Improving New Product Development: Focus on Process and People for Best Results

Michael Glessner and Cathi Crist

As medical device companies engage in the business challenge of creating new products in a highly regulated market, two key factors slow innovation. First, companies too often rely on FDA-required compliance systems to drive innovation. These systems are focused on enabling the automated maintenance of design controls, and do not ensure creativity or good business outcomes for a business. Even for those companies that do implement product management systems like product lifecycle management (PLM), failing to embrace process improvements and staff interaction behind organizational change and system adoption can stop innovation in its tracks.

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. While mandated systems for design requirements, complaint capture and corrective actions help companies continuously improve their products over time, they are not enough to ensure financial success in the marketplace. These systems were simply not designed to drive innovation – but PLM systems do exist that can encourage new ideas and foster creativity.

All companies, especially medical device companies, need

a thoughtful product development process that links with mandated systems to improve the overall innovation performance for the company. This parallel business process must be built upon the organizational learning from the mandated systems. These processes can combine, with information captured in mandated systems as formal inputs to the product design process. Organizations can embrace everything they've learned from past product development cycles and better inform the design community of past lessons.

Once an organization understands the need for an overhaul to the innovation process, they must tread carefully. System-based process improvements may not be easy to implement with technology but the true challenge lies in organizational adoption and change management. People, who are the most valuable assets, can be overlooked when implementing a new system, even as millions of dollars are put on the line. But organizations must remember that the difference between a successful implementation and a failure lies in the hands of the people who use it.

Often times, system implementations take a once fairly simple, visible paper process and reconstruct it within the screens and tables of a system. When this happens, frustration and confusion can inhibit user adoption. To implement a new process effectively, organizations must recognize that they are re-engineering a business process, not just a single system, and it must be framed as such to end-users.

The development of user documentation and dedicated training programs are critical to the success of any new process. For medical device companies, this is particularly important. With tight regulation and strict compliance requirements, medical device companies are often wary of new processes. Training and user support can substantially increase adoption.

Improved new product development cannot come from simply following the requirements of the FDA. Medical device companies must go beyond compliance and embrace innovation. Larger adoption of improved new product development processes, and greater understanding of the challenges around people and change management can substantially increase profitability through innovation.

Michael Glessner is a Senior Manager at Kalypso. He has more than 30 years of consulting, management and entrepreneurial experience. Michael has extensive experience systematically commercializing products and technologies, developing strategy and deploying enterprise technologies for life sciences, A&D and manufacturing clients. His areas of expertise include new product development, business and innovation strategy, front end of innovation and open innovation. Michael also has deep experience architecting and aligning PLM solutions to enhance strategic results.

Cathi Crist is a Senior Manager at Kalypso. She has over over 20 years of engineering, product development, operations management and consulting experience across multiple industries with an emphasis in life sciences. Cathi has extensive innovation and product development experience in addition to deep operating expertise in FDA quality system requirements for device development

and design control to her clients.

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