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Slaying the Start-up Nemesis

Part 1 of 3: Outsourcing

Many people in early-stage medical device and pharmaceutical companies perceive the Food and Drug Administration as a fiendish monster waiting to blow their technology into oblivion. Certainly obtaining clearance from the agency is one hurdle to a marketable clinical product. There are other roadblocks just as real, and most of them are of a company's own creation. Here are the ones I would list as the top three: undercapitalization, dysfunctional teams, and lack of product market. This article deals with the first issue. It will not provide a list of tried and true methods for obtaining more money to solve this problem. It will, however, encourage you to think more broadly, to re-define the problem and approach the search for solutions in a different manner using one specific example of an effective means for controlling costs – outsourcing.

Money is required to hire the people needed to develop technology. To obtain substantial funding, a company must also advance its technology. For a start-up company, this is a true catch-22. Compounding this situation is the idea that many highly trained, experienced people are needed, the more expertise the better. Top-tier personnel are costly. How does a company gain a qualified team without committing to a huge cash burn?

Outsourcing is one possible resolution for this dilemma. Outsourcing permits a company to stay lean and get the job done efficiently. The specific knowledge/skill gaps of the current development team are targeted, and the company maintains greater control over cash flow. If funds run low, product development can be scaled back to preserve seed capital. When new resources are found, the project can be brought back to full speed and scale. Just imagine – no new candidates to interview, to hire, and to relocate. Equally important, none to terminate when money runs low, the project is over or the technology shifts direction.

Early-stage companies need many of the same skill sets and expertise as larger corporations to operate effectively. They do not, however, need an equal amount of regulatory, financial, marketing, etc. expertise 40 hours a week, 52 weeks a year. More importantly, they do not need the accompanying salaries. With effective outsourcing, a company pays only for personnel hours used to reach specific deliverables, e.g. a product regulatory strategy or a pre-market submission to the FDA, a financial audit or tax filing, a market analysis or a focus group study. Select service providers that are experts in each specific area of need and that stay current with applicable, ever-changing requirements. Be certain to contract those who will furnish not only advice but

also concrete deliverables, such as documents and reports which meet stringent FDA or other agency requirements. Outsourcing staff requirements gives small companies a way to get specific high-level expertise, bolster the organizational chart, and reduce the overhead burden.

Another option for reducing fixed expenses is retained expertise. Some support firms will, for a reasonable fee, provide an executive on retainer, allowing access to needed skills, knowledge, and resumes. This provides a high level of specific field expertise to supplement an organization's capability without the expense of a full-time person. It also gives early-stage company business plans and web sites greater legitimacy.

Hiring one individual provides only that individual's knowledge, skill, and experience. Working with an outside service organization provides the combined experience of the team of experts assembled for the specific requirements of the start-up company. One word of caution – choose a service provider with proven communication skills, preferably one who involves several members of the team during the negotiation phase and who clearly articulates, reiterates, and responds to the company's needs and expectations.

Outsourcing can provide highly qualified expertise, efficiency, and lower cost to meet targeted skill sets and experience. For the same reasons it is wise to consider outsourcing technology or laboratory functions to contractors who specialize in your area of need and comply with applicable GLP, GMP and ISO regulations. We work with many companies who are developing novel technologies and believe special [expensive] facilities are needed for every aspect of product development. While there are some cases in which this is necessary, there are not many. One successful medical device company we know contracted hardware manufacture and software development as well as biocompatibility, sterility, and stability testing to separate firms,. They also used external firms to write their FDA submissions, scientific manuscripts, and marketing and instructional materials. This device company retained complete control of their complex products by developing them under strict Design Control, by verifying product performance in-house, and by using in-house personnel to closely monitor international clinical trials. Contracting functions to qualified suppliers allowed the device company to stay lean, to stay focused on their core technology, and to move their products quickly to market.

Your company can do this also!

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