Harder Than It Looks:
Medical Device Startups

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as published in HPC World, Summer 2004

When it comes to evaluating a prototype, medical device startups should understand that there is no formula that guarantees success in developing new medical devices in a startup environment. However, if medical device startups pay attention to development issues early, view prototypes skeptically and get advice of experts early, their odds of success can be improved.

You saw the prototype working. The preliminary clinical data looked promising. There was a huge market need for the product. It looked like a sure thing. Then, two years later than anticipated, the product finally gets to market. Development costs millions more than expected. Worst of all, because it took so long to get to market, you now have three competitors that didn't exist when you made the investment. How could everything go so wrong despite all the due diligence that went into the deal? How could it happen more than once? What can you do to prevent it from happening again?

Prototype Pitfalls

You can be swayed by a prototype that looks almost like a finished product. But prototypes are not products. They are not even close to being products because of the amount of work necessary to follow good design, development and documentation practices required by FDA design controls. Don't be lured into thinking that the prototype just needs a pretty cover before you can start shipping product.

Technical due diligence for medical device startups usually begins with the traditional analysis of the underlying technology by technology experts. That can only assure you that the product is based on sound science and research. It does not tell you how much work is needed to complete the development of a saleable product.

Medical device development experts also need to look at the quality of the engineering to estimate just how much it will cost to convert the prototype to a product. Do not trust the estimates of the engineers and scientists who created the prototype. Because of their closeness to the technology, they will almost always underestimate

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how much development work remains. Chances are, the engineers and scientists have limited experience in developing medical devices into manufacturable products.

Look at the documentation that has been created for the prototypes. Is it up to the FDA's design control requirements? How much work will it take to rework the documents to get them into a usable form to start product development in a regulated environment?

Remember, the goal is not to rewrite the documentation to make it look like design controls were in place. The goal is to document that the development took place with proper design controls.

If the startup divulges that the documentation needs a "touch up" for compliance purposes, it can probably be assumed that a controlled design process was not being followed, and the prototype developers don't have a clear understanding of the design control requirements for medical devices.

Building the Team

You're investing not only in the technology, but also in the team that will convert the technology or prototype into a saleable product. How much of the team exists? How much are you investing in the ability of the startup to attract product development talent? Is the development team experienced in medical device product development?

Recognize that product development in a regulated industry such as the medical device sector requires special skills, adherence to good engineering principles and processes, and a familiarity with the regulatory requirements.

If the startup reveals that it is depending on a "guru," or that the technical team has not done medical device development before - "but product development is all alike" - due-diligence alarms should be sounding.

If a development team does not exist, or if it must be expanded significantly, several options are available. All have their potential merits, and all have their potential risks.

Building a development team with full-time employees has the benefit of keeping the technology developoment close to home. Assuming the employees stay, they are available for long-term maintenance and upgrades of the product. But building a team of new hires is not without risk. How long will it take to find a team with medical device experience? Will they work well as a team? Will you be able to keep them long-term for future support? What are the ongoing costs and needs for the team?

Many startups rely on independent contractors who work onsite. The advantage of this approach is that the technology is developed and controlled onsite. The long-term cost is reduced because the contractor is gone at the end of the project and is no longer an expense. The risks are similar to those for employees. How long will it take to find the contractors you need? Will they work well with employees as part of a team or are they too independent? Who will coordinate the efforts of a group of independent contractors? And there's an additional drawback: It is unlikely that the same contractors will be available for future support of the product.

Outsourcing product development is often appealing for startups. Long-term cost and overhead commitments for employees can be minimized. The team may already be in place and probably has worked together successfully on past projects.

A good outsource company can significantly reduce time to market. If medical device development outsource companies are used, you'll benefit from hiring their specific expertise not only in technology and product development, but also in compliance experience and project management.

Choose Carefully

Because outsource companies pose their own risks, you need to perform due diligence when selecting them. They will become as important to your investment as the startup in which you have invested. Verify that they have successfully completed medical device projects in the past. Ask for the specific role they played on the project. Verify it with the reference.

Ask to meet the team that will develop your product. Verify that the company actually has the resources it claims. How many on the team have medical device experience? When was their last medical device project? What is the company's track record with

medical device development projects? What percentage of projects started have made it to market? Have they ever abandoned a development project? Have any of their devices ever been involved in a recall or patient safety event?

Intellectual property is a crucial issue. Who will own it? Some outsource companies try to retain IP ownership of rights. That's unacceptable. Make sure you own what you paid for. Verify that past clients' intellectual property has not been used in your product, exposing your to patent-infringement claims.

Engineer the Relationship

If outsourcing makes sense for at least part of your product development project, what can you do to use the resource to your best benefit? Part of it comes down to good engineering of relationships.

When using expert outsource companies, let the experts do what they are expert at doing. If you are hiring experts in medical device software, let them advise you on processor, operating system and development-language selections. Don't box in your experts with unnecessary constraints. Follow their advice; let them do things the way they have successfully done in the past. It will be the least risky path to success.

Also, ask the experts how long they think the development project will take, and how much it will cost. Do so before you have set budgets and committed to schedules. Presumably, the outsource partner has had years of experience in estimating projects. Take advantage of its expertise.

The best results happen when the outsource company becomes a partner in the development process. Being a partner means aligning incentives, not becoming adversaries in a contractual contest.

Many startups attempt to transfer their development risk to the outsource partners by demanding rigid fixed-price development contracts. This gives the development company a large share of risk with no potential for sharing the rewards of a successful project.

In fact, it sets up a relationship in which the developer has every incentive to do the least work possible for the fixed price. Furthermore, the developer has the added incentive to identify every possible "out-of-scope" task to add to the "fixed" price. The incentives are not aligned; the "partners" become adversaries.

Time-and-materials contracts are more appropriate for new-product development in which the work scope changes frequently as the project evolves. Unscrupulous developers could, of course, interpret this as an incentive to run up the hours on a project to maximize their profit. However, a good due diligence process in selecting outsource partners should uncover any past evidence of such activity. Furthermore, sound project-management processes will provide an early warning of any such attitudes at the outsource company.

Define project metrics before the development project gets underway. Agree with your outsource partner what metrics you will use to measure success or failure. Agree on whose responsibility it is to collect and maintain the metrics. Review the metrics weekly with the outsource partner. Use the metrics to predict and manage problems before they get out of hand. Do not use them simply to document how the project got into trouble.

Incentivize Your Partner

Think about using incentives for your outsource partners. It will make your company and project stand out from the other projects they may be working on at the same time. Conversely, penalties will also make your company's project stand out, but not necessarily in the way you would like.

Remember, one reason for choosing outsource partners is for long-term support and maintenance of the product. How eager will the partner be to enter into another potentially penalizing project?

If incentives are used, offer incentives similar to those of the startup's employees working on the project. It is important for the employees, contractos and outsource partners to act as one cohesive team. Engineer the incentives so that one team member cannot succeed through another team member's failure.

Make sure that all team members understand what a success is and what a failure is. It sounds too easy, but all too often, individuals interpret team failure as individual success. For example, an operating system is chosen over one team member's objections. That team member now sees it as a personal success when

the project is late or doesn't work properly because of the "wrong" operating system selection. Align interests so that team members work together to anticipate and avoid problems rather than take them head on to prove a point. If one member of the team fails, the whole team fails.

Don't bring in too many outsource partners. Each partner will require some management resources from the startup company. Too often, multiple outsource partners have overlapping skill sets and end up competing for each other's business. Determine if this is a possibility early in the selection process. Avoid the situation, if possible. If not, create incentives that will not allow one outsource partner to succeed through anouther partner's (and potential competitor's) failure.

There is no formula that guarantees success in developing new medical devices in a startup environment. But there are best practices. Serial investors in the medical device industry can improve their odds of success by paying attention to development issues early; viewing prototypes skeptically; getting the advice of experts early; advising their clients in selecting development teams; and in helping startups engineer good development-team relationships. Find a process that works, and stick with it. Find outsource partners that work, and stick with them.

ABOUT THE AUTHOR:

David Vogel is the founder and president of Intertech Engineering Associates, Inc.

Dr. Vogel was a participant in a joint AAMI/FDA workgroup to develop a standard for Critical Device Software Validation which was subsequently included in the IEC 62304 Software Lifecycle Standard. He was also a participant on the joint AAMI/FDA workgroup to develop a Technical Information Report (TIR) for Medical Device Software Risk Management. Currently, Dr. Vogel is a member of the AAMI/FDA workgroup developing a TIR on Quality System Software Validation.

A frequent lecturer for workshops and seminars on topics related to medical device development and validation, Dr. Vogel also is the author of numerous publications and holds several patents.

Dr. Vogel received a bachelor's degree in electrical engineering from Massachusetts Institute of Technology. He earned a master's degree in biomedical engineering, a master's degree in electrical and computer engineering, and a doctorate in biomedical engineering from the University of Michigan.

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