FDA Compliance and Human Factors: Take-Aways from the 2012 Medical Device Summit

by Michael Glessner and Cathi Crist

We recently attended the 2nd annual Medical Device Summit Workshop event, which covered key issues in complaints, medical device reports, FDA inspections and CAPA (corrective and preventative action) systems. The seminar boasted excellent speakers from the industry and the FDA, and topics that explored what it really took to successfully implement these mandated systems. It was a great opportunity to network with other medical device innovation professionals, and based on the conversations we had and the speakers we saw, we left the event with two key take-aways from a new product development perspective.

First, as a Kalypso white paper (Beyond Compliance: Medical Device Product Development) states, for a medical device company to truly thrive in this regulated industry, their management needs to think and act beyond the compliance requirements of the FDA. Though these mandated systems for design requirements, complaint capture, and corrective actions will help companies continuously improve their products over time, they are not enough to ensure financial success in the market place. Companies still need a thoughtful product development process that links with the mandated systems, and also enhances the overall innovation performance for the company. This parallel business process needs to build upon the organizational learnings from the mandated systems, leveraging them as formal inputs to the product design process, and better informing the design community of past lessons. So the bottom line here is that it’s not enough to just follow the requirements of the FDA for new product development success, medical device companies must go beyond compliance.

Second, Garth Conrad, Senior Director of Quality for Medtronic, made a strong case that human factors are often overlooked when it comes to systems-based process improvements, and that these human factors make the difference between a successful implementation and frustration for all involved. “Human factors” describes the study of the way humans relate to the world around them, in this case a new business system.

Conrad pointed out that many system implementations take a fairly simple, visible paper process and reconstruct it within the screens and tables of a system. This typically confuses users, especially those who only interact with the system a few times a year. To implement a new process effectively, implementers need to first recognize that they are re-engineering a business process, and frame their approach from this perspective. They can then systematically define user profiles, ensure process usability, develop user documentation and then create training programs to communicate the roles effectively. Without considering the “human factor” dimension adequately, implementations are prone to poor results.

This insight also challenges software vendors to better design their systems for their end users. The end users probably had a simple form that was the backbone of their previous, paper-based process, so how can software companies use that form to help users recognize their process and understand what they need to do? Think of what the Apple iPhone demonstrated with all its easy to understand applications. The packaged software company that solves this challenge first will have a significant competitive advantage.

What do you see as critical to new product development success in medical devices or life sciences? Have you successfully implemented a new system where attention to human factors played a role in its success? Are there aspects of user interfaces that you particularly like or dislike?

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