

Taking the Lead in R&D

Device firms that outsource research and development are better equipped to focus on their core competencies, which ultimately leads to improved efficiency.

Michael Barbella, Managing Editor

His title reflects that of a corporate executive, but Craig Berky really is more an educator these days.

"The one thing I underestimated when we started this company was the amount of time we spend educating customers," said Berky, vice president of research and development at Interplex Medical LLC, a five-year-old medical design, development and

save money, nor does it guarantee success. Poor choices can lead to time-consuming and costly fixes.

Choosing the right outsourcing partner is important in all stages of the product development process, but it is perhaps most critical during the research and development (R&D) stage. Turning an idea into a tangible product is the core responsibility of R&D, and it is a process that gives medical device firms a competitive edge in today's global marketplace. Generating growth through innovation has become essential for companies to succeed.

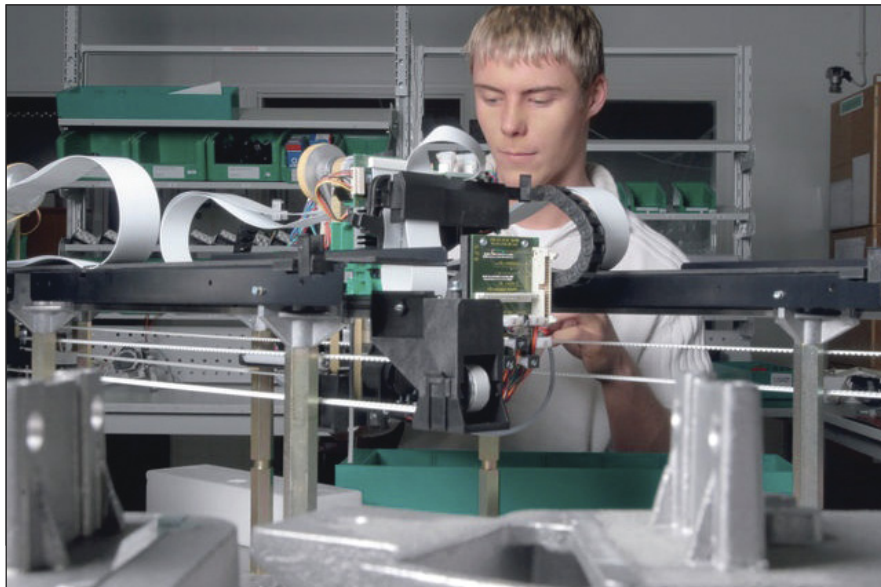
The increasingly competitive marketplace, however, has made growth more difficult to achieve. Foreign and domestic competition has forced device firms to find ways to get new products to the market quickly. As a result, R&D departments are now under tremendous pressure to develop new products.

This pressure to get products to the market quickly has led many device firms to outsource R&D in recent years. Initially hesitant to relinquish control of ideas, technical designs and manufacturing processes, the medical device industry finally has begun to embrace the idea of outsourcing R&D.

"Vertical integration was the way to go at one time. Companies once adopted the philosophy of doing everything themselves," Berky noted. "But that is changing. We're starting to see people liquidate their companies where they need to. We're starting to see companies that had reputations of never outsourcing now starting to outsource."

Why Outsource R&D?

The reasons behind the change in attitude toward outsourcing R&D are as varied as the companies adopting the practice. Cost is a major factor for some companies, particularly those with limited R&D budgets or those with-



Many medical device companies traditionally have been hesitant to outsource research and development projects because they do not want to share key strategies and confidential information with outside firms. This attitude, however, is changing as companies realize the multiple benefits of outsourcing. Photo courtesy of BIT Group.

assembly service provider based in Milford, Ohio. "When customers come here, they want to do the right thing. Smaller companies seem to be under heavy financial constraints and want to do things as quickly and as cost effectively as possible. But that's not always the best way to go."

Particularly when outsourcing is part of the equation. Reducing expenses is almost always a smart business move, but medical device firms have proven to be the exception to this rule. Over the last several years, OEMs and other companies that outsource parts of the product development and manufacturing process have learned a valuable lesson: choosing the least costly outsourcing partner does not necessarily

out the staff to conduct the proper research.

Staffing can present some exceptionally thorny issues for companies. Device firms looking strictly to cut costs may outsource R&D if experienced personnel can be found elsewhere for a lower wage. Or, companies may choose to outsource R&D if they are unable to find qualified staff or they do not have the budget to hire as many workers as needed. Companies without the staff to conduct thorough research often find it easier and more economical to outsource R&D than go through the process of finding and hiring workers.

“The hiring process for engineers is time-consuming,” said Steve Maylish, vice president of business development for Source Scientific LLC, a BIT Group company based in Irvine, Calif., that designs, develops and manufactures medical devices. “You can spend three, four or five months trying to find qualified staff engineers for your project. Then, once hired, you need the new group to perform as a team. They may or may not all be a good fit.”

Finding the people you need, however, can be difficult. Companies must wade through the potential pool of applicants and determine whether they are better at designing a product based on a concept or designing the next generation of an existing device (which Maylish referred to as “sustaining engineering”).

Even with a qualified, sizeable R&D staff though, some businesses find it easier and more cost-effective to outsource. For example, a large device firm that does not have sufficient resources for a product development project may look outside for R&D help in order to get the product to market quicker.

“Say a company has three engineers available part-time on a project, and in order to get started in four or five months, the company needs to hire three additional full-time engineers. And let’s say the project will take two years,” Maylish explained.

“You can ask an outsourcing group to fully engage a seasoned team without the process delays inherent in interviewing, hiring, orienting and forming a design

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team,” he continued. “To accelerate the project once an outsourcer is selected, a large company designates a project manager and approves the budget. Outsourcing may take six months off a project schedule. To decelerate a project, you introduce decision by committee, constraints on the design process, unreasonable expectations and a large dose of risk aversion. This can unwittingly hinder the design process and quickly slip the schedule.”

Besides losing focus, larger corporations are more conservative and have little, if any, flexibility in design control. The quality systems of these firms is usually bloated and filled with various requirements about product development procedures. As one industry expert noted to *Medical Product Outsourcing*: “Some companies have never seen a different way of doing things. They just want to do things a certain way and that’s it.”

Device firms that choose to outsource R&D not only give the development team more freedom with product designs, they also help reduce the overall cost of getting their equipment to the market.

Businesses that do not develop products on a regular basis also can benefit from outsourcing R&D. Industry experts estimate that most firms develop new products every three to five years, which can seem like a lifetime in the medical device sector. Considering that some devices (pacemakers, for example) can become obsolete in as little as 18 months, companies that dabble in product development two or three times every decade are better off finding a partner that handles product development and design on a more frequent basis.

“Some companies have an infrequent need for specialist product design and de-

velopment services, and it is not feasible to build and maintain these in-house capabilities,” said Warren Hancock, a director at Invetech, a company that specializes in product development and custom automation for the medical, industrial and consumer markets.

“Outsourcing can offer better solutions than ad hoc design teams because external service providers can tap into scale and learning economies that they have developed through their experience and longevity in the business,” he added.

Of course, the reasons for outsourcing R&D are not always so complicated. Battelle, a nonprofit research and development company, has helped countless customers overcome creative roadblocks and provide R&D teams with a fresh perspective. The Columbus, Ohio-based firm also has provided customers with expertise when needed. In some instances, the assistance has led to larger product development jobs for the firm.

“With Battelle, people bring us in when they hit a roadblock to get them past a sticking point, or help provide the [product development] team with a new perspective,” said R. Reade Harpham, director of Industrial Design and Human Factors at Battelle Medical Device Solutions. “Sometimes that has led to a bigger issue where the customer outsourced to us a subset or a subsystem of a clinical design. We’ve done small work, and we’ve been a virtual outsource partner for some firms. We’ve also assisted customers who were resource-constrained and needed someone to come in and help them.”

The ABCs of Outsourcing R&D

One of the most important factors in out-

sourcing R&D—or any part of the product development process—is choosing the right outsourcing partner. But before that choice can be made, companies that are considering outsourcing must first determine why they are seeking outside help.

The answer to that question will help a company determine the type of outsourcing partner it needs. For example, a device firm that wants to get a product to market quickly would benefit from partnering with a company that can improve speed to market. Likewise, if a company lacks engineering expertise, then obviously, it needs to partner with a firm that has the proper engineering resources.

Industry experts, however, warn against outsourcing R&D solely for cost purposes. Partnering with a contract manufacturer to reduce product development costs can definitely benefit a device maker's bottom line, but a narrow-minded focus on saving money will most likely end up costing the company more money in the long run.

"Cost is always something that is considered, but it has not been the main concern with most companies," noted Tim Bowe, CEO and co-founder of Foliage, an 18-year-old company in Burlington, Mass., that develops PC, embedded, and Web-based medical devices. "It's more important to get a product to market within a certain window than save 10 or 20 percent. If you save 10 or 20 percent on a product that cost a couple of million dollars to develop, but you're six months late to market, or develop the wrong product, you can easily lose \$10 million or \$20 million dollars. You have to figure out why you are outsourcing and what your primary goals are. You have to understand what the real drivers are for your company."

Once a company has figured out the reasons behind its desire to outsource R&D, it is ready to choose a partner. The choice is going to depend upon a number of factors (such as technical requirements of the project, contracting costs, trust and information-sharing), but the most important of these factors will be the outsourcing partner's familiarity with medical device development.

The partner also should be knowledgeable about U.S. Food & Drug Administration and international regulations,



Outsourcing R&D projects can help drive product innovation and enable companies to remain competitive in the global market. Photo courtesy of BIT Group.

including device classification and good manufacturing practice requirements. In addition, outsourcing partners should have in-depth knowledge about risk management and quality systems requirements, as well as design control and its importance in early product development.

Besides the expertise in medical device regulations and product development, R&D outsourcing partners should have a corporate culture that is similar to the company farming out the work. Similar corporate cultures can help the companies form a good working relationship and foster communication among those developing and designing the product.

Another essential step in outsourcing R&D is assigning a project manager to oversee the product development process. Project managers not only help keep the project on schedule, they also can help ensure that R&D is not duplicated at multiple locations. Plus, project managers can make sure that the lines of communication between both partners remain open and that there is an effective collaboration effort between the teams.

"Companies need to have someone in-house to interface with the outsourcing firm—someone who can take the lead and make informed decisions. You'd be surprised how many questions come up when you start a project. For the first month or so, it's

nothing but defining product requirements, such as 'what software is going to be used?' or 'what operating conditions are required?' Someone needs to answer the technical questions and keep the project on track," BIT's Maylish explained.

Addressing Concerns

No matter how good a match a potential outsourcing partner may be, there are times when it just doesn't make good business sense to contract out R&D. The most obvious scenarios are those in which companies have the ability in-house to conduct market research and design a device. In those cases, it may be more cost effective to use existing staff.

Invetech's Hancock also warned companies against outsourcing R&D before the "fundamental science/ technology and the outcome of research" is sufficiently understood. Contracting out R&D work too soon, he claimed, will result in a return to the lab, or worse, a product recall.

Maintaining control over a medical device also can keep R&D work within the confines of the company developing it. Corporations that design and develop a Class III medical device, for example, would most likely conduct its own R&D to ensure the product meets FDA requirements and will not be recalled once it is on the market.

Besides cost factors and the desire to

maintain control over a design, companies may decide against outsourcing R&D to safeguard their core competency and protect their IP. Businesses that outsource their core competency risk losing both their competitive edge and the expertise that makes them valuable to customers.

“Companies should always be concerned about their IP and whether there is a way to separate IP so they don’t have to share it. If you can’t do that, then you should make sure there are controls on the IP with your partner organization and that can be difficult to do but not impossible,” Foliage’s Bowe said. “If I was a manager and I was outsourcing R&D, particularly to an emerging market, I would want to make sure my core competency and my IP were covered—something we always do with our clients.”

Protecting IP in emerging markets, though, is easier said than done. Outsourcing R&D to emerging markets—particularly those in Asia—have ballooned over the last 10 years, as device firms look overseas to take advantage of highly educated and trained workers at a cheaper cost.

Countries such as China and India have become centers of medical device innovation due to changes in government attitudes, direct government investments, liberalization of those countries’ economies and an increased effort to develop a technology-oriented population.

The changes in China and India have resulted in an increase in the quality and components of medical devices produced there. Devices manufactured in Asia are usually cheaper than those produced elsewhere, and those that meet quality requirements and international standards have become attractive to healthcare providers struggling to stay afloat during economic downturns.

Despite its financial advantages, however, many companies considering outsourcing R&D are hesitant to partner with Asian firms due to IP concerns, industry experts told *MPO*. Most businesses with an original idea or design patent that idea or design to protect it from being illegally copied. But global patents do not exist, leaving companies without a way to fully

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protect its IP in Asia.

“China is making efforts to make companies accountable for patent infringements, however, is that becoming the norm in practice?” asked Bill Dunlevy, vice president of medical devices at Battelle. “I don’t think companies in the U.S. are confident that will be the norm. China has improved in holding companies accountable for patent infringements, but many U.S. companies are still shy about introducing products into that market.”

Concerns over IP protection have prompted Interplex Medical to carefully consider the best way to utilize its operations in foreign countries. The firm has a division in Mexico and another one in China.

“We are not outsourcing R&D just yet,” Berky noted. “You read magazines, and it says that [outsourcing to Asia] is good. But when you talk to customers, you find out it’s not as good as they say it is. There’s definitely a hesitancy of our customers to go to the Asian market if you are coming up with a novel idea. Companies are concerned with IP and people taking their idea. The Chinese have a very different philosophy when it comes to IP. What our customers have experienced is if it is not covered under Chinese patents, it’s fair game.”

China is not oblivious to the criticism. Last year, China’s State Council approved a National IP Strategy that commits the government to consider developing specialized IP courts.

The strategy also proposes establishing a central IP court in Beijing. Other goals outlined in the strategy include: improving existing judicial interpretations; refining litigation procedures, including expert witnesses and technical investigations; improving policies relating to patent standards; and developing the mechanisms for compulsory licensing.

The commitments to improve IP en-

forcement were prompted by two World Trade Organization cases launched by the U.S. government last year.

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Outsourcing R&D enables medical device firms to reduce costs, minimize business risks and get products to the market more quickly.

In addition, the move can help companies increase efficiency by allowing them to focus on their core competencies.

By shifting non-core components of R&D to an outsourcing partner that specializes in product development, testing and sustenance, companies can focus on their core competencies in the R&D value chain, such as architecture and design and product strategy.

Establishing an outsourcing partner also can provide device firms with greater flexibility in design, which ultimately can lead to a better product.

Obviously, companies without an in-house R&D staff are the most logical candidates to outsource produce design and development. But even firms with large R&D teams can benefit from outsourcing. Foliage’s Bowe explains:

“Assuming you have a stable work force and you develop a product every three or four years, they may not really be an R&D staff. They may not be up to date on the technology or the latest design techniques. Once you make a major investment in development technology and [product] design techniques, you may not get the opportunity to use that again right away. So all you’re left with is an application staff, not a development staff. That’s a very ineffective and error-prone approach to product development. Working with a partner that can quickly put a team together and design your product is the better way to go.” ♦