

## **FOR IMMEDIATE DISTRIBUTION**

### **Company Contact:**

Patricia Patterson, CPT

Agilis Consulting Group, LLC

480.614.0486

[ppatterson@agilisconsulting.com](mailto:ppatterson@agilisconsulting.com)

### **Arizona-based Consulting Firm Presents at FDA's Launch of Home Use for Medical Devices**

*Agilis' President, Patterson, Leads Workshop about Medical Device Labeling and  
Training for Home Use*

**PHOENIX** – May 11, 2010 – On April 20, 2010 the FDA launched its Home Use Initiative to address the challenges of healthcare professionals and consumers using complex medical devices in the home. With this initiative, the FDA is raising the bar for more oversight on home use medical devices and their associated instructions and training. The National Association for Homecare and Hospice (NAHC) estimates that approximately 7.6 million individuals in the US receive home healthcare from roughly 17,000 paid providers. This does not include the tens of thousands of unpaid family and friends who provide home healthcare.

On May 24, 2010, the FDA will hold a national workshop to solicit information from nearly 250 representatives from health care providers, academia, human factors experts, medical device distributors, manufacturers, professional societies, patient advocate groups and patients on the challenges surrounding the safe and accurate use of medical devices in the home.

The Agency has invited Arizona-based Agilis Consulting Group's Pat Patterson to speak at the workshop on the issues associated with labeling and training for home use and to lead a follow-up break-out session. Output from the workshop will help the FDA develop guidance for both pre- and post-market surveillance actions.

Ms. Patterson is a recognized expert in a specialized area of human factors that develops proven methods of significantly improving how people learn to correctly use devices, especially complex medical devices.

As Ms. Patterson explains it, "It's a privilege to be invited to this watershed event. Anyone that's had someone explain to them how to set the time delay on their camera, and then tried to do it an hour later understands the problem. We have proven that performance-based methodologies can improve safe and accurate user performance for

professionals and consumers in the home. This will ultimately reduce medical errors, improve the quality of life and lower healthcare costs.”

According to Jeffrey Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health, “Using complex medical devices at home carries unique challenges. Caregivers may lack sufficient training, product instructions may be inadequate or overly technical, and the home environment itself may pose environmental or safety hazards that can affect the product’s functioning.”

The FDA defines human factors as the “science and the methods used to make devices easier and safer to use.” The FDA now requires manufacturers to conduct appropriate human factors analysis and testing during all phases of medical device development before it can receive clearance. The FDA considers the device labeling and training as part of the user interface. “Users” include healthcare professionals and consumers in all care settings.

Agilis Consulting Group specializes in guiding device manufacturer’s development processes to comply with the FDA’s design regulations which stress human factors processes that significantly reduce use errors and improve user acceptance and satisfaction.

Ms. Patterson is a contributor to the recently published standard *HE75: Human Factors Design for Medical Devices* by the Association for the Advancement of Medical Instrumentation (AAMI) and is a member of AAMI’s Medical Devices and Systems in Home Care Applications committee. Her next article titled *A New Labeling and Training Technology for Homecare Technology* will appear in AAMI’s award winning Horizons specialty magazine on Home Healthcare scheduled for publication Spring 2010.

#### **About Agilis Consulting Group, LLC**

Agilis Consulting Group, founded in 2000, is a privately held company based in Cave Creek, Ariz. Through Human Factors Engineering, design of user labeling and training, Agilis helps its clients achieve faster regulatory clearance, fewer product liability risks and lower after-sale support costs. Agilis’ clients have reported a 97% improvement in product safety and satisfaction. Clients include Fortune 100 pharmaceutical and medical device companies as well as startups. See [www.agilisconsulting.com](http://www.agilisconsulting.com).

###