

The Path to Developing a New Product: R&D Investment – Some Advice

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

This article is part four 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.

In past articles for this column, I discussed how to pick a design and development partner for your innovation. I have talked about what to expect from partners through to preparing for onshore and offshore manufacturing. Today, I want to share some advice about Research and Development (R&D) investment.

I work in the product development field, and I have often had clients approach me with their products for various industries, including the health and wellness market. These products and projects can be at any stage: from the early steps where the client will need development assistance to a mature stage where all they require is extra counsel before heading to manufacturing.

Progressing Towards Manufacturing: Assessing Roadblocks & Risks

As a product design and development professional, one of the issues that I encounter in these particular situations is that clients occasionally misconstrue when the development process is complete and when more input – financial or otherwise – is necessary before manufacturing. This situation poses a conundrum. The client is eager to proceed, and the development firm sees roadblocks ahead.

I can understand why clients are eager to transition to development execution. First: costs. More research and exploratory development will cost more money. Second: scheduling. There may be objectives that will slip with delays brought about by further work. However, my job carries an obligation to provide you, my client, sound advice and assessment and help you bring your product to market expeditiously, with certainty, with risks eliminated, so that you can be confident. And happy, as a client!

Risk is the key factor where applied research or extensive prototyping is required and should be encouraged. And this process takes time.

I can speak from experience here. A growing trend health and wellness device industry focuses on collecting clinical statistics and data to provide a metric or measurement meaningful to a practitioner. Be it something as simple as adding a heart rate monitor into a wearable device up to more complex device designs that measure an explicit part of a person's physical health.





These devices all carry a similar architecture; they typically utilize some form of sensor to achieve the measurement(s) of a physiological property and then require some added data processing. In the situation where there is a proven sensor solution to measure the target metric, development execution is typically a straightforward exercise.

However, suppose the sensor or strategy where the particular sensor application and its implementation is unknown or has no precedent. In that case, development is significantly more complex, with more research needed because your design partner will want to mitigate any element of ambiguity to demonstrate efficacy. But the essential puzzle remains the same: how to know when a product is ready for manufacturing and how to know when more investment of time and money is necessary.

This is important for any device, but particularly for medical and wellness products that rely on sensing, data collection, and processing of the data to provide a practitioner with the necessary information to perform an assessment and prescribe a treatment.

An Example

I can illustrate a project that my team worked on, in which the client wanted to improve on a pre-existing strategy for studying an aspect of organ health and performance.

A quick background: the client had an innovative concept which relied on legacy technology that, while a clinically accepted strategy for measurement and physiological correlation, was old-school technology, cumbersome, and required skilled practitioners to administer the tests.

The sensor technology used for the legacy device was not ideal - it did not provide the exact data needed and required significant data processing to provide meaningful information. In essence, the legacy device and methodology was a compromise. Enter the client who was a practitioner in this space and had a great idea for implementing new sensor technology to provide quicker and better measurements.

The client was confident that his new concept was simple to implement, and he wanted a complete product redevelopment. The client approached me, and we had some initial discussions. I asked some key questions and was able to identify the issues as we talked about the history and the use of the legacy device. I advised caution, knowing that this project would require some additional applied research. Even though implementation seemed straightforward, I suggested that we should prototype the device and work out some potential issues that I saw to be a risk.

The most critical issue I saw stemmed from the fact that all of the historical data generated through the legacy devices were (mathematically) in a much different form. Immediately, I knew that this would have a profound impact on implementation. So, even though the latest sensor technology was superior to anything available in the past, and the data that the new device would generate would be undeniably better, the conundrum would be: how to correlate this new data with the historical and clinically accepted data.

While a correlation of the data would be possible through mathematical transformations, the new device's data set would need significant manipulation to transform it into something that could be compared with the legacy data, explaining my suggestion for some applied research. This would be necessary to validate the platform and to assess the risks, taking into account the number of sensors, the configuration, and implementation.

Thankfully, the client opted to engage in more research that would allow us to converge on a more viable solution. The development costs increased, but per-device costs were minimized, the functionality was significantly better, and above all, we were able to save them from a significant and potentially costly pivot.

Interestingly enough, most clients (in many cases, knowledgeable practitioners) feel that they have reached a certain level of maturity and that more development is unnecessary. After discussion and thoughtful assessment of risks, they choose to pursue further research and afford the necessary time to vet out a solution, or they decide to roll the dice and pursue expensive development.

In general, clients do not want to hear that they need to invest more time and money into their product scoping stage. Some decide to pursue development with a partner who has told them what they wanted to hear; others heeded the advice and ultimately converged on a gate to proceed or exit the effort. Some clients pursued development prematurely and either lost appetite for development once the risks became clear, or they simply ran out of money along the way. Clients who fully understand and embrace the need for R&D, and who fully validate their concepts are successful innovators.

Lessons Learned

The lesson to be learned here is that new technological improvements rarely are easily implemented into a design. New technologies may require significant investment and time to validate. In situations like this, a development platform or device must be prototyped, and the appropriate due diligence performed before engaging in formal development. The aim here is not to discourage clients from development, but to expose the effort and time necessary for a successful project. Many benefits arise from the investment in time; the platform will provide a basis for functional requirements, but more importantly it can validate that the concept.



Use your development partner as a tool to leverage. Your success will strongly depend on their experience, insight, and ability to properly align you with a platform that will meet your needs. Heed their advice; if there is no clear road to implementation, you should expect to invest in R&D to understand the risks better. You may find a path, or there may not be an easy path, and you can choose not to take it.

Either way, it will cost you less for the outcome.



About the Author



Charles (Ed) Becze, Ph.D., is a co-founder of Pegmatis, Inc. Over his career, he has worked with Pratt & Whitney, Ford, and an electronics Original Equipment Manufacturer (OEM). Pegmatis Inc is home to a team of highly experienced software, hardware, and manufacturing professionals who are proud to have produced some award-winning products, many of which you may have in your own homes. Connect with Ed on LinkedIn or contact him for more information at [Pegmatis.com](https://www.pegmatis.com).