out a sketch idea that took two hours (inexpensive), than a 3D rendering that took 20 hours (quite costly). The form logic defined by user studies will quickly define the "look." This gives the designer a great starting point to define the direction of the products' visual branding.

Once early concepts are agreed upon, features, concepts, ergonomics, colors, texture, and feel are explored. Quick execution renderings are more easily created and modified than SolidWorks files, allowing for quick turns and iterations that generate additional ideas. Early in the process is the time to explore usability, human factors, ergonomics, and user interaction. Using rough models, the various embodiments of the design concepts are explored for their effect on the client's perception, interaction with the product, and potential use errors. There are always follow-on refinements and iterations. The user and designer will also evaluate how well the device fits its environment.

On the software side, a user interface can be tested via simulation on a laptop or tablet computer. Start with a wireframe (flow chart) of the software screens and first develop the "world" your software will live in. What are the common menu items? How does one navigate from screen to screen? What is the design style or "look" of the interface? An industrial designer or artist with experience in the latest screen styles can be very useful here.

Once the screen design rules are established, the entire graphical user interface (GUI) can be modeled using a design tool. The design tool runs on a computer, has all of the screen-to-screen links, and can create the actual look of the GUI. The net result is an accurate simulation of how the actual software will look and operate.

Potential end users can then perform an assessment to evaluate ease-of-use and identify potential use errors, such as lack of information or inability to understand the screen. Tools such as MockupScreens, ForeUi, or even MS PowerPoint can create screen mockups. Other methods of simulated-use testing involve tools that will compile the actual code into a version that runs in a demo mode. Languages such at QT or Java, or WxWidgets with C++ or python can be great for this process. Exploration in a methodical way from the very beginning produces an end product with much greater potential for market success.

## Human Factors Examples

One company decided to get its product out and in the hands of users without human factors and usability studies. The product was well received, but once the sales group had to carry it onto planes, it became apparent the height of the device was oversized by an inch. If this had been considered in the beginning, the device would have been designed with different dimensional requirements and no added cost. Instead, the enclosure had to be redesigned, which had a ripple effect throughout the device's internal components and mounting hardware.

Another company was developing a software GUI for a medical device to be used by consumers. The designers, being young with strong eyesight, had no problem viewing the small details they had designed into the display screens. But in testing older users, it was clear all of the fonts needed to be larger and the fine detail of the screen was confusing.

If done well, the human factors effort should improve the design, improve usability, and add features and benefits not previously considered. As far as the FDA is concerned, human factors and usability should prove the development was based on feedback from representative users and the device was validation tested to confirm it can be used safely and effectively under the expected use conditions.

Concerning human factors, the FDA states, "The testing should be comprehensive in scope, adequately sensitive to capture use errors caused by the design of the user interface, and should be performed such that the results can be generalized to actual use."

Human factors validation testing criteria, according to the FDA:

- The test participants represent the intended (actual) users of the device.
- All critical tasks are performed during the test.
- The device user interface represents the final design.
- The test conditions are sufficiently realistic to represent actual conditions of use.

A new component to the usability work is documentation. According to the FDA: "Documenting your risk management, HFE/UE (Human Factors Engineering/Usability Engineering) testing, and design optimization processes (e.g., in your design history file as part of your design controls) provides evidence that you considered the needs of the intended users in the design of your new device and determined that the device is safe and effective for the intended users, uses and use environments. When it is required, providing information about these processes as part of a premarket submission for a new device will reduce the need for requests for additional information and facilitate

FDA's review of all HFE/UE information contained in your submission…"

The FDA proposes a report format that addresses usability concerns during the development process. The report should contain the following topics:

1. Descriptions of intended device users, uses, use environments, and training
2. Description of device user interface
3. Summary of known use problems
4. Analysis of hazards and risks associated with use of the device
5. Summary of preliminary analyses and evaluations
6. Conclusion

Number 4 identifies and adds use hazards to the formal risk analysis process. Use hazards must be evaluated for severity, probability of occurrence, and detectability. Mitigations need to be identified and demonstrated to reduce risk through validation testing to an acceptable level. The report should describe the identification, evaluation, and final assessment of all serious use-related hazards for the device.

The FDA does an excellent job of describing its expectations in the guidance entitled, "Applying Human Factors and Usability Engineering to Medical Devices." This new process, as of a year ago, pulls use-related risks into the design control process. For the FDA, the largest concern is possible user errors causing serious harm to the patient or operator. For medical device companies, avoiding post-launch issues as users struggle with training, find the interface confusing, don't like working with the device, or eventually experience repetitive stress injury should also be extremely important. The best way to meet the new requirements is to enlist an industrial designer to be a critical member of your development team. ❖

*Steve Maylish has been part of the medical device community for more than 30 years. He is currently chief commercial officer for Fusion Biotec, an Irvine, Calif.-based contract engineering firm that brings together art, science, and engineering to create medical devices. Early in his career, Maylish held positions at Fortune 100 corporations such as Johnson & Johnson, Shiley, Sorin Group, Baxter Healthcare, and Edwards Lifesciences.*

*Dave Hines is an inventive and experienced top-level industrial designer with exceptional project management and presentation skills. With over 25 years in the industrial design profession he has consistently demonstrated the ability to design and produce useful and highly marketable products. His designs have been featured in international design yearbooks and design magazines. He is credited with numerous design awards, design patents and was featured on the TV show, "American Inventor." Hines has a BS in industrial and product design from California State University, Long Beach.*