

Full-Service Outsourcing Paving the Way in the Medical Device Industry Companies Looking for One-Stop Shop for All Outsourcing Needs

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Outsourcing has long been a hot button issue in all segments of the life sciences industry. In the medical device sector, outsourcing initially took hold in the manufacturing phase, and companies raced across borders and oceans to capitalize on low-cost labor for potentially large profit gains. As the outsourcing model continues to mature, companies are realizing that outsourcing other key areas of product design and development, most notably research and development, can impart large productivity gains that translate into competitive advantages.

In the face of this paradigm shift towards outsourcing several components of medical device development, contract manufacturers can no longer fulfill all the outsourcing needs of their customers, causing medical device companies in turn to expand their universe of external partners. But problems arise when too many outsourced firms are involved. Relying on a number of suppliers to drive a medical device to market can be inefficient, time-consuming and wrought with missteps. Medical device manufacturers are now seeking partners that can provide full-service outsourcing, completing all phases of device development, from market research through prototype build and equipment design.

Several trends are further highlighting the need for one-stop shop partners and increasing the benefits of such a strategic move, including rapid market growth and the emergence of new industry-spanning market segments.

The State of the Medical Device Industry

A \$75 billion market, the medical device industry is characterized by high profit potential and, therefore, intense competition. With the aging population and the growing demand for homecare and self-administered medical treatments, the medical device industry is poised for continued growth, currently estimated to be 8 to 10% per year.¹ To gain a competitive edge in this lucrative market, medical device companies must adapt to continually evolving challenges and differentiate themselves with breakthrough products that beat competing devices to market.

Yet, as competition intensifies, medical device companies must not only work faster and smarter to succeed, but they must also do so with fewer resources. Globalization coupled with mergers and acquisitions and new market entrants are intensifying cost pressures, and firms must streamline operations to stay competitive. This continues to spark the contract manufacturing flame, as inexpensive foreign labor is one pathway to win the cost war for some products.

However, producing low-cost products is usually not the most lucrative strategy, especially in an industry where thinking outside the box is not a luxury, but a necessity. Stifling innovation for efficiency's sake will quickly lead a company down the "me-too" product path, with reduced market share and profitability.

To truly impact the bottom line and explode revenues, companies must devote resources to creating breakthrough products. These revolutionary products are often the result of innovative

thinking and multidisciplinary expertise. However, as technologies advance and medical care becomes more complex, companies also need highly specialized know-how to solve puzzling health concerns and improve quality of care.

This is evident in two of the most promising sectors of the medical device industry - the U.S. advanced drug delivery market, which is projected to grow more than 18 percent and exceed \$76 billion by 2014,² and the combination products market. Combination products are classified as two or more regulated components - drugs, medical devices, or biologics - combined through physical or chemical means. Already valued at \$5.4 billion in 2004, the global market for combination products is achieving annual growth of 10 to 14 percent per year.³ These growing segments require specialized skills, such as pharmaceutical formulation, as well as knowledge of polymer engineering, fluid control, etc.

Internally maintaining such an extensive array of relevant knowledge is simply not feasible for most companies, making the case for outsourced research and development. Similar arguments can be made in favor of working with market research companies to uncover the next urgent medical need in order to direct R&D efforts.

As outsourcing grew in popularity, it became common for a medical device company to deal with a marketing consulting firm, design engineering company and a contract manufacturer for one project. And this is how over-outsourcing came to be.

The core objective of any outsourcing initiative is to capitalize on the specific strengths of external firms for economies of scale and productivity. This works well until too many players get involved and the law of diminishing returns sets in. Simply stated, as the number of outsourced partners increase, the resulting rise in productivity begins to wane and the inefficiencies of over-outsourcing quickly become apparent.

Firms recognize that outsourcing can be used to gain a competitive edge in an aggressive market. Now, however, firms are seeking the ultimate partner with the full-range of expertise to provide end-to-end project support, avoid the pitfalls of over-outsourcing and still achieve the blockbuster product.

Why the Move Toward Full-Service Outsourcing

With full-service outsourcing, medical device companies can regain control of the device development process and enhance productivity. The absence of erroneous parties eliminates transition hiccups, reduces miscommunication and speeds the project from design through manufacture.

Coordinating the activities of multiple firms can be cumbersome and time consuming. Working with one outsourced partner also alleviates the medical device company of much of the project management burden. Using one partner to manage the entire supply chain, from materials suppliers to manufacturers will reduce the amount of resources that need to be dedicated to running the product development process. It will also elevate the relationship from simply a vendor-supplier contract into a partnership.

Greater protection of intellectual property also ensues, which is highly beneficial in an industry where innovative breakthroughs are keys to success. The best kept secrets are just that – secrets. The more parties that become involved in the development of a proprietary, potentially market-revolutionizing product, the greater the chance of information leakage.

One important caveat to be aware of with full-service outsourcing is that the level of expertise of the partner is more critical than in a typical outsourcing relationship. It is imperative that the selected partner possess knowledge that spans the vertical and horizontal horizons of product development. If not, innovation will be sacrificed for the efficiency benefits of a one-stop shop. Not only must the outsourced partner possess technologies and skills from a multitude of industries, but it must also have expertise that spans the entire product development cycle, from market research through manufacturing. The fruits of a partnership with a multifaceted firm that is up-to-date on the latest technologies are more likely to result in a proprietary product that cannot be copied.

Pitfalls of a Piecemeal Approach

As the old adage says, “Too many cooks spoil the broth,” and many medical device projects have been plagued by delays and inflated costs due to inefficiencies caused by poor project flow.

Given the brief window of time that determines whether a product is revolutionary or a me-too copycat version of the blockbuster, medical device companies cannot afford to waste time. Yet one of the most common problems encountered by firms that overextend their outsourcing relationships is a delayed product launch. Symptoms include insufficient coordination, miscommunication and oft missed deadlines.

This problem was experienced by a medical device developer that sought to take a disposable device controlled by an electromechanical console to market. This company utilized a design engineering firm for concept development, an offshore IT engineering firm for software development and a contract manufacturer. Communication between all parties was cumbersome due to cultural and language barriers as well as time differences. Additionally, the software firm’s lack of medical industry expertise further derailed the project and led to wasted time and numerous errors. If the project had been entrusted to one firm with medical, software and manufacturing expertise, costly miscommunication and delays would have been avoided.

The piecemeal product development strategy also commonly falls prey to the band-aid approach, where continual adjustments are required after the initial design has been finalized. This stems from involving too many partners with shortsighted vision that do not consider the total requirements of the project. Working with one partner that understands the entire device development process, including manufacturing issues, can overcome this hurdle.

An outsourced partner that designed without considering the needs of manufacturing not only raised costs of one medical device company’s project, but also detracted from the product’s quality. Tasked with creating a design concept for a console used in clinical environments for direct patient care, the contracted design firm finalized the prototype and passed it to the

manufacturing team. By this time, significant funds and a large amount of time were dedicated to the set design. The manufacturing team recognized that the concept as designed possessed numerous flaws and ergonomic issues, and would require costly assembly in the field. Revamping the design concept in the manufacturing stage also proved costly. Had the design firm and manufacturing team been one, design flaws would have been uncovered early in the design process, avoiding costly rework and continual product evolutions.

In the case of one diagnostic device development project, the external design firm did not consider what would be feasible in terms of manufacturing throughput. To produce the product in the volumes desired, the contract manufacturer would need to employ more workers on the manufacturing line than physically possible. This, too, could have been avoided by a cohesive product development team.

Regulatory compliance can also be at risk if too many parties are involved in a device development project. Myopic vision can prevent identification of a possible safety hazard or result in a flawed clinical study to the tune of millions of dollars. Working with an experienced firm that understands all regulatory implications can help steer medical device manufacturers down a compliant pathway. Regulatory guidance is especially important for combination products developers, who face a more complicated regulatory process due to the novelty of their products.

While opportunities abound in the medical device industry, only a relatively small number of companies will succeed in bringing blockbuster devices to market. This is because success requires the right mix of market demand, practical product innovation, engineering expertise and project management skills. Although full-service outsourcing is not a replacement for a manufacturer's creativity or industry experience, it can round-out these skill sets and bring them into alignment. Emerging product segments like combination products, which call into action medical, pharmaceutical and biotech expertise, will amplify the need for multidisciplinary full-service outsourcing. Manufacturers that seize opportunities to bring outsourcing under one roof will be poised for blockbuster success.

About the Author

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Sources

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