Speed to Market or FDA Compliance? It Must Be Both

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Medical device manufacturing companies don't have the luxury of being able to choose between either focusing on speed to market or FDA compliance. Rather, they must address both equally. Balancing product development effectiveness with regulatory compliance is yet another strategy on the road to success. This article provides tips on how this can best be accomplished.

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Medical device organizations are navigating the challenging waters of regulatory compliance while simultaneously trying to keep their heads above the pace of innovation. Many leading companies in the last several years have been hit with an injunction, undergone a product recall, or found themselves operating under FDA consent decree. At the same time, the demand for growth has never been greater.

With these conflicting market pressures, companies feel the need to pick one over the other: Speed to market or FDA compliance? To survive, this "pick one" approach is no longer good enough; it must be both. Designing and maintaining an effective, high-functioning innovation engine while, at the same time, ensuring full FDA compliance is of paramount importance.

When it comes to implementing product development processes that comply with regulations, many companies have overcompensated, resulting in overly bureaucratic systems that are impacting delivery performance and causing them to come up short on time to market, R&D ROI, new product revenue, and the ability to meet scheduled predictability goals.

Currently, medical device companies are under the gun to reevaluate their product

development processes and determine how best to implement an approach that meets design control requirements while ensuring a fast, effective flow of successful new products.

While a major obstacle in achieving improved product development performance is how to apply design control processes without becoming overly bureaucratic, leading companies demonstrate a clear understanding of the intent behind design controls and have structured their product development process accordingly. The leaders generally take one of two approaches—either a single process structure encompassing both business and design control work flows, or two separate but aligned systems.

Single Process Structure

With a single process structure, all elements of the product development process are captured within design control procedures using a set of detailed standard operating procedures and work instructions to describe the who, what, and how for each task, whether the task is governed by FDA regulations or not. For example, business-oriented processes—market assessment, intellectual property assessment, or project financial justification—are spelled out within the same set of work instructions as the Design and Development Plan or Requirements Traceability Matrix.

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This approach has the advantage of keeping all development procedures in one place with one system designed to address both business and quality system needs. However, this approach combines rigidly controlled design control requirements with more business-oriented processes that the FDA is not concerned about and therefore, can unnecessarily bog down project teams that require more flexibility to adapt business processes to specific project needs. After all, the FDA is concerned about product safety and efficacy, not whether a product makes money or fits the company strategy.

By intermingling business-oriented processes with design control procedures, companies inadvertently increase the opportunities for non-compliance. Once a company starts down this all-in-one path, process bureaucracy can grow as layer upon layer of procedure detail is added to cover each work flow scenario or corner case, regardless of whether or not the tasks are governed by design controls. With more detail, project teams are left with less—not more—flexibility to manage a project’s business needs. Nowhere is this phenomenon more evident than in

companies who have experienced a recent FDA warning letter or consent decree. These companies tend to err on the side of more prescriptive procedures, not less. The process pendulum swings to the far end of the bureaucracy spectrum and, as a result, delivery performance suffers.

Figure 1 uses a two-by-two matrix to contrast varying levels of compliance burden (i.e., compliance process bureaucracy) against a spectrum of new product development process maturity. The highest performing companies fall in the upper right hand quadrant, achieving:

Companies who found themselves in one of the other three quadrants were not getting the business results they desire. The goal is to move one's company to the upper right quadrant without jeopardizing regulatory compliance, ultimately achieving a mature product development process coupled with low compliance burden.

Separate but Aligned Systems

Top performing medical device companies have established two separate, but aligned systems as an alternative to the single process structure. Business-oriented processes that require room for judgment and flexibility are set up as a supplement to rigorously controlled design control procedures. While an important part of the overall delivery process, deliverables such as business plans, go-to-market strategies, sales plans, and support plans do not go through the same level of process adherence scrutiny as design control deliverables such as the Design and Development Plan, Requirements Traceability Matrix, Risk Management Plan, Design Validation Report, or Manufacturing Transfer Plan. However, linkages between the two distinct processes are highlighted to draw attention to interdependencies or key connection points. (Figure 2)

Companies that have adopted this approach have discovered additional opportunities to streamline by decreasing the total number of development deliverables and reducing the number of deliverables that need to be circulated for sign off. One leading medical device company went so far as to not require any signatures on their business deliverables, as going back to each executive to collect a signature provided no added value and only delayed the process. Instead, Governance Committee approval at each phase gate ensures that the deliverables are complete and provide the information necessary to make the phase gate go/no-go business decision.

Another leading company, with a mature, high performing phase gate process, decided to document their business and design control procedures under one quality system, but established two distinct deliverable categories. Prescriptive templates without room for interpretation are in place for deliverables that fall under design controls. All other process documentation, including business-oriented deliverables, use simplified outlines that leave room for the judgment of experienced project team leaders. Project team leaders can also recommend eliminating certain process steps or deliverables without having to go through

multiple layers of approval. They simply include their recommended exceptions in their initial project plans. The only caveat is for those deliverables ordinarily required in the Design History File which require formal written justification.

Other process definition and work flow practices that save time and avoid development delays include meeting with the FDA early and often to receive feedback before starting full-scale development, validating as soon as production equivalent product test units can be produced, and testing only subsystem design elements that are new instead of complete product systems.

Conclusion

Finding the right balance between what can seem like competing objectives—product development process maturity and full FDA compliance—is critical for the success of medical device companies. Though a single process design has the advantage of one system for both business and quality system needs, this approach increases opportunities for non-compliance and hinders project teams that need flexibility to adapt business processes to specific project needs. Separating business-oriented processes from rigidly-enforced design control procedures enables project teams to use judgment and experience in adapting process guidance to specific project needs without jeopardizing design control compliance. Leading companies are taking this path in order to meet the dual challenges of speed to market and compliance in NPD and are delivering safe, effective, and commercially successful products as a result.

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