Perspectives on Time to Market—Part 3

For your area of the industry, what is your best recommendation for getting a medical device to market faster?

David Rosen
Partner, Foley & Lardner LLP

My recommendation for the fastest way to get a medical device to the market is to gain a thorough understanding of the information and data that FDA is expecting to see in a premarket notification submission [i.e., 510(k)] or in a premarket approval application (PMA) and to generate the necessary data and provide it and other required information in the application. FDA has issued a significant number of guidance documents to assist the industry. Also, the medical device databases on the FDA website are a good source of information on predicate devices, as well as on information included in PMAs. I also encourage companies to meet with staff in the Center for Devices and Radiological Health (CDRH) through the pre-IDE process. Through this process, a company is able to provide its proposed development plan and obtain valuable feedback from CDRH staff. CDRH's Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) also provides helpful advice to companies. Finally, a company can engage consultants and attorneys with significant knowledge to assist in the generation of data and the preparation of submissions that can be reviewed and expeditiously cleared or approved by FDA.

Gopal Saraiya
Market Development Manager, Eastman

There are two key components to help bring state-of-the-art injection-molded medical devices to market more quickly than average:

- Early and ongoing collaboration among the entire product development team, including design engineers, material suppliers, equipment manufacturers (OEMs), and molders
- Selecting the optimal materials for the device early in the design process

A collaborative approach ensures all stakeholders share expertise, understand deadlines, and make decisions together to help create durable, reliable medical devices that meet marketplace demand and increase patient safety and comfort.

To streamline the development process and create a successful device, it’s essential to evaluate the application functionality and the environment it will perform in, as well as understand the advantages of different materials and how they are processed. Material suppliers, OEMs, and molders can help brand owners and design engineers identify essential material characteristics, such as durability, chemical resistance, clarity, color-stability, temperature resistance, ease of processing, and secondary operations.

To help keep product development on schedule, material suppliers can offer technical services expertise, including design modification for manufacturability, tooling, processing, testing, and secondary operations. This assistance can reduce costs, save time by limiting manufacturing disruptions, and ensure production of quality, functional, and aesthetically pleasing medical devices.

Steve Raiken
President, RENY

Using a modular tooling approach will speed the product development cycle and cleanroom injection molding will enable companies to speed through the mold build to validated product transitions. Since the majority of medical devices today are produced in quantities under 100,000 units per year, this approach allows OEMs to enter clinicals quickly and confidently, speeding up the path to product approval and sale. Using a modular approach with production quality molds will allow companies to easily validate parts with no additional production tooling needed for launch requirements.

Tim J. Morton
Design Director, Product Development Technologies (PDT)

There are several recommendations I'd make to speed a medical device to market, but first it's imperative to identify and clarify the need. Be sure to substantiate the device's creation and understand how its usage will differ by user and location while gaining a full understanding of the business and economics of the industry.

Sacrificing front-end strategy and understanding in the interest of speed is a poor decision. A product without a market is a failure whether it is completed quickly or not.

A great way to shave time off the development cycle is to fully understand regulatory requirements from the beginning and insist your development partners do too. Small decisions can add up to big time investments. A 510k submission is a much less time-intensive process than a PMA, for example, and changes made during the FDA's review of a PMA can push you right back to the beginning.

Similarly, make sure your team and partners understand the manufacturing process. Looking to experts in this field can save massive amounts of research time because they can immediately identify appropriate materials and processes to ensure success. Firms with vast medical development experience can readily name materials that will perform under sterilization, for example, or can handle regular contact with fluids or blood.

Ultimately, the two most important steps in ensuring a smooth and efficient development process are to plan in the beginning and to choose your partners wisely.

Julie Dykstra
Counsel, Business Department, Barnes & Thornburg

The world of medical device regulation in the United States can be very difficult for foreign and domestic manufacturers and distributors to maneuver.

Step one for a medical device company should be the engagement of regulatory and legal experts early in the development process. One of the most difficult aspects of getting a medical device to market is knowing where to begin (i.e., what are the steps for marketing and in what order they are to be taken). Essentially, medical devices are subject to the general controls of the Federal Food, Drug & Cosmetic Act that are contained in Title 21 of the Code of Federal Regulations. These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labeling, and monitoring its performance once the device is on the market.

Step two in the marketing process is to make absolutely sure that the product that you wish to market is a medical device; that is, does it meet the definition of a medical device in section 201(h) of the FD&C Act.

Step three is to determine how FDA may classify your device—which one of the three classes the device may fall into. Unless exempt, FDA will classify your device. Classification identifies the level of regulatory control that is necessary to ensure

the safety and effectiveness of a medical device. Most importantly, the classification of the device will identify, unless exempt, the marketing process—either premarket notification [510(k)] or premarket approval (PMA)—the manufacturer must complete in order to obtain FDA clearance/approval for marketing.

Step four is the development of data and/or information necessary to submit a marketing application, and to obtain FDA clearance to market.

These regulations can be complex and technical; therefore, engaging regulatory and legal experts early in the development process will greatly increase the speed of the device to market.