Buy it or Build it? The Great Start-up Dilemma

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Whether venture capital or angel-funded, medical device start-up companies are often brought to life by doctors with big ideas who have found a quicker or more effective way to treat a particular pathology. Many of these doctors are entrepreneurs at heart and are most happy when immersed in the adrenaline rush of a new start-up. But no matter how novel the device, the passion and zeal behind that drives these new medical innovations must be channeled into a process that will make the idea a commercial success.

Clean Room at Peridot

The goal of most medical device start-ups is to be purchased outright by one of the large medical device companies. However, since clinical results are critical to selling a start-up for top dollar, manufacturing multiple prototypes is often the first priority.

A solid manufacturing strategy to design, develop and prototype the new medical device will include a controlled manufacturing environment that addresses all relevant regulatory issues and will allow for manfacturing the initial prototype up to as many as the hundreds of thousands which may be used during the clinical phase. And that’s where the big question comes into play: Do we build it or do we buy it?

Build It? Full Control, No Matter the Cost

One approach to prototype manufacturing is to lease manufacturing space, buy equipment, recruit, hire and train staff, and set up a production line—creating a complete production infrastructure. Yes, this eliminates the delays that can be encountered when working with a contract medical device manufacturer, but it is also an enormous undertaking involving a significant investment of time and

resources. A typical multi-component, minimally-invasive surgical device will involve human resources, facilities managment, regulatory staff and a team of sophisticated manufacturing professionals in a variety of disciplines.

The obvious advantage of this approach is that the start-up then has complete control of their destiny. Schedules are not affected by other customers' needs as they might be with a contract manufacturer who must juggle multiple projects with competing agendas. The singular focus is to get that sole product through the pipeline and into clinical trials as quickly as possible. Quality concerns can be addressed immediately by internal staff and potentially dealt with before they affect the schedule. In many cases, time to market is the defining criteria to satisfy investor expectations.

However, the creation of a vast and cumbersome organization is often stifling to the creative entrepreneurial forces that created the start-up in the first place. Additionally, when the time comes to sell, many start-ups find that there is little or no value to the potential buyer, despite the great investment made by the original investors. Many well-intentioned, heavily-funded start-up factories end by selling their lightly-used, once very expensive equipment for a fraction of what they paid since the buyer already has established factories to support future builds.

Buy It? Making the Most of Your Resources

The alternative is to work with an established medical device contract manufacturer. Experienced contract manufacturers bring new designs to life by leveraging their capabilities in manufacturing, quality and regulation, and in turn free the start-up to focus on device development, clinical issues and pre-sale marketing.

Peridot provides Contract Manufacturing services to hearing aid industry

One drawback to this approach is that few medical contract manufacturers are able to tackle complex mechanical and electro-mechanical devices with full in-house

control of the various processes. The excessive reliance on sub-contractors often results in quality control issues, as well as unwelcome scheduling delays.

For example, a typical minimally-invasive disposable device might consist of a plastic handle, trigger, gears, cams, springs, stampings, cannula, hypo tubing, specialty fasteners, CNC machine components such as jaws, end effectors at the distal end, and the implant or therapy being delivered. Most contract manufacturers have a core competency, such as catheter build, and rely on a network of “approved” sub-contractors to handle manufacturing demands outside of their purview.

Contract Manufacturers: What You Really Need to Know

While most contract manufacturers promise supply chain management services, choosing a contract manufacturer with the largest number of in-house core competencies (as they apply to a typical minimally-invasive device) is usually the logical best choice. Why? Less chance that the drilled and reamed end effector won't fit on the custom manufactured clevis pin. Less chance of a late delivery of a critical part of the assembly made by a subcontractor that causes the entire project to grind to a halt, wasting the scheduled clinical or cadaver lab time. Simply put, the more vertically integrated the contract manufacturer, the greater chance the start-up clinical and marketing goals will be met or even exceeded.

No matter which contract manufacturer you choose, two things should be scrutinized: that they have a reliable network of approved subcontractors, and the purchasing/materials staff to support that effort. Finally, when shopping for a contract manufacturer, don’t settle for a mail-in quality survey from critical suppliers. Make time for an on-site survey to effectively evaluate their true capabilities.

If your start-up elects to work with a contract manufacturer, choosing well is critical to the exit strategy. Finding a contract manufacturer that possesses the proper balance of in-house capacity and professional supply chain management can save time, improve efficiency and build a firm foundation for financial success.

Pat Pickerell is the President of Peridot. Partnering with his wife, Debra VanSickle, Pat set to work outfitting a small workspace with the necessary equipment. Pat and Debra opened Peridot in 1996. Since then, he has guided the company through its growth from a small, rapid prototyping and product development specialist to its current structure, offering complete end-to-end precision manufacturing and clean room assembly services to a wide range of industries. These days, Pat plays a supervisory role at Peridot, and spends his free time fishing, writing and recording music, and developing his latest venture, Joulebox.net, a fine-art jewelry and home accent manufacturer.

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