Countdown to Product Launch

For medtech marketers, early planning is the first step toward achieving a successful product launch.

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Illustration by BARTON STABLER

Eager to debut its new portable imaging device, a medical technology company completed its exhibitor application early and ended up with a prime booth location at the annual meeting of an important clinical specialty association. Visitors would be arriving at the exhibition area in just five hours. There was only one problem: the company had not yet received FDA approval to begin selling its product.

Should the company have waited for FDA approval before reserving booth space at the event? If so, the company might have been relegated to an obscure location with little traffic. Such a dilemma illustrates what medical device manufacturers constantly deal with when preparing for product launches.

The ideal situation, of course, is to time and plan all activities so that the market is ready to receive a new product just as the manufacturer is ready to deliver that product. This article looks at steps that medical device manufacturers can take to ensure that their product launch is both timely and successful.

The Planning Time Line

"There can be no single cookie-cutter approach for launching a medical product," says Aimee Corso, senior vice president for the medical devices and technology practice of Fischer & Partners (Marina del Rey, CA). "We work with our clients to begin launch plans as soon as a product's regulatory pathway is established. Launch execution can begin as soon as the company commences work with outside investigators. These audiences become the first customers and key third-party endorsers to support additional customer growth."

Planning for a product launch is usually a two- to five-year process, depending on whether the product is a new one or an extension of an existing product line or technology. "A new technology means a different form, fit, or function," says Tim Garde, senior vice president at Ted Thomas and Associates (Philadelphia), the marketing communications agency of Vox Medica (also Philadelphia). "Coming up with a whole new device can take as long as five years, depending on the time required to get the right clinical trials going and obtain FDA clearance to market." In pharmaceutical manufacturing, Garde notes, it can take even longer.

A successful launch depends on a carefully constructed marketing plan, which experts agree should be put into motion very early in the product development process. "Near the beginning of the process, we identify the target market and compile a description of the features and benefits

of the particular product, the target price, the estimated volume, and so on," says Steve Emery, point-of-care diagnostics marketing manager for Agilent Healthcare Solutions Group, a division of Agilent Technologies Inc. (Palo Alto, CA). "From there, we continually refine the plan over the course of the development process until approximately six months prior to product launch, when we have a complete marketing plan that details all the different aspects of distribution, positioning, competitive statements, and so on."

Outside Counsel

The scope of the product launch should be the determining factor in deciding when to bring in outside marketing resources. Is the product being launched a replacement? Is the manufacturer entering a new market? Competitively, is the company first to market? Does the company have a differentiating feature that distinguishes it from its competitors?

After defining the scope of the product launch, a company like Agilent would typically bring in an agency toward the beginning of the process so that agency staff members can work with the client in defining the positioning as well as the external messaging for the product.

For a major launch, Agilent prefers to bring in agency resources sooner rather than later. This way, the agency can help formulate the marketing plan. "We want them involved so that they can offer strategic counsel," says Heidi Wilson, senior public relations manager at Agilent. "They can provide insight that is valuable for the process, in terms of how the product is positioned and ultimately received among various audiences. They bring a wealth of experience, since they usually work with a number of clients."

Jon Weston, senior business unit manager at Gambro BCT (Lakewood, CO), says that his company is getting the agency involved even earlier. "For instance, I'm currently working on a pathogen inactivation technology, and we'll probably be getting our agency involved three years in advance of potential approval to do some fundamental work in positioning and branding."

Garde also advises involving an agency as early in the process as the point when the company is still developing its business plan. "The business plan should include results from market research, and that work is part of what an advertising agency does. It can be done anywhere from one to two years prior to launch," he explains.

"One of the biggest oversights when it comes to launching a new product is that companies often fall into the trap of thinking that product positioning and branding do not need to occur until a product is approved for market," adds Ron Marrocco, vice president for the device practice at Lehman Millet Inc. (Boston). "In reality, the most successful product launches occur when positioning and branding are considered very early in the process."

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There are times, however, when the ideal planning time frame just won't work. During the third week of March this year, a client called Jerome Reicher, president of ARRCO Medical Advertising (Norwood, MA), to ask for help with a product launch set to occur in June. "We told the client that it could be done, but that it would be tight. We are providing them with print collateral, which can be developed in a short period of time. We should also be able to develop an ad in that time frame. But looking objectively at the total market, we probably won't make our biggest impact until around September," he says.

Market Analysis

A medical device manufacturer should begin market analysis early. This entails performing competitive reviews of what's already in the marketplace, what's working, and what's not working—both from a technological point of view and from a product-positioning point of view. Price comparison studies are also necessary, as are clinical outcome studies. "In the healthcare market, strong clinical trial results are usually an integral part of a new product launch. Trying to launch a product with weak information is a nightmare," notes Patricia Malone, principal of Stratagem Healthcare Communications (San Francisco).

"We launched Coherent Medical's VersaPulse PowerSuite laser for the treatment of benign prostate hyperplasia (BPH). It was a new way to treat this condition and we went up against the gold standard, transurethral resection of the prostate (TURP). Fortunately, we had great clinical results. We positioned the product as equal to TURP, but with more patient benefits. The result was that it overtook TURP as the preferred surgical means of treating BPH," Malone says.

Garde notes how important it is in the research phase to get information on who the key stakeholders are, what decisions they make, and how influential reimbursement is. "A lot of products are either Medicare Part A or Part B, and they fall into various payment categories. Pricing decisions

are sometimes made based on reimbursement, but a lot of other things are often considered, such as the longevity of the product, or product service provided to the end-user, the clinician, or even the individual who is dispensing the product," he says.

Charles Versaggi, president of Versaggi Biocommunications (San Francisco), observes that marketing departments often fail to do enough homework to make sure that the product has a clear reimbursement path. "A campaign can be very successful in terms of getting the word out to physicians and consumers, but manufacturers oftentimes later find that providers have a hard time getting the product reimbursed from insurers because it doesn't fall clearly within a particular DRG reimbursement code," he says.

Corso adds, "There are multiple decision makers in today's medical product marketplace. It isn't enough to have just physicians on board. Effective launch campaigns often need to speak to those who pay for the cost of the product or have the final purchase decision. Those audiences could include hospital administrators, group purchasing organizations, insurers, or the government."

During the market analysis process, the manufacturer must create the unique selling proposition that will separate the new product from the competitor's product. Garde advises bringing in the sales team early in the process. This will get them motivated, make them part of the decision-making process, and allow them to help carve out that unique selling proposition.

Trade Show Attendance

After identifying key audiences and developing a solid message strategy, marketing communications tactics will usually be tied to one or more key industry events. It is widely known within various specialties which professional meetings are the most important, and most manufacturers will have made a commitment to exhibit at those events a year in advance. Not doing so will cause the exhibitor to end up in a "last-minute" location with little traffic.

Trade show attendance is very important, says Weston of Gambro BCT. "It's a nice stage where a lot of your customers are coming to you in one spot, so you've got their attention

and it's a great opportunity to showcase what you have." The shows are so important to Agilent that the company employs a marketing communications director whose sole job is to be responsible for all of the trade shows that Agilent attends.

The typical manufacturer will reserve a large booth space in a good location well in advance of a show date, but it may not be until six months before the show that the company's marketing and sales VPs determine which product they will actually headline during that show.

The Marketing Mix

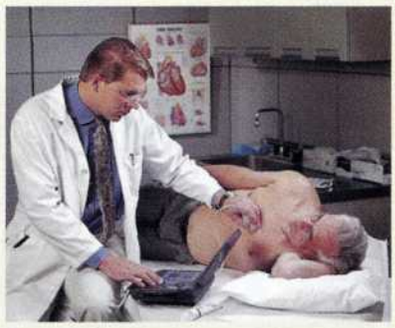
Advertisers understand that, in the medical industry, it is easy to segment the market, which accounts for how critical it is to tie product introductions into trade shows. "If a client has a specific product that is aimed at orthopedic surgeons or gynecologists, for example, the advertising agency can segment the market in a short period of time. If the agency does a very astute media buy, it can completely saturate the market," says Reicher.

Simultaneously, a good marketer will establish a presence at relevant accredited medical education courses while developing white papers or other publications about the new product. Peer influence and endorsement is a viable tactic as well. Manufacturers of medical products will frequently bring in professional athletes or movie stars to promote products. Christopher Reeve, for example, has been seen doing promotional endorsements for a new wheelchair.

"One of the best tools for preparing a launch is the ability to leverage published papers or abstracts from peer-reviewed journals. Whether they form the basis for an ad or a media relations campaign, these articles provide a solid foundation for any marketing plan. In order to have these materials at launch, they must be in the planning stages as soon as clinical work begins," Corso says.

It's Official . . .

Agilent Healthcare Solutions Group (Palo Alto, CA) officially launched its OptiGo point-of-care ultrasound device during the annual meeting of the American College of Cardiology (Bethesda, MD) in March. The company brought in its marketing agency nine months prior to launch, when a 510(k) notification had already been submitted and Agilent was waiting for clearance. "A good time to bring in an agency is when the company has already submitted the application, because it's confident that the product will gain FDA approval, and it usually has a plan for when to announce the product," says Heidi Wilson, senior public relations manager at Agilent. Typically, the launch announcement will occur during a major industry trade show or important industry event, which enables the launch team to select an announcement date well in advance.



Agilent's OptiGo ultrasound device.

The Power of Media Relations

Establishing credibility for a company's claims goes a long way toward supporting its sales efforts. The most effective way to do that is through a media relations program. It can take several months to build a relationship with the editorial staff of key publications, but if a device manufacturer can get an article published where there are third-party endorsements, public relations counselors agree that it will be worth much more than an advertisement.

"If you've got a really compelling story that discusses various types of benefits, you can probably get someone to run an article on your product, and that one article will live on forever," Reicher says.

With a well-placed story in a print publication, for example, the manufacturer can include reprints of the article in its sales kit. The manufacturer can also use those reprints in a direct mailing campaign and have them available at a trade show booth. But perhaps one of the biggest benefits of having an article published in a trade publication is that other editors will see the article and develop their own stories based on it.

In the long run, a company cannot support a program on media relations alone. It must plan to buy advertising, run a direct mailing campaign, and engage in other marketing communications activities.

Marrocco refers to the dynamic market for coronary stents to illustrate the value of an integrated marketing campaign. "There are many different coronary stents on the market today. So when a new stent with a new name is brought to market, something must influence the interventional cardiologist to try it. What is that something? How is the product unique from what is already on the market? Once this is understood, a campaign must be crafted that will communicate this message to the cardiologist. A campaign is not just advertising, but a series of communications vehicles

that enable a manufacturer to seat its product in the mind of its audience in a way that is memorable and unique."

Federal Regulations

"Preparing to launch a medical product involves an added layer of complexity because of the need to meet federal regulations," Malone notes. "At Stratagem, we employ a consultant to review many of our pieces to be sure that they meet guidelines established by FDA."

"In their zeal to launch a product, first-time marketers often fail to do a thorough check with the company's regulatory staff to make sure that their product literature has been cleared with FDA," Versaggi adds. "We were involved in a major launch last year that was derailed when the company had to pull back all of its literature and relaunch the product because it was 'pushing the envelope' on what it could say in its marketing claims. This can be a very expensive oversight."

Agilent's Emery advises that company marketers need to be fully apprised of the regulatory route that their product will take through FDA, since that information will have a direct bearing on the timing of their launch activities. The Web site of FDA's Center for Devices and Radiological Health (CDRH) offers a self-service source of regulatory information for medical device and radiation-emitting products called Device Advice (http://www.fda.gov/cdrh/devadvice). For marketing personnel unfamiliar with the agency's premarket approval processes, the site offers a synopsis of the steps involved in obtaining marketing clearance, titled "Getting to Market with a Medical Device" (http://www.fda.gov/cdrh/devadvice/3122.html).

A product that is substantially equivalent to predicate devices already on the market can be cleared via FDA's premarket notification (510(k)) process. Although the statutory time frame for clearance of a 510(k) is 90 days, Emery advises that marketers should plan for the process to take longer. "You want to allow yourself a wider window because FDA could come back with questions about the submission, and that resets the clock as to

when approval will likely come."

A device that is based on a new and previously unapproved technology generally will require an application for premarket approval (PMA), which is a longer process for which FDA often requires a much greater amount of clinical trials data. "The PMA is a longer process for which the timing is less precise," says Emery. "Part of the imprecision is due to the wide range of products under review. At one end of the PMA continuum are devices whose safety and efficacy is in question only because of a subtle technological advance or new intended use, and at the other end are truly revolutionary technologies. Both types of products may require PMAs, but the time for approval can vary from as little as six months to many years, depending on their complexity." To keep on top of the schedule for approval of their product's PMA submission, marketers should stay in regular contact with the company's regulatory affairs staff. In turn, regulatory personnel should monitor the progress of the device submission through FDA, keeping marketing personnel informed about changes or delays that could affect the timing of the launch.

Lengthy product-approval processes are even more common in the pharmaceutical area. "It can take years for a pharmaceutical manufacturer to test its product sufficiently to demonstrate efficacy and lack of contraindications," says Emery. Among pharmaceutical manufacturers, stories are told of inordinately long delays at FDA while companies completed tests of new compounds first on animals, then on human subjects, and finally by means of double-blind placebo-controlled trials. "Getting FDA approval of a new drug application (NDA) can easily take five or 10 years," says Emery.

For medical devices, product managers observe that FDA has dramatically improved its ability to review premarket submissions over the past few years. "One recent improvement is the abbreviated 510(k), which allows for very quick review if the company is only making a very nominal change to its product," says Weston. "As FDA becomes more computerized and able to accept applications on CD, that will really speed things up, too."

Approval Pending

Subject to certain restrictions, a manufacturer is allowed to exhibit a new product while its marketing application is under review. "As you're putting together your trade show booth—especially if there's an important new product coming out—you should try to build your exhibit around that new product," Emery advises. "Even if you don't have approval at that particular point, you can still make a splash as long as you appropriately convey the message and the intent so that customers realize the product is not yet approved for commercial release in the United States."

For example, many companies typically have signs and explanatory materials headed "FDA 510(k) Submitted" or "FDA Approval Pending" at their trade show booths. A company would violate FDA regulations, however, if it actually took orders for or shipped any product in advance of final approval.

Conclusion

When discussing product launches, tales of horror run rampant among medical device manufacturers. "At one time, I owned a home healthcare manufacturing company," Garde confides. "There were times when we worked on products that got killed. Sometimes you spend a lot of money in R&D—anywhere from $250,000 to as much as $3 million—and you still kill the project."

"There's some forgiveness in the medical device marketplace," Reicher assures. "But that time period lasts about three to six months." He cautions that if the product will be two years late in coming out, the company is wasting its money warming up the market and telling prospects about it.

A strong sales component is also critical to a successful launch, as Versaggi attests. "Several years ago, we developed a highly successful marketing strategy for a client only to find out they didn't have a good sales strategy for closing the deal. We failed to realize that their sales cycle was several months longer than anticipated. Eventually, they ran out of money and the company folded before revenues became reality," he says.

Failure can also occur when marketing has done such a good job that demand exceeds supply and the manufacturer cannot ship product fast enough. Medical device companies are becoming increasingly aware of manufacturing issues that can kill a product launch, and they are working hard to avoid those problems. "That's often the logjam in the medical device industry," Reicher says. "It's not so much getting into the market as it is having enough product available to respond to the market's needs.

"If that problem isn't resolved within about six months, the product becomes simply another medical device that never quite made it into the marketplace," Reicher concludes. "Then customers lose interest in the company and turn their attention to the competition. That's why timing is so important."

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