By Stephen B. Wilcox, PhD, FIDSA

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HIGH-STAKES DESIGN

It's easier to focus your attention when a design mistake has a high probability of killing somebody or—from the opposite point of view—when your good design has the opportunity of saving hundreds or thousands of lives. If you have little or no experience in the medical product arena, this can be a refreshing field because it is different from most other applications of ID.

What I love the most about medical product development is that I never hear clients say things like:

- "I don't care if the product works. I only care if customers will perceive that it works enough to buy it."
- "Don't talk to me about play value. Talk to me about what my boss thinks the mothers will buy."
- "Of course there are no real differences between the products at different price points. Our job is to create the illusion that there are real differences between the products at different price points."
- "Issues like product quality are not really that important, given that the product will be obsolete within a year."
- "Does anybody really need a product like this? Probably not, but good design will make people think that they need it."

These are all actual quotes, collected over the years from non-medical clients. But I've never heard this kind of thing from clients in the medical industry. The stakes are higher. Says one medical client: "What makes us all very serious about what we do is our knowledge that not one of our customers could live for one extra minute if our products did not exist. Think about it. Our product is as crucial to the survival of our users as their hearts or their livers are." This gives you the flavor of what medical product development is, or can be, all about.

The whole environment of medical product development has an intensity that stems from the fact that the stakes are so high. This tends to give everyone involved a seriousness of purpose. You simply don't find the sort of corner cutting and slapdash design procedures that are common in other areas of product design, at least not most of the time.

In general, cool styling is less important than it is for most other product categories. **It doesn't usually hurt for a medical product to look really cool, but it doesn't tend to help much either.** Appearance is relevant but not as much as it is for, say, a toaster or an automobile.

Special Requirements and Restrictions

While having a serious sense of purpose is probably the best thing about the medical world, dealing with the Food and Drug Administration (FDA) is perhaps the worst. **There are mountains of requirements for product characteristics, for the design process itself and for how you document what you do.** For example, the FDA mandates a multi-step process for designing medical products that has to be carefully documented in a Design History File.

Designers have to know a lot about these various requirements. Most of them are perfectly reasonable and result in products that are less likely to pose safety or efficacy problems. I don't know anyone who thinks dealing with the FDA is fun, however. Designers already have to juggle several balls, and the FDA's requirements add yet another ball to the juggling act.

Purchasing decisions also can be remarkably complex. A typical product is specified by a group purchasing organization (GPO) and approved by a committee of physicians, who don't always have to conform to the GPO's specifications. Hospital administrators, biomedical engineers (who maintain and repair equipment), nurses and various other professionals also usually have a say and sometimes even have the power to veto a decision. If you don't adequately understand this complexity, you may ignore issues that are crucial to the success of a product.

The Importance of Clinical Issues

In order to be effective, the designer also has to develop an in-depth understanding of relevant clinical issues. This means that if you're working on cardiac products, you have to learn a lot about cardiac rhythms, the various cardiac-related clinical syndromes, etc. If you're working on surgical products, you have to know quite a bit about the surgical procedures that the product will be used for.

The clinical issues are sometimes at odds with what a designer might consider to be good human factors. Left and right are typically reversed, for example, because physicians are used to thinking of the patient's left and right as he or she faces the physician. Also, there are often conventions and habits that don't make any sense but are maintained because physicians have been doing it this way for decades.

Design education doesn't prepare you for grappling with complex medical and scientific information. But if you like to learn weird new things that make great topics for dinner-party conversations, medical product development could be for you.

Blood and Guts

If you design medical products, you inevitably have to see those products in action, which means that you have to spend some time hanging around hospitals and/or other medical facilities. Before you enter, make sure your vaccinations are up to date; different vaccinations will be required by various medical facilities. You should also get some blood-borne pathogen training so you can avoid contracting AIDS or hepatitis.

Like any other exotic culture, the medical world has its own rules that are not particularly intuitive to an outsider. And as in any other exotic culture, you violate the rules at your peril. As one example, try walking into an operating room during a procedure without your mask

on. Despite the deafening Latin music that may be play-
ing and the apparent concentration of the various physi-
cians and nurses on the procedure at hand, everyone
will stop what they're doing to stare at you in horror. On
second thought, maybe you shouldn't try this.

Another common pitfall for designers is getting in
the way. Avoiding doing so can be a challenge when
you're trying to videotape a procedure in a room that is
reminiscent of the stateroom in *A Night at the Opera*.

Finally, depending on what product areas you work
in, you will probably have to get over your squeamish-
ness about blood and guts. In the interest of decorum,
I'll refrain from giving examples.

Extended Job Benefits

In most types of ID, you get to work with smart engi-
neers, marketing folks and other designers in developing
products, but the users of the products are not always
the best clientele. Medical product design, on the other
hand, provides designers with a unique opportunity to
work with physicians, nurses and medical technicians
who are interesting and committed to what they do.

Another advantage of working on medical products
is that you get to go into hospitals and see your prod-
ucts being used to save lives. And finally, you get to
wear scrubs. You no longer have to feel envious of
those clinical professionals you see walking down the
street in their scrubs. **If you're really lucky, you get to
walk around with a mask and one of those little tied-in-
the-back hats that you see the real pros wearing.**

Like the liquor business, medical product design is
counter-cyclical. People don't stop needing pacemakers
or dialysis systems when the economy takes a down-
turn; on the contrary, they probably need more of them.
Of course, medical design isn't for everybody, but if you
get the bug, it's hard to kick. ●

Pros & Cons of Medical Design

Is medical product design for you? Consider the fol-
lowing ways in which it differs from other ID fields:

- **The stakes are high**. Everyone involved tends to be committed and serious about the product being designed. If you're cynical about what you do, this isn't the arena for you.

- **Cool styling usually takes a backseat** to other design aspects. You have to deal with the FDA and a myriad of FDA requirements.

- **Purchasing decisions are complex** and can add to the challenge of the product design process.

- You have to **learn a lot about the clinical issues** involved in the product.

- You have to **be able to handle yourself in clinical settings**. This means avoiding fainting at the sight of blood as well as adhering to esoteric "cultural rules" and documenting procedures without getting in the way.

- You get to see your stuff in hospitals. Your products can make a real difference.

- You get to work with really smart people.

- You get to wear scrubs! ●

—Steve Wilcox, FIDSA