

Agilis Consulting Raises the Bar for Performance-Based Training

Clinical Trials' Initial Success Robust at 2 Year Mark

LifeScan, Inc. a Johnson & Johnson Company (Milpitas, CA) recently concluded a clinical trial of their new Harmony™ INR Monitoring System. The trial included 268 patients where patient performance was measured three different times post training—at 12 weeks, one year and two years. At each end point, the patients were observed by nurses as they performed independent blood testing to determine their prothrombin time. Finger sticks for blood samples were properly done 97.8% of the time and accurate test results were obtained 70.1% of the time with NO help from the nurses. Most importantly, these results were robust even at the two year, post training measurement. LifeScan attributes this success to Human Factors and to the human performance-based training program developed by Agilis.

Medical device manufacturers are increasingly concerned about Human Factors (HF) components of their product design. Marketers, quality assurance people and risk management teams are all learning how including HF can improve designs, save time and reduce the possibility of use-related medical errors. Not only is the FDA's Human Factors Engineering Group of the Center for Devices and Radiological Health (CDRH) pushing for more involvement of HF during product development, but companies are finding HF a strategic advantage in an increasingly complex competitive market environment. Less demand for customer service, no costly upgrades in the field and high customer satisfaction/adoption—describes a successful and profitable product. HF makes a definite difference.

Outcomes Predict Product Success

LifeScan's product development team wanted patients to have a positive attitude about using the Harmony device and they needed patients to be confident in their ability to self-test with the device. Agilis designed a training program for the patients to assure these outcomes. Successful training was defined as "The patient will use the Harmony Monitor to produce INR result from a sample of blood with a deviation of less than +0.5 INR units compared to the result presented by a healthcare professional."

Shari Kipp, Senior Marketing Manager with LifeScan, says, "Our team asked Agilis to bid on providing what we saw as a relatively routine training project. Agilis helped us see the bigger picture. They brought focus to this project. They showed us the micro (patient) impact and led us to the macro—the business case--impact. Their HF-based approach

allowed us to reach our desired outcomes in 3 months versus the projected 6 to 8 months. Not only that, but with this program we believe our per-training/delivery cost will be reduced by as much as 60%.”

Agilis’ performance-based training program produced excellent initial results. Even more impressive were the Statistical Performance Results shown at two years post training.

Statistical Performance Results, Regression Statistics

Conducted	Comparison	N	Slope	Intercept	Correlation Coefficient	Sy.x
During clinical trials	PST vs. Lab	1041	1.04	-0.11	0.94	0.22
During clinical trials	PST vs. HCP	1042	1.01	-0.04	0.95	0.20
1 year later	PST vs. HCP	546	1.01	-0.04	0.97	0.14
2 years later	PST vs. HCP	1120	1.04	-0.10	0.96	0.17

Source: Agilis Consulting, LLC

“PST” is “patient self test,” where the Harmony INR Monitoring System (PST) is compared to the Laboratory Reference Method (LAB) and to Healthcare Professionals (HCP).

Ms. Kipp expanded on her experience with Agilis, “They were always on time and on budget—a disciplined group. They helped me look good.” Brian Earp, then Senior Manager of Clinical Research at LifeScan commented on his experience with the Agilis team, “If I had the opportunity to do this over again, I would have engaged a human performance professional team like Agilis in the initial product design and throughout the clinical evaluation process.”

Lessons Learned

Summarizing the successful clinical trial, Pat Patterson, President of Agilis Consulting, LLC noted the following:

- Successful product launch depends on effective patient training yielding desired outcomes,
- Positive patient experience with the device during training enhances their willingness to use it and
- Effective, performance-based training significantly influences marketing strategy.

About Agilis Consulting

Agilis Consulting, LLC produced these results for the Harmony product through their innovative approach to Human Factors and performance-based training. Key to Agilis’ success is the company’s Customer Performance Profile© --a proprietary method guiding decisions regarding product design, information, labeling and training. Patterson, says, “We

create a Customer Performance Profile based on what the real user does now. We focus on desired medical outcomes not just behaviors.”

Customer Performance Profiles describe a performance based on targeted or actual customers. It includes the customer’s desired medical outcome using their language as well as:

- Criteria for producing the desired outcome including measurable accuracy, quantity, quality and time;
- Key behaviors needed to produce the outcome including frequency, complexity, speed, consequences of error and psychosocial issues and
- Measuring the desired performance at normal conditions, off-normal circumstance and emergency situations.

Agilis also uses the formula $W=V-C$ to discipline their HF interventions, where Worth (W) is equal to Value (V) minus Cost (C).

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