The Path to Developing a New Product: The Product Development Lifecycle – a Simple Overview

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This article is part two 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 my last column, I spoke a bit about the choice of a development partner. To summarize, to bring a great idea to market, you will need to have a design and development partner to accompany you on what is quite a formal journey, understanding that there may be several pitfalls along the way. I assumed that you have a business plan with sufficient funds available to sustain development costs. I also presumed that you, along with your chosen partner firm, had generated the requirements that define your product and had determined that it will meet a market need. And a final assumption was that you would need to prepare for a factory or manufacturing relationship.

The following phases represent the next steps to consider and expect from your development partner to bring your product to life. Generally speaking, in design and development language, these phases fall under what we call the "development lifecycle."

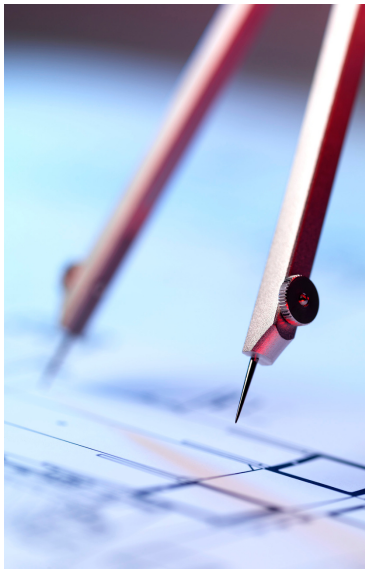
The Development Lifecycle

Discovery

Your kickoff discussions with your development partner will typically start with a "discovery" phase, which serves several purposes. First, your partner will review your requirements and assess if they can comply with the asks in the document. Second, and more importantly, the partner firm should be looking for technology risks or gaps that perhaps you may not have considered.

Formulating a Plan

At this point, a great partner will begin the formulation of a plan that will validate those risks and mitigate them. This is a critical phase where the development trajectory starts; you and the team make clarifications, and once aligned, the team begins to develop a viable development plan. The requirements that we spoke of last time are a necessary aspect of this phase. Having this plan means that you will have an estimate of costs and an understanding of risk.



Designing the Product Architecture

Your next step in the journey, the development of architecture, may seem nebulous. So far, all you have is a conceptualization of your vision but nothing tangible. Your partner will be focusing on formulating a product architecture to meet your requirements, and during this phase, they will highlight technological unknowns and assign risk factors.

With the unknowns and risks now identified, the design and development team can place them into a formal plan for mitigation. This phase establishes the system upon which you will base your product solution. The known risks are highlighted and prioritized for validation for the next stage in development.

Engineering Validation

Once the preliminary architecture phase is complete, this is where "true" development begins. This phase is called the "engineering validation" phase. During the engineering validation phase, the team executes, or builds, the architecture to bring a testable platform into reality and to provide a tangible system to perform product validation.

Recall that it is critical to establish requirements before you begin development. This is precisely why: the platform that will be delivered (in other words, a prototype) tests your product architecture, be it software, hardware, or both, against the requirements at a fundamental level for viability. You've taken your vision, the team has made a prototype, will your product work in the real world?

Depending on the design's complexity and the inherent risks, the engineering validation phase can take multiple cycles to vet and complete.

I should point out that in no way can any development partner move to the next stage until they have mitigated all the risks, or you and the team have adjusted and removed any features that may no longer be part of the product that you aim to produce. The only way to progress through product development is when you have finalized the product's features at this stage.

The engineering validation phase is critical in the "development lifecycle" for many reasons. First, it prototypes the product in a low-cost form to provide a tangible platform to test. Second, it begins the critical process of assembling the necessary partners for production. This aligns each player in the concert for the upcoming effort. Typically, this phase lasts the longest by duration, and you must be patient. You have to trust that your partner will coordinate this effort to prepare you adequately for the next development phase.

Delivery

You have come this far, and the journey has been full of bumps and bruises. Fear not, as you are close to completing the journey! Once your development partner is confident that the engineering validation phase is complete and there is 100% alignment between the product and your vision – AND that what you have contemplated will be delivered, you are officially entering the "design validation" phase.

Speaking from experience, this is where the "official" architecture is delivered. There should be no more risks or ambiguity in this stage. This stage should be viewed as simply execution – your development team knows exactly what to deliver and how.

Your development partner has by now validated hardware and software solutions that can be delivered. They will also have aligned all your partners for bringing your product into the market and they will ensure the final version of tooling, hardware, and (and to a certain extent the software) that you intend to ship.

This is the platform you will do your formal validation testing on, in addition to any agency and regulatory certifications that are required. So, at the end of this stage, the product needs to be fairly mature.

Typically, the next stage of development can be dovetailed into the following phase – manufacturing your product but there are some risks associated with moving ahead too quickly. The maturity of your development partner's skill and experience will determine the risk level of proceeding and you should only continue on if your development partner is comfortable doing so.

Validation

You have finally reached the point where you are going live – congratulations! Your product design is mature, validated, and has met all certifications that are necessary to ship the product. Now comes the “process validation” stage.

Of course, this is primarily targeted at a hardware product and is a necessary stage. Ideally, your design partner has engaged with your final hardware manufacturer from the beginning of the process, but depending on the product volumes, this may not be the case. I should expand on this somewhat as it is important information.

Typical large-scale contract manufacturers rarely engage in prototype development. They are not geared up to perform prototyping tasks unless there is a huge potential for revenue. So, there may be a transition to your final manufacturing partner. During this stage – your development partner's hard work will come to fruition; the assembly lines, the manufacturing tests, the supply chain, packaging are established and hardened to get you to a final product that you will ship. There is still much work to do here, but the end is in sight and you can begin to deliver on your commitments.

Conclusion

Development is rarely easy. I have tried to highlight the process your development partner should take but there are many tasks that you and your partner must undertake and for which both you and your partner must be accountable. It is simply impossible to capture the entire recipe for product development, however, this is the process in a nutshell. Many will have taken this as "common knowledge". However, based on my experience, there are many who will find this to be a refreshing lesson.

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.