Beyond Compliance: The Role of Human Factors in Medical Device Development

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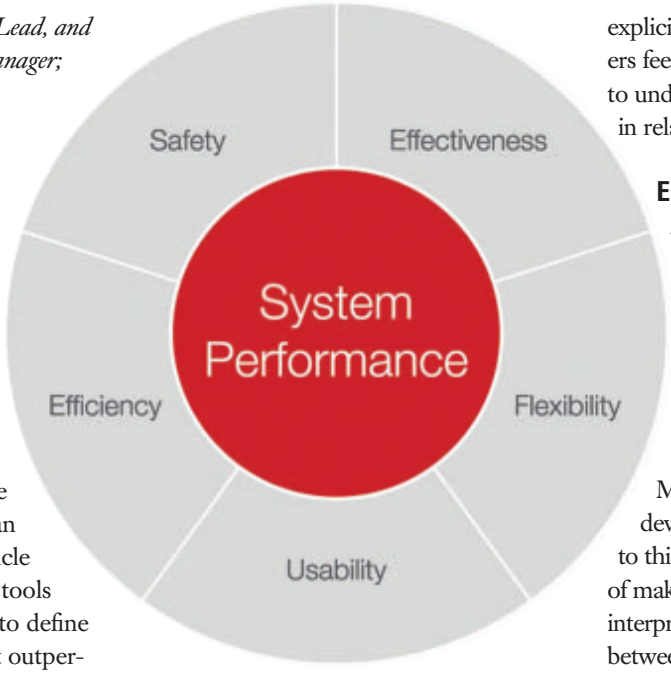
The profile of human factors in medical device development has increased significantly, largely due to it playing a critical role in gaining regulatory approval for a medical device. However, for many, the focus on demonstrating safe and effective use can dominate the project involvement for human factors professionals. This article discusses how human factors tools and techniques can also help to define how to develop products that outperform their competition.

To be successful a medical device needs to overcome two challenges. Firstly, it needs to make it to market, and secondly, it needs to offer a recognizable advantage over its competitors.

Making It to Market

IEC 62366 is an international standard that outlines how human factors should be integrated into the process of medical device development. As compliance with the standard is critical for regulatory approval, the introduction of the standard has served to increase the salience of human factors within medical device development. So much so, that failure to adequately document the involvement of human factors is seen as a clear project risk.



Regulators such as the FDA focus on safe and effective use. The preferred method for demonstrating this is the simulated use test. This test involves putting the product in the hand of representative users and asking them to perform a set of pre-defined tasks. The test represents a clear barrier to project success. At best, failure means project delays and additional costs for design modifications, at worst; it results in the cancellation of the project and substantial financial losses. Accordingly, it is clearly understandable why such an importance is placed upon it. This focus on simulated use tests, and on safe and effective use, helps to ensure poorly designed products are kept off the market. What it doesn't do; however, is explicitly seek to understand how the users feel about the device, nor does it seek to understand how the device performs in relation to its competitors.

Establishing a Competitive Advantage

Whereas the first challenge, making it to market, posed the question is this acceptable for end users, the second challenge posed is more ambitious as it also strives to be better than its competition.

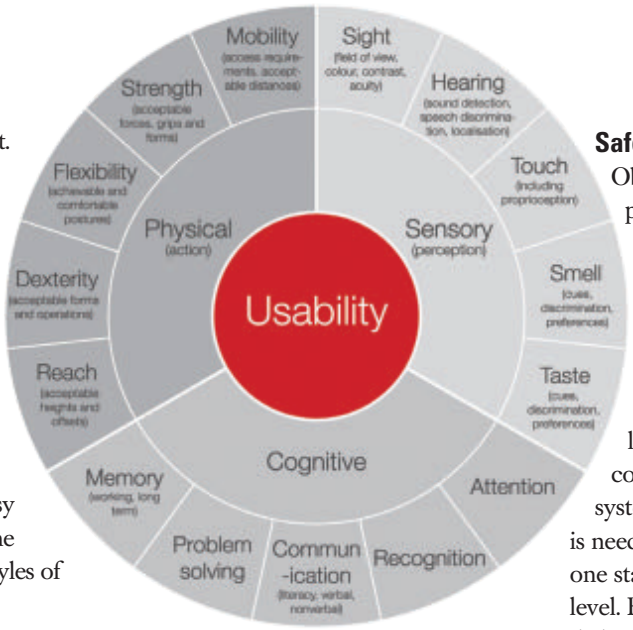
But what does better mean? Most people involved in the medical device development process would like to think that they were in the business of making better devices. However, the interpretation of 'better' is likely to change between the diverse range of stakeholders. For those intimately involved in the manufacturing process, such as production engineers, there is likely to be a keen focus on the cost effectiveness of the devices. For others with a market focus, the emphasis may be on commercial viability.

Systems Thinking

We can learn a lot about how good a medical device is by thinking of it as part of a system. At the most basic level, this system includes the medical device and the patient. However, it could also include other people, such as healthcare professionals or caregivers, or other artefacts such as other devices, drugs, training materials, instructions for use, apps, etc.

Once this system has been defined, the

next step is to define what is important. This is critical as it essentially establishes, at a high-level, the criteria for assessing the system and, in turn the medical device. The exact values attributed will vary depending on the system, however, they are likely to include the core values that the FDA is interested in, safety and effectiveness, along with additional values such as efficiency (how long it takes to setup the device), usability (how easy it is to use), and flexibility (how well the product fits the range of different lifestyles of its target population).



Measuring Performance

The system's values can serve as an excellent vehicle for comparing a proposed medical device against the product it is planned to replace, or its direct competition. Likewise, by thinking in more abstract terms, it is also possible to make a comparison with other types of devices or therapies used to treat the same condition. To aid these comparisons, it is advantageous if the differences in performance can be quantified. This is where the use of human factors tools and techniques comes in.

Efficiency

One of the most common techniques used within human factors is task analysis. This involves describing each of the core tasks that a user must conduct with a device. For example, this may include, unpacking, reading instructions, preparing the device, administering a dose, and disposal. Each of these high level tasks is further decomposed until a series of base level task steps is defined (e.g. rotate dial, slide button forward).

The number of task steps alone is often a useful indication of the efficiency of a device and its complexity of use; however, more detailed assessments can be made by coding each task step. Time data can be used to provide a description of efficiency. Likewise, task steps can be represented on spatial arrangements using a tool called link analysis. For example, for medical installations this can be used to predict the number of operator footsteps required in a typical day.

Usability

The usability, or inclusivity, of a design can be assessed in a number of ways. A useful starting point is to consider each of the task steps against three aspects of human performance. (1) Sensory – the ability to see, hear, feel, smell or taste the device. (2) Cognitive – the ability to understand the device and remember how it works. And (3) Physical – the strength and dexterity required to use the device.

There are a multitude of tools that can be used to quantify usability. Anthropometric datasets can be used to describe the percentage of a given population that would be excluded from use by the size of a product of the force required to actuate it. Likewise, data on those with sensory capabilities can also be used to determine how many users would be excluded by certain color choices or text sizes.

Flexibility

Standardization is a clear challenge for medical device developers. Even subtle changes to color may require a separate regulatory submission. Accordingly, a single device system (e.g. device, labelling, packaging, IFU, training aids, support mechanisms) is often required to meet the many different ways of using the device. Imaginative solutions are required to build flexibility of use into the device system without introducing the burden of additional regulatory overhead.

Safety

Observations of representative users play an important role in assessing the safety of a device; however, the unsafe acts that can be considered are limited to those that can be observed. Given that medical devices can be manufactured in billions, and misuse can have adverse effects, low frequency errors are of obvious concern. Accordingly, a structured and systematic approach to error prediction is needed. From a human factor standpoint, one starting point for this is at a task based level. For example where tasks such as dialing up a dose step can be subject to errors of omission, performing too much, performing too little, or performed in the wrong direction, etc.

Effectiveness

Simulated use trials provide a very useful indication of the influence of human factors on the effectiveness of a device – that is the ability of users to operate the device without impacting its efficacy. Planning, preparation and rigorous study design is key to gaining valid insights as is using a representative sample of the intended end users.

What Should the Role Be?

So returning to the question posed in the title, what should the role of human factors be? The introduction of IEC 62366 makes it clear that the first challenge of demonstrating safe use is a minimum requirement.

Human factors is not simply a tool for regulatory compliance. The vast majority of medical devices operate in a competitive market, and while the product selection may not always lie with the end user, usability and system performance are increasingly shaping purchasing decisions.

Accordingly, the definition of system values and their quantification plays a critical role in informing the project direction and setting commercial, as well as regulatory, expectations for the device. Beyond compliance, the end-to-end integration of human factors tools and techniques in the design process is critical for designing a commercially successful device. MDT