

The Path to Developing a New Product: Some Advice for Health and Wellness Start-Up Companies

By: Charles (Ed) Becze, Ph.D.

This article is part one of a four-part series that takes a deep dive into the process involved with bringing an innovative idea to fruition. From concept to creation. First published in Medical Device Manufacturing News.

I am approached several times per year by an entrepreneur or inventor to discuss the support and development of a new concept to fill a particular wellness need. These clients are often clinicians or practicing physicians who have the idea but not the knowledge necessary to design, develop and manufacture to bring that idea to market. Their concepts typically fall into a couple of categories: one, an idea that will either encompass or enhance a technology ecosystem (hardware and software, and something that aligns with what is in vogue with technology and is therefore relatively straightforward); or, two, an idea for which solutions will require concrete and unique design and development to fill a therapeutic or clinical need. Rarely can an entrepreneur handle this on his or her own. In both of these situations, a competent development partner will help. Rarely can an entrepreneur handle this on his or her own. In both of these situations, a competent development partner will help.

Selection of your partner

You, the person with the idea, have the vision. Your partner should have the skills to get your idea to market. They should have a complete understanding of the requirements above and beyond the concept, e.g., certification requirements, testing, and validation. Also, your design partner must have demonstrated substantial knowledge to execute development in this space. The key question to ask is, "What is their experience"?



Cost considerations

When developing a new product, there are rigorous processes to follow that must, at the same time, allow for flexibility because hurdles will appear during the development lifecycle. All this will cost money, and the old saying "you get what you pay for" is particularly apt for new product design and development. Select your partner based on skill – and alignment with your vision.

Even if you are self-funded, and even if you have access to a design team, it is my experience that there is a stage where investment is typically required to commercialize products. Your development partner will be integral to get you there.



Demands on your time

You have a day job, and your time is valuable. At the outset, your development partner will need you quite extensively. You will have to split your time and efforts between your day job and your invention. You are part of a team now, you have the product knowledge, and your partner has the development knowledge. As your product matures, you will have less involvement. In fact, as the hardware, software, test, validation, certification teams take over, you may be less involved than at the kickoff of the project. Nevertheless, count on extensive involvement at the beginning. Not providing the necessary effort will stretch out your project.

Design iterations

In any vertical, be it medical, aerospace, or consumer electronics, product development requires a precise series of steps: design (and test), development, validation, and delivery.

Regardless of how simple the idea is, rarely should you move to a more mature development cycle until you are 100% confident that your solution meets your vision and does not inflict any unwanted conditions.

Thus, count on a significant amount of design iterations to converge on your product. This is not a cash grab for your development partner; this is to protect you and your investment and allow for a successful development lifecycle. Ultimately, you will be responsible for what the partner has designed for you. Does it meet your goals? As simple as it seems, the crucial first step is to document the concept in detail. The documentation serves two purposes; you are positioning your business for a legitimate and effective development lifecycle, and it helps you understand your value proposition for investment purposes.

Correlation with historical data

Technology, in general, changes rapidly. However, this does not directly translate into the careful world of medical devices. Be very mindful when requiring correlation of historical data to validate your idea with modern means. There are oceans of clinical data captured by the limited technology of yesterday. Modern sensing technologies can provide far better clinical data. Today, we have at our disposal endless low-cost sensors available for integration into wellness devices. Still, one cannot directly translate historical data into diagnostic information and have the efficacy correlate.

If your product requires rationalization using historical clinical data, you should consider the efficacy of that data. It would be best if you planned a validation cycle to prove your device's efficacy and perform any necessary correlations to obtain legitimacy.



One step at a time

Lastly, my advice to all entrepreneurs: do not boil the ocean and understand your roadmap. I usually advise all clients to understand the minimum viable product they can sell. Features in medical devices are often expensive to validate, and this will add complexity and cost. Thus, keep the feature set to a minimum that will meet your needs. That is not to say that you should restrict your vision; a roadmap is necessary so that your development partner can design the system with future functionality and expandability in mind but focus your implementation on the minimum viable concept.

Product development is exciting, but it does require a thoughtful approach. I have attempted to outline some common mistakes that start-up companies make. Avoiding these mistakes will not guarantee success, but it can keep your costs minimized. The most important aspect is to select a partner that will help you navigate the challenges you will face during development.

About the Author



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