Perspectives on Balancing Development Success, Part I

With the development of a medical device, how do you best achieve a balance between time to market, cost savings, and regulatory compliance?

Joe Rotino
VP of RA/QA, Acting VP of Engineering, Pro-Dex Inc.

Approaching product development through the lens of Concurrent Engineering is what enables Pro-Dex Inc. to achieve a balance between accelerating time to market, cost-efficiency, complying with all regulatory requirements, and delivering a superior quality product.

The most important part of this process is bringing in representatives at the very start from all the cross-functional teams within engineering, regulatory affairs and quality assurance, manufacturing, procurement, and business development to assess the full scope of the project.

Each of these disciplines have their own needs and concerns related to the development and manufacture of the product, so it’s important to get multiple perspectives up front.

For example, the procurement team is concerned with what materials are needed and the availability of them. Engineering will be looking at material types, tolerancing, and part requirements. RA/QA is interested in elements that could affect the final product, its classification, and registration. Manufacturing needs an understanding of tooling and fixtures, setups, and required programming.

Bringing these multidisciplinary insights together from day one allows the team to create a plan with cost, compliance, and speed to market in mind as well as effectively execute that plan, meeting project requirements, schedules, timelines, and budgets.

W. Stephen Beversluis
Director, QA & Regulatory Affairs & Business Development, Precision Medical Products Inc.

The medical device development process is a very detailed step by step approach that can take an idea from concept to reality. Needless to say, it is very important for development teams to spend the time and effort to balance “time to market, cost savings, and regulatory compliance”. This ensures a successful product launch that will enable your device to provide the quality of life that you developed it for.

That being said, it is crucial that quality and regulatory compliance take precedence over time to market and cost savings. Short cuts taken on items required by the regulatory bodies or decisions driven by lower cost in the end may negatively impact your success and, possibly, the health and well being of the individual(s) being treated.

If you plan your development process intelligently and follow the quality system requirements for design and development wisely, you can achieve your time to market goals and be successful.

Rick Gallisa
Industry Director, Life Sciences, Apriso Corporation

When considering how to best balance time to market, cost savings, and regulatory compliance, I would propose that design is clearly the leading contributor. Design for efficacy is paramount; however, design for manufacturing is the critical factor for time to market, cost savings, and compliance.

Traditionally, the medical device industry innovated products with modest concern about cost, anticipating that sufficient operating margins would more than offset R&D, costly manufacturing, and compliance costs. But, given increasing regulatory and global competitive pressures, this strategy is simply no longer viable.

In my role at Apriso, I see an industry with pervasive focus on manufacturing excellence. This starts with design, but quickly enters technology transfer from R&D, pilot operations, and manufacturing scale up. That funnel of activities dictates what efficiencies will be validated into structured and compliant production operations.

Many of our customers are taking a hard look at their manufacturing processes to address these pressing issues. They are putting sophisticated systems in place to manage costs while realizing benefits, such as accelerated new product introduction, resulting from greater consistency in their business and manufacturing processes. Embracing this type of strategy results in higher quality and lower costs—the balance required for profitability.

Steve Raiken
President, RENY

Traditionally, the medical device injection molding paradigm has been prototype then production. This has meant aluminum molds for product development, then transfer to a manufacturing group who will oversee design and procurement of production class A molds and validation activities.

With "speed to market" becoming more important to improving ROI, companies are increasingly overseeing R&D efforts with manufacturing and quality engineers. Questions are being asked, "How can we combine the prototype, production, and validation process?"

The answer lies in hybrid "prototype to production" injection molding. Or the use of modular hard steel components to build standard size cavity insert sets that facilitates faster production mold building and validation. For years, the software industry had been writing each piece of code as a new project. Then along came C++, which allowed a programmer to use building blocks from a library of tested code. But these libraries tend towards specialized application. The molding industry must change from being everything to everybody to specialization. A few companies are specializing only in medical molding. RENY has been refining this concept. Because we are solely in the medical device industry, we focus on the complete development cycle of a medical device. And we have developed modular tooling systems, pre-planning the validation requirements. Using hard steel milling to manufacture hard tool steel inserts that are then assembled into a standardized base results in a production mold that can be production validated while assembly methods are being developed. Being vertically integrated with cleanroom molding on-site allows for ready feedback between mold maker and molder.

Using modular tooling blocks reduces the time and cost to market and increases reliability by using tested designs and pre-manufactured components. Hybrid molding does provide a complete solution from prototype to production.

James Wilson
Principal, Continuum

There are a few key things necessary to achieve this delicate balance. Three critical ones are:

Early collaboration with downstream partners—The market, supplier pricing, and regulatory approval are not within your control. The steps to pass regulatory requirements must be factored into the schedule early on; to mitigate risk, test as early in the process as possible.

Create a realistic business plan—If it's a new product, don't count on mature market pricing at launch; your partners are likely to price for market risk unless you compensate them otherwise. Have contingency funding available to keep valuable and non-contingent efforts going if time to market is a high priority and other aspects of the program get hung up in a period of uncertainty.

Design for success—Identify the differentiation that matters to the people that use, sell, service, prescribe, or train people on your product. That is your must have. Assess your regulatory path and tweak things that don't compromise the differentiation but improve time to market and spend the least amount of time on cost reduction. Get the right product out fast. Cost-savings can be iterated after release with additional time to analyze/optimize design solutions.

John J. Smith, M.D., J.D.
Partner, Hogan Lovells US LLP

Understanding how FDA regulates your medical device is crucial to balancing time to market, cost, and regulatory compliance for a new product. In situations where the regulatory pathway or data necessary to support clearance or approval is uncertain, or if clinical or extensive preclinical data may be needed, seeking agency

feedback via the pre-IDE process is an important step after a design is finalized and proof of principle established. Sponsors need to be willing to adapt their marketing or regulatory strategies based on FDA feedback, as it's often necessary to modify the product or to seek stepwise clearances to achieve an ultimate goal. Even where no prior discussion with the agency seems necessary, sponsors need to be realistic with their marketing submissions and be prepared for surprises in the form of extensive requests for additional information or a prolonged review process. Simply put, careful planning, good communication with FDA, flexibility, and a certain amount of pragmatism are all part of making the process as efficient as possible.

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