

Why Should You Outsource Product Development?

Development of a successful medical device requires considerable skills and resources. Whether you are a startup, small business, or large corporation your company may not possess the necessary infrastructure and technical expertise to address every facet of product development. Here, we will consider the advantages of outsourcing medical device development to an experienced partner.

Get your product to market faster

Most experienced outsourcing teams have long-established workflow and communication protocols built over years of experience. Informed by their own history, they will know the common mistakes and pitfalls associated with the type of device you have in mind, saving you time and expense on unnecessary mistakes. Design decisions will be proactive, saving time and capital, not reactive with a less experienced team. Why not use an already highly functioning team to bring your device to market faster? Specialized skill and knowledge in the medical device field are often difficult to find. How long will it take to find and hire an internal team with the right skillset?

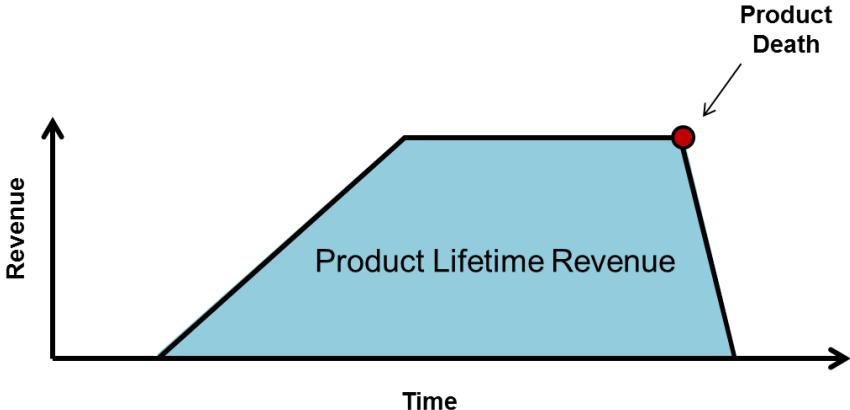
Here are three more often-overlooked issues with internal product development teams:

- 1) The true cost of hiring an internal team is not just the salary of employees--it is salary + 25% taxes and benefits + 25% overhead + 15% non-productive time. Let's assume that an engineer's salary is \$80,000 per year. The true cost is $\$80,000 + \$20,000 + \$20,000 + \$12,000 = \$132,000$, or 40% above the engineer's salary. This does not include the cost of purchasing specialty equipment that may be required.
- 2) Depending on a project cost associated with non-productive time, it may even be higher. An internal engineering team may not have any work to do while you are waiting for clinical data, or response from FDA. Accumulative down time for an engineering team can be over a year.
- 3) Time and energy associated with managing your own team. Often it is easier and less stressful to manage an established contractor than to manage your own team. By using a contract product development team, management does not need to worry about human-resource-related activities.

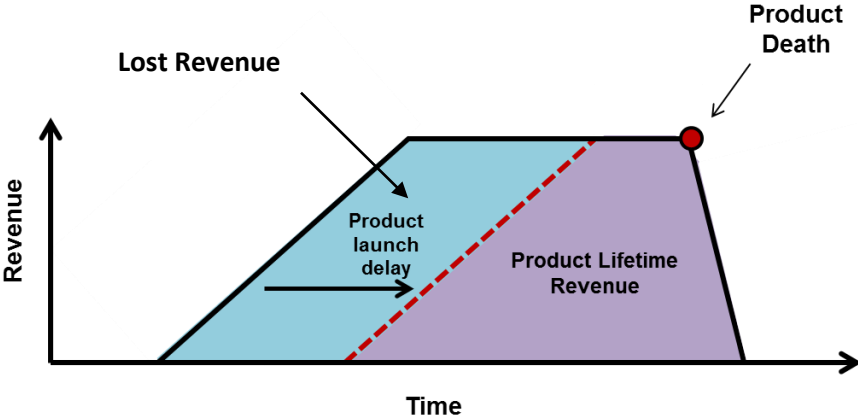
Your outsourcing partner is essentially a phone call away and can dedicate resources to your project immediately. This saves you the time and money involved in finding qualified employees, providing a workspace, establishing protocols, and navigating regulatory processes.

Speed is Critical

How important is a fast route to a finished product? Product lifetimes are finite, so a speedy time-to-market is crucial. Below is an illustration of a typical life cycle for a medical device. Revenue from product sales grows and eventually plateaus after the product is adopted by the reachable segment of the market. Revenue generation slows when the product becomes obsolete, e.g. it is replaced by a superior or cheaper product.



Here is what it looks like if the same product's launch is delayed. The product's growth phase and expiration date remain the same. A delay results in a significant loss of revenue over the lifetime of the device.



Given that every product has a fixed market expiration date, it is clear that a quick and efficient product development phase is essential. Our research suggests that even minor delays in bringing a product to market are expensive: a 6 month lag can cost you a quarter of total profit over the lifetime of a product! Time is the single most important factor in the medical device development process. In fact, all the other good reasons we list below essentially boil down to reducing the amount of time it takes to get your product ready for the marketplace—it's that important. Since development costs are the same in both cases, amortizing the development costs over lower revenue greatly reduces profit. One could argue that longer development time drives the costs up.

Lower the initial capital (and time) required to get a minimum viable product (MVP).

When you outsource product development, you do not have to invest scarce time and capital creating product development resources. An established outsourcing outfit will have the correct tools for the job—they have the benefit of foresight, and have likely accumulated state-of-the-art equipment when it was available at a low cost. Because firms that focus on product development amortize their investment in equipment, systems, and people over many more projects than a small medical device firm, and can complete the project with substantially lower cost. Your company may not have the luxury of waiting for opportune moments to make large purchases and may be forced to decide whether to forgo a potentially product-enhancing feature for the sake of cost.

Hiring an internal team is expensive and involves invisible costs that are often overlooked. How many people will you need to cover the breadth of knowledge required? Will they be full- or part-time? Will they be paid with equity and/or stipend? What will you do with those employees during any lull in progress or regulatory delays? A large component of the value of outsourcing your product development comes from being able to hire a highly skilled and capable team as needed. This frees your organization from the long-term commitments required in hiring employees, saves on costs like health insurance and other benefits accompanying hiring an in-house development team.

Get expert insight into your product's design

Another advantage of outsourcing is that it gives you access to experts with years of experience. Industry-spanning expertise and deep understanding of manufacturing processes, FDA regulations, and materials is advantageous in order to develop an innovative product, and your organization may have difficulty finding (and paying for) this expertise elsewhere.

It is also important to note that an experienced outsourcing partner has brought many other products to fruition. A fresh look at your product by an industry expert can be incredibly valuable in adding features, improving quality and reducing costs; or to inform you of downsides not recognized because you are enthused about your ideas.

A good outsourcing partner will also be well-versed in the current regulatory procedures. Knowing which details require attention and which do not can save you time, capital, and considerable headache. Here is where finding a partner with extensive experience with similar devices is key.

Maintain an entrepreneurial culture

Market pressures often force your product to change quickly or become obsolete. Will your full-time staff have the skills and expertise to adapt quickly? Will their knowledge base still be relevant

and useful if the product needs to change? An in-house team may need to spend a lot of energy on compliance and optimization, leading them farther away from what your team needs: innovation.

Outsourcing product development to a team familiar with the lean development process will ensure that it can move quickly and react to unanticipated situations easily. This will free your team to do what it does best, and you can spend your time managing your company.

How to select an Outsource Product Development (OPD) company that suites your needs:

- When you are looking for an OPD partner make sure that their quality system is versatile enough to meet your needs. For example, if you already have a quality system to manage your Product Development make sure that the OPD partner can work within that system for the duration of the PD cycle, and then transition to their own quality system for manufacturing portion of the project.
- Research your future OPD partner's established track record and make sure it is compatible with the details of your project. If the company specializes in catheter development and has no experience with injection molding, they may not be the best partner for a project that requires mostly injection-molded parts.
- Make sure that your project size aligns with the company's portfolio. Your OPD partner should be willing to invest to grow their capabilities to make your project successful. In addition, be sure that your project is properly scaled for the company so that you will not be lost among other "more important" projects.
- It is very beneficial if the company culture of your OPD partner aligns with your expectations of the partnership. If your company has a strict suit-and-tie dress code, working with a company that has a casual atmosphere may make you feel uncomfortable during visits.
- Consider geography. It is much easier to work with an OPD Company that is within driving distance. Your onsite participation in the project may be beneficial for meetings, prototype evaluations, or first manufacturing builds. It is much faster and less stressful to be able to get in your car and drive to the development site. Problems and issues can be resolved much faster face-to-face than by phone or email. It is also much more fun to celebrate success in person!

How to optimize your working relationship with your OPD Company:

- Your company should have a very good relationship with the project lead (and as much of the team as possible) at the OPD Company.
- Clearly define the scope and budget for the project and make sure that any changes to scope and/or budget are clearly and rapidly communicated to you or a project lead inside of your company.
- Make sure that responsibilities for each company are clearly defined. For example, define if the OPD should use your quality system on theirs. If a mixed quality system is used, make sure to define whose quality system is used for what aspect of the project. Clearly define which company is responsible for testing, regulatory, manufacturing, and other aspects of the project. These details should be accurately defined in a Quality Plan for each project.
- The lines of communications should be open in both directions. Bad news should be communicated as fast and efficiently as good news. Once there is potential for a budget to increase, the scope to change, or for technical problems, you and your OPD partner should be working together as soon as possible to address and resolve these issues.

Common sticking points when considering outsourcing product development:

Organizations unfamiliar with the outsourcing process often have hesitations about entering into a partnership. Here are some of the most common concerns:

- **Loss of control.** On the contrary, your company has gained a valuable collaborator. You guide the ship, but the ship has an experienced crew and (hopefully, if you choose the right partner) a long history of success.
- **Product development team is far removed from the customer.** If the goal of product development is to achieve product-market fit, it may seem counter-intuitive to essentially keep your development team isolated from your customers. On the contrary, delegating development to another team frees YOUR team to do what they do best: figure out what your customers want.
- **Time sunk into managing an off-site team.** If you are working with an established product development company with a well-defined product development process and well-developed customer communication tools, communication is easy and constructive, not time consuming. As above, this allows your management team to spend time performing

core business activities, and importantly, to get “out of the building” to better understand customer needs.

- **Intellectual property protection.** One great way to defend your IP is to get your product to market quickly—something that an experienced development team can help you achieve.
- **Untested resource.** It is natural to hesitate when hiring a new team to develop your idea. Make sure you choose one with deep industry knowledge and experience. How comfortable are they in this space? How long has the team worked together? What have been their successes? Failures? All of these are important questions to ask when choosing a developer.
- **Learning curve.** Your company has spent considerable time and effort understanding the nuances of your market, and it is reasonable to hesitate when tasked to bring another team up to speed. But if your chosen medical device developer has been operating for very long, they will also have an extensive history of lessons learned the hard way. Often, they will be able to steer you away from common pitfalls and snags that may not have occurred to you, and this can save you valuable time.

To Be Clear

Outsourcing your product development is not the same as simply passing the ball to another team. Instead, you are collaborating with a firm with specialized knowledge that is difficult to find and potentially prohibitively expensive to hire otherwise. A good external product development team will work closely with you to ensure that together, you are achieving the agreed-upon benchmarks on the way to your common goal: a successful product. The right product development team can guide you from napkin sketch to initial market while saving time and investor money along the way.

Questions?

Contact Us at...

Occam Design
1044 East Chestnut Street
Louisville, KY 40204
502.714.7200
www.occamdesign.com