MPO
MEDICAL PRODUCT OUTSOURCING

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Designing For The Human Touch

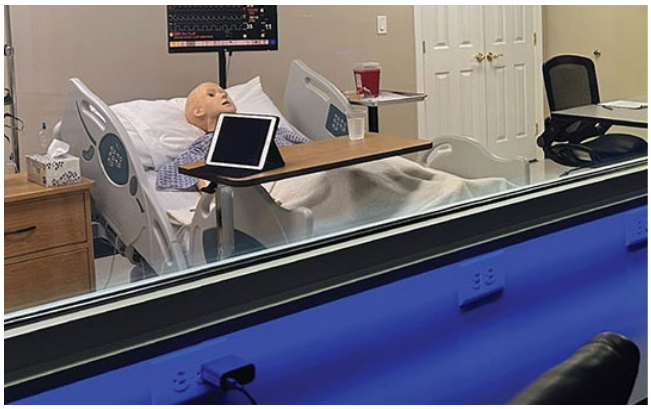
Human factors engineering is a critical piece of medical device development that not only improves user experience but is also required for regulatory clearance.

MARK CRAWFORD • CONTRIBUTING EDITOR

Human factors engineering (HFE) in the medical device industry is a well-established practice, a result of progressive international standards and U.S. Food and Drug Administration (FDA) guidance over the last 15 years. "It used to be that HFE was 'nice to have' and something that could reduce business risk, but now it is an expectation of the FDA and the major regulatory authorities around the world," said Christina C. Mendat, managing director for Eurofins Human Factors MD, Eurofins' U.S. HFE testing lab in Charlotte, N.C.

HFE has seen significant advancements in recent years and plays an expanding role in ensuring the safety, effectiveness, and usability of medical devices. In addition to FDA regulations, medical device manufacturers (MDMs) must also comply with other standards such as IEC 62366-1, which incorporate HFE principles throughout the product lifecycle.

MDMs are expected to consider the needs of their intended users and how their products are used in the end-use environment. They are expected to fully evaluate their medical devices for any use-related hazards that could cause harm—for example, by implementing and evaluating risk control effectiveness through formative studies. "Once complete, manufacturers must provide data that demonstrate all use-related hazards have been mitigated as much as possible through a human factors validation test in the U.S. [called a human factors summative study in the EU]," said Mendat.



Years ago, HFE and user experience (UX) design were separate disciplines. Today, the fields are merging as devices themselves traverse the gap between simplicity and complexity.

"Doctors and scientists expect an elevated user experience with medical devices and applications similar to that offered by their personal computing devices, while emerging tech for consumer devices such as self-driving and driver-assist vehicles requires a more human factors-centric approach to design," said **Dorothy Shamonsky, chief UX strategist for Integrated Computer Solutions**, a Waltham, Mass.- based provider of software engineering and human-centric user experience design services for the medical device industry.

A sharper focus on user-centered design principles—which includes conducting comprehensive user research, usability testing, and iterative design improvements—ensures that these

devices are intuitive, safe, and appropriate for a wide range of users.

"User-centered approaches to device development are also essential for creating products that meet real-world market needs to maximize market penetration," added Philip Remedios, CEO and director of design and development for Black-Hägen Design, a Dunedin, Fla.-based interdisciplinary user research and product design firm.

HFE today is integrated into risk management processes to identify and mitigate potential use errors that could lead to patient harm or adverse events. This integration requires that manufacturers conduct thorough risk assessments, including task analyses and use-related hazard analyses, to address usability issues early in the design phase.

Design for Manufacturability

Medical products that make use of HFE programs are generally separated into two groups—medical devices and combination products. These two product types use HFE programs the most.

HFE should be integrated throughout the entire development process. Without the collaborative process created by design for manufacturability (DFM), product development teams often stay siloed, slowing down communication and information-sharing. Determining how users interact with a proposed technology or device early in product development will enhance the design quality and reduce use risk across all intended markets.

"HFE is best initiated at the beginning of the design process where methodologies like contextual inquiry, virtual reality, and rapid-prototyping techniques are applied that can direct subsequent development with near certainty that the device will be highly marketable, either in clinical or at-home settings," said Remedios.

Another advantage of practicing iterative user engagement is that it enables teams to collaborate with regulatory agencies to review HFE-derived test data periodically throughout the design process, thus reducing the risk of failure or setbacks during the agency approval process—thereby saving time and money.

The goal of HFE is to help create an end product that is highly market-relevant and includes the optimal functions, features, and product workflow adaptations identified by HFE testing. Often when MDMs come calling with rush requests, it is usually because usability issues have been identified late in the development process, where major changes to the design at this stage often come at a substantial cost.

"To prevent this, human factors professionals recommend early and frequent touch points with users so that designers and engineers can iterate on the design with little impact to cost," said Jennifer Samproni, chief technology officer for the Health Solutions business at Flex, an Austin, Texas-based provider of end-to-end product development and manufacturing services for diverse industries, including healthcare. "Flex incorporates user input at all stages of development for medical devices—from generative research and formative usability testing through to validation. This sets companies up for success by the time summative testing takes place."

HFE/UX teams don't just rely on technology changes to make a medical device design as user-friendly as possible; they must also take time to observe, in detail, how the device is used by the patient or end-user and factor those discoveries into the design.

HFE professionals have quickly learned that what patients say they do is never quite the same as their real behaviors. Therefore, it is vital to ask them to describe what they do and then observe them interacting with the device. What patients tell you provides insight into their perception of usability,

utility, and the user experience. In contrast, watching how people behave reveals how they physically use the design, sometimes highlighting "workarounds" and "hacks" that can lead to design improvements.

Contextual inquiry (CI) is a valuable research method that greatly enriches the development team's understanding of user workflows and other challenges. CI also reveals users' explicit and implicit needs by seeing how they interact with devices or systems in real-life contexts. The rich, qualitative data gathered through CI supports evidence-based decision-making throughout the design process.

"CI helps inform design decisions and prioritize features and functions that are most valuable to users, supports regulatory submissions, and guides future iterations of the product to ensure that the final product is both useful and used," said Remedios. "Understanding the context of use is also critical for meeting regulatory requirements. Insights from CI can also support compliance efforts by providing documented evidence of user-centered design practices."

Integrated Computer Solutions always strives to make user workflows as efficient as possible, which typically involves finding ways to reduce the number of steps in getting to the end result for any process. "While it's a simple solution, it is surprising how many people do not bother to count steps or clicks and instead waste more of the user's time than necessary," said Shamonsky. "The power of an illustration is also huge in a complex interface. A small diagram can be the difference between a user not understanding how a control works and the user instantly grasping the concept."

Ergonomic design is another strategy whereby all decisions made throughout the development process are considered through the lens of the user/patient. For example, the perfect combination device must be usable, intuitive, and obvious in its use and operation. Aesthetic signals that articulate form, texture, color, and materials can also have big impacts on the overall user experience and patient outcomes.

Latest Trends

MDMs are utilizing HFE to develop smart devices and smart system technologies—devices that help people make clinical decisions and adhere to their medicines. Connected devices also 'talk' to each other—for example, insulin pumps and continuous glucose monitors. AI and machine learning enable devices to get progressively smarter as they analyze and incorporate data results in real time. Although these advanced devices are at the leading edge of innovation, they can introduce unintended use-related hazards that must be understood and thoroughly designed.

"For instance, if patients become too reliant on a smart medical device, they may not know if they are not receiving the therapy as intended," said Mendat. "A smart device's functionality cannot stop at intelligence; its programming also must incorporate assurance that the user fully grasps the capabilities and limitations of the technology."

Other robust trends include the integration of AI to enhance usability and the user experience and the use of digital twins and virtual reality to create training environments that simulate reality without potentially harming real humans. Also, HFE engineers are being asked to create mobile interfaces that are more user-friendly and can be seamlessly integrated with existing healthcare systems to enhance remote monitoring and user engagement/adherence.

As the main point of contact for essential interactions between the device and the user, the user interface (UI) must be as intuitive and easy to use as possible—a UI that creates even the slightest confusion can lead to costly redesigns or reduced sales. To properly evaluate UI, "usability considerations and HFE are collected and applied for device set-up, including un-packaging, calibration, device maintenance, cleaning, battery or part replacement, and usage within the care setting," said Greg Montalbano, co-founder and COO of MIDI PD, a Smithtown, N.Y.-based product development firm that helps MDMs develop their products.Display footnote number:1

A device's size and shape, particularly in handheld, wearable devices, or disposables, can impact the effectiveness of the UI. "Information delivery elements, such as indicator lights, displays, and auditory and visual alarms, are another example," added Montalbano. "Also included is the cognitive logic workflow of the overall user-system interaction, composed of how, when, and what form the information or feedback is delivered. Other factors include hardware control components like displays, switches and buttons, accessories, peripherals, and packing and labeling, including instructions for use training manuals, and other informational materials."

To manufacture higher-quality products with fewer iterations and shorter time to market, DFM is increasingly desired by MDMs—bringing together designers, engineers, and HFE and user experience experts to share their expertise to make the best possible product. These viewpoints can clash at times, but usually develop into collaborative relationships.

"As an industrial designer, I'm often debating project details with my engineering partners," said Reed DeWinter, co-founder and medical device design director for New York City-based Humanfactors Design Works, which provides research, design, and engineering services to medical device companies. "I wonder sometimes if they'd prefer the world to be comprised of black boxes of various size and proportion—this ensures ease of manufacture and also makes engineering a snap. But a black box isn't very comfortable or useful in the operating room. More accommodating is an instrument whose contours have been sculpted to fit the surgeon's hand, whose interface won't fatigue fingers during arduous procedures, whose surfaces won't reflect and blind under the hot lights."

Similarly, designers sometimes design themselves into a corner, and rely on engineers to help course-correct: for example, "this detail is going to require too many mold actions" or "this detail would result in an undercut" and even "this detail requires a magical material that doesn't yet exist." This is where DeWinter sees the correlation between human factors and manufacturing. "We want to push for certain details—that complex contour, that specialized grip texture—where savvy engineers and manufacturing experts work with design in their best attempt to provide optimal human factors—features that sometimes push against typical notions of what's practical, or even advisable."

Too many MDMs look for HFE help late in the development phase—typically wanting to conduct a human factors validation test, thinking this is the only compulsory activity. However, it is always more successful from a development standpoint to have MDMs engage early on with HFE teams to refine the product design and ensure mitigations are effective—prior to commissioning the final human factors validation test.

"HFE design changes are best identified early in medical product development cycles to decrease cost and minimize impact to timelines," Samproni added. Recent successes she has seen include:

- Enhancing the magnification of a dose window on an injection pen to decrease dosing errors
- Changing the layout of a UI for imaging software to facilitate ease of use and faster diagnosis
- Improvements in error messages/warnings on various types of displays that led to fewer use errors

Technology Plays Its Part

The expansion of remote work tools has had an enormous effect on remote user research and testing. Remote work tools have simply become more robust and user-friendly due to the competition for popularity. People have also become well-versed in remote meetings and collaboration and are more accepting of its use.

An orthopedic client recently hired Humanfactors Design Works to embark on an objective, global investigation into companies, universities, and independent labs in order to paint a detailed picture of the nascent smart implant landscape—from niche tinkerers to established developers—to evaluate this technology and its impact on the orthopedic industry. "This is sensor technology as applied to orthopedic implants, whose integrations enable surgeons and researchers to record and analyze real-time feedback post-operatively the implant recipient's performance metrics," said DeWinter. "This data can then be used to evaluate the implant's performance, surgery's level of success, and condition of the patient's new joint. In fact, this data could lead to some new surgical procedure, or a new approach, that would require new instrumentation or new implants, all of which would have a fundamental impact on human factors."

AI and augmented reality are the latest technology trends, particularly with respect to diagnostics/imaging. "One of the most interesting aspects of this for the human factors professional is evaluating users' willingness to 'trust' a technology," said Samproni. "This is a significant potential barrier in the adoption of these tools. For example, in the diagnostics space, physicians need to have insight into the algorithm used to identify a potential tumor so that they can determine whether to rely on the data generated."

Human factors engineers can draw on research related to establishing trust to help minimize those barriers. Some factors that increase individuals' trust in a technology include the belief that the technology is reliable and consistent, that it is capable of performing what it is meant to do, and that it will be helpful should things go wrong. Therefore, in the case of AI, healthcare professionals will be more likely to trust the technology "if it delivers consistent results, if there is transparency into the variables included in the calculations, and if there is assistance available in the interface should they run into trouble," continued Samproni.

For HFE/UX, some professionals are using AI as a tool to assist developing task analyses, use-related risk analyses, and reporting HFE data. "However, it is Eurofins Human Factors MD's position that AI is a complement and cannot take the place of classical training and dissecting what is representative of sound human factors, and what is not," said Mendat. "AI is only as good as the person who is inputting the information into it. Humans for human factors testing remains the constant."

Shamonsky agreed.

"Good design strategy will always be needed," she said. "Sometimes the right tools can help, but mostly good design skills lead to the best outcomes."

Moving Forward

Small changes often have the biggest and most impactful influences on design—a tiny design change or a tweak to the instructions for a device can have a big impact. Even something as small as changing the break-loose force on a plunger for a prefilled syringe could significantly reduce the chance of expelling medicine prematurely. Where a widget is located on a graphical user interface can make the difference in programming a safe versus a lethal dose of medicine. "Or the 'cancel' button that, at first glance, looks like the 'next' button due to location or color—something that trips up many users who then lose all their progress within an interface," said Shamonsky.

Is HFE always worth it? In most cases, yes—especially as devices become more complex, smaller, and have more functionality. Conducting HFE can also help build rapport with FDA examiners, which speeds up the overall submittal process.

A common misconception by MDMs is that human factors activities are expensive, when in fact, they are much, much lower compared to clinical trial costs, noted Mendat.

"The issue is that many companies do not budget for these costs during their planning," she said. "Thus, when they seek out help, they don't have the budget or the timeline. What these manufacturers come to realize is that the cost and time of human factors activities is minimal compared to restarting the timer for a rejected submission due to the lack of meaningful human factors data."

Sometimes HFE firms develop their own proprietary equipment and methods to go beyond what is considered standard for a typical HFE/UX process.

For example, "it is incumbent upon designers and engineers to figure out the hows and whys that conspire to make effective dosing so problematic," said DeWinter. "It's not fun to watch a neuropathic septuagenarian fumbling with an inhaler while struggling to catch a breath."

To get better data, Humanfactors Design Works has developed custom fixtures that contain various MDM/custom sensor technologies like accelerometers, load cells, microelectromechanical systems, and flow sensors. These fixtures have been specifically designed to be seamlessly integrated with, for example, a functional prototype that will be operated by users. "These cutting-edge sensors are capable of graphing real-time data to intuitive custom software that we developed to accurately track, measure, and assess patient performance as it pertains to personal dosing regimens and behaviors."

Once the HFE data has been captured, it must be presented to the FDA as part of the submittal package for the proposed device. This can be confusing and time-consuming to organize because the data is often stored with the HFE partners who carried out the testing. "This results in disjointed documentation that is difficult to trace and evaluate, not to mention increases the burden on the FDA reviewers," said Mendat.

To ease this bottleneck, Eurofins has assembled use-related risk analyses (URRAs), labeling design, and human factors validation test protocols into a single package that provides the FDA with a cohesive and traceable submission. "We view our role as presenting data and information in a clear and efficient manner so FDA examiners can glean the real use-related risks of a product right away, without having to wade through endless pages of information," said Mendat.

In addition, there are still some MDMs stuck in what might be called "legacy thinking"—the belief that usability and safety can be achieved by mechanical or software engineers alone, rather than someone with special training and skill in that area. In the end, they are probably doing more work to correct their designs that did not quite comply with regulatory requirements regarding HFE.

There continues to be a perception by some MDMs that HFE simply involves reading the guidance and/or that it is "common sense." "That is just not the case," stressed Mendat. "Human factors is a multi-disciplinary field that encompasses cognitive psychology, information processing, humancomputer interaction, and industrial engineering. We need to rely on our trained professionals with industry experience—human experience."

DeWinter noted that until we can achieve some state of "telepathic mind-meld" to fully understand user experience, MDMs and HFE professionals will continue to rely on focus groups, interviews, observations, and other activities to meaningfully understand patient needs.

"In some ways, human factors research is merely an attempt to empathize—to anticipate how one might optimally use something that will eliminate struggle, increase joy, and reminisce satisfaction," said DeWinter. "Ultimately, what seems obvious, and arguably most ethical, is to design your product to leverage the user's behavior and abilities, rather than expect users to adjust their behavior to effectively use your product."