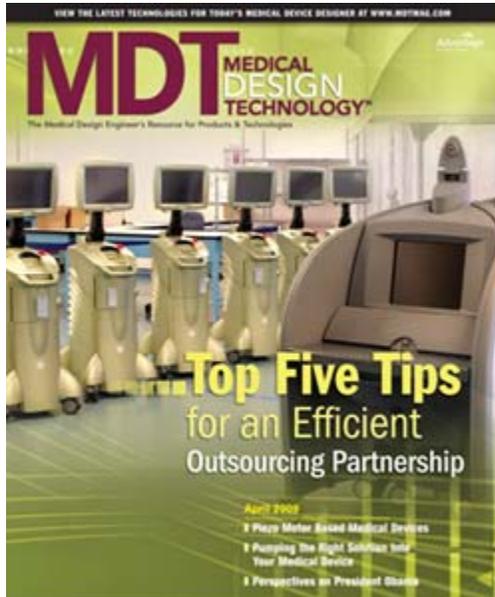


Top Five Tips for an Efficient Outsourcing Partnership



While outsourcing in the medical device manufacturing industry is growing, there are still a large number of companies who have very little or no experience with this process. For them, it can be a daunting task to determine how best to proceed with this new partner and what to address in order to help ensure success. This article highlights five tips to help companies avoid missteps that could lead to costly delays or even failure.

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April 2009

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For medical device design companies, working with a contract manufacturing and engineering resource can be an unnerving experience. Often companies aren't quite sure what they should look for in a partner. Whether a company is new to outsourcing or has been working with a manufacturing or engineering partner for years, tough economic conditions and changing technologies may leave one wondering how to make the most of a partnership, or what outsourcing can do to enhance a product or product development lifecycle.

The following five tips address the key questions that should be considered when selecting an outsourcing partner, how to best approach the new partnership, and strategies to pave the way for a smooth and efficient project.

Tip 1: Take an honest assessment of all documentation before beginning a project.



Cogmedix produces Class I and Class II medical and clinical devices for innovative companies bringing new medical and clinical products to the market.

All design and manufacturing projects include associated documentation from all phases of the project to date. When beginning work with an outsourcing partner, a complete assessment of all documentation

including all assembly, test, and final acceptance criteria is essential. Some designers choose to bypass this exchange of documents and instead ask the outsourcer to create a "Requirements Document" or scope of work to serve as the foundation for a project guideline. However, be advised: on average, working with an outsourcer to create a "Requirements Document" can often add \$5,000-\$25,000 to the cost of a project estimate depending on the amount of detail missing from the initial package.

Providing complete documentation at the onset of a project can also help avoid the need for reverse engineering. The more information provided to the outsourcing partner, the better. For example, recently, a Cogmedix client saved over \$20,000 and dramatically reduced the risk to the project when important missing documentation was recovered, eliminating the need for reverse engineering.

The ultimate goal of the selected outsourcing partner should be to assist the company in eliminating tribal knowledge from a product. In order to gain control of the product's design or assembly process, the company needs to "give it up." By giving control to a trusted and knowledgeable contract partner, the appropriate qualification questions will be asked, appropriate information will surface, and all the data will be clearly documented. This eliminates tribal knowledge and enhances the design timeline and overall "produce-ability" of the product.

Tip 2: Work with a contract manufacturer with a diversified domestic and global supply-chain network.

Contract manufacturers with expansive supply-chain networks are able to secure world-class prices and contingencies for varying quantities of parts. By providing well developed supply management capabilities and a secure infrastructure, outsourcers can optimize cost across their entire customer base.

Contract manufacturers with a diversified supply-chain network and strong purchasing leverage are inherently better equipped to rapidly adjust to the constant changes in a business and industry in order to meet fluctuating demands. Flexibility is one of the primary assets a company is purchasing when it selects a trusted partner. The best resources can turn on a dime for the company, so ensure the selected partner is well-capitalized so they are able to handle the ramp-up or ramp-down scenarios associated with new product launches.

Tip 3: Weigh the true and total cost of doing business.

The Total Cost of Ownership must include a true assessment of the costs associated with transitioning a product out of development and into scaled manufacturing. This assessment needs to be inclusive of all training, tooling, service, support, sustaining engineering, and manufacturing engineering, as well as documentation creation, finalization, and validation. Competent engineering and manufacturing partners can typically provide a company with a realistic estimate of projected costs at the start of a project.

For companies on the verge of outsourcing a project, often the temptation is to choose a contract manufacturing partner based solely on the price per unit cost. Don't be too short sighted. If all transition steps and costs are not truly considered prior to bringing a product to market, costly challenges are likely to occur downstream that could result in poor product quality, performance, brand damage, and high field service costs.

Since the outsourcing partner is responsible for establishing the supply chain, training all manufacturing personnel, absorbing the cost of manufacturing process fluctuations along with infrastructure costs related to space, general tooling, climate control, and other general overhead expenses, the manufacturing partner is able to minimize capital expenditure by leveraging their existing internal operation.

Tip 4: Decide what's right for the business.



Contract manufactured medical devices are widely used in a variety of markets such as critical care, home healthcare, emergency room, and industrial laboratories.

The company should focus on its core competencies and core technology while leveraging a partner for a broad experience base and breadth of knowledge in various technologies, methodologies, and personnel.

It is the company's responsibility to retain and improve the core technology that provides its true advantage in the marketplace. Let a trusted outsourcing partner assist with the rest as their vast capabilities and global networks are ripe to be leveraged in new product designs.

In this tough economic climate, companies are often faced with difficult decisions over which skills to maintain and which to let go until the general economy begins to improve. Partnering with a contract manufacturer will allow a company to maintain the technical resources that are critical to retaining its core competency and leverage the broad-based capabilities of its trusted outsource partner—truly the best of both worlds.

Consider also, the cost required to build an infrastructure to support the product design. Vertical integration can be costly. If capital is better used in other areas, consider outsourcing internal machining, printed circuit board, or field service responsibilities to a trusted turnkey resource. Focusing on what the company does best will not only improve the product, but will also help reduce the total cost of production.

Tip 5: Protect the company and the product.

Before entering into a partnership with a contractor, consider the lifecycle of the product and how it is being protected. As technologies, economic conditions, and regulations evolve, a product will need to remain competitive and compliant. Part of a contract manufacturer's job is to offer expertise and knowledge throughout the development process and ensure a safe and efficient product or project.

A trusted contract manufacturing partner can help protect the company and product in the following ways:

- Develop disaster plans that include offsite storage of valuable documents and qualified alternate sources of supply. Eliminate sole-sourcing of components. In a critical time-to-market development, when one supplier cannot deliver parts in the necessary timeframe, an alternate supplier should be ready to step in to allow the product to make its market entry deadline.
- Continually assess part obsolescence, particularly with electronic devices. With mature products that use vintage electronic chips, a supply chain can dry up as modern chip designs supplant older ones.

- Stay ahead of compliance issues and other international green initiatives. It is the contract manufacturing partner's responsibility to assist in providing important information pertaining to FDA, ISO, RoHS and other regulatory requirements. Staying ahead of these changing requirements helps ensure a product will be compliant with relevant regulations and production will not be delayed. As the contract engineering partner for a renewable energy product entering the marketplace, Cogmedix recently advised our client of an upcoming EPA deadline for phasing out an ozone-depleting refrigerant presently used in the product design. Work-around plans are now being implemented to provide an alternative design to support a "green" refrigerant.

Conclusion

A new outsourcing partnership can be an overwhelming experience if one isn't sure what to look for or how to guarantee that the company's assets are being protected. Following these five simple tips will help to create an efficient, cost-effective outsourcing experience.

Online

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