

## Design for Use: An Integrated Approach to Product Development

Chris Evans

**In 2009, after more than five years in development, the members of an integrated drug delivery device team from West, The Tech Group and Insight Product Development gathered in Raleigh, NC for a final round of usability testing. This stage included mock self injection by perspective in-home users of a proprietary device with the potential to challenge the auto-injection market with a new, easy-to-use design featuring visual, audible and tactile features to help end users comply with drug delivery instructions.**

After several days of usability testing were conducted, the results spoke for themselves. More than 97% of the respondents operated the [West](#) [1] ConfiDose auto-injector system successfully. But perhaps the most significant detail was that each respondent correctly administered the dose without instructions or training.

“It was certainly welcome news,” said Rick Gillespie, Program Director, West Delivery Systems. “This round of usability testing verified that design improvements to the ConfiDose auto-injector system had, in fact, optimized the intuitiveness of the device.”

Later testing, which included more formal training through written ‘Instructions for Use’ or verbal instruction, helped ensure that the auto-injector system was nearly foolproof.

Such usability trials represented the culmination of research and testing efforts from a team of designers and engineers from West, its subsidiary, The Tech Group, and outside consultants Insight Product Development. The latter, an industrial design firm, helped optimize the product’s external look and user-interface while West’s engineers perfected the proprietary internal workings and overall functionality.

The collaboration, which began in 2007, helped ensure proper human-factors considerations had been given to the auto-injector system’s design, per CDRH/FDA guidelines. The research sessions with users also helped bring ConfiDose to market faster and more effectively than West otherwise could have done.

Explained Gillespie, “At the very start of the development process, we knew a fair amount of time and resources would be dedicated to human-factors and usability, and we also knew we did not possess that expertise internally. We needed a partner whose knowledge and commitment would match West’s ambitions for a unique, user-friendly system like ConfiDose.”

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Published on Medical Design Technology (<http://www.mdtmag.com>)

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Gillespie managed the development of the ConfiDose auto-injector system from its inception in 2006, when West acquired his small device development company, Pharmapen, early that year. During the initial two-year design program, his team in Athens, Tex. worked closely with designers, product managers and team leaders in West's Delivery Systems group, and relied heavily on the vast technical/engineering resources of West's contract manufacturing subsidiary, The Tech Group, to guide the design for manufacture and production planning. Regulatory, financial and global marketing support was also provided by West's corporate offices.

However, to help with the final piece of the medical device development puzzle, Gillespie and his team needed specialists in human-factors and usability research. They called on Insight Product Development.

Glenn Thorpe, a Vice President in West's Delivery Systems Group, headed the selection process: "West wanted to be sure that we chose a firm that represented a potential long-term partner. We foresee many device development programs like this within West Delivery Systems, and searched for a firm with an incredible depth of knowledge and expertise in user research."

Factors involved in the search included the need for not only overall design know-how, but also expertise on the development process itself and associated regulatory concerns. Design control knowledge, ISO compliance, quality systems as well as ideology all needed to align with West to create the perfect partnership.

"In the end we chose Insight because we felt they were a great match for this and other similar programs," noted Thorpe. "Their user-based research approach, experience with medical device development and complimentary mindset and personalities made Insight the partner we needed."

With ConfiDose's basic technology platform developed and preliminarily engineered by Gillespie's group in Athens, the collective team went to work optimizing the design for efficient manufacturing. This ultimately led to the creation of a tooling and assembly strategy to quickly produce molded prototypes for both lab and field testing.

At the same time, Insight assembled the appropriate human-factors and usability development plan, which would utilize multiple ethnographic and observational research sessions, user interviews and in-house ergonomic evaluations. Such testing would provide much more detailed data than a typical focus group.

Insight's aim was to provide West with a deeper view into the emotional needs and desires of the intended user, as well as to gather the user's perspective on features and visual cues providing intuitiveness. Such details were important to West, which has extensive experience developing medical products for use by clinicians in hospitals, etc., but less knowledge regarding any associated differences between where a device is used (clinic, doctor's office, patient's home) and who is using it (doctor, patient, care giver). Since ConfiDose was intended for in-home use to self-administer injected medication, research protocol was designed to address the user's lack of clinical background and skill.

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The development team designed a device interface that is effectively useable with little or no technical knowledge or training. To that end, the final design presented obvious and failsafe interaction points, simplifying the steps required for safe and effective use.

Throughout the process, various methodologies were used in a 'closed-loop' structure, offering several opportunities to 'revise and retest,' thus identifying and quickly implementing the best functional attributes. The integrated team helped to keep the project moving and development timing on track. Having continuous and consistent manufacturing support, working with The Tech Group from the earliest possible point in the design process, along with the strategic insertion of Insight's research and design group, West was able to truncate what could have been a hopelessly linear development lifecycle.

Working together, this team experienced first-hand how integrated involvement speeds the design process, minimizes risk and helps ensure project success. West is currently scaling up production and will have the first fully-validated sample lots of the ConfiDose auto-injector system available for customer trials in 2010.

**Chris Evans** is the Managing Director of West Innovation Concepts.

*Editor's note: Since their collective work on this project, West and Insight have entered into a collaborative agreement to jointly work on the development of proprietary IP on behalf of both West and mutual customers. Additionally, West's medical device contract manufacturing subsidiary, the Tech Group, is now part of the newly formed Delivery Systems business unit.*

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[1] <http://www.westpharma.com>