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Slaying the Start-up Nemesis

Part 3 of 3: Technology Evaluation

In earlier articles in this series, I discussed solutions to two of the obstacles facing early-stage medical device and pharmaceutical companies: undercapitalization and dysfunctional teams. This article deals with the third major barrier - lack of product market. As a product development company we see many terrific technologies. We are scientists and engineers - we find technology irresistible. Of course your idea is worthy of a Nobel Prize! Of course your idea represents a paradigm shift! The base technology is the most fascinating, and often the most critical, component of any new product. But is there a market? We have been involved in numerous product successes but we also have developed products that never made the impact we thought they would. For inventors it is about impacting the world, not just about making a profit. Potential investors [ever notice the big impact in definition a single letter can make?] however, tend to give money the nod. Lack of honest product evaluation has sunk many startup companies and can financially hurt a mature firm. Over many years of assessment, we have developed methods to help better determine which technologies will succeed. This article, the final one in this series, is an overview of steps we use to evaluate a technology.

We often see products developed in this order:

Product Design: this is the most interesting phase. Inventing a product is full of discovery and mountain climbing and few limits. This is fun stuff especially for a science-based company.

Product Development: Pay money for license and set up → discovery research → field trials → crunch data → tweak product.

Manufacturing Design: OK, we have a product. How are we going to make this in quantity? Do we set up production lines in-house or farm out to OEM?

Regulatory Plan: Before we can sell this medical product we need to get FDA permission. What kind of submission do we need? Has anyone here ever done one of these?

Marketing Plan: Only now is serious thought given to some basic questions. How are we going to sell this product, through distributors or our own sales force? Who is the customer? How do we advertise it?

Distribution/Delivery System: How do we get this to the end user?

This scenario can lead to a mountain of debt for a poorly executed product with no market. Much of this can be avoided with a systems approach that uses a heads-up design-control-driven approach that guides product design and development, marketing, manufacturing, and regulatory in cooperation from conception of an idea to the delivery of your product to the final consumer.

The first thing we do is assess the potential products that a technology could yield. Is there a real need for those products, are there major limitations to existing products that we can solve, or are we developing this just ‘because we can’? If the technology can be used for new clinical products, we scour the scientific literature, the FDA website, and patent listings for relevant [free or low-cost] information. With this list in hand, we start to determine who might buy this product, which companies already sell into that market, the price points, and the delivery methods.

Once we have gathered background information we formulate a detailed concept definition and questionnaires for ‘thought leader’ and potential customer focus groups. The concept definition document describes unique technology issues and hurdles, as well as market acceptance issues garnered from the discussions and surveys. The market research is important for two reasons. The first and most obvious is that at some point someone needs to shell out money to buy what you have made, and in great enough quantity that you can make a profit. Why spend millions of dollars and many years to develop a ‘wonderful’ product that no one will buy?

The second reason for this is that, at least for medical products, the FDA will not review a submission for market clearance of a product that has no clinical utility. For medical products, the concept document must include unmet needs and clinical relevance of the device or drug. Keep in mind that clinical practice can differ substantially between the US, Europe, and other portions of the world; you cannot make assumptions about product utility from a single market. One company performed extensive clinical trials in US and submitted an application to FDA for a product already cleared to market and used in Europe. The agency rejected the submission based not on quality of data or performance characteristics of the test but only because “product had no market” in US. The cost and time for clinical trials and for submission in US could have been avoided with proper analysis and knowledge of that market.

What precise market is the technology going to target? If it is a clinical product, where will it be used – the clinical lab, the OR, the ER, physicians office, home? There will be different acceptance issues for physicians, hospital staff, lab technicians, and patients. Are those responsible for buying the product disengaged from the end user? Are the billing and the profit centers disconnected? If so, how will you bridge that gap? Many medical devices are highly specialized products that have a short market lifetime, compounding the challenges for these companies and increasing the importance of good market analysis.

Is there entrenched competition or will you be first in the market? If you are going to be first, are you going to be able to change the status quo? The ‘way it has always been done’ is still competition, is already accepted, and is probably the most difficult to change, particularly if inexpensive. Cost is not the only point of competition; for medical products, competition for patients [in clinical trials and in final market] is intense. The adage “you can build a better mousetrap but if you do not market it to the right people, it will not sell” describes only one of the potential obstacles. For example, some newer technologies allow tests that are normally performed in a hospital clinical lab to be done at point-of-patient-care. One would expect that products based on these technologies would be a home run. However, these systems are in direct competition with those established [profit-center!] central labs. Through CLIA, the central lab is held responsible for POC test results, even though they are not done under their direct control. Thus, POC tests might be opposed by the very people asked to evaluate the new technologies. As archaic as many current methods and technologies are, the old “we have always done it this way” mindset is hard to break – for myriad reasons. You have to provide the market with overwhelming evidence – not just reasons – that the technology provides better lives, healthcare, whatever. In addition, being first into a particular niche can be further complicated if the reimbursement strategy and CMS codes have not been defined.

If you are not going to be first, then how are you going to distinguish the product: by quality, price, or ease of use? A technology may be innovative and your developed product robust and useful, but if the real competition is an entrenched, inexpensive product, you will have a steep and difficult climb to market acceptance. Better to understand this early; some products are just too far ahead of their time. They do not stand a chance - at least until they can be retargeted to meet a new need that the established technology cannot fill. It is hard to out-Amazon Amazon but there are plenty of niches left, a lot of pain to eradicate, and lives to save. Fifteen years ago, a certain company developed 10 products based on their patented technology through clinical trials and agency clearance. The products were too revolutionary for the clinical lab of that time and company folded. Today the market has changed - three large companies are vying for rights to that technology.

For medical products, a critical early step is to create a correct regulatory strategy. This determines the most expensive part of product development, clinical trial design. Will the submission be reviewed by one FDA division or is this a combination product? Is there a predicate to which we can compare? Should we stage submissions in sequence for new indications for use, for patient populations, or for sample types? A detailed strategy will outline all of the steps and requirements and will keep the project on the most direct track to market and reduce costly mistakes. One company contacted us only after they had been told that their product would require human clinical trials and clearance by premarket notification – a 510k – to FDA. That information was incorrect,

as their product was a Class I device that was exempt from major FDA regulation. We were able to provide clear justification for that decision in time to save the company the time and expense of clinical trials, of writing a submission, and of waiting for agency clearance. The company only needed to register with agency – a very simple, no-cost procedure – and manufacture the product under GMP - to launch the product to market.

Delivery is another critical aspect of this evaluation. Can the product be made stable? Can it be delivered effectively? You may have a great product, but if it costs too much in time, effort, or money to get it to the customer, who is going to pay the price? Knowing early in the design process how the product will need to be delivered to make it marketable gives the development team a chance to design out constraints or make the product more robust to withstand the heat of summer shipments or the storage of the product in unconditioned spaces. If you provide a centralized service such as testing, you not only have to market the service, you have to simplify shipping requirements for the customers as much as possible by providing containers, coolant, labels, designated shippers – whatever is required.

Because their primary interest is fastest track to commercialization, potential investors now require business plans that include detailed strategy, tactics, and milestones. For medical products, those include the steps and documents that are FDA-mandated under design control. Potential investors are likely to be favorably impressed with a business plan if potential pitfalls are clearly addressed and solutions provided. Is manufacturing feasible? Do we need customized – expensive – manufacturing equipment for the product? Are there qualified OEM? These can be addressed early, and planned for, allowing efficient transfer of a technology from R&D to manufacturing.

This is not an exhaustive list. Scrutinizing these elements will lead to other questions and concerns that must be examined before any large investment of time or money in product development. This type of analysis is not a waste of time but rather is a kind of insurance policy. It is not a guarantee of success because there simply are too many variables in getting a product to market, but for each variable you can identify and address, you are one step closer to a fulfilling your company goal – a useful, well-designed product that sells.

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