Successfully Introduce Your Product in Eight Steps

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So, you have a great idea for a medical product. What's next?

Your goal is to get it commercialized into the market, but you also need to think about other short- and long-term goals, the exit strategy, building your team, and a host of other issues.

This article is intended to help you identify the eight major steps in the process of getting a product onto the market. While this is by no means an exhaustive list of the activities you might need, it is intended to be a general overview of the important issues to think about as an early stage company.

Step One: Plan Your Exit Strategy

It may seem backward, but before anything else, it's really important to figure out your exit strategy. Doing so establishes your roadmap moving forward. Some things to consider are costs and timelines to launch. You will also need to figure out if your goal is to remain on the market and develop more products, sell or partner with a larger brand.

You should consult with experts in the various areas throughout the development and launch of the product, even if you have experience developing a medical device.

Plan for contingencies. The famous saying is, "A poorly planned project takes three times as long as planned. A well-planned project only takes twice as long."

Keep in mind that things are not exact in the early stages, and it may take extra time and money to get through to your goal.

Step Two: Build a Team

Nobody can do it all themselves, especially in the medical device world. Think about the core business functions you will need to be successful. There's sales and marketing, development, regulatory, legal, finance, and manufacturing. If funding is tight you can consider adding advisors in an equity for service arrangement, although this isn't always ideal. You can also add people as paid consultants, which costs more up front, however, it allows you to retain your equity.

The specifics largely depend on your needs and end goals.

Among the experts you will need, be sure to find experts in the market, funding, intellectual property, regulatory aspects, technical challenges, and sales.

Step Three: Test for Feasibility

In reality, this starts from day one. Feasibility is about the important questions you need to ask yourself, such as the total available market for your idea. You also need to consider the estimated market penetration. Of course, these numbers vary by market, type of device, and the current competition. Getting an honest idea of your possible (and likely) market share is absolutely imperative. This is one of the biggest concerns in terms of predicting when entrepreneurs might miss the mark.

You should also determine if your device is truly disruptive or if you are going to play on price. This is very important, because if it's a play on price, you really have to show a very significant savings to the health groups. That is because invoking change is difficult into these systems.

Food for thought: a lot of medical products are bought under contract from large distributors. That makes it incredibly difficult to come in with a single product that, for example, say offers a 10 percent cost savings. Such a discount wouldn’t make up for the disruption to the purchasing system of the health group.

There is also a reimbursement aspect to consider at this point. Are there billing codes for the product? Also think about and define the problem or need that the product addresses. It might be a really cool and innovative idea, but how real is the problem that the product addresses?

One way to figure out feasibility is to do some honest voice of customer research and, no offense to inventors, but they are typically the last people to ask about how good their idea is, and what kind of problem it addresses. You really need to get some objective, critical voice of customer data. The goal is to ascertain if the product really solves a significant problem.

Step Four: Create a Funding Checklist

Obtaining funding is often a big hurdle, one that many underestimate. For this set of tasks, the value of market research and feasibility cannot be overstated.

First you need to know what your development and launch costs will be. Even with a concerted effort in determining costs early on, there will be unexpected expenses along the way. For example, standards testing, if you have a product that is

electromechanical or includes software, can be expensive. Unfortunately, until the product is developed to a certain stage, it's difficult to ascertain a definitive number on those costs, however, it’s a good exercise to take your best guess when you can.

Depending on your exit strategy and device classification, intellectual property (IP), and regulatory issues come with real costs. The cost of manufacturing transfer, which is the art of transferring a final design into a production setting, is often underestimated. It requires many task-heavy steps, such as creating standard operating procedures and qualifying suppliers. Further, sales and marketing are significant, and necessary expenses. Initial production start-up costs, tooling, and inventory build-up must also be considered.

Of course, you also need to plan for delays and contingencies when you are coming up with your total number. Note that funding sources do expect that you have skin in the game, and that the total launch costs are identified.

Once you have a reasonable list of all of your anticipated expenses, and you’ve put skin in the game, it’s time to look for additional funding. The first group of possible funding resources is often referred to as the “Three F’s:” Friends, Family, and Fools. In addition to your own skin in the game, these resources are often the first tranche before moving on to more traditional sources.

Beyond those resources, there are banks, financial institutions, private equity, angel investors, and venture capital. They all come with strings, tradeoffs, and caps. Make sure you understand what you are agreeing to and that the investment end goal is aligned with your end goal.

Strategic alliances are a great way to fund a program as well. For example, you may have a plastic sub-assembly that you'd like to make and you have a good relationship with an injection molding firm. It could be that they can help you with tooling, and startup costs.

Step Five: File Intellectual Property

When considering your intellectual property, there are some important questions to ask. Is the market crowded, e.g., are there a lot of patents on similar technologies or technologies that achieve the same clinical effect? (Note, this is also part of the feasibility section). Can IP be obtained or is the technology you are working on so obvious it isn’t warranted. Keep in mind, a patent is not the only way to protect your IP. You can look into trade secrets, for example.

Consider obtaining a “freedom to operate” letter from a patent attorney. These letters might be more expensive than an actual patent application, because there's a lot of

liability on the patent attorney's part in creating this freedom to operate. However, it is a valuable tool when you need to ensure you won't infringe on someone else once you launch your product. Such protection makes sense if you are going into a field where there are one or more big players or a lot of small players, or if there is a player that has a reputation for litigiousness.

There are a lot of questions surrounding IP, but perhaps the most important one to ask yourself is "Why do you need it?" If your first answer is the protect your idea, that's good, but consider the cost to defend your IP.

It can cost half a million dollars or more to defend a patent. And if it is you versus a big player, guess who will have the funding to see that fight through to the end? What you are really after is with IP is valuation of your idea. IP increases the value of your portfolio to potential investors and it assures them of some risk reduction.

Step Six: Regulatory Strategy

In the country you intend to launch this product, you'll need to determine the device classification and regulatory path. In the most general terms, Class III devices are those at the highest risk go through premarket approval (PMA), while Class II devices often pursue a 510(k) clearance. 510(k) is a predicate based process, which enables device developers to use devices already on the market that are "significantly equivalent" to gain market access. The most common argument for choosing a 510(k) is that your device improves on existing products through improved patient outcomes, enhanced safety, reduced waste, better access, significant savings on price, etc.

The cost differential of a 510(k) and a PMA is exponential. PMAs require more clinical data, more time, and come with a high submission price tag. 510(k)s are not cheap, but they are more affordable, and offer a way to gain market access more quickly. In addition, from a financial standpoint, 510(k)s add value to an IP portfolio.

One of the most valuable activities is a pre-submission meeting with FDA. But please note: this is not a meeting for FDA to tell you what to do. This is a meeting where you present to the FDA your device and marketing claims, get some early feedback, and some direction on how to give your desired submission plan the best possible chance of success.

The pre-sub meeting has costs associated. For one, you will likely need to retain a third-party regulatory resource and commission research to identify possible predicate products, and determine if a pre-submission meeting is warranted.

It's always key to balance your marketing claims and IP approach with the regulatory path. Make too many claims, and your regulatory path could become prohibitive. Make too few claims, and you may not attain market differentiation.

Step Seven: Study the Technical Challenges

I'm using technical challenges to indicate a fairly broad category that includes risk assessments, design, packaging, production costs and volumes, supply chain, and materials. These topics often require they're own focused articles (several thousand, even). You'll need to consider capital investments required, tooling, assembly lines, and the investment of inventory. Consider lead times, and how they line up with commercial pressures.

Step Eight: Select a Sales Method

Determining the feasibility of sales and how your product is going to be sold is is critical and often not given the priority that is required. Some chose to build a sales staff internally, but that can be expensive and time consuming. A staff requires salaries, commission, and an organizational alignment, among other things. The benefit is you get the focus and dedication to your products.

Another option is an independent rep. This is usually commission based, meaning you won't need constant payroll. However, sales reps have line cards and may be selling 5-20 different products. You are going to get a portion of their attention and energy.

Whatever sales method (or combination) chosen, the most important thing is to dive deep into how your target client works. You need to understand how group purchasing organizations make decisions, learn the governing principles of pricing, bundling, and packaging.

Will your device be a capital expense? If so, you might need a different access approval process.

Getting a sales channel established is probably one of the trickiest parts of the process. That's why large OEMs, who already have the sales horsepower can make excellent partners. They can simply plug-in your product and leverage their sales channels.

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Keystone's Proven Process

Process, Process, Process

Of all the steps you will take to get your product to market, acquired, or however you define your end goal, the single most important activity is to establish your process and stick with it. At Keystone Solutions Group, we guide our clients through a 4-step process: Discover, define, develop, and deliver.

- Discover - This is not about discovering your idea, it's about discovering who you're going to be working with on this, making sure there's value alignment, and there's the right market alignment. Then you make a decision to proceed and engage.
- Define - This is a very important aspect that often gets glossed over: Define the voice of customer. Marketing claims, the IP strategy, the regulatory path, all the things that are essential to achieve your goals are under this process step.
- Develop - This is the big category that includes all the aspects of design, analysis, testing, prototyping, sourcing, quality control, regulatory strategy and management.
- Deliver - This includes transferring the final design into a manufacturing setting, finalizing packaging, pilot production runs, and marketing and sales, as well as finding that sweet spot in the distribution channels.

Make no mistake, you are headed for a rollercoaster ride, no matter how prepared you are. However, in the end, you will find a huge sense of accomplishment and value. And once you've been through the rigors of this process, it does get easier.

If there is just one final piece of advice, it would be to deliver more than you promise. Come in early for deadlines, prepare more than you think you need, and be your own worst critic, both of your idea and the market potential.

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