

Outsourcing For Product Success and Restful Nights

The potential benefits of outsourcing are well known, but the decision to contract with subcontract partner can be daunting. This article examines how to determine if a product is suitable for outsourcing and the steps to take to identify and qualify the correct outsourcing company.

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Selecting the right products

Entering into an outsourcing program can promote development of new medical products, simplify internal operations and lead to more profitability for a company. When organized, executed and supervised properly an outsourcing program is a turnkey operation that encompasses all the pivotal aspects of the supply chain. As well as manufacturing, it can include logistics and project management, engineering assistance, financing, vendor selection, production planning, quality control and inspection, inventory and warehousing and customer support (Figure 1).

The best opportunities lie with existing products that are proven winners and have all their compliance certificates, but are labor intensive to produce. A proper outsourcing program can drive out extraneous costs and make a mature product a revitalized profit provider.

When considering outsourcing it is important to first determine the overall goal of the company/its medical products division by answering these questions:

- Is the objective to reduce costs, increase quality, or both, while maintaining delivery performance?
- Will the initiative be directed at mature products, or at new products that are ready to ramp up to commercial production runs, or at all products?
- Are there similarities such as materials and processes within the products that enable several to be combined to take advantage of economies of scale?

Once the overall strategy is determined, then each product can be evaluated. Typically, the types of products that will gain the most from being outsourced are ones that

- are mature or about to reach the mature product lifecycle stage
- require many production and assembly steps
- have a production run of fewer than 50000 pieces.

For a mature product the benefits can be exceptional, including extending its sales life and enabling it to remain cost competitive. Naturally there are no hard and fast rules and each product needs to be reviewed and all variables scrutinized. When considering a product for outsourcing, points to consider are:

- What line items can be replaced? For example, to meet the United States (US) Food and Drug Administration (FDA) requirements, what materials can be considered for substitution? Will any materials considered for substitution require recertification with the FDA?
- What testing evaluations are required for each component and for the final assembly?

Is there flexibility in the sterilization method that is employed, for example, is a change possible from ethylene oxide to gamma? What is the sterilized life of the product? Does sterilization need to be

performed in the US or can it be done in China, and if so, how does the shelf life affect delivery, whether this is by air or sea? Medical device companies will need to review these issues with their outsourcing partner so that the proper balance of technique and shipping can be formulated

Finding the right subcontractor

The next stage is to select the outsourcing company. There are numerous potential companies, however, many are simply brokers who act as go-betweens and do not have any long term relationships or vested interest with the actual factory that undertakes the work. This is where the greatest danger lies, especially for medical products that involve strict manufacturing, sterilization and quality control specifications. Although contract manufacturers in China have recently made significant improvements in medical device technology and product quality, the real challenge is to identify the correct factory and thoroughly manage the product at every stage. Some criteria to look for are:

- Is the company set up to work at any point from manufacturing to assembly and packaging?
- Does the “locally” based outsourcing company have the proper credentials? These include ISO 9001 and ISO 13485 certification, clean room facilities, local customer service and project management/engineering experience. Does it have employees working for the client in the overseas factory?
- How often does the “local” contact visit the plant overseas? Who is the client’s contact in the overseas factory and can he or she be contacted if necessary?

Successful projects

Burton Medical (www.burtonmedical.com) is an example of a successful outsourcing operation. A provider of high quality medical lighting for health care clients, it was fighting competition from lower quality, lower priced products particularly for lights used in doctors’ offices and surgical areas. When it outsourced its products, it was able to upgrade the materials it employed, provide the superior workmanship that it is known for, and produce a better product at a lower cost, which allowed it to beat its competitors. The main advantage was that moving to a proper, qualified outsourcing program maintained Burton’s stringent Underwriter Laboratories and International Electrotechnical Commission standards. Burton is ISO 13485 certified, registered with the FDA and is licensed as medical device manufacturer. Burton’s lights are certified for medical use and perform to the regulatory requirements of different regions around the world.

Outsourcing can also provide relief for a product line that is overflowing with too many products. Allen Field Company (www.allenfield.com), a manufacturer of proprietary and custom fittings, found that delegating production to an overseas resource lowered costs and enabled its business to expand by adding to, and diversifying, its product line. Robert Ahearn, Vice President of Sales and Marketing for the company has a positive story. “We needed full time support because of the large number of products we offer. The only way we were able to succeed is because we were assigned a dedicated, US-based project engineer to help us. Outsourcing to China gave us a competitive edge in price and freed up internal resources so we were able to focus more on sales, marketing and new product development.”

Although a medical device manufacturer’s flagship products are usually the quickest to evaluate and hand over to an outsourcing company, new products as well as those from small companies can also benefit. One example is the Labor Lert (www.laborlert.com) contraction timer, which required product design, electronic engineering, manufacturing and packaging (Figure 2). The compact, hand-held device tracks labor contractions with the press of a button. Functions include the contraction timer that measures length, frequency and the averages of up to six consecutive contractions. Additional features include a due date countdown for the main display, date and time, and a lanyard so that the device can be worn. Patricia Conley, the owner of the company, said, “For us it was a turnkey operation. We gave everything we had to our contractor and they were able to do it better. From the

packaging clamshell, the insert with art, to the point-of-purchase display that holds 12 units, we were able to get all of this redesigned [and] to work more efficiently. We're dealing with just one company and getting the exact product we wanted, on time and for the agreed price."

Qualifying the company

It is important to ensure that the outsourcing company that is selected, the people supervising production and the people at the factory are qualified. For example, one way to do this is to institute a test program for medical components production, including injection molded items, printed circuit board assemblies and various subassemblies together with providing full box-build assembly. In this way the client can confirm the manufacturing capabilities and, most importantly, that the quality system is certified to ISO 9001 and ISO 13485 and that the outsourcing company has Class I, Class II and Class III clean room capabilities.

Elements of success

An outsourcing program can be successful and worry free if the proper steps are taken and followed. The elements are straightforward:

- Identify your need and micro-manage it.
- Qualify your factory partner overseas by visiting personally, in this way personal relationships can be developed and an audit can be made to ensure that the required quality standards are in place.
- Do not assign the project to an unknown friend, family member or broker.
- Be forever vigilant.
- Never relinquish hands-on control.
- Build on your relationship with your partner overseas with frequent phone calls and "video visits" together with face-to-face meetings when possible.

When looking for an outsourcing company, the essentials are experience, knowledge, planning and diligent work.