

GUIDE TO OUTSOURCING

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All Signs Point to Outsourcing

A survey of device companies indicates that the industry will continue the trend of using contract manufacturers and other outsourcing partners.

A recent survey of individuals within the medical device industry found that certain market forces have aligned to create strong market conditions—a perfect storm, so to speak.¹ A perfect storm scenario is a domino-like alignment of certain elements that create an exceptional situation. In the medical device manufacturing industry, these aligning market forces are the growing market demand and the need for high-quality products, compliance, and efficiency. In the survey, device manufacturers emphasized these three needs as critical factors in their selection of an outsourcing partner.

Thomas Medical Products Inc. (Malvern, PA) conducted the survey to gain a better understanding of challenges facing device companies today and to determine the areas in which device companies anticipate their most critical challenges in the future. The survey's intent was to obtain baseline data that would be gathered and benchmarked annually.

Although factors such as demand shifts and regulatory changes create a moving target to monitor and respond to, one thing appears to be a constant: the medical device industry is growing, and it will continue to do so. But gaining perspective on the implications of current and emerging needs as well as shifting priorities in this industry can be a challenge. Understanding these implications can help device manufacturers determine whether to outsource.

As noted by industry analysts Frost and Sullivan,

Demand for medical devices is influenced by the increasing patient population and the focus on healthcare cost containment and preventive therapies. The structure of the medical device industry keeps changing due to new acquisitions and mergers. Multinational manufacturers are consolidating in order to establish a greater presence around the globe. Technological innovation is imperative for sustainable growth and competitive advantage in the medical device industry.²

The Respondents and the Survey

Many respondents had cross-functional job descriptions, so the total breakdown does not equal 100%. Respondents included those involved in the following areas: finished product manufacturing (59%), product

engineering (57%), prototype design (34%), product testing (23%), product distribution (22%), and finished goods packaging (14%). The disciplines of the 120 respondents included research and development, marketing, manufacturing, regulatory affairs, quality assurance, and sales. The results provide important insights into trends in the production and distribution sectors of the market.

The results showed that time-to-market constraints were the most pressing across all respondent types. In fact, 89% of those surveyed indicated that they are challenged by time-to-market constraints, and 90% noted that product quality is the most important driver when selecting an outsourcing partner for engineering or production. Regulatory compliance was also a critical priority to 78% of respondents.

The Market

The financial community is clear on the aggregate growth estimates for the global medical device sector, forecasting growth from \$100 billion to \$500 billion in the next five years.³ The medical device industry has for some time been noted as a fast-growing area. Estimates of the size of the outsourcing portion of the market vary widely; however, one study reports that the contract manufacturing sector alone generates \$3.4 billion in revenues and is growing at more than 15% annually.³

Driving Demand

Increased outsourcing is being driven by several factors. Novel devices are coming onto the market (e.g., percutaneous-delivered therapies using highly sophisticated catheter delivery systems). Therefore, device companies need innovative and high-quality medical device design and manufacturing techniques that meet or exceed their in-house capabilities. Other factors include an aging (but active) population and more minimally invasive surgical techniques. These conditions have also aligned to create the perfect storm of opportunity for all involved in the development, production, and distribution of medical devices.³

One key factor driving the growth of outsourcing is that from a therapeutic and overall cost standpoint, procedures that use medical devices are on the rise. For example, looking only at cardiology, the use of invasive surgery techniques, such as coronary artery bypass graft (CABG) procedures, has declined over the past 10 years.⁴ Interventional cardiologists are getting either better or similar results with much less risk by using percutaneously delivered drug-eluting coronary stents and atrial fibrillation ablation.

Figure 1. (click to enlarge) Many respondents found time-to-market constraints challenging. Nearly all respondents experienced challenges across job functions.

The survey found that nearly 90% of respondents are pressured by such market demands. An overwhelming number of respondents (89%) noted that time-to-market constraints are either “very” or “somewhat” challenging (see Figure 1). Nearly all respondents experienced challenges across job functions.

What Manufacturers Outsource

Respondents indicated that they plan to increase the use of outside partners in several key areas. These areas include finished device manufacturing, component manufacturing, and product development, including parts acquisition and prototype design and development. Figure 2. (click to enlarge) Most study respondents will either increase or remain the same in their use of outside vendors across all job functions.

Respondents said they plan to increase or remain at the same level of outsourcing (see Figure 2). For example, half of all respondents will continue the same level of outsourcing their finished product manufacturing. An additional 30% said they would increase the amount of this type of outsourcing.

Quality, Compliance, Time to Market, and Cost

Quality—the ability to deliver high-grade or superior products to customers—was by far the most critical concern to the respondents of the survey. Across the board, producing quality products was the key consideration in bringing on an external partner. Figure 3. (click to enlarge) Nearly all respondents agreed that quality is the most important capability when selecting a vendor.

To better understand the qualities and capabilities that are most important to device companies, the survey asked, “What are the most important attributes of an external product development and/or manufacturing firm?” Nearly all of the respondents (91%) cited quality as the most critical attribute. An additional 6% said that quality was “somewhat important.” Compliance and time to market were also rated highly (see Figure 3). Only after these key considerations were met did price come into consideration.

These findings clearly indicate that device manufacturers depend on their contract manufacturers or other outsourcing partners to help them achieve business objectives and deliver quality products to their markets. Contract manufacturers must develop high-quality products that consistently meet or exceed regulatory requirements.

In addition, device companies should expect their contract manufacturers to be able to differentiate their core strengths and manufacturing capabilities. Device companies should examine a number of suppliers to

determine which has the most flexible, state-of-the-art facilities and techniques.

Increasingly, global medical device companies are requiring their partners to use Six Sigma and lean manufacturing techniques. In the past, a contract manufacturer with ISO 13485 certification was a minority. Today, such certification is often a basic requirement just to be invited to the proposal process. Medical device manufacturers are also requiring that their partners incorporate more-exhaustive process validation into the product development phase.

Another expectation is shorter lead times to support companies' push to increase inventory turns and decrease warehouse costs. As a result, it is now common for medical device manufacturers to require outsource partners to incorporate kanban inventory replenishment techniques. Device companies should expect partners to attract and retain the best people—from manufacturing engineers to technicians and customer service staff. In addition, device companies should expect their partners to have a proven track record for delivery of quality products on time.

Planning Ahead

The survey also found that device companies rely on the flexible and expandable capacity of contract manufacturers to meet their product demand. From a manufacturer's perspective, it is critical to prioritize the most important needs and to articulate those to the contract manufacturer.

To be successful, both device companies and contract manufacturers will become increasingly focused on anticipating market needs. Answering the following questions should help medical device companies find common ground with their outsourcing partners for mutually beneficial collaborations:

- * What is your company's specialty area (e.g., cardiology, dialysis, anesthesia, home healthcare, etc.)?
- * Is the device to be developed or manufactured Class I, Class II, or Class III? The class affects the device's development, regulatory pathway, financial liability, and complexities.
- * What gaps do you need your partners to fill (e.g., engineering resources, distribution, packaging, or finished-device manufacturing)?
- * Is the quality system of the contract manufacturer sufficient for the device being manufactured? Both the contract manufacturer and medical device company should do a gap analysis of their quality systems.

Mutually agreeing on what needs to be included in the quality system of the contract manufacturer should be done before manufacturing begins.

* How will the transfer of developed products to manufactured products be managed? Using one company for development and another for manufacturing can complicate the process and can increase time to market. It is important to ensure that engineering designs created in the development phase support designs for manufacturability.

* What are the current and expected national and global demands for the finished device? If demand is expected to increase, then device companies should request year-over-year pricing decreases. However, if demand is expected to fall, be prepared that a contract manufacturer may expect year-over-year volume commitments.

* What are the current and expected average selling prices (ASPs) for the finished devices? (Low ASPs generally equate to high-volume production.) Does the contract manufacturer have access to low-cost manufacturing?

* Do the ASPs combined with expected demand support the margins that each company along the continuum requires? For example, an 80% gross profit looks great on paper, but is it realistic given the multiple parties that must operate profitably? Internal profit margin requirements do not dictate ASPs—the market does.

Conclusion

This survey of the medical device industry identified a number of market forces that are influencing the use of outsourcing partners for everything from product development to finished device manufacturing. With this trend, however, device companies noted that the need for high-quality products, compliance, and efficiency are critical factors in selecting the right partner.

The medical device industry is growing and will continue to do so, and increased outsourcing is one way that manufacturers can keep up with changing demands and a dynamic market. Understanding these implications can help device manufacturers determine whether to outsource.

Mark Kesti is vice president of marketing and sales at Thomas Medical Products Inc. (Malvern, PA). He can be reached at 610/296-3000 or at mkesti@thomas-medical.com.

References

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