

Debunking the Myths about Outsourcing Medical Device Design

By Robert R. Andrews, Medical Division Manager, Foster-Miller, Inc.

Outsourcing has long been a hot button issue in all segments of the life sciences. In the medical device industry, outsourcing initially took hold in the manufacturing phase, and companies raced across borders and oceans to capitalize on cheap labor for large profit gains. As the outsourcing wave continues to mature, this strategy is no longer strictly applied to manufacturing processes. Medical device manufacturers are realizing that outsourcing other stages of medical device production, most notably research and development, can result in large productivity gains, innovative products and competitive advantages.

This paradigm shift toward contracting upstream medical device development functions is a result of the gradual debunking of the myths surrounding outsourcing R&D. As these misconceptions are dispelled, medical device manufacturers are beginning to leverage external engineering expertise to produce superior medical devices.

Misconceptions about Outsourcing Design Functions

There are many common myths about the dangers of outsourcing R&D. As with most myths, a little research into the facts of external engineering can quickly allay most fears.

The following examples debunk often expressed objections to involving outside firms in high level processes:

- *Myth:* “Outsourcing design functions will compromise intellectual property and leak trade secrets.”
Fact: Medical device companies can choose only to work with partners that sign strict confidentiality agreements and release patent rights after projects are complete. Non-disclosure agreements can and should be signed even before a contract is agreed upon so that information disclosed in initial discussions can be protected, even if the talks do not result in a partnership. It should also be noted that trade secrets are sometimes better protected when in the hands of a third-party. This is because these partners are not obvious targets for employee recruitment by competitors, hiding the trail to core design knowledge.
- *Myth:* “We are experts in our sector and a third party cannot replicate our knowledge.”
Fact: Experienced engineering firms can offer extensive multidisciplinary expertise to supplement internal skills, leading to superior and market dominating products. Internal experience and market knowledge are still a key input to the team development effort. More often than not, groundbreaking products are the result of know-how from several industries. Companies focused in one industry tend to get tunnel-vision, relying too heavily on standard industry practices and procedures. Involving a third party not only brings a fresh approach to the drawing board but it can also integrate technologies unfamiliar to the medical device manufacturer.
- *Myth:* “We already outsource other functions and do not want to have too many partners.”
Fact: It’s true that too many cooks spoil the broth. Therefore, it’s important to find a design firm that can offer soup-to-nuts product development support, from concept to manufacturing system design. A full-service outsource partner will complete all aspects

of the project through production, seamlessly transferring the technology to manufacturing. This will reduce the number of partners and streamline operations.

- *Myth:* “I will lose control over my processes.”
Fact: Involving an engineering firm can bring greater control to medical device development because external partners are bound by contract to perform. Projects completed internally are often not regulated as heavily and can quickly run over budgets and deadlines. When outsourcing, have all parties agree up front to regularly scheduled meetings and continual project status updates. Clear documentation should be provided by your partner measuring project status versus set limits to make sure projects stay on track and on time.

Problems Solved by Outsourcing Design

Due to many of the misconceptions mentioned above, medical device manufacturers sometimes choose not to involve third parties in their design phases until crises arise or sales are lost. Two common issues that could have been avoided by involving third-party design firms from project inception are explored below.

- *Problem:* A medical device manufacturer designs a diagnostic device in-house. After the design is complete, the firm researches existing equipment to find the best manufacturing method. However, standard equipment is not capable of mass producing the designed device. The company spends significant resources on revamping existing equipment to handle the designed device, setting back the product launch date and increasing costs.
Solution: Design for Manufacturing and Assembly (DFMA) is a mantra of experienced engineering firms. These companies design with production in mind and call upon years of experience to know what is possible and what is not. Anticipating the needs of manufacturing during design results in products that are manufacturable and eliminates surprises at the eleventh hour.
- *Problem:* A medical device manufacturer evaluates its product portfolio and realizes that a large percentage can be classified as “me-too” products, with low profit margins and minimal market share.
Solution: To break the mold and lead the pack, companies need forward thinkers who know what the market needs and will need, and which emerging technologies can be applied to best satisfy those needs. Full-service design firms provide services including market analysis and testing and technology forecasting, providing invaluable insight that can lead to revolutionary products and market dominance.

Outsourced design promises to hasten the pace of innovation in the medical device industry. By taking advantage of rapidly advancing contract R&D services, medical device companies can help secure their future as market leaders.

About the Author

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