CEOCFO: Ms. Patterson, what is the vision and focus for Agilis Consulting Group, LLC today?

Ms. Patterson: The vision for Agilis is to help medical device and pharmaceutical clients get good devices into the hands of users as quickly and trouble free as possible. We’re here to help our clients clear FDA or other regulatory agencies, so that they can put good medical devices and drug-delivery products into the hands of their users.

CEOCFO: You used the word good a couple of times. Do you evaluate before you take on a client? What is your definition of good?

Ms. Patterson: As a human factors firm, good means that the device or drug delivery product has met the criteria for safe and accurate use in the hands of users. FDA’s fundamental question is “Show us the body of evidence that your device or drug delivery product can support safe and accurate user performance.” We know human factors and we know what FDA expects to see. Our role is to guide clients through this process as efficiently as possible. I usually refer to it as clearing the regulatory hurdles with minimal drama!

CEOCFO: Do most companies recognize the need for help or do companies often turn to you when they have started and now see it as a problem?

Ms. Patterson: We see both. Some companies, especially the larger companies, may already have internal human factors expertise and they simply don’t have the capacity to do the work. However, even these companies will often prefer to have an outside expert conduct the final validation work to ensure there’s no appearance of bias. Other clients don’t have internal expertise and may attempt to do this work themselves, or they ask for help from vendors they’ve worked with before
who are not experienced in human factors for medical devices. This usually doesn’t end well. Human factors is still relatively new to this industry and some clients don’t understand the differences between clinical research, market research and human factors research. All three are very important; but not understanding the differences can seriously derail a successful submission not to mention what it does to the launch timeline.

**CEOCFO: Would you please define human factors engineering?**
**Ms. Patterson:** Human factors engineering is the scientific discipline of applying our understanding of human behavior, characteristics, abilities, and limitations to the design of a system and then evaluating the effectiveness of that design. As applied to medical devices and drug delivery products, human factors focuses on eliminating or reducing risk involved with using a product – risk to the user and risk to the patient. For example, what safety mechanisms can be incorporated into the design of a pen injector to prevent unintentional needle sticks? What does the user need to know in the instructions for use to help them avoid a needle stick? Human factors has been applied with great success in military, aviation and other industries, but is still relatively new to the medical industry. Not until FDA published its draft human factors guidance in 2011 and its final guidance in 2016 were many companies prepared to incorporate human factors into their regulatory strategy. In describing FDA’s human factors guidance, one client said to me “FDA has unleashed a human factors tsunami on the medical device industry that will change everything!”

**CEOCFO: How do you design the study and what might you find?**
**Ms. Patterson:** Study design is driven by three components - users, the environments of use, and how users are expected to interact with the device components. The latter is a rather detailed description of how users interact with the medical devices including their perceptual, cognitive and manual action requirements for safe and accurate use. A very important aspect in this analysis is identifying what can happen if a ‘mistake’ occurs. In medical human factors, we don’t use the term ‘user’ error but instead say ‘use’ error because FDA considers it the manufacturers’ responsibility to design its device for specific users and specific environments. Blaming the user for not reading the instructions or failing to pay attention is not acceptable! This doesn’t mean the device must be perfect, but it goes back to the basic regulatory question of seeking evidence of safe and accurate use. We know how to help clients build that body of evidence.

For example, a fundamental question FDA or any regulatory agency will ask of a drug delivery device such as an auto-injector or inhaler is “How does the user know if they’ve received their full dose?” Or, with the proliferation of home use mobile devices that enable lay users to conduct certain body assessments for remote diagnosis by their healthcare provider, there’s an assumption that if someone has a smart phone they know how to use all of its functions. A well-designed human factors study will test these assertions and produce data that lay users can (or cannot) tell if they’ve received a full dose or if they know how to download the app from the internet. Healthcare professionals present their own unique challenges as users of medical devices. They may have experience with a number of similar but different devices, and this can cause confusion. For example healthcare professionals may be very familiar with several devices prescribed in their clinics to treat patients with Type II diabetes.
We often see in human factors testing how they assume they know how to use a similar-looking device because they expect it to operate the same as the devices used in their clinics; they won’t bother to look at the instructions! I remember one nurse who proudly asserted his medical expertise during a study without realizing he’d just severely injured his patient (under simulated use of course!).

Some people think human factors is about user preferences – what does the user like, would the user recommend this device to others? These people are confusing industrial design or market research with human factors. For others, they may take false comfort in knowing there is a very, very small chance that anything bad could happen when using its device. Both of these assumptions are wrong when human factors is applied to medical. It’s not about user preference – it’s about risk. While manufacturers do and should be concerned if users like their device, that has nothing to do with regulatory clearance. We can help clients optimize their device design so users will prefer it, but that is in addition to evaluating safety and accuracy. As far as presenting a very small, minimal risk of harm, human factors is quite the opposite. FDA doesn’t care if there’s a one-in-a-million chance something can happen. They want to know what is the risk to the user if that one-in-a-million chance does happen and what has the manufacturer done to mitigate it.

Another important component for successful studies is to put the user in the right simulated environment and as closely as possible, in the right mindset. We’ve seen studies fail simply because the study participants were made to feel that they were being tested on their ability to complete tasks, rather than completing tasks to help us evaluate the device. No one wants to be put on the spot or made to feel uncomfortable. How you actually conduct the study plays is a major factor for success.

**CEOCFO:** How often is it bad instructions?

**Ms. Patterson:** A lot! More than most people would ever imagine!

**CEOCFO:** I am just the opposite. I tend to pay quite a bit of attention to the instructions and wish there was proper guidance more often.

**Ms. Patterson:** I look at them too! In fact, that is one of our areas of expertise! I am a Special Government Employee (i.e., expert consultant) to FDA because of my expertise in this area and members of Agilis teach an industry-wide course for AAMI (Association for the Advancement of Medical Instrumentation) on how to design and evaluate instructional materials. How to test instructions for use is probably the hottest topic in the industry right now. Manufacturers have gotten quite good at the engineering aspects of product development, but too often the instructions get away from them. As one client recently told us, ’I had no idea how difficult it was to write instructions that people can understand and follow!”

**CEOCFO:** Are you able to recognize that if things are written in small print they might not be as easy to follow? How do you overcome that issue as well as and manuals have five different languages and fold in every direction? No matter what the product it makes it hard, let alone something medical?

**Ms. Patterson:** In some cases there are industry guidelines concerning font size. HE75 is an industry standard that provides human factors design guidelines. Contrast tends to be a very important component with printed instructions and electronic displays. Here’s where it becomes important to know your users – and not just their demographics. Over the
Many people over the age of 50 begin to have diminished eyesight. In one study, we found that nurses over the age of 50 had difficulty reading the display on a hand-held device. The client didn’t want to change the display because of cost. After several tests it became evident that the device would never clear FDA without a design change – which they eventually made. Because we specialize in regulatory style human factors testing, clients mistake that to mean you only test when the device or the instructions are done or nearly done. That may be too late and will always be more expensive. Some problems can only be discovered by running properly designed and conducted human factors evaluations and the earlier the better.

CEOCFO: How do you encourage doctors, who are busy, to take part in these studies and come into a simulated lab?
Ms. Patterson: Many professional people as well as the lay people such as those with diabetes or pulmonary or cardiovascular difficulties, want to help make devices better. They want to contribute. Of course, they’re also compensated for their participation, but it’s usually not a huge amount of money – just enough to make it worth their time. This is standard practice.

CEOCFO: Are there many companies that do human factor testing in your arena? What is the competitive landscape?
Ms. Patterson: Many companies do human factors. Because medical is a regulated industry and requires in-depth knowledge and experience, far fewer companies work in medical and of those, very few work exclusively in medical as we do. We only work with medical devices and drug delivery products. I recently purchased a new wall oven and it took the instructions and two calls to customer support to understand how to use some of the functions. This was frustrating, but certainly not risky. With a medical device, risk is almost always involved, from a delay in achieving medical benefits to much worse. Remember that research that was published by the US Institute of Medicine in the late 90’s that caught everyone’s attention – To Err is Human’. Medical ‘mistakes’ or use errors can too easily translate into harm to the user or patient. This is serious business within a regulated industry and it’s why we focus on medical and only on medical. For example, in the past pharmaceutical companies would buy a device to deliver its drug from third party manufacturers based on cost and timeline. Now they understand that that device delivering their drug is a new ‘system’ and will require human factors testing. We have several large pharmaceutical clients that now include human factor data in these purchasing decisions.

CEOCFO: Once you do the study and you give them the results would you then continue working with a company on interfacing with the FDA? What is the whole range of services at Agilis?
Ms. Patterson: Companies will generally come to us at one of two process points: they’re in early product development and know human factors will be a major factor downstream and want to design out problems early, when it’s less expensive, or they’re in the later stages of product development and are preparing to submit to FDA. While earlier is better, we can help clients wherever they are in the process. Sometimes, they have a legacy device already on the market that they want to make changes to and find out now they have to do human factors. A few clients have had serious problems with devices on the market and either pulled if off market or were ordered to by FDA. We tailor our services to wherever the client is in the process. We design and conduct the studies,
analyze the data and write the report. Human factors in medical uses qualitative data more so than quantitative data. A successful report is more than crunching the numbers. In fact, statistics holds very little weight in a human factors report for a medical device – another major difference between human factors research and clinical or market research. We work with our clients to make sure the report tells the regulators a compelling story in support of clearance (of course assuming the data support this!). FDA has told us that approximately 60% of the human factors submissions it reviews are initially rejected because of deficient study design, risk analysis, or data analysis. For almost 20 years, Agilis has successfully helped medical device clients clear FDA with our human factors expertise. In that time, FDA has never rejected the human factors work from an Agilis client.

CEOCFO: Is Agilis Consulting well-known in the industry?
Ms. Patterson: Yes, we are and expect this will continue!

CEOCFO: Do you have to do much outreach or are people coming to you?
Ms. Patterson: Most of our clients who come to us are either repeat clients or they have been referred to us by other clients. However, we still do reach out including marketing and presenting at conferences and industry meetings. As an expert consultant to FDA, I’ve presented at a number of FDA sponsored events. When I ask a new client how they found us, I’m always amazed to hear "I saw your name on an FDA agenda, so I figured you must know what you’re doing!"

CEOCFO: What has surprised you as Agilis has grown, evolved and prospered?
Ms. Patterson: Just how much I love this industry! I have worked in other industries over my long career. I love medical and I love our clients. It is one of the few places where you can really make a tangible difference in people’s lives! I just get a thrill out of that and it’s as tangible today as it was 20 years ago.

CEOCFO: What is next for Agilis Consulting Group, LLC?
Ms. Patterson: We’re growing. We’re growing and I want to make sure that we grow intelligently and maintain our quality and client service. It’s not easy for a client to get a medical device or drug delivery product on the market. We want to help them – at least as far as the human factors requirements. There are some really interesting things that are happening in the medical industry and it’s rewarding to be part of that.