

## HUMAN FACTORS: Critical to Customer Satisfaction

### What are human factors?

The FDA defines human factors (HF) as the interaction of people and equipment. In addition to people's abilities, environment and equipment design, the FDA includes the information provided to support optimal performance including medical and pharmaceutical labeling and training. For medical marketers – the product objective is to improve human performance, reduce per-product delivery costs and reduce the likelihood of use error and patient injury. Human factors can help.

### Who cares about human factors and why?

The end users/customers do not know much about HF, but they know when a product works. They know when they can understand a medication label and when they cannot. Manufacturers may not know why they care about human factors, but they know when they have a successful product. They also know when they have so many customer service calls that profits are reduced. They care about HF when significant "upgrades" have to be made to devices already in the field. They certainly know when they have to initiate a recall.

**The FDA definitely cares about human factors. The agency is so concerned that it has created new initiatives to encourage manufacturers to include HF in product labeling and design.**

## AGILIS CASE STUDY for LIFE SCAN, INC.

### The CUSTOMER

**LifeScan, Inc.**, a Johnson & Johnson company based in Milpitas, California, with 2,500 employees worldwide

### The CHALLENGE

Meeting FDA human factor guidelines to gain FDA clearance for its new Harmony™ INR Monitoring System

### The SOLUTION

Using Agilis' human factors approach to create more effective product design, labeling, and training

### The RESULTS

- ▶ Reached desired outcomes in half the time.
- ▶ Sustained peak client performance two years after initial training

“Initially we saw our new product introduction as a routine training project, but Agilis helped us see the bigger picture. They showed us the micro (patient) and macro (business case) impacts. **Their human factors approach helped us reach our goal in three months versus the projected six to eight months**, and produced a human performance-based training program that contributed to high retention and measurable performance. **This could reduce our per-product delivery costs by up to as much as 60 percent.**”

Shari Kipp  
LifeScan Senior Marketing Manager

## Fundamental truths about humans.

Many medical marketers use focus groups, interviews, and early design testing to learn about customers, and feel that this covers human factors. But there are fundamental truths about human performance that these common research methods overlook.

*For example:*

When asked, customers say they want more information. But, performance tests show that this actually interferes with their ability to achieve their desired results using the product.

Most marketing research assumes attitudes influence performance, but the opposite is true. To improve customer attitudes toward your product, first focus on improving customer performance while using it.

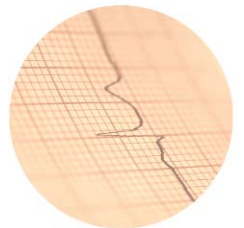
Customer preferences and opinions usually do not correlate with their ability to achieve their desired results.

## A performance-based approach matters.

Research over the last twenty years validates the superiority of a performance-based approach in information and product design. Some companies, like Ethicon, Inc., a Johnson & Johnson Company (Somerville, NJ, USA) and the US Army have published measurable results from a performance-based HF approach.

- **81% decrease in the time needed to find target information**  
Ethicon 1997
- **54% reduction in errors on task**  
Schaffer 1982
- **2 to 3.5% reduction in grade level reading requirements**  
US Army 1997
- **A five-fold increase in customer satisfaction**  
Motorola 1996
- **A two-thirds reduction in training time**  
Motorola 1997

*Source: Agilis Consulting, LLC*



## Why consider Agilis Consulting Group?

Agilis (from the Latin 'agile') is committed to helping the medical device, diagnostics, and pharmaceutical industries achieve measurably enhanced medical outcomes through superior customer satisfaction.

Customers who find products and labeling that meet their goals, (safe, fast and easy to use), perceive them to be of exceptional quality and translate this into higher customer satisfaction. This means lower per product delivery costs and higher returns.

### Agilis can work with you in whatever way best serves your specialized needs:

- Strategize how you can use human factors to improve customer satisfaction
- Conduct a diagnostic analysis on your current product design and labeling
- Train and educate your staff how to apply basic human factors methods and techniques to improve product design and labeling
- Provide human factors design and development including labeling and training on your next new product development project

For more information please contact us at:  
Telephone: 480.614.0486 Email: [info@agilis](mailto:info@agilis)  
or visit our website at: [www.agilisconsulting.com](http://www.agilisconsulting.com)

*Agilis is a proud member of the following organizations: Human Factors and Ergonomics Society • the International Society for Performance Improvement • the American Association for Clinical Chemistry • the American Diabetes Association.*

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“ I knew Agilis had experience working with diagnostic manufacturers, and that **their performance-based approach was aligned with the FDA's human factors demands.** If I had it to do over again, I would have engaged a professional human factors team sooner – in the initial product design and throughout the clinical evaluation process.”

**Brian Earp,**  
formerly Senior Manager  
Clinical Research, LifeScan

**Agilis** Measurable performance. Meaningful results.

9611 North 100th Street • Scottsdale, AZ 85258 USA  
Telephone 480.614.0486 • Fax 928.441.1988  
[www.agilisconsulting.com](http://www.agilisconsulting.com)